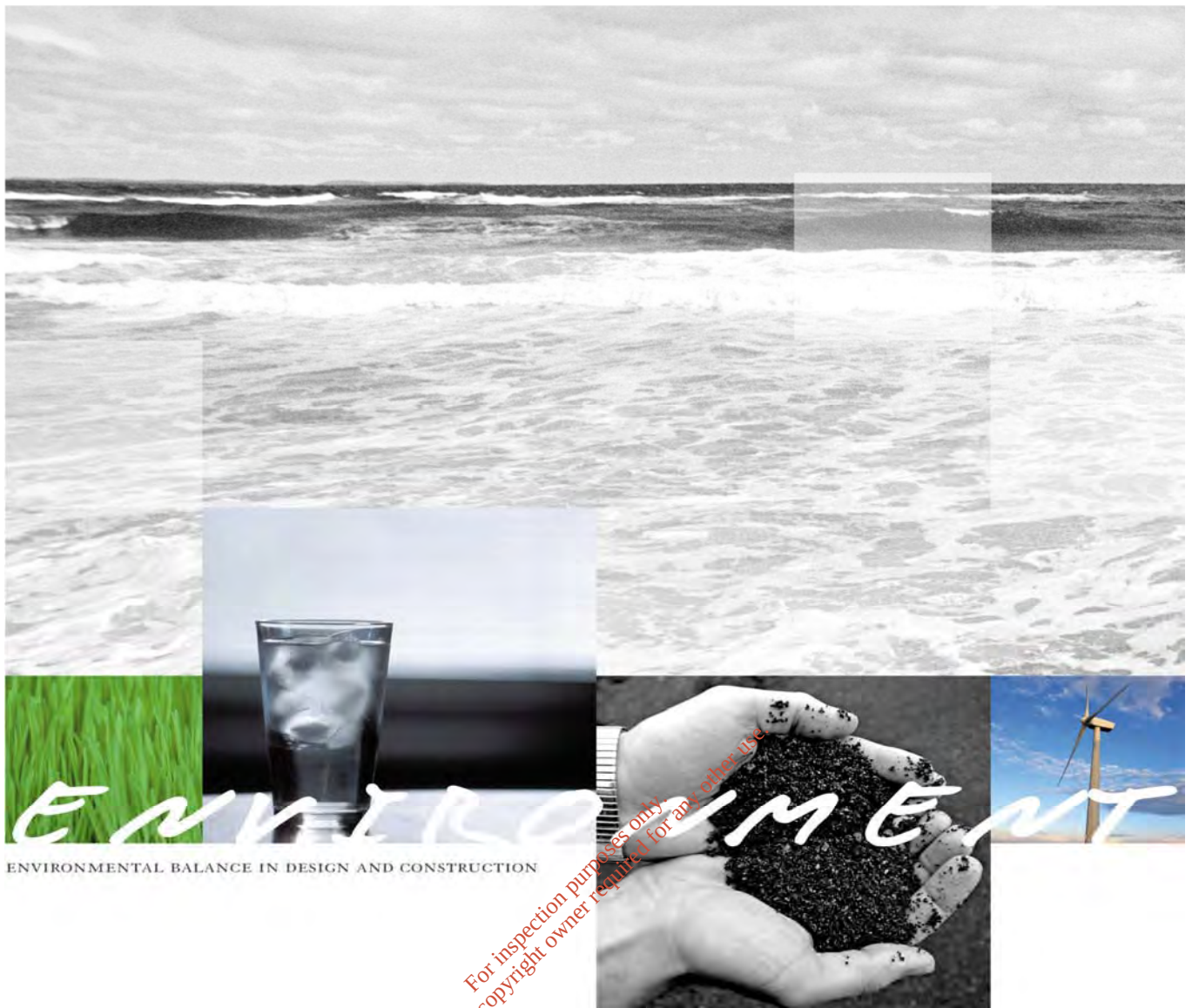


Appendix 3

Baseline Report

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ATTACHMENT I.4 BASELINE REPORT

ELI LILLY

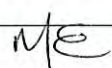
NOVEMBER 2014



ATTACHMENT I.4 BASELINE REPORT

ELI LILLY

User is Responsible for Checking the Revision Status of This Document

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Abstract: This baseline report forms Attachment I.4 for the IE licence review application for Eli Lilly's facility at Dunderrow, Co. Cork. It was prepared in accordance with the requirements of Article 22(2) of Directive 2010/75/EU on industrial emissions (IED). The purpose of the report is to determine the state of contamination of soil and groundwater at the time the report was drawn up in order that a quantified comparison may be made to the state of the site upon the permanent cessation of the IE activity. The baseline status is uncontaminated by hazardous substances.

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EXECUTIVE SUMMARY

This is a baseline report for Eli Lilly's facility at Dunderrow, Co. Cork. The requirement for a baseline report was triggered by the Directive 2010/75/EU on industrial emissions (IED), as Eli Lilly is applying to the Environmental Protection Agency (EPA) for a review of their industrial emissions (IE) licence. Section 1.4 of the IE licence application form on *Existing Environment and Impact of the Activity* seeks a baseline report, where the activity involves the use, production or release of relevant hazardous substances and having regards to the possibility of soil and groundwater contamination. The Commission produced guidance on the content of the baseline report in May 2014, *European Commission Guidance concerning baseline reports under Article 22(2) of Directive 2010/75/EU on industrial emissions*. This baseline report has been prepared in accordance with this Guidance.

The purpose of the report is to determine the state of soil and groundwater contamination at the time the report is drawn up in order that a quantified comparison may be made to the 'state' of the site upon the permanent cessation of the IE activity.

The facility is operated under an IE Licence (P0009-03) with the principal activity being the manufacture of pharmaceutical and veterinary products. It has been licensed by the EPA since 1995. The facility was established by Eli Lilly in 1981 on a greenfield site, 5 km from Kinsale in Co. Cork. There is a complete site history.

Based on the information gathered in Stages 1 to 4, it was determined that a baseline study was required for this site.

A list of relevant hazardous substances was compiled and an assessment of potential pollution risk was carried out. Two historical incidents were identified where there was potential for contamination of soil and /or groundwater with hazardous substances. The design and operation of the facility is such that the potential for future contamination of groundwater or soil is mitigated. There is a robust groundwater monitoring database as groundwater is monitored at 8 wells on site biannually for a range of relevant parameters. This data shows no evidence of contamination by hazardous substances. Existing soil data for the site was limited and therefore a targeted subsoil investigation was undertaken.

Ten subsoil samples were analysed for a range of relevant parameters and both the field screening and the laboratory results indicated no evidence of contamination.

Each of the 7 stages completed were documented and are presented in this report which represents the final stage (Stage 8) in the preparation of a baseline report.

Relevant hazardous substances have been, are and will continue to be used and produced at the Eli Lilly facility in Dunderrow, Co. Cork. Process changes over the years have seen a significant reduction in the volume of those substances used. The current state of the soil and groundwater with respect to hazardous substances is uncontaminated.

1 INTRODUCTION

This baseline report forms the response to Section 1.4 of the IE licence review application for Eli Lilly's facility at Dunderrow, Co. Cork. It is being prepared in accordance with the requirements of Article 22(2) of Directive 2010/75/EU on industrial emissions (IED).

The purpose of the report is to determine the state of soil and groundwater contamination at the time the report is drawn up in order that a quantified comparison may be made to the state of the site upon the permanent cessation of the IE activity.

1.1 The Facility

Eli Lilly (Irish Branch) is located in Dunderrow, Co. Cork, some 5 km from Kinsale town in a predominantly rural area. The Dunderrow site covers an area of approximately 150 ha and was used primarily for agricultural purposes prior to its purchase by Eli Lilly in 1976. Production commenced at the facility in 1981 manufacturing pharmaceuticals. Originally the Kinsale site's main focus was on manufacturing and supplying of medicines and while this focus continues onsite, the facility is also expanding to develop a centre of technical excellence in innovative new medicines. As a result Kinsale is now focused on three core business activities, namely:

- Small Molecule Active Pharmaceutical Ingredient (API) Supply
- Small Molecule Commercialisation
- Biopharmaceutical Commercialisation and Supply

The facility was first licensed by the EPA in 1995.

Since 1981, several new facilities have been constructed and commissioned on site. Eli Lilly is currently commissioning its newest facility, a biotechnology manufacturing facility (IE43). This new facility is the primary reason for this licence review application. A map of the facility is included in Appendix 2.

Due to the nature of the manufacturing process, there are a number of hazardous substances used and produced on site. The usage of bulk solvents on site has reduced by an estimated 40% over the last 4-5 years as a result of the introduction of newer less solvent intensive manufacturing processes together with a move to aqueous based biotechnology manufacturing processes.

As demonstrated in Appendix 1, there are a large number of different chemicals used on site as part of the process operations. They are divided into the following categories:

- Bulk materials
- Reagents
- Products and intermediates
- Processing aids
- Cleaning and maintenance materials.

1.2 Requirement for Baseline Report

The facility's principal activity under its current licence is the manufacture of pharmaceutical and veterinary products. Section I of the IE licence review application form on *Existing Environment and Impact of the Activity* seeks a baseline report, where the activity involves the use, production or release of relevant hazardous substances and having regards to the possibility of soil and groundwater contamination.

Article 22 of the IED states:

Where an activity involves the use, production or release of relevant hazardous substances and having regard to the possibility of soil and groundwater contamination, a baseline report is to be drawn up before starting the operation of the installation or before a permit for the installation is updated for the first time after 7 January 2013.

The report will form the basis for a comparison with the state of contamination upon definitive cessation of activities. Where information produced pursuant to other national or Union law reflects the state at the time the report is drawn up, that information may be included in, or attached to, the baseline report.

It specifies that a baseline report should contain at least the following information:

- (a) *information on the present use and, where available, on past uses of the site; and*
- (b) *where available, existing information on soil and groundwater measurements that reflect the state at the time the report is drawn up or, alternatively, new soil and groundwater measurements having regard to the possibility of soil and groundwater contamination by those hazardous substances to be used, produced or released by the installation concerned.*

1.3 Scope of the Baseline Report

The Commission produced guidance on the content of the baseline report in May 2014, *European Commission Guidance concerning baseline reports under Article 22(2) of Directive 2010/75/EU on industrial emissions*. This baseline report has been prepared in accordance with the Guidance.

The Guidance establishes a number of key tasks that should be undertaken to firstly determine the need for a baseline report and secondly the steps required to produce it. Eight stages have been identified with:

- Stages 1-3: decide whether a baseline report is required
- Stages 4-7: determine how a baseline report is to be prepared
- Stage 8: determine the content of the report.

If Stages 1-3 demonstrate that a baseline report is not required, there is no requirement to progress to Stage 4, but a record of Stages 1-3 must be submitted to the EPA.

The 8 stages of preparing a baseline report are summarised in Table 1.1.

Table 1.1: Main Stages of Preparing the Baseline Report

Stage	Activity
1	Identify which hazardous substances are used, produced or released at the installation and produce a list of these hazardous substance
2	Identify which of the hazardous substances from Stage 1 are 'relevant hazardous substances' (see Section 4.2). Discard those hazardous substances that are incapable of contaminating soil or groundwater. Justify and record the decisions taken to exclude certain hazardous substances.
3	For each relevant hazardous substance brought forward from Stage 2, identify the actual possibility for soil or groundwater contamination at the site of the installation, including the probability of releases and their consequences, and taking particular account of: • the quantities of each hazardous substance or groups of similar hazardous substances concerned • how and where hazardous substances are stored, used and to be transported around the installation • where they pose a risk to be released • In case of existing installations also the measures that have been adopted to ensure that it is impossible in practice that contamination of soil or groundwater takes place.

Stage	Activity
4	Provide a site history. Consider available data and information: - In relation to the present use of the site, and on emissions of hazardous substances which have occurred and which may give rise to pollution. In particular, consider accidents or incidents, drips or spills from routine operations, changes in operational practice, site surfacing, changes in the hazardous substances used - Previous uses of the site that may have resulted in the release of hazardous substances, be they the same as those used, produced or released by the existing installation, or different ones Review of previous investigation reports may assist in compiling this data.
5	Identify the site's environmental setting including: - Topography - Geology - Direction of groundwater flow - Other potential migration pathways such as drains and service channels - Environmental aspects (e.g. particular habitats, species, protected areas etc.) - Surrounding land use.
6	Use the results of Stages 3 to 5 to describe the site, in particular demonstrating the location, type, extent and quantity of historic pollution and potential future emissions sources noting the strata and groundwater likely to be affected by those emissions – making links between sources of emissions, the pathways by which pollution may move and the receptors likely to be affected.
7	If there is sufficient information to quantify the state of soil and groundwater pollution by relevant hazardous substances on the basis of Stages (1) to (6) then go directly to Stage 8. If insufficient information exists then intrusive investigation of the site will be required in order to gather such information. The details of such investigation should be clarified with the competent authority.
8	Produce a baseline report for the installation that quantifies the state of soil and groundwater pollution by relevant hazardous substances.

For ease of reading this report followed the above step-by-step process. Stages 3 and 6 were undertaken together.

2 REQUIREMENT FOR A BASELINE REPORT (STAGES 1 & 2)

This section includes:

- Stage 1: A list of hazardous substances used, produced or released.
- Stage 2: A list of 'relevant hazardous substances'.

2.1 Stage 1: Hazardous Substances

Hazardous substances are defined as being:

"Substances or mixtures as defined in Article 3 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures".

Article 3 of the same Regulations defines:

"A substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in Parts 2 to 5 of Annex I is hazardous and shall be classified in relation to the respective hazard classes provided for in that Annex".

A list of all process related raw materials, intermediates, products etc., which are been used, produced or released on site are included in Table A.1 of Appendix 1. This list was then filtered to remove non-hazardous substances. That list is included as Table A.2 in Appendix 1.

2.2 Stage 2: Relevant Hazardous Substances

Article 3(18) of the IED Directive defines 'relevant hazardous substances' as meaning *"substances or mixtures defined within Article 3 of Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) which, as a result of their hazardousness, mobility, persistence and biodegradability (as well as other characteristics), are capable of contaminating soil or groundwater and are used, produced and/or released by the installation"*.

Table A.2 of Appendix 1 is a list of relevant hazardous substances used at the Dunderrow facility. This list was created by eliminating substances which are deemed non-hazardous to soil and groundwater, or highlighting substances which are hazardous to either soil or groundwater using the following steps:

(Please note that the list of hazardous and relevant hazardous substances was prepared electronically. Substances that were 'eliminated' from the investigation, were not deleted, but shaded in grey and noted so that they can be filtered out of the table if required.

2.2.1 Step 1 Identification of hazardous substances to groundwater.

This list was compiled for using Table G.1 (ii) from the licence application as it identifies those substances that are hazardous to groundwater as determined by the EPA¹ in accordance with the European Community Environmental Objectives Groundwater Regulations 2010 (S.I. No. 9 of 2010) and using historic records to determine substances that were used since 1981 on site but are no longer in use. The EPA classification of hazardous and non-hazardous substances to groundwater is not exhaustive, therefore, a number of the substances on the list are either 'not determined' or are 'N/A' as they do not appear in the EPA document. Therefore only substances which are defined as non-hazardous to groundwater, can be eliminated from the list.

¹ Classification of Hazardous and Non-Hazardous Substances in Groundwater, EPA 2010

2.2.2 Step 2 Identification of hazardous substances to soil.

In accordance with the European Communities (Classification, Packaging and Labelling of Dangerous Preparations) Regulations 2004 (S.I. No. 62 of 2004 as amended by S.I. No. 13 of 2008), risk phrases are assigned to dangerous substances. Risk phrase, R56 denotes 'Toxic to soil organisms.' The list of substances used at the Dunderrow facility was filtered for R56. There are no substances on the list that is toxic to soil organisms.

Table A.3 in Appendix 1 is a list of all relevant substances that were either identified as hazardous to soil or groundwater, or which could not be ruled out as non-hazardous.

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3 STAGES 3 & 6: IDENTIFICATION OF POTENTIAL POLLUTION RISK AND SITE CHARACTERISATION

Each substance brought forward from Stage 2 was considered in the context of the site to determine whether circumstances exist which may result in the release of the substance in sufficient quantities to represent a pollution risk either as a result of a single emission or as a result of accumulation from multiple emissions.

The possibility of site-specific pollution was assessed based on:

- the physical state of the substance
- the location of each hazardous substance on the site and how it is moved around the site
- the presence and integrity of containment mechanism, nature and condition of site surfacing, location of drains, services or other potential conduits for migration

The guidance note prompts the user to carry out site inspections of structures, surfaces, drains, gullies, manholes, drainage routes, outfalls and to determine emission points and identify if any indirect emissions to ground take place. This was not necessary for this facility as all of this information is readily available. As detailed in the other Attachments for this IE licence review application, this is a highly automated and controlled site – Eli Lilly primarily uses a Foxboro I/A Distributed Control System (DCS) to control and monitor process equipment, utilities, and support systems. Controls stem from the existing IE licence (P0009-03) and the Environmental Management System is based on the ISO 14001 Environmental Management Systems model. The extensive management and control systems on site as summarised in Sections 3.1 and 3.2 of this chapter, significantly reduced or eliminates the potential of pollution occurring. Section 3.3 examines the possibility of pollution based on quantity of substances stored and the scale of the operation and Section 3.4 records circumstances where pollution may have occurred.

3.1 Management Measures in Place to Mitigate Impacts to Soil or Groundwater

3.1.1 Site Management

The facility currently employs approximately 470 staff. The management structure for the environmental management of the site is set out in Attachment C of the licence review application. Each team has a dedicated Team Leader who provides leadership and day-to-day managerial oversight for the respective teams. The team leaders in turn report directly to a member of the Site Lead Team with responsibility for each of these respective environmental management functions at the site.

3.1.2 IE Licence

The facility has been licensed by the EPA since 1995, when its first IPC licence was granted. The licence was reviewed twice during that period and in December 2013 the activity was determined by the EPA to fall under the IED and the licence was transferred to an IE licence. The licence places conditions on the operation of the site and sets limits on emissions.

3.1.3 Environmental Management System

Eli Lilly has developed and implemented an Environmental Management System (EMS) for the Kinsale site is based on the ISO 14001 model. The main objectives of this EMS are:

- To develop Eli Lilly's Environmental Policy Statement
- To implement an effective programme of environmental protection and conservation measures to meet the objectives of the Environmental Policy
- To set targets to improve its environmental performance. This is done through the implementation of the annual Environmental Management Programme.

Eli Lilly strives to make continual improvements in waste minimisation and recycling efforts, undertakes ongoing development of the environmental management system, carries out regular internal audits and frequently reviews operating procedures.

3.2 Control Measures in Place to Mitigate Impacts to Soil or Groundwater

There are no direct discharges to groundwater from the facility. The facility has been designed and is operated in accordance with BAT.

Table 3.1 is a summary applicable BAT Conclusions, BAT reference document(s) (BREFs) and BAT guidance document(s). Attachment 1.8 of the licence review application contains detailed information on each of these documents and how the relevant BAT measures are applied at the Dunderrow facility.

Table 3.1: Relevant Decisions on BAT Conclusions, BREFs and BAT Guidance Documents

Title of Document
Integrated Pollution Prevention and Control. Reference Document on Best Available Techniques (BREF) for the Manufacture of Organic Fine Chemicals, European Commission, 2006
BREF on Common waste water and waste gas treatment/management systems in the Chemical Sector, European Commission, 2003
BREF on Emissions from Storage, European Commission, 2006
BREF on Industrial Cooling Systems, European Commission, 2001
BREF for Waste Incinerations, European Commission, 2006
REF on Economic and Cross-media Effects, European Commission, 2006
REF on the General Principles of Monitoring, European Commission, 2003 (monitoring of emissions from IED-installations)

The Accident Prevention and Emergency Response section (3.2.7) also outlines the measures that would be taken to prevent potential pollution risks. There is a Site Emergency Plan (SEP) in place at the facility which is in place to respond to all conceivable emergencies that could arise. The SEP would be implemented by the site Emergency Response Team (ERT).

A summary of the applicable containment measures for storage and handling is as follows:

Movement of Materials

The vast majority of pipework on site is over ground with hard surface underneath pipe racks carrying hazardous substances. The majority of pipe racks run alongside roadways and areas where there is a lot of regular personnel movement therefore any leak that occurs can be quickly identified and addressed. CCTV cameras are strategically located around site and are continuously monitored by security personnel. This can also assist in the identification of any developing leak in the pipeline conveyance system. Pipelines carrying hazardous materials are also on a site inspection programme that is executed by experienced engineers.

Where underground pipes exist, they are doubly contained and are inspected and monitored regularly.

The physical state of each substance was used to eliminate substances from the list based on risk. Gases were eliminated as there is no potential risk at this site for pollution of groundwater or soil from gases. Solids were eliminated based on the control systems described below.

3.2.1 Storage and Use of Solids and Associated Risk

All production related solids materials are stored in secure, contained warehouses on site. Access to these areas is restricted to trained warehouse operatives who deliver material to production operations as required. All hazardous solids are stored in UN approved combination packaging which consists of at least two layers of packaging. Material is transported to production areas on pallets by trained forklift operators. All movement is over hard surface areas thus minimising the risk to soil or groundwater from any spillage occurring as a result of an incident during transport. Any spillage can be responded to immediately by the site Emergency Response Team. Handling of hazardous solids within the production area is highly controlled with numerous containment measures in place to prevent personal exposure. This also minimises the risk of a spill that could lead to loss of containment within the building. Again any spill within the building is immediately reportable and will be dealt with by the site Emergency Response Team.

3.2.2 Storage and Use of Drumstock Liquids and Associated Risk

The main drum store (IE15) is used for the storage of drum stock solvents, acids and bases. The bunded capacity of this area is 1.3 million litres with solvent volumes stored typically in the 200,000-300,000 litre range while acid and base storage volumes range from 20,000-40,000 litres.

All drum stock is stored in dedicated bunded areas with controlled/monitored drainage systems. Transport of drum stock occurs over hardsurfaced roadways that have drainage systems routed to a site containment pond with online monitoring systems. Any incident causing release of material during site transport can be collected in the pond and treated as necessary. All site stormwater drainage systems are on a routine maintenance programme that ensures the integrity of the system is maintained thus the risk to soil or groundwater from such an event is negligible. Drum stock is used within production areas in a very controlled and contained manner. Any spillage occurring in a production area is immediately addressed by operations personnel or the site Emergency Response Team. Any material not locally contained will be collected in the production area floor drains and routed to an external holding tank. The contents of this tank can be pumped to the relevant treatment area (Incineration, WWTP). Again there is negligible risk to soil or groundwater from such an event.

3.2.3 Storage and Use of Bulk Liquids and Associated Risk

The bulk solvent storage facility (tank farm) is designed to hold up to 45 tanks. The tank farm currently holds 28 tanks, including additional spare capacity. The main solvent tank farm has capacity to hold up to a million litres of solvent at any one time.

The usage of bulk solvents on site has reduced by an estimated 40% over the past 4-5 year period as a result of the introduction of newer less solvent intensive manufacturing processes together with a move to aqueous based biotechnology manufacturing processes.

All the fixed bulk storage tanks are surrounded by contained bunds (110% capacity) that are designed to contain material in the event of flammable or toxic liquid spills. Fixed foam and firewater protection systems are installed in keeping with current standards and expectations. The current bulk storage facilities on site comply with BAT as outlined in the 2006 Emissions from Storage BREF document.

The waste solvent storage area comprises of a group of seven tanks, which store liquid wastes for incineration. All of the tanks in the waste solvent tank farm were replaced with new tanks in 2007, built to a much higher specification than the original tanks. These are pressure rated vessels that can be operated at much higher pressure relief settings thus minimising vapour breathing losses. Wastes stored here are segregated into primary waste, which is mostly organic solvent and secondary waste which is mostly water, contaminated with some solvent and other organic residues.

All the waste solvent storage tanks are surrounded by contained bunds. Fixed foam and firewater protection systems are installed around this area.

The old tank farm had the capacity to hold approx. 800,000 litres of waste solvent and had a turnover of approximately 10 million litres of solvent waste per annum.

The new solvent waste tank farm has the capacity to hold approx. 900,000 litres of waste solvent with a current annual turnover of approximately 6 million litres. The current waste solvent storage facilities on site meet many elements of BAT as outlined in the 2006 Emissions from Storage BREF document.

All bulk solvent storage/waste solvent storage occurs in overground tanks located in bunded areas that drain to collection sumps that can be routed to either incineration or waste water treatment as necessary. There are no releases to surface water from any of these storage locations. These bunds and sumps are on a site maintenance programme to assess the integrity of the system on a regular basis thus minimising the risk to soil or groundwater in the event of a spill in the bunded area. Transfer of solvent to and from these storage tanks (both new and waste solvent) occurs in overhead lines where the ground underneath is hardsurfaced (concrete) so that any potential leak is prevented from entering the soil or groundwater. Run off from any such leak is captured in the site storm water drains which are routed to the containment pond and material can be collected from there and treated as necessary. All site stormwater drainage systems are on a routine maintenance programme that ensures the integrity of the system is maintained thus the risk to soil or groundwater from such an event is negligible. The delivery of bulk solvent to production processes within the building is controlled and monitored closely by operations personnel. Any leak/spill can be quickly addressed by operations personnel or the site Emergency Response Team. Any material not locally contained will be collected in the production area floor drains and routed to an external holding tank. The contents of this tank can be pumped to the relevant treatment area (Incineration, WWTP). Again there is negligible risk to soil or groundwater from such an event.

3.2.4 Wastewater Treatment

There are two wastewater treatment plants (WWTP) on site, (a Biological WWTP and an Incineration process WWTP) for the treatment of:

- Process wastewater arising directly and indirectly (equipment cleaning, floor washing, abatement systems etc.) from manufacturing
- Utility wastewater (steam and hot water generation, purified water production and cooling systems)
- Sanitary/foul wastewater (canteen, washrooms and toilets and is similar in composition to normal domestic sewage)
- Contaminated surface water
- Incinerator quench water (thermal oxidiser)

Over the past 5 year period a significant investment has been made in upgrading the existing biological WWTP facility to increase the capability of the plant while also improving effluent quality and providing additional groundwater protection thorough secondary containment measures. The WWTPs can currently cater for up to 460 m³/day and with modifications to the existing system, for 600 m³/day.

There is a low point in the natural site gradient for the WWTP and incineration facilities. It served as a natural collection point for any material spills/leakages in this area. The fact that there is no evidence of historical contamination at this location indicates that the integrity of the containment systems in this area has been maintained over the years.

3.3 Circumstances under which Emissions May have Occurred

Circumstances under which emissions may have occurred via accidents or incidents, routine operations or planned emissions were examined for this baseline report. Two incidents involving hazardous substances were identified.

3.3.1 Historic Leak in Main Solvent Tank Farm Drainage

In the early 1990's, faults developed in the main solvent tank farm drainage system. It is a possibility that minor contamination could have occurred on the Southside of the main solvent tank farm. The drainage system was subsequently upgraded and controls put in place to ensure integrity of the system was maintained. The solvents stored there at the time were VOCs.

3.3.2 Heavy Fuel Oil Leak

There was an historic leak from an underground heavy fuel oil (HFO) pipeline in 1995-96 which was subsequently replaced by an overhead pipeline in 1996. The leak was minor in nature and was detected early through routine surface water monitoring. All contaminated soil was removed and treated. An oil interceptor was installed to remove residual oil contamination from surface and subsurface (land drainage) water in the area. The oil interceptor was removed once clean-up was complete in 2003. The leak was detected at the eastern boundary of IE34.

3.3.3 Historic MTBE Contamination Event

MTBE is a non-hazardous substance and is therefore not within the strict scope of a baseline study but it is included to make the report representative of the baseline condition of soil and groundwater with respect to all substances used and not just those that are hazardous to soil and groundwater. Details of this incident are included in Section 4.1. The incident has been the subject of extensive monitoring and remediation and is included in more detail in Attachment 1.5 of the licence review application.

3.4 Outcome from Stages 1 to 3

Gases and solid substances were eliminated from the list of substances brought forward from Stage 2 (Table A.3 of Appendix 1).

Table A.4 of Appendix 1 is the list of relevant hazardous substances that have been or are used or produced on site. It includes bulk liquids and drumstock liquids. There are 92 substances on the list, 7 of which are identified as hazardous to groundwater. It was not possible to eliminate the remaining 85 substances, as the status of many of the substances is 'undetermined' or they were not included on the EPA list¹. Of the 7 substances there are 3 chemicals:

- Toluene
- Ethylene Dichloride (1,2-dichloroethane)
- Dichloromethane

In light of the above assessment of the site specific pollution possibilities based on quantities of materials stored, the scale of the production of the facility and the two recorded incidents, it was determined that a baseline study was required for the site. A site investigation was planned with the following groups of substances and locations being the focus of the sampling strategy.

Parameters

- Solvents (VOCs, sVOCs, alcohols and acetates)
- Heavy Fuel Oil (Mineral Oil, Polycyclic Aromatic Hydrocarbon (PAHs) and benzene, toluene, ethylbenzene and xylene (BTEX))
- Waste Acceptance Criteria – the full suite of parameters specified in the Annex to EU Council Decision establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to Directive 1999/31/EC. The Annex, which is commonly known as the Landfill Waste Acceptance Criteria (WAC), sets threshold limits for a range of inorganic and organic parameters that characterise a waste as suitable for disposal to an inert, non-hazardous or hazardous waste landfill.
- Total Organic Carbons (TOC)

Sampling Locations

Locations were chosen:

- downgradient of the main solvent farm
- downgradient of the old waste solvent farm
- downgradient of the new/existing waste solvent farm
- downgradient of IE15 main drum storage warehouse
- downgradient of the Main production spine and WWTP
- downgradient of IE8
- at the point of historic HFO leak (east of IE34)

One sampling location was chosen to represent a greenfield area of the site, upgradient of the facility.

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4 STAGES 4 & 5: SITE HISTORY AND ENVIRONMENTAL SETTING

4.1 Stage 4: Site History

A summary of the developmental and operational history of the site is as follows:

- In 1976, Eli Lilly and Co. purchased a 112 acres site in Dunderrow, Kinsale Co. Cork
- Since 1976, a further 40 acres has been purchased
- Currently, c. 80% of the site is occupied by development
- In 1978 construction began on-site
- In 1979, the IE2 Laboratory was built
- Production commenced at this facility in 1981
- Although originally intended as a facility to produce agricultural products, the site started its operations dedicated solely to human pharmaceuticals. The Kinsale facility supports the development, as well as manufacture and supply, of many of the company's newer medicines. The site uses advanced chemical and biological processes to produce a range of active pharmaceutical ingredients (API) that provide a medical benefit. These products are further processed at various facilities to supply medicines to patients worldwide
- In 1984, IE8, the second production facility was added as well as IE2 a small production facility
- In 1988, the IE8 production facility was expanded
- In 1995, animal health products were introduced and produced at the facility
- In 1999, IE16 small scale, high containment facility was commissioned
- In 2000, IE16 a large scale facility was constructed
- In 2002, a new laboratory and office (IE28) was constructed
- In 2004, a new clean manufacturing facility (IE30) was constructed
- In 2007, the IE30 facility achieved complete validation
- Since 2010, the Kinsale facility has invested in small molecule commercialisation which involves the chemical synthesis and the commercialisation of new molecules. Several new medicines are currently undergoing development work in Kinsale. New manufacturing technologies such as process analytics and continuous processing are also being deployed in Kinsale as part of this development (Building IE2)
- In 2006, Lilly announced that Kinsale would become the main centre for the manufacture and supply of active ingredients for its new biopharmaceutical medicines
- Biopharmaceutical manufacturing, commercialisation facilities and engineering laboratories (Building IE42) were commissioned in 2009 and the first batch of a monoclonal antibody (mAb's) medicine was produced
- In 2010, the manufacture of animal health products was transferred to a third party and their production in the IE3 facility ceased
- In 2011, production of medicines for regulatory approval commenced in the new biotechnology manufacturing facility (Building IE42)
- In 2011, Lilly announced the expansion of the production capacity for biopharmaceutical products at the Kinsale plant with the addition of a new biotechnology manufacturing facility (Building IE43). This was completed in 2014. It is planned to commence commissioning in 2014.

There are no disused over or underground storage tanks or waste disposal/treatment areas onsite. There are also no direct emissions to groundwater from the site. A map of the facility is included in Appendix 2.

4.1.1 Incidents on site – hazardous substances

There are two recorded incidents of potential release of hazardous substances. Please refer to Section 3.4.

4.1.2 Existing Data on Groundwater and Soil

There are 3 existing sources of information regarding soil and groundwater quality at the facility. They include predominately groundwater monitoring datasets, with some limited soil analysis, which have been compiled from:

- licence compliance monitoring (groundwater)
- the response to the MTBE pollution incident (groundwater)
- a subsoil investigation conducted under IE3 to facilitate its demolition

A summary of each is given below.

Groundwater Licence Compliance Monitoring

Groundwater monitoring has been carried out biannually in accordance with the licence at a number of groundwater wells. There are currently 8 groundwater wells monitored on-site. Monitoring of the following parameters is conducted; pH, COD, Conductivity, Major cations, Major anions, Metals (Hg, Cd, Tl, As, Pb, Cr, Cu, Ni, Zn) and Trace Organics. The groundwater samples are screened biannually for the priority pollutant list substances (such as CLP 40, US EPA volatile and/or semi-volatile).

With the exception of MTBE (discussed below), monitoring results show that groundwater generic assessment criteria such as Groundwater Threshold Values (GTVs) or Interim Guideline Value (IGVs) were not exceeded in 2013 nor is there an upward trend in results for a substance since monitoring began. GTVs were established in Ireland in 2010 by the Environmental Objectives (Groundwater) Regulations of 2010 (S.I. No. 9 of 2010). IGVs were established by the EPA in 2003 to set interim values in Ireland under the Water Framework Directive (2006/60/EEC) until further criteria were established at Community level. The IGVs were established by 'Towards Setting Interim Guideline Values for the Protection of Groundwater in Ireland – Interim Report, EPA 2003.'

MTBE Pollution Incident

There is one known pollution incident of the non-hazardous substance MTBE where residual impacts are confined to a localised area of the on-site groundwater aquifer at well 18 (previously named RW-1). The presence of MTBE in this area relates to an historic incident that occurred in 2003 in the IE8 production building. The presence of MTBE in this area relates to an historic incident that occurred in 2003 in the IE8 production building. The MTBE impacts in the groundwater are now considered largely remediated, however remediation efforts are ongoing to further improve and sustain the quality of the groundwater at this localized area of the site aquifer. MTBE continues to be detected, now at low levels below the Agency's Groundwater Interim Guideline Value of 30 µg/l. Further details on this incident are included in Attachment I.5 of the licence review application form.

Subsoil Investigation beneath IE3

An assessment of the subsoil quality underlying the IE3 building was undertaken in 2013 as part of proposed demolition works. The building at IE3 was operational until 1997 and a range of organic solvents were used within the building when it was active.

The demolition process included the removal of the building, the foundations and some of the underlying subsoils. While there were no known pollution incidents in IE3 the assessment of the subsoils was carried out to determine if the past use of the building could have impacted on the subsoils and also to characterise those subsoils that will require removal and off-site disposal.

The solid samples were tested for TOC, BTEX (benzene, toluene, ethylbenzene and xylene) PCB, Mineral Oil and PAH. Leachate generated from the samples was tested for arsenic, barium, cadmium, chromium, copper, mercury, molybdenum, nickel, lead, antimony, selenium and zinc, chloride, fluoride, soluble sulphate, phenols, dissolved organic carbon (DOC) and total dissolved solids (TDS). The parameter range was based on the site history and the need to establish a comprehensive environmental baseline for the soil quality for the proposed development.

Based on the historical use of solvents in IE3 in various manufacturing process the soil samples were also analysed for volatile organic compounds (VOCs) and semi-volatile organics (SVOC). Laboratory analysis indicated that the subsoils were uncontaminated and suitable for recovery and/or disposal as inert waste.

4.2 Stage 5: Environmental Setting

4.2.1 Soils

Site investigations works conducted on site have confirmed the soils underlying the site comprise a reworked grey or grey brown sandy clayey gravel or gravelly clay with concrete constituents.

The indigenous soils comprise grey brown and reddish brown, sandy gravelly clay with medium to high cobble content. It is thought that these soils represent heavily over consolidated ablation till with local fluvio-glacial outwash deposits. The glacial till matrix is predominantly clay in nature but silt dominant till is also known to occur at the site, and was as identified during the earthworks phase of IE42.

4.2.2 Bedrock

The bedrock underlying the site is of Lower Carboniferous age, and is belong to the Kinsale and the Courtmacsherry Formations. The Kinsale Formation consists mainly of calcareous mudstones or muddy limestones, while the Courtmacsherry Formation comprises calcareous mudstone, calcareous siltstone and limestone.

4.2.3 Hydrogeology

The main aquifers in the southwest Cork region are isolated sand and gravel deposits. These predominantly occupy narrow stretches along the rivers, including the Bandon River. The Geological Survey of Ireland has devised a system for classifying the aquifers in Ireland based on the hydrogeological characteristics, size and productivity of the groundwater resource. The three main classifications are Regionally Important Aquifers (RI), Locally Important Aquifers (LI) and Poor Aquifers (P). The Geological Survey of Ireland aquifer classification for the site and surrounds is (PI) Poor Aquifer – bedrock which is Generally Unproductive except for Local Zones.

Groundwater movement in the bedrock is concentrated in fractures and fissures, and along bedding planes. These occur predominantly close to the bedrock surface. Ground water movement beneath the site has been interpreted as generally following the topography of the site, refer to Section 4.2.5 below for further detail.

Subsequent to the MTBE incident in 2004, geophysical surveys were carried out on site to determine potential preferential migration pathways for the contamination in the bedrock aquifer. Two main fracture zones were identified in the south of the site which are in a north-south and a northwest-southeast orientation. Pumping tests indicated connection between wells along the identified bedrock fracture zones with a radius of influence around each well in the region of 100 m.

4.2.4 Groundwater Vulnerability

The Geological Survey of Ireland groundwater vulnerability maps show that the main vulnerability rating under the site is 'High (H)'. The combination of poor aquifer and high vulnerability gives a resource protection zone rating of PI/H.

4.2.5 Groundwater Flow & Use

Groundwater to the north east and south east of the site flows in a south easterly direction towards the River Doon which corresponds with the local and on-site topography. The groundwater flow direction in the southern region of the site is seen to have a south westerly flow direction following site topography to the southern side of the River Doon valley.

The groundwater abstraction from production wells W16 and W17 in the north western region of the site influences the groundwater flow direction in this region of the site, creating a cone of depression in the water table in that area.

A groundwater flow divide is seen to be present in the eastern area of the site with an element of groundwater to the west towards the pumping wells and to the south east toward the River Doon valley. A groundwater pumping test carried out in 2011 determined that there are confined aquifer conditions on site and showed that the on-site abstraction has no impact on the river water levels and the confined aquifer conditions indicate no direct hydraulic connection between the groundwater and the surface.

A substantial proportion of the water used in the Lilly plant is supplied by ground water from a series of onsite boreholes. In 2013, 248,152 m³ of groundwater was used in the plant. There are no direct discharges to the ground or groundwater on site and a comprehensive series of measures are in place to protect the groundwater under the site.

The results of a GSI well search for the area of the site indicates that there are no large groundwater abstraction wells located in the immediate vicinity or catchment area of the site.

4.2.6 Hydrology

The site is located in the Doon river catchment which is set in a dominantly rural coastal/agricultural hinterland. The topography of the local area is dominated by rolling hills with steep valleys. A number of private residences and farm buildings are located within the river catchment. The dominant hydrological features in the area are the Bandon River Estuary and Kinsale Harbour. A stream flows in an approximate northeast-southwest direction through the Lilly site. This stream originates in the hills of Clogheen and Tuckene, several kilometres to the northeast of the site, and enters the River Bandon at Doon Creek, approximately 1 km to the southwest of the site. A small tributary stream has been culverted throughout the length of the plant site. The culverted stream flows in an approximately north-south direction through the site and discharges into the larger stream at the south eastern site perimeter.

4.2.7 Ecologically Protected Areas

The nearest proposed Natural Heritage Area (pNHA) is located over 2 km from the facility. It is a portion of the tidally influenced Bandon Estuary. There are no protected areas of any Groundwater Dependant Terrestrial Ecosystems (GWDTE) in the immediate vicinity of the site.

4.2.8 Surrounding Land use and Interdependencies

The primary land use in the area up-gradient of the site is agriculture. The main sources of agricultural pollution are farmyard percolating to ground in surface runoff. Land spreading of agricultural waste, if not managed correctly, can also lead to contamination. Results of groundwater sampling carried out in 2011 as part of an assessment of abstraction potential on site, indicates that nitrates are not exceeding drinking water standards and the faecal contamination is low. Therefore there does not appear to be a land spreading issue affecting the nitrate groundwater concentrations beneath the site.

4.2.9 Pathways

There are a number of potential connections on site between the above ground activities and the subsurface environment. The risk of these acting as potential pathways is mitigated by site design, site management and operational procedures.

All of the facilities have been developed on a hardstanding area with integrated drainage systems and bunding where required. The drainage system also incorporates roads, car parks and pathways. Surface water collected on site via the drainage network is managed in a surface water collection system with an attenuation pond. There is continuous monitoring of the pond and automated shut-down systems in the event of trigger level breaches.

Storage facilities and tanker unloading areas as discussed in Stage 3 are designed in accordance with BAT. The vast majority of pipework on site is over ground with hard surface underneath pipe racks carrying hazardous substances. CCTV cameras are strategically located around site and are continuously monitored by security personnel. Pipelines carrying hazardous materials are also on a site inspection programme that is executed by experienced engineers. Where underground pipes exist, they are doubly contained and are inspected and monitored regularly.

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5 STAGE 7: SITE INVESTIGATION

A site investigation was carried out on site to characterise the baseline conditions of soil across the facility. There is a large groundwater dataset for the site that is representative of groundwater flow and activities, but soil sampling to date was limited to specific areas. Eli Lilly retained O' Callaghan Moran & Associates (OCM) to carry out the subsoil investigation. It was completed in September 2014 and the full report is included as Appendix 2. A targeted sampling regime was used. Ten boring locations were selected as per Table 7.1. Figure 2.2 of the full report (Appendix 2) shows the site layout and boring locations.

Table 5.1: Soil Boring Locations

Soil Boring Location I.D.	Site Location	Significance
S-1	East of security building	Upgradient, greenfield – representative of background conditions
S-2	South of main solvent tank farm	Downgradient of area of minor contamination from fault in tank farm drainage system and also scale of tank farm
S-3		
S-4		
S-5	East of IE34	Area of historic HFO leak
S-6	South of old waste solvent tank farm	Scale of old waste solvent tank farm
S-7	South East of new waste solvent tank farm	Scale of new waste solvent tank farm
S-8	Downgradient of main production spine and WWTP	Scale of operations
S-9	Downgradient of main drum store	Scale of drum storage
S-10	Downgradient of IE8	IE8 –site of MTBE pollution incident

The soil boring was supervised by the Consultant and logged. Samples were screened for VOCs in-situ; VOCs were not detected. No visual or olfactory evidence of contamination was noted in the fill or underlying subsoils. Composite subsoil samples were collected to 1m and a second sample was collected in all boreholes except S-5 from 1-2 m. The second sample was held in the event of contamination detected in the first sample. S-5 terminated at bedrock at 1.6 m. Samples were couriered to an independent UKAS accredited laboratory in the UK. The soils samples were analysed for:

- Landfill Waste Acceptance Criteria (WAC) from Annex II of Directive (1999/31/EC)
- TOC, BTEX, PCB, Mineral Oil and PAH, VOCs, sVOCs, alcohols and acetates
- Leachate generated from the samples was tested for arsenic, barium, cadmium, chromium, copper, mercury, molybdenum, nickel, lead, antimony, selenium and zinc, chloride, fluoride, soluble sulphate, phenols, dissolved organic carbon (DOC) and total dissolved solids (TDS).

Results were compared to:

the thresholds specified in Annex II of Directive 1999/31/EC (WAC), and to the UK Environment Agency Soil Guideline Values (SGVs).

The laboratory analysis confirms that the subsoils are uncontaminated. No evidence was found of relevant hazardous substances VOCs (including 1,2-dichloroethane and dichloromethane), the PAH toluene or of HFO from the historic leak.

6 STAGE 8: SUMMARY OF FINDINGS

This chapter includes a brief summary of each of the stages completed to produce this baseline report.

6.1 Requirement for Baseline Report

The facility is operated under an Industrial Emission Licence (EPA Licence Ref No P0009-03) with the principal activity being the manufacture of pharmaceutical and veterinary products. Section I of the IE licence application form on *Existing Environment and Impact of the Activity* seeks a baseline report, where the activity involves the use, production or release of relevant hazardous substances and having regards to the possibility of soil and groundwater contamination.

6.2 Scope of the Baseline Report

The Commission produced guidance on the content of the baseline report, *European Commission Guidance concerning baseline reports under Article 22(2) of Directive 2010/75/EU on industrial emissions*. This baseline report has been prepared in accordance with the Guidance.

The Guidance establishes a number of key tasks that should be undertaken to firstly determine the need for a baseline report and secondly the steps required to produce it. Eight stages have been identified with:

- Stages 1-3: decide whether a baseline report is required
- Stages 4-7: determine how a baseline report is to be prepared
- Stage 8: determine the content of the report.

During this process, Stages 1-3 demonstrated that a baseline report is required and Stages 4-7 were completed, resulting in this baseline report.

6.3 Stage 1: Hazardous Substances

A list of all raw materials, intermediates and products used on site was compiled. The vast majority of substances on the list are classified as hazardous. The non-hazardous substances were denoted as such on the list and eliminated² from the baseline investigation process.

6.4 Stage 2: Relevant Hazardous Substances

Relevant hazardous substances are those which are capable of contaminating soil or groundwater. Using Annex 1 of *Classification of Hazardous and Non-Hazardous Substances in Groundwater*, EPA 2010, the list of hazardous substances was checked to determine their classification. Annex 1 is not an exhaustive list of all substances, therefore the following notes were applied to the table: hazardous, non-hazardous, not determined, or N/A (where the substance was not included on Annex 1).

Substances with the risk phrase R56 are toxic to soil organisms. None of the substances on the list have the risk phrase R56. Risk phrases are as per the European Communities (Classification, Packaging and Labelling of Dangerous Preparations) Regulations 2004 (S.I. No. 62 of 2004 as amended by S.I. No. 13 of 2008).

² Substances were not removed from the list, but once eliminated from the investigation, were shaded in dark grey and noted so that the list can be filtered to remove them.

6.5 Stage 3: Identification of Potential Pollution Risk

Each substance brought forward from Stage 2 was considered in the context of the site to determine whether circumstances exist which may result in the release of the substance in sufficient quantities to represent a pollution risk either as a result of a single emission or as a result of accumulation from multiple emissions. Gases and solids were eliminated from the list based on their physical state and controls on site.

The management history of this site is an important factor in decision making for this baseline report. The site was a greenfield site before Eli Lilly purchased it for development. Since operations commenced the site has and is subject to environmental management controls and is designed and operated in accordance with BAT. This site is also a highly automated and controlled site and monitoring data is available since operations commenced.

There have been two incidents involving the potential release of hazardous substances to soil or groundwater since operations commenced. Both incidents were minor in nature. The locations of both incidents were included in the subsoil assessment. Other locations were chosen for the soil sampling based on historic potential pollution risk and future potential pollution risk. The rationale for choosing these locations was the quantity of substances stored and scale of the operation. There are appropriate controls in place to mitigate any risk to the environment and there was no reason to choose these locations other than the scale of materials stored and the scale of the process. These areas include the:

- the bulk solvent storage facility
- the waste solvent storage area
- the main drum storage warehouse
- the main production spine and WWTP

6.6 Outcome of Stages 1-3

In light of the above assessment of the site specific pollution possibilities based on quantities of materials stored, the scale of the production of the facility and the two recorded incidents, it was determined that a baseline study was required for the site.

6.7 Stage 4: Site History

The site history is fully documented. There have been three incidents on site. Two of the incidents involved hazardous substances, were minor in nature and were subject to site investigation and remediation at the time. The third event was an MTBE pollution incident. MTBE is non-hazardous and therefore is not directly applicable to this baseline report, however Eli Lilly has included details of the event and the ongoing remediation.

A review of all monitoring results and site investigations was carried out. The site has been licensed by the EPA since 1995, so there is a significant database of licence compliance monitoring results. Groundwater monitoring has been carried out biannually for a range of pollutants including the priority pollutants list substances. There were no exceedances of hazardous substances in 2013, nor is there an upward trend in parameters concentrations since monitoring began.

A subsoil investigation on the ground beneath IE3 was carried out in 2013 as part of proposed demolition works. Soil samples were tested for a range of parameters based on the site history. Laboratory analysis indicated that the subsoils were uncontaminated and suitable for recovery and/or disposal as inert waste.

6.8 Stage 5: Environmental Setting

A review of the environmental setting was carried out. The area is predominantly rural and the main activity upgradient of the facility is agriculture. The site is located in the Doon river catchment which is set in a dominantly rural coastal/agricultural hinterland.

The dominant hydrological features in the area are the Bandon River Estuary and Kinsale Harbour. A stream flows in an approximate northeast-southwest direction through the Lilly site. There are no protected areas of any Groundwater Dependant Terrestrial Ecosystems (GWDTE) in the immediate vicinity of the site. The soils underlying the site comprise a reworked grey or grey brown sandy clayey gravel or gravelly clay with concrete constituents. The bedrock underlying the site is of Lower Carboniferous age, and is belong to the Kinsale and the Courtmacsherry Formations. The Kinsale Formation consists mainly of calcareous mudstones or muddy limestones, while the Courtmacsherry Formation comprises calcareous mudstone, calcareous siltstone and limestone. The aquifer classification for the site is (PI) Poor Aquifer – bedrock which is Generally Unproductive except for Local Zones. The groundwater vulnerability rating under the site is 'High (H)'. Groundwater flow is interpreted as being in a south easterly direction on the eastern side of the site and as being in a south westerly direction on the western side of the site. There are a number of potential connections on site between the above ground activities and the subsurface environment. The risk of these acting as potential pathways is mitigated by site design, site management and operational procedures.

6.9 Stage 7: Site Investigation

A site investigation was carried out on site to characterise the baseline conditions of soil across the facility. The soils samples were analysed for:

- Landfill Waste Acceptance Criteria (WAC) from Annex II of Directive (1999/31/EC)
- Organic Carbon (TOC), BTEX (benzene, toluene, ethylbenzene and xylene) PCB, Mineral Oil and PAH, VOCs, sVOCs, alcohols and acetates
- Leachate generated from the samples was tested for arsenic, barium, cadmium, chromium, copper, mercury, molybdenum, nickel, lead, antimony, selenium and zinc, chloride, fluoride, soluble sulphate, phenols, dissolved organic carbon (DOC) and total dissolved solids (TDS).

Results were compared to:

the thresholds specified in Annex II of Directive 1999/31/EC (WAC), and to the UK Environment Agency Soil Guideline Values (SGVs).

The laboratory analysis confirms that the subsoils are uncontaminated.

Appendix 1

Stages 1-3 Identification of Substances

Table A.1 List of All Substances

Table A.2 Stage 1 - List of Hazardous Substances

Table A.3 Stage 2- List of substances that may be hazardous to soil or groundwater

Table A.4 Stage 3 - List of Relevant Hazardous Substances

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Material/ Substance(1)
2-PROPANOL
1,2-Dimethoxyethane
1,3-dimethyl-2-imidazolidinone
10% Benzyl Alcohol in Toluene (2191308)
2-(N-MORPHOLINO)ETHANE SULFACID SOD SALT
2-(N-MORPHOLINO)ETHANE SULFONIC ACID
2,4-DIAMINO-6-HYDROXYPYRIMIDINE
20% Diisobutylaluminum Hydride in Toluene
2-CHLOROETHANESULFONYL CHLORIDE
2-ETHYL-1-BUTANOL
2-Fluorotoluene
2-METHYLTETRAHYDROFURAN
4-(P-Hydroxyphenyl)-Butan-2-one
5% Palladium on Carbon
ACETIC ACID 100 %
Acetone
Acetonitrile
Acetylacetone
ACETYL CHLORIDE
Activated Carbon (Ecosorb C947)
Alcohol s d no. 3a absolute
Amberlyst 15 Resin
Anhydrous Ammonia
AMMONIUM CHLORIDE
Amyl Acetate (98%)
ANTI-FOAM C EMULSION
Atomoxetine Hydrochloride
Atomoxetine Mandelate
Baricitinib
Bentonite clay
Benzodiazepine Hydrochloride
Benzoic acid tech
BENZOTETRAZOLE
Benzothiophene
Benzyl Alcohol
Benzyl Edroxetine Fumarate (LSN2398789)
Beta Ketosulfide
Bis(pinacolato)diboron
Boron trichloride
Bromine
BROMOBENZIMIDAZOLE
CARBON DIOXIDE GAS
Caustic Soda 25%
CD-17 MEDIA
CHEMATIC 1700CL
Chlorodimethoxy triazine
CHLOROPYRIMIDINE INTMD
CHO CELL CUSTOM ACID FEED

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CHO CELL CUSTOM NEUTRAL FEED
CHO CUSTOM ACID FEED W/O TYROSINE
CHT HYDROXYAPATITE RESIN
CIP100
CIP200
Cis-3,5-dimethylpiperidine
CITRIC ACID ANHYDROUS POWDER 60 GU
CUSTOM NEUTRAL FEED W/O GLUCOSE
D, l-Octopamine hydrochloride
Darco G60
Deazaguanine acid
DEC-Bromosulfoxide (DBS)
DEXTROSE (GLUCOSE ANHYDROUS)
DIBASIC SODIUM PHOSPHATE CRYSTALS
Di-chloro-bis-cyclooctadiene
Dichloromethane
Diesel
Dimethyl sulfoxide high purity grade
Dimethylformamide
DPEPhos
70% di-tert-butyl dicarbonate in tetrahydrofuran
ETHANOL 70% SOLUTION
Ethyl acetate
ETHYLAMINE (70% SOLUTION)
Ethylene Dichloride
Ethylene Glycol (Dowcal 100)
Formic acid 98 percent
FUMARIC ACID
GLACIAL ACETIC ACID
GLP FC
Granular Salt
GSEM SUPPLEMENT
HEPES BUFFER
Heptane
HYDRAZINE (35% AQUEOUS)
HY10275 PHOSPHATE MICRONISED
HY10275 PHOSPHATE SEED
HYDRANAL-COMPOSITE 5 K ONE
HYDRANAL-COULOMAT AG
HYDRANAL-WORKING MEDIUM K SOLVENT
Hydrobromic Acid
Hydrochloric Acid
Hydrogen
HYDROXYQUINOLINE
Isobutanol
Isopropyl alcohol
K-tBuO in Tetrahydrofluoride (KTB in THF)
L METHIONINE SULFOXIMINE
L(+)-mandelic acid
LACTAM 55962

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LACTIC ACID (30%)
L-ASPARAGINE MONOHYDRATE
L-ASPARTIC ACID
L-CYSTINE
LGlutamic acid diethyl ester hydrochloride
Liquid nitrogen
L-proline
LSN 2808053
LSN 417420
LSN2963227
LSN3030577 (BORONATE ESTER 577)
LSN247460 (AZA-INDOLE 460)
LSN2835219
LSN3090771 Potassium Bisulphite Adduct
LSN2523800 Benzylaminotetrazole Azepane
LSN2524875 (Evacetrapib Methyl Ester)
LSN2484595 (Evacetrapib anhydrate)
LSN3189129
LSN2157217 Chloro Pyrazine
LSN2794612 SEED
LSN3135709 solvate (PYRAZOLCARBOXAMID Ether Int)
LSN2801653 SEED (PYRAZOLECARBOXAMIDE F2)
L-TYROSINE
L-TYROSINE DISODIUM DIHYDRATE
LY2523301 - 'BOC-SM'
LY2523303 - HCl SALT
LY2523355 - EG5
LY2553929 FUMARIC ACID SALT
LY2553929 FUMARIC ACID SALT SEED
LY2784544
LY2189265 (Glp-Fc)
LY2127399 (LA294)
LY2439821 (LA426)
LY3009806 (IMC-1121B)
LY2801653
MAB SELECT RESIN
Magnesium Turnings
MEDIUM R ACIDIFIED
MEM AMINO ACID SOLUTION
Methanesulfonic acid Technical
METHANOL
Methyl Ethyl Ketone
Methylglyoxylate
Methylparaben
MTA ALDEHYDE
MTA Glutamate
Methyl Tert Butyl Ether
N,N-DIMETHYLFORMAMIDE
Nalco 77261
Nalco Water Treatment 1318

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Nalco Water Treatment 22310
Nalco Water Treatment 3DT289
Nalco Water Treatment 77211
Nalco Water Treatment 77393
Nalco Water Treatment 93033
Natural Gas
N-Butanol
N-ETHYLMORPHOLINE
N-HEXANE
Nitric Acid
Nitrogen (oxygen free)
N-methylindole-acetamide
N-methylmorpholine
N-methylpiperazine
N-TETRABUTYLAMMONIUM HYDROXIDE
Olanzapine
ORTHO-PHOSPHORIC ACID 85%
Oxalyl chloride
OXAZEPINE METHYL ESTER 2629863
OXAZEPINE METHYL ESTER 2629863 SEED
Palladium 10% on carbon
Palladium (Pd-100)
Pd 134 (Xant-Phos) Palladium dichloride
Pamoic acid
Pemetrexed Disodium Heptahydrate
Phenyl Methyl Amino Propanol
PHOSPHORIC ACID
PHOSPHORUS OXYCHLORIDE
PIPERAZINE
Piperidinoethylchloride (hcl)
PiperidinyI Ethoxy Benzoic Acid
PiperidinyIEthoxyPhenol (PEP)
Platinum 5% on carbon, water wet
POLYSORBATE 80 VEGETABLE
Potassium Acetate
POTASSIUM BICARBONATE
Potassium Carbonate
POTASSIUM CHLORIDE
Potassium hydroxide
POTASSIUM PHOSPHATE MONOBASIC
Potassium t-amylate in toluene
Potassium tert-butoxide
Propanol
P-Toluene sulfonic acid 96%
Q SEPHAROSE HIGH PERFORMANCE RESIN
Raloxifene Hydrochloride
Sabre P1074XL
Salt
5-Benzylmorpholine Mesylate (Production intermediate material 2463667)
SERINE

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Silica-Thiol Resin
SOD PHOSPHATE MONOBASIC MONOHYDRATE GU
SODIUM ACETATE ANHYDROUS
SODIUM BICARBONATE - CELL CULTURE GRADE
SODIUM BISULFITE
Sodium Carbonate
SODIUM CHLORIDE
SODIUM CITRATE GRANULAR
SODIUM HYDROXIDE
Sodium Hypochlorite
Sodium Meta Bi Sulphite
SODIUM PHOSPHATE DIBASIC
SODIUM PHOSPHATE MONOBASIC MONOHYDRATE
Sulfuric acid 50%
Sulphuric Acid 96% Bulk
t-Amyl Alcohol
Tetra-n-Butyl Ammonium Iodide
TCN Production intermediate material
TERTIARY BUTANOL
TETRADECYLTRIMETHYLAMMONIUM BROMIDE
TETRAHYDROFURAN ANHYDROUS
Tin (ii) chloride anhydrous
Toluene
TRIETHYLAMINE
Triphenylphosphene
TRIS BASE
TRIS HYDROCHLORIDE
Tripotassium phosphate
TRITON X-100
Trypan Blue
YEASTOLATE MEDIA - ULTRAFILTRATE (50x)

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Material/ Substance(1)	Danger ⁽²⁾ Category	Amount Stored (tonnes)	Annual Usage (tonnes)	Nature of Use	R ⁽³⁾ - Phrase	Stage 1 Ruled out based on Danger Category
2-PROPANOL	F,Xi	Note 1	Note 1	Production raw material	11,36,67	N
1,2-Dimethoxyethane	F (Highly Flammable), Xn (Harmful), Reproductive Category 2	3	5	Production raw material	R60; R61; R11; R19; R20	N
1,3-dimethyl-2-imidazolidinone	Xn (Harmful), Xi (Irritant), Reproductive Category 3	10	5	Production raw material	R21/22, R36/37, R41, R63	N
10% Benzyl Alcohol in Toluene (2191308)		Note 1	Note 1			N
20% Diisobutylaluminum Hydride in Toluene	F (Highly Flammable), C (Corrosive)	0.1	0.1	Production raw material	R11; R38; R48/20; R63; R65; R67; R14/15; R17; R35	N
2-CHLOROETHANESULFONYL CHLORIDE	T+ (Very Toxic)	Note 1	Note 1	Production raw material	R22; R26; R34	N
2-ETHYL-1-BUTANOL	Xn (Harmful)	3	12		R21, R22	N
2-Fluorotoluene	F (Highly Flammable), Xi (Irritant)	15	20	Production raw material	R11, R36/37/38	N
2-METHYLTETRAHYDROFURAN	F (Highly Flammable)	3	12	Production raw material	R11; R19; R22; R36/38	N
4-(P-Hydroxyphenyl)-Butan-2-one	Not classified as a hazardous substance.	1	5	Production raw material		N
ACETIC ACID 100 %	Flammable, Corrosive	1	14	Production raw material	R10, R35	N
Acetone	F (Highly Flammable), Xi (Irritant)	50	150	Production raw material	R11, R36, R66, R67	N
Acetonitrile	F (Highly Flammable), Xn (Harmful), Xi (Irritant)	50	80	Production raw material	R11, R20/21/22, R36	N
Acetylacetone	Acute Tox. 4; Flam. Liq. 3	0.05	0.1	Production raw material	R10, R20/21/22	N
ACETYL CHLORIDE	F (Highly Flammable), C (Corrosive)	Note 1	Note 1	Production raw material	R11; R14; R34	N
Alcohol s d no. 3a absolute	F(Highly Flammable), Xn (Harmful)	50	350	Production raw material	R11	N
Amberlyst 15 Resin	Not assigned an overall EC classification.	0.5	2	Production raw material	R36	N
Anhydrous Ammonia	Toxic, corrosive, dangerous for the environment	6	30	Utilities	R10, R23, R34, R50	N
AMMONIUM CHLORIDE	Acute Tox. 4 (oral); Eye Irrit. 2	0.05	0.1	Production raw material	R22; R36	N
Amyl Acetate (98%)	Flammable	40	100	Production raw material	R10, R66	N
ANTIFOAM C EMULSION	Xn (Harmful)	0.025	0.1	Production raw material	R50, R53, R62	N
Atomoxetine Hydrochloride	T (Toxic), Xi (Irritant), N (Dangerous for the Environment)	5	20	Production final material	R23/25, R41, R50/53	N
Atomoxetine Mandelate	T (Toxic), Xi (Irritant), Xn (Harmful), N (Dangerous for the Environment)	0.25	20	Production intermediate material	R22, R23, R41, R50/53	N
Baricitinib	Xn (Harmful)	1	2	Production material	R61; R48/22	N
Benzodiazepine Hydrochloride	Xn (Harmful), Xi (Irritant)	1	50	Production intermediate material	R20/22, R41	N

Benzoic acid tech		0.1	1		R37, R41	N
BENZOTETRAZOLE		Note 1	Note 1			N
Benzothiophene	Not assigned an overall EC classification.	20	50	Production intermediate material	none	N
Benzyl Alcohol	Acute Tox. 4 (oral); Acute Tox. 4 (inhalation); Eye Irrit. 2	0.5	1	Production raw material	R20/22	N
Benzyl Edivoxetine Fumarate (LSN2398789)		0.5	1	Production intermediate material		N
Beta Ketosulfide	N (Dangerous for the Environment)	30	60	Production raw material	R51/53	N
Bis(pinacolato)diboron	Eye Irrit. 2; Skin Irrit. 2; STOT SE 3	1	2	Production raw material		N
Boron trichloride	T+ (Very Toxic), C (Corrosive)	20	70	Production raw material	R14, R26/28, R34	N
Bromine	T+ (Very Toxic), C (Corrosive), N(dangerous to the environment)	0.5	1	Production raw material	R26, R35, R50	N
Caustic Soda 25%	Contains Sodium Hydroxide (C = 7.4 - 25%), C (Corrosive)	20	400	Production raw material	R35	N
CHEMATIC 1700CL	C (Corrosive), Xn (Harmful)/ C (Corrosive), N (Dangerous to the environment)	0.5	8	Stainless steel cleaner	R22, R35/ R31, R34, R50	N
Chlorodimethoxy triazine	Xn (Harmful), C (Corrosive)	0.25	1.5	Production raw material	R20/22, R 34, R 41	N
CIP100	C, Xn	15	40	Production raw material	R22, R35, R	N
CIP200	C, Xi	15	60	Production raw material, Maintenance & Utilities	R34, R36	N
Cis-3,5-dimethylpiperidine		0.1	1			N
CITRIC ACID ANHYDROUS POWDER 60 GU	Xi (Irritant)	0.01	0.2	Production raw material	R36	N
D, l-Octopamine hydrochloride	Xn (Harmful) (Irritant) Xi	0.25	1		R22, R36/37/38	N
Darco G60	Not classified	0.15	0.5	Production raw material		N
Deazaguanine acid	Not assigned an overall EC classification.	0.15	0.5	Production intermediate material	Not assigned an overall EC classificatio	N
DEC-Bromosulfoxide (DBS)	Not classified as a hazardous substance.	Note 1	Note 1	Production intermediate material		N
Di-chloro-bis-cyclooctadiene	Acute Tox. 4; Skin Irrit. 2; Eye Irrit. 2; STOT SE 3	0.005	0.01	Production raw material	R20/21/22, R36/38	N
Dichloromethane	Xn (Harmful)			Production raw material	R40	N
Diesel	Carcinogen, dangerous for the environment, flammable	20	40	Utilities, Maintenance & Utilities	R20, R38, R40, R51/53, R65	N
Dimethyl sulfoxide high purity grade	Xi (Irritant)	5	100	Production raw material	R36/37/38	N
Dimethylformamide	T (Toxic), Xn (Harmful), Xi (Irritant), Reproductive Category 2	15	100	Production raw material	R20/21, R36, R61	N
70% di-tert-butyl dicarbonate in tetrahydrofuran	T+ (Very Toxic), F (Highly Flammable), Xi (Irritant)	0.2	0.5	Production raw material	R11, R26, R36/37/38	N
ETHANOL 70% SOLUTION	F (Highly Flammable)	20	20	Production raw material	R10	N
Ethyl acetate	F (Highly Flammable), Xi (Irritant)	50	200	Production raw material	R11, R36, R66, R67	N
ETHYLAMINE (70% SOLUTION)	F+ (Extremely Flammable); Xi (Irritant)	Note 1	Note 1	Production raw material	R11, R35, R37	N

Ethylene Dichloride	F (Highly Flammable), T (Toxic), Xn (Harmful), Xi (Irritant), Carcinogen Category 2	75	250	Production raw material	R11, R 22, R 36/37/38, R45	N
Ethylene Glycol (Dowcal 100)	Xn (Harmful)	25	10	Maintenance & Utilities	22	N
Formic acid 98 percent	C (Corrosive)	0.5	1	Production raw material	R10, R35	N
FUMARIC ACID	Xi (Irritant)	0.01	0.5	Production raw material	R36	N
GLACIAL ACETIC ACID	C (Corrosive)	0.1	1	Production raw material	R10, R35	N
GLP FC	Not classified as a hazardous substance.	1	10	Production material		N
Granular Salt	Not classified as a hazardous substance.	2	20	Maintenance & Utilities		N
Heptane	F (Highly Flammable), Xn (Harmful), Xi (Irritant), N (Dangerous for the Environment)	50	50	Production raw material	R11, R38, R50/53, R65, R67	N
HYDRAZINE (35% AQUEOUS)	Acute Tox. 4; Skin Corr. 1B; Skin Sens. 1; Carc. 1B; Aquatic Acute 1; Aquatic Chronic 1	0.02	0.05	Production raw material	R45, R20/21/22, R34, R43, R50/53	N
HY10275 PHOSPHATE MICRONISED		Note 1	Note 1			N
HY10275 PHOSPHATE SEED		Note 1	Note 1			N
HYDRANAL-COMPOSITE 5 K ONE		0.02	0.05	Production raw material		N
HYDRANAL-COULOMAT AG		0.02	0.05	Production raw material		N
HYDRANAL-WORKING MEDIUM K SOLVENT		0.02	0.05	Production raw material		N
Hydrobromic Acid	C (Corrosive); Xi (Irritant)	1	4	Production raw material	R34; R37	N
Hydrochloric Acid	C (Corrosive)	20	100	Production raw material	R34, R37	N
Hydrogen	F+ (Extremely Flammable)	0.25	25	Production raw material	R12	N
HYDROXYQUINOLINE	Not classified as a hazardous substance.	0.25	1	Production intermediate material		N
Isobutanol	Xi (Irritant)	40	50	Production raw material	R10; R37/38; R41; R67	N
Isopropyl alcohol	F (Highly Flammable), Xi (Irritant)	45	100	Production raw material	R11, R36, R67	N
K-tBuO in Tetrahydrofluoride (KTB in THF)	F (Highly Flammable), C (Corrosive), Xn (Harmful)	0.5	2	Production raw material	R11, R14, R19, R35, R36/37	N
L METHIONINE SULFOXIMINE	Xi (Irritant)	0.01	0.1	Production raw material	R36/37/38	N
L(+)-mandelic acid	Xi (Irritant)	0.075	5	Production raw material	R37, R41	N
LACTAM 55962	Classification Pending	Note 1	Note 1	Production intermediate material		N
LACTIC ACID (30%)	Acute Tox Oral (Cat 5), Acute Tox Dermal (Cat 5) Skin Irritation (Cat 2), Serious eye damage (Cat 1)	0.5	1	Production raw material		N
L-ASPARTIC ACID	Xi (Irritant)	Note 1	Note 1	Production raw material	R36	N
Liquid nitrogen	Not assigned an overall EC classification.	25	500	Production raw material	none	N
L-proline	Xi (Irritant)	0.1	0.1	Production raw material	none	N
LSN 417420	Xn (Harmful)	0.225	1	Production intermediate material	R22	N

LSN2963227	T (Toxic); Repr. Cat 2	0.015	0.5	Production intermediate material	R25; R61	N
LSN247460 (AZA-INDOLE 460)	Xn (Harmful)	0.05	0.1	Production intermediate material	R22	N
LSN2835219	Repr. 1B; STOT RE 2	0.05	0.1	Production intermediate material	R60; R61	N
LSN3090771 Potassium Bisulphite Adduct	Flam. Solid 1	2	5	Production intermediate material		N
LSN2524875 (Evacetrapib Methyl Ester)	Repr. 2, Aquatic Acute 1	2	5	Production intermediate material	R63, R50/53	N
LSN2484595 (Evacetrapib anhydrate)	Repr. 2, Aquatic Acute 1	2	5	Production intermediate material	R63, R50/53	N
LSN2157217 Chloro Pyrazine	Acute Tox. 3; Skin Irrit. 2; Eye Irrit. 2	0.02	0.05	Production intermediate material	R25; R36/37/38	N
LSN2794612 SEED	Muta (Cat 2), Repr (Cat 2)	0.02	0.05	Production intermediate material	R46, R60/61	N
LSN3135709 solvate (PYRAZOLCARBOXAMID Ether Int)	Acute Tox. 4; Carc. 2; Repr. 1B; STOT - RE 1	0.2	0.5	Production intermediate material		N
LSN2801653 SEED (PYRAZOLECARBOXAMIDE F2)	Acute Tox. 4 (oral); Repr. 1B; STOT RE 1	0.01	0.05	Production intermediate material	R22; R62; R48/25	N
L-TYROSINE	Xi (Irritant)	Note 1	Note 1	Production raw material	R36/37/38	N
L-TYROSINE DISODIUM DIHYDRATE	Xi (Irritant)	0.01	0.05	Production raw material	R36/37/38	N
LY2523301 - 'BOC-SM'		Note 1	Note 1			N
LY2523303 - HCl SALT		Note 1	Note 1			N
LY2523355 - EG5		Note 1	Note 1			N
LY2553929 FUMARIC ACID SALT		Note 1	Note 1			N
LY2553929 FUMARIC ACID SALT SEED		Note 1	Note 1			N
LY2801653	Acute Tox. 4 (oral); Repr. 1B; STOT RE 1	0.1	0.5	Production final material	R22; R62; R48/25	N
MAB SELECT RESIN	F (Highly Flammable)	0.1	1	Production raw material	R10	N
MEM AMINO ACID SOLUTION	C (Corrosive)	0.01	0.1	Production raw material	R34, R41	N
Methanesulfonic acid Technical	C (Corrosive)	0.5	15	Production raw material	R34	N
METHANOL	F (Highly Flammable), T (Toxic)	50	1000	Production raw material	R11, R23/24/25 - R39/23/24/25	N
Methyl Ethyl Ketone	F (Highly Flammable), Xi (Irritant)	Note 1	Note 1	Production raw material	R11, R36, R66, R67	N
Methylglyoxylate	Xi (Irritant)	0.1	0.5	Production raw material	R36	N
MTA Glutamate	Not assigned an overall EC classification.	3	5	Production intermediate material	Not assigned an overall EC classification	N
Methyl Tert Butyl Ether	F (Highly Flammable), Xi (Irritant)	25	100	Production raw material	R11, R38	N
N,N-DIMETHYLFORMAMIDE		Note 1	Note 1	Production raw material	R61, R20/21, R36	N
Nalco 77261		5	12	Maintenance & Utilities		N
Nalco Water Treatment 1318		2	3	Utilities		N
Nalco Water Treatment 22310		0.5	2	Utilities		N
Nalco Water Treatment 3DT289		2	6	Utilities		N
Nalco Water Treatment 77211		0.5	2	Utilities		N
Nalco Water Treatment 77393		1	1	Utilities		N

Nalco Water Treatment 93033		5	12	Utilities		N
Natural Gas			7*10 ⁶ m3	Maintenance & Utilities		N
N-Butanol	Xn Harmful, Xi Irritant	25	50	Production raw material	R10, R22, R37/38, R41, R67	N
N-ETHYLMORPHOLINE	F (Flammable), C (Corrosive), Acute Tox (Cat 4)	0.02	0.05	Production raw material	R10, R34, R21/22	N
N-HEXANE	F (Flammable), Xn (Harmful), N (Dangerous for the Environment)	Note 1	Note 1	Production raw material	R11, R38, R48/20, R62, R65, R67, R51/53	N
N-methylindole-acetamide	Not classified as a hazardous substance	0.1	0.5			N
N-methylmorpholine	F (Highly Flammable), Xn (Harmful), C (Corrosive)	0.5	3	Production raw material	R11, R22, R34	N
N-methylpiperazine	C (Corrosive)	3.5	15	Production raw material	R10, R34	N
N-TETRABUTYLAMMONIUM HYDROXIDE	C (Corrosive)	0.01	0.1	Production raw material	R35	N
Olanzapine	T (Toxic), Xi (Irritant)	6.5	15	Production final material	R25, R36, R43, R52	N
ORTHO-PHOSPHORIC ACID 85%	C (Corrosive)	0.5	5	Production raw material		N
Oxalyl chloride	T+ (Very Toxic), C (Corrosive)	2	20	Production raw material	R14/15, R20/22, R29, R35, R37	N
OXAZEPINE METHYL ESTER 262	Not classified	Note 1	Note 1	Production intermediate material		N
OXAZEPINE METHYL ESTER 262	Not classified	Note 1	Note 1	Production intermediate material		N
Palladium 10% on carbon	F (Highly Flammable)	0.025	0.5	Production raw material	R11	N
Palladium (Pd-100)	Aquatic Chronic 4	0.005	0.01	Production raw material	R53	N
Pd 134 (Xant-Phos) Palladium dichloride		0.005	0.01	Production raw material	R43	N
Pamoic acid	Xi (Irritant)	0.65	1	Production raw material	R36/37/38	N
Pemetrexed Disodium Heptahydrate	T (Toxic), Xi (Irritant), Xn (Harmful) Mutagen Category 3, Reproductive Category 1	0.75	1	Production final material	R36/38, R60, R61, R68	N
Phenyl Methyl Amino Propanol	Xi (Irritant)	5	14	Production raw material	R38, R41	N
PHOSPHORIC ACID	C (Corrosive)	0.5	5	Production raw material	R34	N
PHOSPHORUS OXYCHLORIDE	T+ (Very Toxic), T (Toxic), Xn (Harmful), C (Corrosive)	Note 1	Note 1	Production raw material	R14, R22, R23, R26, R29, R35, R48	N
PIPERAZINE	Acute Tox. 4 (Oral); Eye Dam. 1	0.5	1	Production raw material	R22; R41	N
Piperidinoethylchloride (hcl)	T+ (Very Toxic), C (Corrosive), Mutagen Category 3	25	40	Production raw material	R26/28, R34, R68	N
Piperidinyl Ethoxy Benzoic Acid	Xi (Irritant),	20	40	Production intermediate material	R36	N
PiperidinylEthoxyPhenol (PEP)	Xi (Irritant), Xn (Harmful)	1	5	Production raw material	R22, R37/38-41	N
Platinum 5% on carbon, water wet	Not assigned an overall EC classification.	0.1	1	Production raw material	36/37/38	N
Potassium hydroxide	Xn (Harmful), C (Corrosive)	1	15	Production raw material	R22, R35	N

POTASSIUM PHOSPHATE MONOBASIC		Note 1	Note 1	Production raw material		N
Potassium t-amylate in toluene	C (Corrosive), F (Highly Flammable), Xn (Harmful)	Note 1	Note 1	Production raw material	R11, R14/15, R20, R35	N
Potassium tert-butoxide	C (Corrosive)	2.5	5	Production raw material	R14, R35	N
Propanol		Note 1	Note 1	Production raw material		N
P-Toluene sulfonic acid 96%	Xi (Irritant)	2.5	8	Production raw material	R36/37/38	N
Q SEPHAROSE HIGH PERFORMANCE	F (Highly Flammable)	0.1	0.5	Production raw material	R11	N
Raloxifene Hydrochloride	T (Toxic), Reproductive Category 1, Carcinogen Category 3, N (Dangerous to the Environment)	20	40	Production final material	R40, R50/53, R60, R61	N
Sabre P1074XL	Xi (Irritant)	2	10	Utilities	R36, R38	N
Salt	Not classified as a hazardous substance.	5	20			N
S-Benzylmorpholine Mesylate (Production intermediate material 2463667)	Xn (Harmful), Xi (Irritant)	1	10	Production intermediate material	R22, R36	N
SERINE		Note 1	Note 1	Production raw material		N
Silica-Thiol Resin	Xn (Harmful)	0.05	0.1	Production raw material	R20/21/22	N
SODIUM BISULFITE	Xn (Harmful)	Note 1	Note 1	Production raw material	R22, R31	N
SODIUM HYDROXIDE	C (Corrosive)	2	10	Production raw material	R35	N
Sodium Hypochlorite		1	5	Maintenance & Utilities	31,34	N
Sodium Meta Bi Sulphite		6	20	Utilities	37/38,41,42,43	N
SODIUM PHOSPHATE DIBASIC		Note 1	Note 1	Production raw material		N
SODIUM PHOSPHATE MONOBASIC MONOHYDRATE		Note 1	Note 1	Production raw material		N
Sulfuric acid 50%	Contains sulfuric acid (C = 10 to 51%), C (Corrosive)	4	15	Production raw material	R35	N
Sulphuric Acid 96% Bulk	Contains sulfuric acid (C = 10 to 51%), C (Corrosive)	20	50	Utilities	R36	N
t-Amyl Alcohol	F (Highly Flammable); Xn (Harmful); Xi (Irritant)	3	5	Production raw material	R11; R20; R37/38; R41	N
Tetra-n-Butyl Ammonium Iodide	Acute Tox. 4; Skin Irrit. 2; Eye Irrit. 2; STOT SE 3	0.005	0.01	Production raw material		N
TCN Production intermediate material	N (Dangerous for the Environment)	1	7	Production raw material	R50/53	N
TERTIARY BUTANOL	F (Highly Flammable), Xn (Harmful), Xi (Irritant)	0.01	0.2	Production raw material	R11, R20, R36/37	N
TETRADECYLTRIMETHYLAMMONIUM	C (Corrosive)	0.5	1	Production raw material	R34	N
TETRAHYDROFURAN ANHYDROUS	F (Highly Flammable), Xi (Irritant)	50	40	Production raw material	R11-19, R36/37	N
Tin (ii) chloride anhydrous	Xn (Harmful), Xi (Irritant)	2.5	20	Production raw material	R22, R36/37/38	N
Toluene	F (Highly Flammable), Xn (Harmful), Xi (Irritant), Reproductive Category 3	50	150	Production raw material	R11, R38, R48/20, R63, R65, R67	N
TRIETHYLAMINE	F (Highly Flammable), Xn (Harmful), C (Corrosive)			Production raw material	R11, R20/21/22, R35	N
TRIS HYDROCHLORIDE	Xi (Irritant)	0.5	3	Production raw material	R36/37/38	N
Tripotassium phosphate	Xi (Irritant)	0.2	0.5	Production raw material	R36/37/38	N
TRITON X-100	Xn (Harmful), Xi(Irritant), N (Dangerous to the Environment)	0.1	1	Production raw material	R22, R37/38, R41, R51	N

Material/ Substance(1)	Danger ⁽²⁾ Category	Amount Stored (tonnes)	Annual Usage (tonnes)	Nature of Use	R ⁽³⁾ - Phrase	Stage 2 EC EO Groundwater) Regulations 2010 Hazardous5	Stage 2 EC EO Groundwater) Regulations 2010 Non-hazardous5	In current use C, historic H	Stage 2 Toxic to Soil Organisms R56 Y/N	Stage 1 Ruled out based on Danger Category	Stage 3 Liquid, Soild or Gas	Stage 3 Drum stock or Bulk storage	Stage 3 Ruled out Based on Risk	Stage 1-3 Final List of Relevant Hazardous Substances
2-PROPANOL	F,Xi	Note 1	Note 1	Production raw material	11,36,67	Undetermined	Undetermined	C	N	N	Liquid	Bulk		Y
1,2-Dimethoxyethane	F (Highly Flammable), Xn (Harmful), Reproductive Category 2	3	5	Production raw material	R60; R61; R11; R19; R20			C	N	N	Liquid	Drum		Y
1,3-dimethyl-2-imidazolidinone	Xn (Harmful), Xi (Irritant), Reproductive Category 3	10	5	Production raw material	R21/22, R36/37, R41, R63	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
10% Benzyl Alcohol in Toluene (2191308)		Note 1	Note 1			Hazardous (Toluene)		H	N	N	Liquid	Drum		Y
20% Diisobutylaluminum Hydride in Toluene	F (Highly Flammable), C (Corrosive)	0.1	0.1	Production raw material	R11; R38; R48/20; R63; R65; R67; R14/15; R17; R35	Hazardous (Toluene)		C	N	N	Liquid	Drum		Y
2-CHLOROETHANESULFONYL CHLORIDE	T+ (Very Toxic)	Note 1	Note 1	Production raw material	R22; R26; R34	N/A		C	N	N	Liquid	Drum		Y
2-ETHYL-1-BUTANOL	Xn (Harmful)	3	12		R21, R22	N/A		H	N	N	Liquid	Drum		Y
2-Fluorotoluene	F (Highly Flammable), Xi (Irritant)	15	20	Production raw material	R11, R36/37/38	N/A - hazardous		C	N	N	Liquid	Drum		Y
2-METHYLTETRAHYDROFURAN	F (Highly Flammable)	3	12	Production raw material	R11; R19; R22; R36/38	N/A		C	N	N	Liquid	Drum		Y
4-(P-Hydroxyphenyl)-Butan-2-one	Not classified as a hazardous substance.	1	5	Production raw material		N/A		H	N	N	Liquid	Drum		Y
ACETIC ACID 100 %	Flammable, Corrosive	1	14	Production raw material	R10, R35	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
Acetone	F (Highly Flammable), Xi (Irritant)	50	150	Production raw material	R11, R36, R66, R67	Undetermined	Undetermined	C	N	N	Liquid	Bulk		Y
Acetonitrile	F (Highly Flammable), Xn (Harmful), Xi (Irritant)	50	80	Production raw material	R11, R20/21/22, R36	N/A		C	N	N	Liquid	Bulk		Y
Acetylacetone	Acute Tox. 4; Flam. Liq. 3	0.05	0.1	Production raw material	R10, R20/21/22			C	N	N	Liquid	Drum		Y
ACETYL CHLORIDE	F (Highly Flammable), C (Corrosive)	Note 1	Note 1	Production raw material	R11; R14; R34	N/A		C	N	N	Liquid	Drum		Y
Alcohol s d no. 3a absolute	F(Highly Flammable), Xn (Harmful)	50	350	Production raw material	R11	Undetermined	Undetermined	C	N	N	Liquid	Bulk		Y
Amberlyst 15 Resin	Not assigned an overall EC classification.	0.5	2	Production raw material	R36	N/A		C	N	N	Solid		Y solid	

AMMONIUM CHLORIDE	Acute Tox. 4 (oral); Eye Irrit. 2	0.05	0.1	Production raw material	R22; R36			C	N	N	Solid		Y solid	
Amyl Acetate (98%)	Flammable	40	100	Production raw material	R10, R66	N/A		C	N	N	Liquid	Bulk		Y
ANTIFOAM C EMULSION	Xn (Harmful)	0.025	0.1	Production raw material	R50, R53, R62	N/A		C	N	N	Liquid	Drum		Y
Atomoxetine Hydrochloride	T (Toxic), Xi (Irritant), N (Dangerous for the Environment)	5	20	Production final material	R23/25, R41, R50/53	N/A		C	N	N	Solid		Y solid	
Atomoxetine Mandelate	T (Toxic), Xi (Irritant), Xn (Harmful), N (Dangerous for the Environment)	0.25	20	Production intermediate material	R22, R23, R41, R50/53	N/A		C	N	N	Solid		Y solid	
Baricitinib	Xn (Harmful)	1	2	Production material	R61; R48/22			C	N	N	Solid		Y solid	
Benzodiazepine Hydrochloride	Xn (Harmful), Xi (Irritant)	1	50	Production intermediate material	R20/22, R41	N/A		C	N	N	Solid		Y solid	
Benzoic acid tech		0.1	1		R37, R41	N/A		H	N	N	Solid		Y solid	
BENZOTETRAZOLE		Note 1	Note 1			N/A		H	N	N	Solid		Y solid	
Benzothiophene	Not assigned an overall EC classification.	20	50	Production intermediate material	none	N/A		C	N	N	Solid		Y solid	
Benzyl Alcohol	Acute Tox. 4 (oral); Acute Tox. 4 (inhalation); Eye Irrit. 2	0.5	1	Production raw material	R20/22			C	N	N	Liquid	Drum		Y
Benzyl Edivoxetine Fumarate (LSN2398789)		0.5	1	Production intermediate material		N/A		H	N	N	Solid		Y solid	
Beta Ketosulfide	N (Dangerous for the Environment)	30	60	Production raw material	R51/53	N/A		C	N	N	Solid		Y solid	
Bis(pinacolato)diboron	Eye Irrit. 2; Skin Irrit. 2; STOT SE 3	1	2	Production raw material				C	N	N	Solid		Y solid	
Boron trichloride	T+ (Very Toxic), C (Corrosive)	20	70	Production raw material	R14, R26/28, R34	N/A		C	N	N	Gas		Y,gas	
Bromine	'T+ (Very Toxic), C (Corrosive), N(dangerous to the environment)	0.5	1	Production raw material	R26, R35, R50	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
Caustic Soda 25%	Contains Sodium Hydroxide (C = 7.4 - 25%), C (Corrosive)	20	400	Production raw material	R35	Undetermined	Undetermined	C	N	N	Liquid	Bulk		Y
CHEMATIC 1700CL	C (Corrosive), Xn (Harmful)/ C (Corrosive), N (Dangerous to the environment)	0.5	8	Stainless steel cleaner	R22, R35/ R31, R34, R50	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
Chlorodimethoxy triazine	Xn (Harmful), C (Corrosive)	0.25	1.5	Production raw material	R20/22, R 34, R 41	N/A		C	N	N	Solid		Y solid	
CIP100	C, Xn	15	40	Production raw material	R22, R35, R	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y

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CIP200	C, Xi	15	60	Production raw material, Maintenance & Utilities	R34, R36	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
Cis-3,5-dimethylpiperidine		0.1	1			N/A		H	N	N	Liquid	Drum		Y
CITRIC ACID ANHYDROUS POWDER 60 GU	Xi (Irritant)	0.01	0.2	Production raw material	R36	Undetermined	Undetermined	C	N	N	Solid		Y solid	
D, l-Octopamine hydrochloride	Xn (Harmful) (Irritant) Xi	0.25	1		R22, R36/37/38	N/A		H	N	N	Solid		Y solid	
Darco G60	Not classified	0.15	0.5	Production raw material		N/A		C	N	N	Solid		Y solid	
Deazaguanine acid	Not assigned an overall EC classification.	0.15	0.5	Production intermediate material	Not assigned an overall EC classificatio	N/A		C	N	N	Solid		Y solid	
DEC-Bromosulfoxide (DBS)	Not classified as a hazardous substance.	Note 1	Note 1	Production intermediate material		N/A		H	N	N	Solid		Y solid	
Di-chloro-bis-cyclooctadiene	Acute Tox. 4; Skin Irrit. 2; Eye Irrit. 2; STOT SE 3	0.005	0.01	Production raw material	R20/21/22, R36/38			C	N	N	Solid		Y solid	
Dichloromethane	Xn (Harmful)			Production raw material	R40	Hazardous		H	N	N	Liquid	Bulk		Y
Diesel	Carcinogen, dangerous for the environment, flammable	20	40	Utilities, Maintenance & Utilities	R20, R38, R40, R51/53, R65	N/A		C	N	N	Liquid	Bulk		Y
Dimethyl sulfoxide high purity grade	Xi (Irritant)	5	100	Production raw material	R36/37/38	N/A		C	N	N	Liquid	Drum		Y
Dimethylformamide	T (Toxic), Xn (Harmful), Xi (Irritant), Reproductive Category 2	15	100	Production raw material	R20/21, R36, R61	N/A		C	N	N	Liquid	Bulk		Y
70% di-tert-butyl dicarbonate in tetrahydrofuran	T+ (Very Toxic), F (Highly Flammable), Xi (Irritant)	0.2	0.5	Production raw material	R11, R26, R36/37/38			C	N	N	Liquid	Drum		Y
ETHANOL 70% SOLUTION	F (Highly Flammable)	20	20	Production raw material	R10	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
Ethyl acetate	F (Highly Flammable), Xi (Irritant)	50	200	Production raw material	R11, R36, R66, R67	N/A		C	N	N	Liquid	Bulk		Y
ETHYLAMINE (70% SOLUTION)	F+ (Extremely Flammable); Xi (Irritant)	Note 1	Note 1	Production raw material	R11, R35, R37	N/A		C	N	N	Liquid	Drum		Y
Ethylene Dichloride	F (Highly Flammable), T (Toxic), Xn (Harmful), Xi (Irritant), Carcinogen Category 2	75	250	Production raw material	R11, R 22, R 36/37/38, R45	Hazardous		C	N	N	Liquid	Bulk		Y

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Ethylene Glycol (Dowcal 100)	Xn (Harmful)	25	10	Maintenance & Utilities	22	Undetermined	Undetermined	C	N	N	Liquid	Bulk		Y
Formic acid 98 percent	C (Corrosive)	0.5	1	Production raw material	R10, R35	N/A		C	N	N	Liquid	Drum		Y
FUMARIC ACID	Xi (Irritant)	0.01	0.5	Production raw material	R36	N/A		C	N	N	Solid		Y solid	
GLACIAL ACETIC ACID	C (Corrosive)	0.1	1	Production raw material	R10, R35	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
GLP FC	Not classified as a hazardous substance.	1	10	Production material		N/A		H	N	N	Liquid	Drum		Y
Granular Salt	Not classified as a hazardous substance.	2	20	Maintenance & Utilities		Undetermined	Undetermined	H	N	N	Solid		Y solid	
Heptane	F (Highly Flammable), Xn (Harmful), Xi (Irritant), N (Dangerous for the Environment)	50	50	Production raw material	R11, R38, R50/53, R65, R67	N/A		C	N	N	Liquid	Bulk		Y
HYDRAZINE (35% AQUEOUS)	Acute Tox. 4; Skin Corr. 1B; Skin Sens. 1; Carc. 1B; Aquatic Acute 1; Aquatic Chronic 1	0.02	0.05	Production raw material	R45, R20/21/22, R34, R43, R50/53			C	N	N	Liquid	Drum		Y
HY10275 PHOSPHATE MICRONISED		Note 1	Note 1			N/A		H	N	N	Solid		Y solid	
HY10275 PHOSPHATE SEED		Note 1	Note 1			N/A		H	N	N	Solid		Y solid	
HYDRANAL-COMPOSITE 5 K ONE		0.02	0.05	Production raw material		N/A		H	N	N	Liquid	Drum		Y
HYDRANAL-COULOMAT AG		0.02	0.05	Production raw material		N/A		H	N	N	Liquid	Drum		Y
HYDRANAL-WORKING MEDIUM K SOLVENT		0.02	0.05	Production raw material		N/A		H	N	N	Liquid	Drum		Y
Hydrobromic Acid	C (Corrosive); Xi (Irritant)	1	4	Production raw material	R34; R37	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
Hydrochloric Acid	C (Corrosive)	20	100	Production raw material	R34, R37	N/A		C	N	N	Liquid	Drum		Y
Hydrogen	F+ (Extremely Flammable)	0.25	25	Production raw material	R12	N/A		C	N	N	Gas		Y,gas	
HYDROXYQUINOLINE	Not classified as a hazardous substance.	0.25	1	Production intermediate material		N/A		H	N	N	Solid		Y solid	
Isobutanol	Xi (Irritant)	40	50	Production raw material	R10; R37/38; R41; R67	N/A		C	N	N	Liquid	Bulk		Y
Isopropyl alcohol	F (Highly Flammable), Xi (Irritant)	45	100	Production raw material	R11, R36, R67	Undetermined	Undetermined	C	N	N	Liquid	Bulk		Y

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K-tBuO in Tetrahydrofluoride (KTB in THF)	F (Highly Flammable), C (Corrosive), Xn (Harmful)	0.5	2	Production raw material	R11, R14, R19, R35, R36/37	N/A		C	N	N	Liquid	Drum		Y
L METHIONINE SULFOXIMINE	Xi (Irritant)	0.01	0.1	Production raw material	R36/37/38	N/A		C	N	N	Solid		Y solid	
L(+)-mandelic acid	Xi (Irritant)	0.075	5	Production raw material	R37, R41	N/A		C	N	N	Solid		Y solid	
LACTAM 55962	Classification Pending	Note 1	Note 1	Production intermediate material		N/A		C	N	N	Liquid	Drum		Y
LACTIC ACID (30%)	Acute Tox Oral (Cat 5), Acute Tox Dermal (Cat 5) Skin Irritation (Cat 2), Serious eye damage (Cat 1)	0.5	1	Production raw material				C	N	N	Liquid	Drum		Y
L-ASPARTIC ACID	Xi (Irritant)	Note 1	Note 1	Production raw material	R36	N/A		C	N	N	Solid		Y solid	
Liquid nitrogen	Not assigned an overall EC classification	25	500	Production raw material	none	N/A		C	N	N	Liquid	Bulk		Y
L-proline	Xi (Irritant)	0.1	0.1	Production raw material	none	N/A		C	N	N	Solid		Y solid	
LSN 417420	Xn (Harmful)	0.225	1	Production intermediate material	R22	N/A		C	N	N	Solid		Y solid	
LSN2963227	T (Toxic); Repr. Cat 2	0.015	0.5	Production intermediate material	R25; R61	N/A		C	N	N	Solid		Y solid	
LSN247460 (AZA-INDOLE 460)	Xn (Harmful)	0.05	0.1	Production intermediate material	R22			C	N	N	Solid		Y solid	
LSN2835219	Repr. 1B; STOT RE 2	0.05	0.1	Production Product	R60; R61			C	N	N	Solid		Y solid	
LSN3090771 Potassium Bisulphite Adduct	Flam. Solid 1	2	5	Production intermediate material				C	N	N	Solid		Y solid	
LSN2524875 (Evacetrapib Methyl Ester)	Repr. 2, Aquatic Acute 1	2	5	Production intermediate material	R63, R50/53			C	N	N	Solid		Y solid	
LSN2484595 (Evacetrapib anhydrate)	Repr. 2, Aquatic Acute 1	2	5	Production material	R63, R50/53			C	N	N	Solid		Y solid	
LSN2157217 Chloro Pyrazine	Acute Tox. 3; Skin Irrit. 2; Eye Irrit. 2	0.02	0.05	Production intermediate material	R25; R36/37/38			C	N	N	Solid		Y solid	
LSN2794612 SEED	Muta (Cat 2), Repr (Cat 2)	0.02	0.05	Production intermediate material	R46, R60/61			C	N	N	Solid		Y solid	
LSN3135709 solvate (PYRAZOLCARBOXAMID Ether Int)	Acute Tox. 4; Carc. 2; Repr. 1B; STOT - RE 1	0.2	0.5	Production intermediate material				C	N	N	Solid		Y solid	
LSN2801653 SEED (PYRAZOLECARBOXAMIDE F2)	Acute Tox. 4 (oral); Repr. 1B; STOT RE 1	0.01	0.05	Production intermediate material	R22; R62; R48/25			c	N	N	Solid		Y solid	
L-TYROSINE	Xi (Irritant)	Note 1	Note 1	Production raw material	R36/37/38	N/A		C	N	N	Solid		Y solid	
L-TYROSINE DISODIUM DIHYDRATE	Xi (Irritant)	0.01	0.05	Production raw material	R36/37/38	N/A		C	N	N	Solid		Y solid	
LY2523301 - 'BOC-SM'		Note 1	Note 1			N/A		H	N	N	Solid		Y solid	
LY2523303 - HCl SALT		Note 1	Note 1			N/A		H	N	N	Solid		Y solid	
LY2523355 - EG5		Note 1	Note 1			N/A		H	N	N	Solid		Y solid	

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LY2553929 FUMARIC ACID SALT		Note 1	Note 1			N/A		H	N	N	Solid		Y solid	
LY2553929 FUMARIC ACID SALT SEED		Note 1	Note 1			N/A		H	N	N	Solid		Y solid	
LY2801653	Acute Tox. 4 (oral); Repr. 1B; STOT RE 1	0.1	0.5	Production final material	R22; R62; R48/25			C	N	N	Solid		Y solid	
MAB SELECT RESIN	F (Highly Flammable)	0.1	1	Production raw material	R10	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
MEM AMINO ACID SOLUTION	C (Corrosive)	0.01	0.1	Production raw material	R34, R41	N/A		C	N	N	Liquid	Drum		Y
Methanesulfonic acid Technical	C (Corrosive)	0.5	15	Production raw material	R34	N/A		C	N	N	Liquid	Drum		Y
METHANOL	F (Highly Flammable), T (Toxic)	50	1000	Production raw material	R11, R23/24/25 - R39/23/24/25	N/A		C	N	N	Liquid	Bulk		Y
Methyl Ethyl Ketone	F (Highly Flammable), Xi (Irritant)	Note 1	Note 1	Production raw material	R11, R36, R66, R67	Undetermined	Undetermined	C	N	N	Liquid			Y
Methylglyoxylate	Xi (Irritant)	0.1	0.5	Production raw material	R36	N/A		H	N	N	Solid		Y solid	
MTA Glutamate	Not assigned an overall EC classification.	3	5	Production intermediate material	Not assigned an overall EC classificatio	N/A		C	N	N	Solid		Y solid	
Methyl Tert Butyl Ether	F (Highly Flammable), Xi (Irritant)	25	100	Production raw material	R11, R38			C	N	N	Liquid	Bulk		Y
N,N-DIMETHYLFORMAMIDE		Note 1	Note 1	Production raw material	R61, R20/21, R36	N/A		C	N	N	Liquid	Drum		Y
Nalco 77261		5	12	Maintenance & Utilities		Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
Nalco Water Treatment 1318		2	3	Utilities		N/A		C	N	N	Liquid	Drum		Y
Nalco Water Treatment 22310		0.5	2	Utilities		N/A		C	N	N	Liquid	Drum		Y
Nalco Water Treatment 3DT289		2	6	Utilities		N/A		C	N	N	Liquid	Drum		Y
Nalco Water Treatment 77211		0.5	2	Utilities		N/A		C	N	N	Liquid	Drum		Y
Nalco Water Treatment 77393		1	1	Utilities		N/A		C	N	N	Liquid	Drum		Y
Nalco Water Treatment 93033		5	12	Utilities		N/A		C	N	N	Liquid	Drum		Y
Natural Gas			7*10 ⁶ m3	Maintenance & Utilities		N/A		C	N	N	Gas		Y,gas	

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N-Butanol	Xn Harmful, Xi Irritant	25	50	Production raw material	R10, R22, R37/38, R41, R67	N/A		C	N	N	Liquid	Drum		Y
N-ETHYLMORPHOLINE	F (Flammable), C (Corrosive), Acute Tox (Cat 4)	0.02	0.05	Production raw material	R10, R34, R21/22			C	N	N	Liquid	Drum		Y
N-HEXANE	F (Flammable), Xn (Harmful), N (Dangerous for the Environment)	Note 1	Note 1	Production raw material	R11, R38, R48/20, R62, R65, R67, R51/53	N/A		C	N	N	Liquid	Drum		Y
N-methylindole-acetamide	Not classified as a hazardous substance	0.1	0.5			N/A		H	N	N	Solid		Y solid	
N-methylmorpholine	F (Highly Flammable), Xn (Harmful), C (Corrosive)	0.5	3	Production raw material	R11, R22, R34	N/A		C	N	N	Liquid	Drum		Y
N-methylpiperazine	C (Corrosive)	3.5	15	Production raw material	R10, R34	N/A		C	N	N	Liquid	Drum		Y
N-TETRABUTYLAMMONIUM HYDROXIDE	C (Corrosive)	0.01	0.1	Production raw material	R35	N/A		C	N	N	Liquid	Drum		Y
Olanzapine	T (Toxic), Xi (Irritant)	6.5	15	Production final material	R25, R36, R43, R52	N/A		C	N	N	Solid		Y solid	
Oxalyl chloride	T+ (Very Toxic), C (Corrosive)	2	20	Production raw material	R14/15, R20/22, R29, R35, R37	N/A		C	N	N	Liquid	Cylinder	Y, cylinder	Y
OXAZEPINE METHYL ESTER 262	Not classified	Note 1	Note 1	Production intermediate material		N/A		H	N	N	Solid		Y solid	
OXAZEPINE METHYL ESTER 262	Not classified	Note 1	Note 1	Production intermediate material		N/A		H	N	N	Solid		Y solid	
Palladium 10% on carbon	F (Highly Flammable)	0.025	0.5	Production raw material	R11	N/A		C	N	N	Solid		Y solid	
Palladium (Pd-100)	Aquatic Chronic 4	0.005	0.01	Production raw material	R53			C	N	N	Solid		Y solid	
Pd 134 (Xant-Phos) Palladium dichloride		0.005	0.01	Production raw material	R43			C	N	N	Solid		Y solid	
Pamoic acid	Xi (Irritant)	0.65	1	Production raw material	R36/37/38	N/A		C	N	N	Solid		Y solid	
Pemetrexed Disodium Heptahydrate	T (Toxic), Xi (Irritant), Xn (Harmful)Mutagen Category 3, Reproductive Category 1	0.75	1	Production final material	R36/38, R60, R61, R68	N/A		C	N	N	Solid		Y solid	
Phenyl Methyl Amino Propanol	Xi (Irritant)	5	14	Production raw material	R38, R41	N/A		C	N	N	Solid		Y solid	

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PHOSPHORUS OXYCHLORIDE	T+ (Very Toxic), T (Toxic), Xn (Harmful), C (Corrosive)	Note 1	Note 1	Production raw material	R14, R22, R23, R26, R29, R35, R48	N/A		C	N	N	Liquid	Drum		Y
PIPERAZINE	Acute Tox. 4 (Oral); Eye Dam. 1	0.5	1	Production raw material	R22; R41			C	N	N	Liquid	Drum		Y
Piperidinoethylchloride (hcl)	T+ (Very Toxic), C (Corrosive), Mutagen Category 3	25	40	Production raw material	R26/28, R34, R68	N/A		C	N	N	Solid		Y solid	
PiperidinyI Ethoxy Benzoic Acid	Xi (Irritant),	20	40	Production intermediate material	R36	N/A		C	N	N	Solid		Y solid	
PiperidinyIEthoxyPhenol (PEP)	Xi (Irritant), Xn (Harmful)	1	5	Production raw material	R22, R37/38-41	N/A		H	N	N	Solid		Y solid	
Platinum 5% on carbon, water wet	Not assigned an overall EC classification.	0.1	1	Production raw material	36/37/38	N/A		C	N	N	Solid		Y solid	
Potassium hydroxide	Xn (Harmful), C (Corrosive)	1	15	Production raw material	R22, R35	Undetermined	Undetermined	C	N	N	Solid		Y solid	
Potassium t-amylate in toluene	C (Corrosive), F (Highly Flammable), Xn (Harmful)	Note 1	Note 1	Production raw material	R11, R14/15, R20, R35	Hazardous (Toluene)		H	N	N	Liquid	Drum		Y
Potassium tert-butoxide	C (Corrosive)	2.5	5	Production raw material	R14, R35	N/A		C	N	N	Solid		Y solid	
Propanol		Note 1	Note 1	Production raw material		N/A		C	N	N	Liquid	Bulk		Y
P-Toluene sulfonic acid 96%	Xi (Irritant)	2.5	8	Production raw material	R36/37/38	N/A		C	N	N	Solid		Y solid	
Q SEPHAROSE HIGH PERFORMANCE	F (Highly Flammable)	0.1	0.5	Production raw material	R11	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
Raloxifene Hydrochloride	T (Toxic), Reproductive Category 1, Carcinogen Category 3, N (Dangerous to the Environment)	20	40	Production final material	R40, R50/53, R60, R61	N/A		C	N	N	Solid		Y solid	
Sabre P1074XL	Xi (Irritant)	2	10	Utilities	R36, R38	N/A		H	N	N	Liquid	Drum		Y
Salt	Not classified as a hazardous substance.	5	20			Undetermined	Undetermined	H	N	N	Solid		Y solid	
S-Benzylmorpholine Mesylate (Production intermediate material 2463667)	Xn (Harmful), Xi (Irritant)	1	10	Production intermediate material	R22, R36	N/A		H	N	N	Solid		Y solid	
SERINE		Note 1	Note 1	Production raw material		N/A		C	N	N	Solid		Y solid	
Silica-Thiol Resin	Xn (Harmful)	0.05	0.1	Production raw material	R20/21/22			C	N	N	Solid		Y solid	
SODIUM BISULFITE	Xn (Harmful)	Note 1	Note 1	Production raw material	R22, R31	Undetermined	Undetermined	C	N	N	Solid		Y solid	
SODIUM HYDROXIDE	C (Corrosive)	2	10	Production raw material	R35	Undetermined	Undetermined	C	N	N	Solid		Y solid	
Sodium Meta Bi Sulphite		6	20	Utilities	37/38,41,42,43	N/A		C	N	N	Solid		Y solid	
SODIUM PHOSPHATE DIBASIC		Note 1	Note 1	Production raw material		N/A		C	N	N	Liquid	Drum		Y
SODIUM PHOSPHATE MONOBASIC MONOHYDRATE		Note 1	Note 1	Production raw material		N/A		C	N	N	Solid		Y solid	
Sulfuric acid 50%	Contains sulfuric acid (C = 10 to 51%), C (Corrosive)	4	15	Production raw material	R35	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y

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Sulphuric Acid 96% Bulk	Contains sulfuric acid (C = 10 to 51%), C (Corrosive)	20	50	Utilities	R36	Undetermined	Undetermined	C	N	N	Liquid	Bulk		Y
t-Amyl Alcohol	F (Highly Flammable); Xn (Harmful); Xi (Irritant)	3	5	Production raw material	R11; R20; R37/38; R41	N/A		C	N	N	Liquid	Drum		Y
Tetra-n-Butyl Ammonium Iodide	Acute Tox. 4; Skin Irrit. 2; Eye Irrit. 2; STOT SE 3	0.005	0.01	Production raw material				C	N	N	Solid		Y solid	
TCN Production intermediate material	N (Dangerous for the Environment)	1	7	Production raw material	R50/53	N/A		C	N	N	Solid		Y solid	
TERTIARY BUTANOL	F (Highly Flammable), Xn (Harmful), Xi (Irritant)	0.01	0.2	Production raw material	R11, R20, R36/37	N/A		C	N	N	Liquid	Drum		Y
TETRADECYLTRIMETHYLAMMONIUM CHLORIDE	C (Corrosive)	0.5	1	Production raw material	R34	N/A		H	N	N	Solid		Y solid	
TETRAHYDROFURAN ANHYDROUS	F (Highly Flammable), Xi (Irritant)	50	40	Production raw material	R11-19, R36/37	N/A		C	N	N	Liquid	Bulk		Y
Tin (ii) chloride anhydrous	Xn (Harmful), Xi (Irritant)	2.5	20	Production raw material	R22, R36/37/38	N/A		C	N	N	Solid		Y solid	
Toluene	F (Highly Flammable), Xn (Harmful), Xi (Irritant), Reproductive Category 3	50	150	Production raw material	R11, R38, R48/20, R63, R65, R67	Hazardous (Toluene)		C	N	N	Liquid	Bulk		Y
TRIETHYLAMINE	F (Highly Flammable), Xn (Harmful), C (Corrosive)			Production raw material	R11, R20/21/22, R35	N/A		C	N	N	Liquid	Drum		Y
TRIS HYDROCHLORIDE	Xi (Irritant)	0.5	3	Production raw material	R36/37/38	N/A		C	N	N	Solid		Y solid	
Tripotassium phosphate	Xi (Irritant)	0.2	0.5	Production raw material	R36/37/38			C	N	N	Solid		Y solid	
TRITON X-100	Xn (Harmful), Xi(Irritant), N (Dangerous to the Environment)	0.1	1	Production raw material	R22, R37/38, R41, R51	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y

Material/ Substance(1)	Danger ⁽²⁾ Category	Amount Stored (tonnes)	Annual Usage (tonnes)	Nature of Use	R ⁽³⁾ - Phrase	Stage 2 EC EO Groundwater) Regulations 2010 Hazardous5	Stage 2 EC EO Groundwater) Regulations 2010 Non-hazardous5	In current use C, historic H	Stage 2 Toxic to Soil Organisms R56 Y/N	Stage 1 Ruled out based on Danger Category	Stage 3 Liquid, Soild or Gas	Stage 3 Drum stock or Bulk storage	Stage 3 Ruled out Based on Risk	Stage 1-3 Final List of Relevant Hazardous Substances
2-PROPANOL	F,Xi	Note 1	Note 1	Production raw material	11,36,67	Undetermined	Undetermined	C	N	N	Liquid	Bulk		Y
1,2-Dimethoxyethane	F (Highly Flammable), Xn (Harmful), Reproductive Category 2	3	5	Production raw material	R60; R61; R11; R19; R20			C	N	N	Liquid	Drum		Y
1,3-dimethyl-2-imidazolidinone	Xn (Harmful), Xi (Irritant), Reproductive Category 3	10	5	Production raw material	R21/22, R36/37, R41, R63	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
10% Benzyl Alcohol in Toluene (2191308)		Note 1	Note 1			Hazardous (Toluene)		H	N	N	Liquid	Drum		Y
20% Diisobutylaluminum Hydride in Toluene	F (Highly Flammable), C (Corrosive)	0.1	0.1	Production raw material	R11; R38; R48/20; R63; R65; R67; R14/15; R17; R35	Hazardous (Toluene)		C	N	N	Liquid	Drum		Y
2-CHLOROETHANESULFONYL CHLORIDE	T+ (Very Toxic)	Note 1	Note 1	Production raw material	R22; R26; R34	N/A		C	N	N	Liquid	Drum		Y
2-ETHYL-1-BUTANOL	Xn (Harmful)	3	12		R21, R22	N/A		H	N	N	Liquid	Drum		Y
2-Fluorotoluene	F (Highly Flammable), Xi (Irritant)	15	20	Production raw material	R11, R36/37/38	N/A - hazardous		C	N	N	Liquid	Drum		Y
2-METHYLTETRAHYDROFURAN	F (Highly Flammable)	3	12	Production raw material	R11; R19; R22; R36/38	N/A		C	N	N	Liquid	Drum		Y
4-(P-Hydroxyphenyl)-Butan-2-one	Not classified as a hazardous substance.	1	5	Production raw material		N/A		H	N	N	Liquid	Drum		Y
ACETIC ACID 100 %	Flammable, Corrosive	1	14	Production raw material	R10, R35	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
Acetone	F (Highly Flammable), Xi (Irritant)	50	150	Production raw material	R11, R36, R66, R67	Undetermined	Undetermined	C	N	N	Liquid	Bulk		Y
Acetonitrile	F (Highly Flammable), Xn (Harmful), Xi (Irritant)	50	80	Production raw material	R11, R20/21/22, R36	N/A		C	N	N	Liquid	Bulk		Y
Acetylacetone	Acute Tox. 4; Flam. Liq. 3	0.05	0.1	Production raw material	R10, R20/21/22			C	N	N	Liquid	Drum		Y
ACETYL CHLORIDE	F (Highly Flammable), C (Corrosive)	Note 1	Note 1	Production raw material	R11; R14; R34	N/A		C	N	N	Liquid	Drum		Y
Alcohol s d no. 3a absolute	F(Highly Flammable), Xn (Harmful)	50	350	Production raw material	R11	Undetermined	Undetermined	C	N	N	Liquid	Bulk		Y

Amyl Acetate (98%)	Flammable	40	100	Production raw material	R10, R66	N/A		C	N	N	Liquid	Bulk		Y
ANTIFOAM C EMULSION	Xn (Harmful)	0.025	0.1	Production raw material	R50, R53, R62	N/A		C	N	N	Liquid	Drum		Y
Benzyl Alcohol	Acute Tox. 4 (oral); Acute Tox. 4 (inhalation); Eye Irrit. 2	0.5	1	Production raw material	R20/22			C	N	N	Liquid	Drum		Y
Bromine	'T+ (Very Toxic), C (Corrosive), N(dangerous to the environment)	0.5	1	Production raw material	R26, R35, R50	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
Caustic Soda 25%	Contains Sodium Hydroxide (C = 7.4 - 25%), C (Corrosive)	20	400	Production raw material	R35	Undetermined	Undetermined	C	N	N	Liquid	Bulk		Y
CHEMATIC 1700CL	C (Corrosive), Xn (Harmful)/ C (Corrosive), N (Dangerous to the environment)	0.5	8	Stainless steel cleaner	R22, R35/ R31, R34, R50	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
CIP100	C, Xn	15	40	Production raw material	R22, R35, R	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
CIP200	C, Xi	15	60	Production raw material, Maintenance & Utilities	R34, R36	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
Cis-3,5-dimethylpiperidine		0.1	1			N/A		H	N	N	Liquid	Drum		Y
Dichloromethane	Xn (Harmful)			Production raw material	R40	Hazardous		H	N	N	Liquid	Bulk		Y
Diesel	Carcinogen, dangerous for the environment, flammable	20	40	Utilities, Maintenance & Utilities	R20, R38, R40, R51/53, R65	N/A		C	N	N	Liquid	Bulk		Y
Dimethyl sulfoxide high purity grade	Xi (Irritant)	5	100	Production raw material	R36/37/38	N/A		C	N	N	Liquid	Drum		Y
Dimethylformamide	T (Toxic), Xn (Harmful), Xi (Irritant), Reproductive Category 2	15	100	Production raw material	R20/21, R36, R61	N/A		C	N	N	Liquid	Bulk		Y
70% di-tert-butyl dicarbonate in tetrahydrofuran	T+ (Very Toxic), F (Highly Flammable), Xi (Irritant)	0.2	0.5	Production raw material	R11, R26, R36/37/38			C	N	N	Liquid	Drum		Y
ETHANOL 70% SOLUTION	F (Highly Flammable)	20	20	Production raw material	R10	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
Ethyl acetate	F (Highly Flammable), Xi (Irritant)	50	200	Production raw material	R11, R36, R66, R67	N/A		C	N	N	Liquid	Bulk		Y
ETHYLAMINE (70% SOLUTION)	F+ (Extremely Flammable); Xi (Irritant)	Note 1	Note 1	Production raw material	R11, R35, R37	N/A		C	N	N	Liquid	Drum		Y
Ethylene Dichloride	F (Highly Flammable), T (Toxic), Xn (Harmful), Xi (Irritant), Carcinogen Category 2	75	250	Production raw material	R11, R 22, R 36/37/38, R45	Hazardous		C	N	N	Liquid	Bulk		Y

Ethylene Glycol (Dowcal 100)	Xn (Harmful)	25	10	Maintenance & Utilities	22	Undetermined	Undetermined	C	N	N	Liquid	Bulk		Y
Formic acid 98 percent	C (Corrosive)	0.5	1	Production raw material	R10, R35	N/A		C	N	N	Liquid	Drum		Y
GLACIAL ACETIC ACID	C (Corrosive)	0.1	1	Production raw material	R10, R35	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
GLP FC	Not classified as a hazardous substance	1	10	Production material		N/A		H	N	N	Liquid	Drum		Y
Heptane	F (Highly Flammable), Xn (Harmful), Xi (Irritant), N (Dangerous for the Environment)	50	50	Production raw material	R11, R38, R50/53, R65, R67	N/A		C	N	N	Liquid	Bulk		Y
HYDRAZINE (35% AQUEOUS)	Acute Tox. 4; Skin Corr. 1B; Skin Sens. 1; Carc. 1B; Aquatic Acute 1; Aquatic Chronic 1	0.02	0.05	Production raw material	R45, R20/21/22, R34, R43, R50/53			C	N	N	Liquid	Drum		Y
HYDRANAL-COMPOSITE 5 K ONE		0.02	0.05	Production raw material		N/A		H	N	N	Liquid	Drum		Y
		0.02	0.05	Production raw material		N/A		H	N	N	Liquid	Drum		Y
HYDRANAL-COULOMAT AG														
		0.02	0.05	Production raw material		N/A		H	N	N	Liquid	Drum		Y
HYDRANAL-WORKING MEDIUM K SOLVENT														
Hydrobromic Acid	C (Corrosive); Xi (Irritant)	1	4	Production raw material	R34; R37	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
Hydrochloric Acid	C (Corrosive)	20	100	Production raw material	R34, R37	N/A		C	N	N	Liquid	Drum		Y
Isobutanol	Xi (Irritant)	40	50	Production raw material	R10; R37/38; R41; R67	N/A		C	N	N	Liquid	Bulk		Y
Isopropyl alcohol	F (Highly Flammable), Xi (Irritant)	45	100	Production raw material	R11, R36, R67	Undetermined	Undetermined	C	N	N	Liquid	Bulk		Y
K-tBuO in Tetrahydrofluoride (KTB in THF)	F (Highly Flammable), C (Corrosive), Xn (Harmful)	0.5	2	Production raw material	R11, R14, R19, R35, R36/37	N/A		C	N	N	Liquid	Drum		Y
LACTAM 55962	Classification Pending	Note 1	Note 1	Production intermediate material		N/A		C	N	N	Liquid	Drum		Y
LACTIC ACID (30%)	Acute Tox Oral (Cat 5), Acute Tox Dermal (Cat 5) Skin Irritation (Cat 2), Serious eye damage (Cat 1)	0.5	1	Production raw material				C	N	N	Liquid	Drum		Y
Liquid nitrogen	Not assigned an overall EC classification	25	500	Production raw material	none	N/A		C	N	N	Liquid	Bulk		Y
MAB SELECT RESIN	F (Highly Flammable)	0.1	1	Production raw material	R10	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y

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MEM AMINO ACID SOLUTION	C (Corrosive)	0.01	0.1	Production raw material	R34, R41	N/A		C	N	N	Liquid	Drum		Y
Methanesulfonic acid Technical	C (Corrosive)	0.5	15	Production raw material	R34	N/A		C	N	N	Liquid	Drum		Y
METHANOL	F (Highly Flammable), T (Toxic)	50	1000	Production raw material	R11, R23/24/25 - R39/23/24/25	N/A		C	N	N	Liquid	Bulk		Y
Methyl Ethyl Ketone	F (Highly Flammable), Xi (Irritant)	Note 1	Note 1	Production raw material	R11, R36, R66, R67	Undetermined	Undetermined	C	N	N	Liquid			Y
Methyl Tert Butyl Ether	F (Highly Flammable), Xi (Irritant)	25	100	Production raw material	R11, R38			C	N	N	Liquid	Bulk		Y
N,N-DIMETHYLFORMAMIDE		Note 1	Note 1	Production raw material	R61, R20/21, R36	N/A		C	N	N	Liquid	Drum		Y
Nalco 77261		5	12	Maintenance & Utilities		Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
Nalco Water Treatment 1318		2	3	Utilities		N/A		C	N	N	Liquid	Drum		Y
Nalco Water Treatment 22310		0.5	2	Utilities		N/A		C	N	N	Liquid	Drum		Y
Nalco Water Treatment 3DT289		2	6	Utilities		N/A		C	N	N	Liquid	Drum		Y
Nalco Water Treatment 77211		0.5	2	Utilities		N/A		C	N	N	Liquid	Drum		Y
Nalco Water Treatment 77393		1	1	Utilities		N/A		C	N	N	Liquid	Drum		Y
Nalco Water Treatment 93033		5	12	Utilities		N/A		C	N	N	Liquid	Drum		Y
N-Butanol	Xn Harmful, Xi Irritant	25	50	Production raw material	R10, R22, R37/38, R41, R67	N/A		C	N	N	Liquid	Drum		Y
N-ETHYLMORPHOLINE	F (Flammable), C (Corrosive), Acute Tox (Cat 4)	0.02	0.05	Production raw material	R10, R34, R21/22			C	N	N	Liquid	Drum		Y
N-HEXANE	F (Flammable), Xn (Harmful), N (Dangerous for the Environment)	Note 1	Note 1	Production raw material	R11, R38, R48/20, R62, R65, R67, R51/53	N/A		C	N	N	Liquid	Drum		Y
N-methylmorpholine	F (Highly Flammable), Xn (Harmful), C (Corrosive)	0.5	3	Production raw material	R11, R22, R34	N/A		C	N	N	Liquid	Drum		Y
N-methylpiperazine	C (Corrosive)	3.5	15	Production raw material	R10, R34	N/A		C	N	N	Liquid	Drum		Y

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N-TETRABUTYLAMMONIUM HYDROXIDE	C (Corrosive)	0.01	0.1	Production raw material	R35	N/A		C	N	N	Liquid	Drum		Y
PHOSPHORUS OXYCHLORIDE	T+ (Very Toxic), T (Toxic), Xn (Harmful), C (Corrosive)	Note 1	Note 1	Production raw material	R14, R22, R23, R26, R29, R35, R48	N/A		C	N	N	Liquid	Drum		Y
PIPERAZINE	Acute Tox. 4 (Oral); Eye Dam. 1	0.5	1	Production raw material	R22; R41			C	N	N	Liquid	Drum		Y
Potassium t-amylate in toluene	C (Corrosive), F (Highly Flammable), Xn (Harmful)	Note 1	Note 1	Production raw material	R11, R14/15, R20, R35	Hazardous (Toluene)		H	N	N	Liquid	Drum		Y
Propanol		Note 1	Note 1	Production raw material		N/A		C	N	N	Liquid	Bulk		Y
Q SEPHAROSE HIGH PERFORMANCE	F (Highly Flammable)	0.1	0.5	Production raw material	R11	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
Sabre P1074XL	Xi (Irritant)	2	10	Utilities	R36, R38	N/A		H	N	N	Liquid	Drum		Y
SODIUM PHOSPHATE DIBASIC		Note 1	Note 1	Production raw material		N/A		C	N	N	Liquid	Drum		Y
Sulfuric acid 50%	Contains sulfuric acid (C = 10 to 51%), C (Corrosive)	4	15	Production raw material	R35	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y
Sulphuric Acid 96% Bulk	Contains sulfuric acid (C = 10 to 51%), C (Corrosive)	20	50	Utilities	R36	Undetermined	Undetermined	C	N	N	Liquid	Bulk		Y
t-Amyl Alcohol	F (Highly Flammable); Xn (Harmful); Xi (Irritant)	3	5	Production raw material	R11; R20; R37/38; R41	N/A		C	N	N	Liquid	Drum		Y
TERTIARY BUTANOL	F (Highly Flammable), Xn (Harmful), Xi (Irritant)	0.01	0.2	Production raw material	R11, R20, R36/37	N/A		C	N	N	Liquid	Drum		Y
TETRAHYDROFURAN ANHYDROUS	F (Highly Flammable), Xi (Irritant)	50	40	Production raw material	R11-19, R36/37	N/A		C	N	N	Liquid	Bulk		Y
Toluene	F (Highly Flammable), Xn (Harmful), Xi (Irritant), Reproductive Category 3	50	150	Production raw material	R11, R38, R48/20, R63, R65, R67	Hazardous (Toluene)		C	N	N	Liquid	Bulk		Y
TRIETHYLAMINE	F (Highly Flammable), Xn (Harmful), C (Corrosive)			Production raw material	R11, R20/21/22, R35	N/A		C	N	N	Liquid	Drum		Y
TRITON X-100	Xn (Harmful), Xi(Irritant), N (Dangerous to the Environment)	0.1	1	Production raw material	R22, R37/38, R41, R51	Undetermined	Undetermined	C	N	N	Liquid	Drum		Y

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Appendix 2

Stage 7 Subsoil Assessment

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SOILS ASSESSMENT

ELI LILLY

DUNDERROW

COUNTY CORK

Prepared For: -

Elly Lilly,
Dunderrow,
Co. Cork

Prepared By: -

O' Callaghan Moran & Associates,
Granary House,
Rutland Street,
Cork.

1st September 2014

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- APPENDIX 3** - Laboratory Results

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1 INTRODUCTION

O'Callaghan Moran & Associates (OCM) was requested by Eli Lilly to undertake an assessment of subsoil quality beneath the main site in Dunderrow, County Cork.

This report presents the findings of the investigation, which included the installation of 10 soil borings and the collection and analysis of subsoil samples.

1.1 Background

The facility has an Integrated Pollution Prevention and Control (IPPC) Licence (Reg. No.P0313-01) issued by the Environmental Protection Agency (Agency). The Dunderrow site produces bulk pharmaceutical products.

Eli-Lilly is currently in the process of reviewing its IPPC license. In order to comply with the requirements of Industrial Emissions Directive a baseline soils assessment must be undertaken. This assessment follows the guidelines outlined in the European Commission Guidance concerning baseline reports under Article 22(2) of Directive 2010/75/EU on industrial emissions.

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2 SITE DESCRIPTION

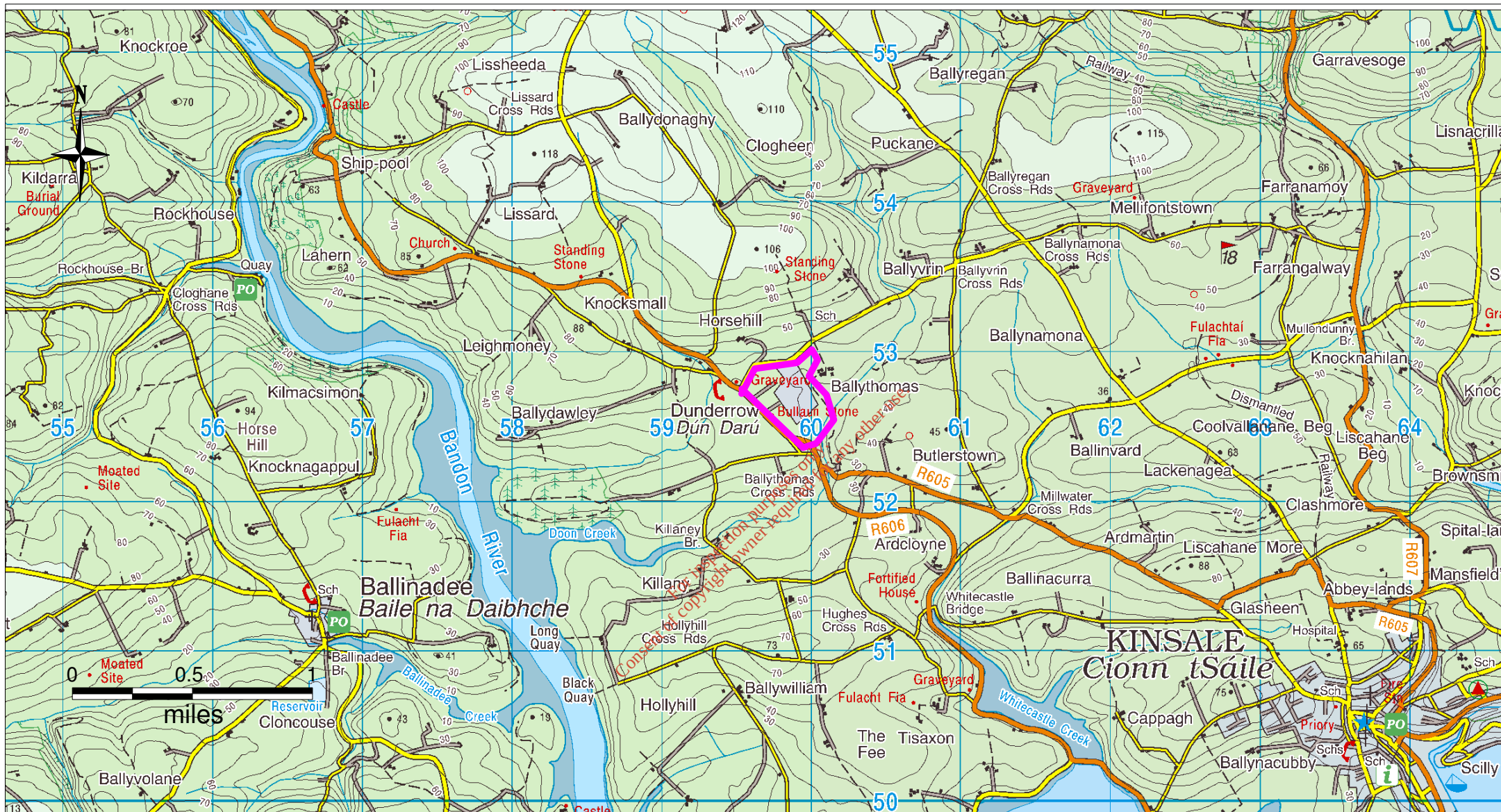
2.1 Site Location and Surrounding Landuse

The site is located in the townland of Dunderrow approximately 4 km to the northwest of Kinsale, County Cork on the R605. The site location is shown on Figure 2.1. The landuse in the surrounding area is mainly agricultural.

2.2 Site Description (Area of Assessment)

The main area of the assessment focusses on the tank farms and wastewater treatment plant to the east of the main buildings on site in close proximity to buildings IE6, IE34, IE4, IE7, IE18, IE8 and IE15. The site layout is presented on Figure 2.2.

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OSI Licence No.
AR0038713

CLIENT

Ground Investigations Ireland

TITLE

Site Location

Legend

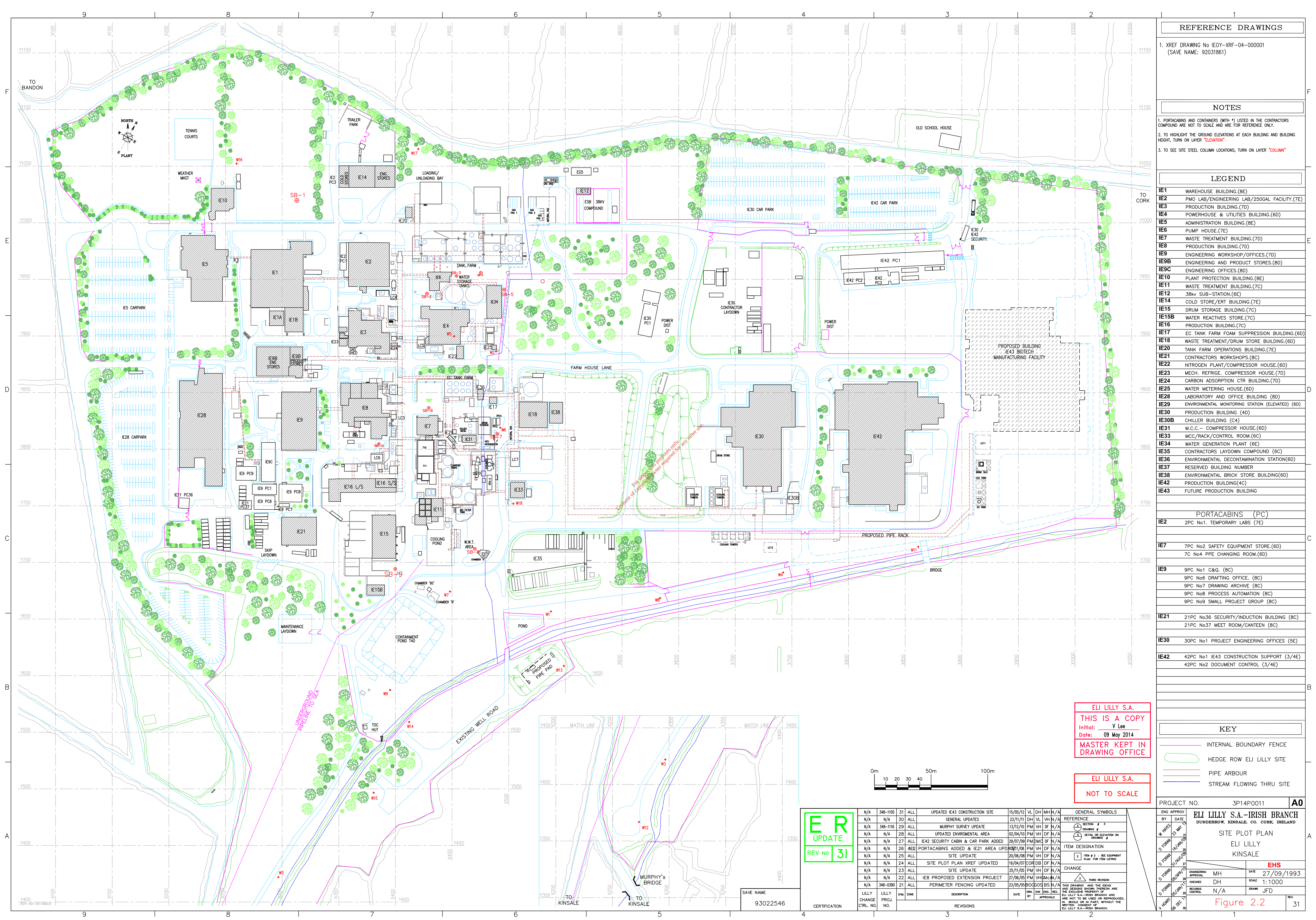


Site Location

FIGURE No.

2.1

SCALE



REFERENCE DRAWINGS

1. XREF DRAWING No IE0Y-XRF-04-000001
(SAVE NAME: 92031861)

NOTES

1. PORTACABINS AND CONTAINERS (WITH *) LISTED IN THE CONTRACTORS COMPOUND ARE NOT TO SCALE AND ARE FOR REFERENCE ONLY.
2. TO HIGHLIGHT THE GROUND ELEVATIONS AT EACH BUILDING AND BUILDING HEIGHT, TURN ON LAYER "ELEVATION"
3. TO SEE SITE STEEL COLUMN LOCATIONS, TURN ON LAYER "COLUMN"

LEGEND

IE1	WAREHOUSE BUILDING.(8E)
IE2	PMO LAB/ENGINEERING LAB/250GAL FACILITY.(7E)
IE3	PRODUCTION BUILDING.(7D)
IE4	POWERHOUSE & UTILITIES BUILDING.(6D)
IE5	ADMINISTRATION BUILDING.(8E)
IE6	PUMP HOUSE.(7E)
IE7	WASTE TREATMENT BUILDING.(7D)
IE8	PRODUCTION BUILDING.(7D)
IE9	ENGINEERING WORKSHOP/OFFICES.(7D)
IE9B	ENGINEERING AND PRODUCT STORES.(8D)
IE9C	ENGINEERING OFFICES.(8D)
IE10	PLANT PROTECTION BUILDING.(8E)
IE11	WASTE TREATMENT BUILDING.(7C)
IE12	38kv SUB-STATION.(6E)
IE14	COLD STORE/ERT BUILDING.(7E)
IE15	DRUM STORAGE BUILDING.(7C)
IE15B	WATER REACTIVES STORE.(7C)
IE16	PRODUCTION BUILDING.(7C)
IE17	EC TANK FARM FOAM SUPPRESSION BUILDING.(6D)
IE18	WASTE TREATMENT/DRUM STORE BUILDING.(6D)
IE20	TANK FARM OPERATIONS BUILDING.(7E)
IE21	CONTRACTORS WORKSHOPS.(8C)
IE22	NITROGEN PLANT/COMPRESSOR HOUSE.(6D)
IE23	MECH. REFRIGE. COMPRESSOR HOUSE.(7D)
IE24	CARBON ADSORPTION CTR BUILDING.(7D)
IE25	WATER METERING HOUSE.(6D)
IE28	LABORATORY AND OFFICE BUILDING (8D)
IE29	ENVIRONMENTAL MONITORING STATION (ELEVATION) (6D)
IE30	PRODUCTION BUILDING (4D)
IE30B	CHILLER BUILDING (C-4)
IE31	M.C.C.- COMPRESSOR HOUSE.(6D)
IE33	MCC/RACK/CONTROL ROOM.(6C)
IE34	WATER GENERATION PLANT (6E)
IE35	CONTRACTORS LAYDOWN COMPOUND (6C)
IE36	ENVIRONMENTAL DECONTAMINATION STATION(6D)
IE37	RESERVED BUILDING NUMBER
IE38	ENVIRONMENTAL BRICK STORE BUILDING(6D)
IE42	PRODUCTION BUILDING(4C)
IE43	FUTURE PRODUCTION BUILDING

PORTACABINS (PC)

IE2	2PC No1. TEMPORARY LABS (7E)
IE7	7PC No2 SAFETY EQUIPMENT STORE.(6D) 7C No4 PPE CHANGING ROOM.(6D)
IE9	9PC No1 C&Q. (8C) 9PC No6 DRAFTING OFFICE. (8C) 9PC No7 DRAWING ARCHIVE (8C) 9PC No8 PROCESS AUTOMATION (8C) 9PC No9 SMALL PROJECT GROUP (8C)
IE21	21PC No36 SECURITY/INDUCTION BUILDING (8C) 21PC No37 MEET ROOM/CANTEEN (8C)
IE30	30PC No1 PROJECT ENGINEERING OFFICES (5E)
IE42	42PC No1 IE43 CONSTRUCTION SUPPORT (3/4E) 42PC No2 DOCUMENT CONTROL (3/4E)

KEY

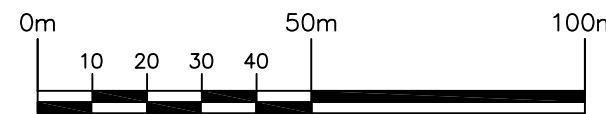
- INTERNAL BOUNDARY FENCE
- HEDGE ROW ELI LILLY SITE
- PIPE ARBOUR
- STREAM FLOWING THRU SITE

PROJECT NO. 3P14P0011

ENG APPROV BY DATE	ELI LILLY S.A.-IRISH BRANCH DUNDERBROW, KINSALE, CO. CORK, IRELAND	DATE 27/09/1993
BY DATE	SITE PLOT PLAN	SCALE 1:1000
BY DATE	ELI LILLY	DRAWN JFD
BY DATE	KINSALE	REV.
BY DATE		Figure 2.2
BY DATE		31

ELI LILLY S.A.
THIS IS A COPY
Initial: V Lee
Date: 09 May 2014
MASTER KEPT IN
DRAWING OFFICE

ELI LILLY S.A.
NOT TO SCALE



ER
UPDATE
REV NO 31

CERTIFICATION

NO.	DATE	DESCRIPTION	DATE	CHK BY	APP BY
1	15/05/12	VL DH MH N/A			
2	23/11/11	DH VL VH N/A			
3	13/12/10	PM VH DF N/A			
4	02/04/10	PM VH DF N/A			
5	29/07/09	PM DMG DF N/A			
6	20/06/08	PM VH DF N/A			
7	19/04/07	COR DB DF N/A			
8	25/11/05	PM VH DF N/A			
9	27/06/05	PM VH DMG N/A			
10	23/05/05	BOGOS BS N/A			
11	23/05/05	BOGOS BS N/A			
12	23/05/05	BOGOS BS N/A			
13	23/05/05	BOGOS BS N/A			
14	23/05/05	BOGOS BS N/A			
15	23/05/05	BOGOS BS N/A			
16	23/05/05	BOGOS BS N/A			
17	23/05/05	BOGOS BS N/A			
18	23/05/05	BOGOS BS N/A			
19	23/05/05	BOGOS BS N/A			
20	23/05/05	BOGOS BS N/A			
21	23/05/05	BOGOS BS N/A			
22	23/05/05	BOGOS BS N/A			
23	23/05/05	BOGOS BS N/A			
24	23/05/05	BOGOS BS N/A			
25	23/05/05	BOGOS BS N/A			
26	23/05/05	BOGOS BS N/A			
27	23/05/05	BOGOS BS N/A			
28	23/05/05	BOGOS BS N/A			
29	23/05/05	BOGOS BS N/A			
30	23/05/05	BOGOS BS N/A			
31	23/05/05	BOGOS BS N/A			

SAVE NAME
93022546

3 SOILS ASSESSMENT

3.1 Boring Locations

The soil borings were cited in locations where historical or current activities have had the potential to impact on soil quality both from historic and ongoing operations at the site.

An upgradient borehole (S-1) was drilled to represent background conditions and this was located to the east of the security building.

Boreholes were drilled in close proximity of the tank farms (S-2, S-3, S-4, S-6 and S-7), the wastewater treatment plant (S-8 and S-9) and downgradient of the process building IE8 (S-10).

A borehole (S-5) was drilled in an area of the site where an historic leak from an underground heavy fuel oil (HFO) pipeline (now removed) had occurred.

Figure 2.2 shows the locations of each of the boreholes installed.

3.2 Soil Boring Installation

The location of underground services were identified on the services drawings and confirmed on the ground using a cable avoidance tool (CAT) before the drilling commenced. Each soil boring location was cleared by Eli Lilly Civil and Electrical Engineers. Where paving was encountered the boring locations were first cored.

The borings were drilled using a DANDO Terrier Drilling 2202 drive sampling rig. This rig utilises a hydraulic hammer to drive 1m cylinders into the ground and retrieve 1m length cores of soil. Each core is retrieved in a dedicated plastic liner, which minimises the risk of cross contamination vertically within the hole and between borings. The boreholes were drilled to a maximum depth of 2m BGL in all locations except borehole S-5 which terminated on weathered bedrock at 1.6m BGL.

Each boring was supervised by an OCM environmental scientist and logged in accordance with BS5930. Soil samples were collected and screened for volatile organic compounds (VOCs) using a Photo Ionisation Detector (PID). Logs of the individual borings including PID readings are presented in Appendix 1. Following sample collection, all of the borings were backfilled with the drilling spoil. The civil contractors on site were to re-instate the paved areas.

3.3 Field Observations

There was no evidence of staining at any of the locations prior to coring. The site is underlain by sandy gravelly FILL with depths of between 0.2m and 1.2m recorded in the boreholes drilled. The subsoils beneath the fill mainly comprise sandy gravelly CLAY between the base of the fill and the top of weathered bedrock. Where bedrock is encountered it typically comprises weathered siltstone/mudstone with clay. The subsoils were not water bearing.

The subsoils were examined in the field for evidence of contamination. There was no visual or olfactory evidence of contamination in the fill or underlying subsoil. Field screening using the PID did not detect VOCs.

3.4 Soil Sampling

Composite soil samples were collected from beneath the granular fill to 1m BGL in all boreholes and from 1-2m in all boreholes except borehole S-5 which terminated at 1.6m BGL. All samples were collected in accordance with OCM's sampling protocol, a copy of which is included in Appendix 2. The soil samples were placed in laboratory prepared containers and stored in coolers prior to shipment to Jones Environmental Laboratories Ltd, an independent UKAS accredited laboratory in the UK.

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3.5 Laboratory Analysis

Laboratory analysis was undertaken to determine if the subsoils had been impacted by the site. While samples were collected at shallow and deep levels in each boring, laboratory analysis was only undertaken on the upper soil samples. If contamination had been encountered the deeper soil sample would then be analysed.

The soils samples were analysed for – the full suite of parameters specified in the Annex to EU Council Decision establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to Directive 1999/31/EC. The Annex, which is commonly known as the Landfill Waste Acceptance Criteria (WAC), sets threshold limits for a range of inorganic and organic parameters that characterise a waste as suitable for disposal to an inert, non-hazardous or hazardous waste landfill.

The solid soil samples were tested for Total Organic Carbon (TOC), BTEX (benzene, toluene, ethylbenzene and xylene) PCB, Mineral Oil and PAH.

Leachate generated from the samples was tested for arsenic, barium, cadmium, chromium, copper, mercury, molybdenum, nickel, lead, antimony, selenium and zinc, chloride, fluoride, soluble sulphate, phenols, dissolved organic carbon (DOC) and total dissolved solids (TDS). The parameter range was based on the site history and the need to establish a comprehensive environmental baseline for the soil quality at the site.

Based on the historical use of solvents on site in various manufacturing process the soil samples were also analysed for volatile organic compounds (VOCs), semi volatile organics (sVOCs), alcohols and acetates.

The methodologies used by the laboratory were ISO/CEN approved or equivalent and the method detection limits (MDL) were all below relevant limits and comparative guidance values.

3.5.1 Laboratory Results

The full laboratory report is in Appendix 3 and the WAC test results are presented in Tables 3.1 to 3.4 which includes, for comparative purposes, the thresholds specified in Annex II to Directive 1999/31/EC.

The VOCs results table also includes the UK Environment Agency Soil Guideline Values (SGV) developed using the CLEA Model for individual, or groups of similar chemicals for use in assessing the chronic risk to human health from long-term exposure to chemicals in soil. The SGVs presented in the Tables are for commercial end use.

3.5.2 Interpretation

Both field screening and laboratory analysis confirms that the subsoils are uncontaminated. The soil samples were all below the inert limit for the waste acceptance criteria. The results indicate that, when excavated, the subsoils could be retained and reused on site for landscaping or other appropriate geotechnical purposes. If the material is to be removed from site it is suitable for recovery and/or disposal as inert waste to suitably licensed or permitted waste disposal facilities.

No other VOCs, sVOCs or alcohols were detected in any of the samples.

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Table 3.1 WAC Analysis														
Sample	S-1	S-2	S-3	S-4	S-5	S-6	S-7	S-8	S-9	S-10	LoD	Inert Landfill	Non-Hazardous Landfill	EPA RANGE
Depth (m)	0.3-1.0	0-1	0.4-1.0	0.25-0.7	0.2-1.0	0.5-1.0	0-1	0-1	0.5-1.0	0-1				
Parameter / Units	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg
Antimony	<	<	<	<	<	<	<	0.03	<	<	0.02	0.06	0.7	0.2-0.3
Arsenic	<	<	<	<	<	<	<	<	<	<	0.025	0.5	2	1.0-50
Cadmium	<	<	<	<	<	<	<	<	<	<	0.005	0.04	1	0.1-1
Copper	<	<	<	<	<	<	<	<	<	<	0.07	2	50	2-100
Chromium	0.026	<	0.032	0.035	<	<	<	<	<	<	0.015	0.5	10	5-250
Lead	<	<	<	0.78	<	<	<	<	<	<	0.05	0.5	10	2-80
Nickel	<	<	<	0.03	<	<	<	<	<	<	0.02	0.4	10	0.5-100
Molybdenum	<	<	<	<	<	0.04	0.03	<	<	<	0.02	0.5	10	0.2-3
Selenium	<	<	<	<	<	<	<	<	<	<	0.03	0.1	0.5	0.2-2
Zinc	0.06	0.04	0.06	0.1	<	<	<	<	<	0.03	0.03	4	50	10-200
Mercury	<	<	<	<	<	<	<	<	<	<	0.01	0.01	0.2	0.03-0.8
Barium	0.10	0.04	0.11	0.12	<	<	<	<	0.05	0.05	0.03	20	100	-
Chloride	8	4	8	13	8	36	6	5	12	8		800	15,000	-
Fluoride	<	<	<	<	4	5	3	<	<	9	3	10	150	-
Sulphate*	28.8	12.9	27.5	32.4	68.5	27.3	19.5	92.3	48	13.8		1000*	20,000	200-1,500
Dissolved Organic Carbon	<	60	60	40	<	<	20	<	30	<	20	500	800	-
Total Dissolved Solids	<	<	<	<	740	<	660	560	<	920	350	4,000	60,000	-
Phenols	<	<	<	<	<	<	<	<	<	<	0.1	1	NE	-
Total Organic Carbon	0.34	0.24	0.15	0.16	0.32	0.11	0.31	0.2	0.17	1.07	%	3**	NE	-
Benzene	<	<	<	<	<	<	<	<	<	<	0.003	6	NE	-
Toluene	<	<	<	<	<	<	<	<	<	<	0.003	6	NE	-
Ethylbenzene	<	<	<	<	<	<	<	<	<	<	0.003	6	NE	-
Total Xylene	<	<	<	<	<	<	<	<	<	<	0.009	6	NE	-
PCB Total of 7	<	<	<	<	<	<	<	<	<	<	0.035	1	NE	-
Naphthalene	<	<	<	<	<	<	<	<	<	<	0.04	NE	NE	-
Acena-phthylene	<	<	<	<	<	<	<	<	<	<	0.03	NE	NE	-
Acenaphthene	<	<	<	<	<	<	<	<	<	<	0.05	NE	NE	-
Fluorene	<	<	<	<	<	<	<	<	<	<	0.04	NE	NE	-
Phenanthrene	<	<	<	<	<	<	<	<	<	<	0.03	NE	NE	-
Anthracene	<	<	<	<	<	<	<	<	<	<	0.04	NE	NE	-
Fluoranthene	<	<	<	<	<	<	<	<	<	<	0.03	NE	NE	-
Pyrene	<	<	<	<	<	<	<	<	<	<	0.03	NE	NE	-
Benzo(a)-anthracene	<	<	<	<	<	<	<	<	<	<	0.06	NE	NE	-
Chrysene	<	<	<	<	<	<	<	<	<	<	0.02	NE	NE	-
Benzo(b)+Benzo-(k)fluoranthene	<	<	<	<	<	<	<	<	<	<	0.07	NE	NE	-
Benzo(a)pyrene	<	<	<	<	<	<	<	<	<	<	0.04	NE	NE	-
Indeno(123cd)-pyrene	<	<	<	<	<	<	<	<	<	<	0.04	NE	NE	-
Dibenzo(ah)-anthracene	<	<	<	<	<	<	<	<	<	<	0.04	NE	NE	-
Benzo(ghi)-perylene	<	<	<	<	<	<	<	<	<	<	0.04	NE	NE	-
Coronene	<	<	<	<	<	<	<	<	<	<	0.04	NE	NE	-
Total 17 PAH's	<	<	<	<	<	<	<	<	<	<	0.64	NE	NE	-
Mineral Oil	<	65	<	<	<	88	<	<	<	<	30	500	NE	-
Notes														
NE - Not Established														
< - Denotes Limit of Detection (LoD) not exceeded														
* - sulphate level exceeding inert waste limit may be considered as complying if the TDS value does not exceed 6,000mg/kg at L/S = 10l/kg.														
**-a higher limit may be accepted provided the DOC values of 500mg/kg is achieved														

Table 3.2 VOC Analysis												
Sample	S-1	S-2	S-3	S-4	S-5	S-6	S-7	S-8	S-9	S-10	LoD	SGV Commercial
Depth	0.3-1.0	0-1	0.4-1.0	0.5-1.0	0.2-1.0	0.5-1.0	0-1	0-1	0.5-1.0	0-1		
Parameter / Units	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l
Dichlorodifluoromethane	<	<	<	<	<	<	<	<	<	<	2	
Methyl Tertiary Butyl Ether #	<	<	<	<	<	<	<	<	<	<	2	
Chloromethane #	<	<	<	<	<	<	<	<	<	<	3	
Vinyl Chloride	<	<	<	<	<	<	<	<	<	<	2	
Bromomethane	<	<	<	<	<	<	<	<	<	<	1	
Chloroethane #	<	<	<	<	<	<	<	<	<	<	2	
Trichlorofluoromethane #	<	<	<	<	<	<	<	<	<	<	2	
1,1-Dichloroethene (1,1 DCE) #	<	<	<	<	<	<	<	<	<	<	6	
Dichloromethane (DCM) #	<	<	<	<	<	<	<	<	<	<	7	
trans-1-2-Dichloroethene #	<	<	<	<	<	<	<	<	<	<	3	
1,1-Dichloroethane #	<	<	<	<	<	<	<	<	<	<	3	
cis-1-2-Dichloroethene #	<	<	<	<	<	<	<	<	<	<	3	
2,2-Dichloropropane	<	<	<	<	<	<	<	<	<	<	4	
Bromochloromethane #	<	<	<	<	<	<	<	<	<	<	3	
Chloroform #	<	<	<	<	<	<	<	<	<	<	3	
1,1,1-Trichloroethane #	<	<	<	<	<	<	<	<	<	<	3	
1,1-Dichloropropene #	<	<	<	<	<	<	<	<	<	<	3	
Carbon tetrachloride #	<	<	<	<	<	<	<	<	<	<	4	
1,2-Dichloroethane #	<	<	<	<	<	<	<	<	<	<	4	
Benzene #	<	<	<	<	<	<	<	<	<	<	3	95
Trichloroethene (TCE) #	<	<	<	<	<	<	<	<	<	<	3	
1,2-Dichloropropane #	<	<	<	<	<	<	<	<	<	<	6	
Dibromomethane #	<	<	<	<	<	<	<	<	<	<	3	
Bromodichloromethane #	<	<	<	<	<	<	<	<	<	<	3	
cis-1-3-Dichloropropene	<	<	<	<	<	<	<	<	<	<	4	
Toluene #	<	<	<	<	<	<	<	<	<	<	3	4,400
trans-1-3-Dichloropropene	<	<	<	<	<	<	<	<	<	<	3	
1,1,2-Trichloroethane #	<	<	<	<	<	<	<	<	<	<	3	
Tetrachloroethene (PCE) #	<	<	<	<	<	<	<	<	<	<	3	
1,3-Dichloropropane #	<	<	<	<	<	<	<	<	<	<	3	
Dibromochloromethane #	<	<	<	<	<	<	<	<	<	<	3	
1,2-Dibromoethane #	<	<	<	<	<	<	<	<	<	<	3	
Chlorobenzene #	<	<	<	<	<	<	<	<	<	<	3	
1,1,1,2-Tetrachloroethane	<	<	<	<	<	<	<	<	<	<	3	
Ethylbenzene #	<	<	<	<	<	<	<	<	<	<	3	2,800
p/m-Xylene #	<	<	<	<	<	<	<	<	<	<	6	3,200
o-Xylene #	<	<	<	<	<	<	<	<	<	<	3	2,600
Styrene	<	<	<	<	<	<	<	<	<	<	3	
Bromoform #	<	<	<	<	<	<	<	<	<	<	3	
Isopropylbenzene #	<	<	<	<	<	<	<	<	<	<	3	
1,1,2,2-Tetrachloroethane #	<	<	<	<	<	<	<	<	<	<	3	
Bromobenzene	<	<	<	<	<	<	<	<	<	<	2	
1,2,3-Trichloropropane #	<	<	<	<	<	<	<	<	<	<	4	
Propylbenzene #	<	<	<	<	<	<	<	<	<	<	4	
2-Chlorotoluene	<	<	<	<	<	<	<	<	<	<	3	
1,3,5-Trimethylbenzene #	<	<	<	<	<	<	<	<	<	<	3	
4-Chlorotoluene	<	<	<	<	<	<	<	<	<	<	3	
tert-Butylbenzene #	<	<	<	<	<	<	<	<	<	<	5	
1,2,4-Trimethylbenzene #	<	<	<	<	<	<	<	<	<	<	6	
sec-Butylbenzene #	<	<	<	<	<	<	<	<	<	<	4	
4-Isopropyltoluene #	<	<	<	<	<	<	<	<	<	<	4	
1,3-Dichlorobenzene #	<	<	<	<	<	<	<	<	<	<	4	
1,4-Dichlorobenzene #	<	<	<	<	<	<	<	<	<	<	4	
n-Butylbenzene #	<	<	<	<	<	<	<	<	<	<	4	
1,2-Dichlorobenzene #	<	<	<	<	<	<	<	<	<	<	4	
1,2-Dibromo-3-chloropropane #	<	<	<	<	<	<	<	<	<	<	4	
1,2,4-Trichlorobenzene #	<	<	<	<	<	<	<	<	<	<	7	
Hexachlorobutadiene	<	<	<	<	<	<	<	<	<	<	4	
1,2,3-Trichlorobenzene #	<	<	<	<	<	<	<	<	<	<	7	
Notes												
< - Denotes Limit of Detection (LoD) not exceeded												

Table 3.3 sVOC Analysis											
Sample	S-1	S-2	S-3	S-4	S-5	S-6	S-7	S-8	S-9	S-10	LoD
Depth	0.3-1.0	0-1	0.4-1.0	0.5-1.0	0.2-1.0	0.5-1.0	0-1	0-1	0.5-1.0	0-1	
Parameter / Units	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l
Phenols											10
2-Chlorophenol	<	<	<	<	<	<	<	<	<	<	10
2-Methylphenol	<	<	<	<	<	<	<	<	<	<	10
2-Nitrophenol	<	<	<	<	<	<	<	<	<	<	10
2,4-Dichlorophenol	<	<	<	<	<	<	<	<	<	<	10
2,4-Dimethylphenol	<	<	<	<	<	<	<	<	<	<	10
2,4,5-Trichlorophenol	<	<	<	<	<	<	<	<	<	<	10
2,4,6-Trichlorophenol	<	<	<	<	<	<	<	<	<	<	10
4-Chloro-3-methylphenol	<	<	<	<	<	<	<	<	<	<	10
4-Methylphenol	<	<	<	<	<	<	<	<	<	<	10
4-Nitrophenol	<	<	<	<	<	<	<	<	<	<	10
Pentachlorophenol	<	<	<	<	<	<	<	<	<	<	10
Phenol	<	<	<	<	<	<	<	<	<	<	10
PAHs											
2-Chloronaphthalene	<	<	<	<	<	<	<	<	<	<	10
2-Methylnaphthalene	<	<	<	<	<	<	<	<	<	<	10
Naphthalene	<	<	<	<	<	<	<	<	<	<	10
Acenaphthylene	<	<	<	<	<	<	<	<	<	<	10
Acenaphthene	<	<	<	<	<	<	<	<	<	<	10
Fluorene	<	<	<	<	<	<	<	<	<	<	10
Phenanthrene	<	<	<	<	<	<	<	<	<	<	10
Anthracene	<	<	<	<	<	<	<	<	<	<	10
Fluoranthene	<	<	<	<	<	<	<	<	<	<	10
Pyrene	<	<	<	<	<	<	<	<	<	<	10
Benzo(a)anthracene	<	<	<	<	<	<	<	<	<	<	10
Chrysene	<	<	<	<	<	<	<	<	<	<	10
Benzo(bk)fluoranthene	<	<	<	<	<	<	<	<	<	<	10
Benzo(a)pyrene	<	<	<	<	<	<	<	<	<	<	10
Indeno(123cd)pyrene	<	<	<	<	<	<	<	<	<	<	10
Dibenzo(ah)anthracene	<	<	<	<	<	<	<	<	<	<	10
Benzo(ghi)perylene	<	<	<	<	<	<	<	<	<	<	10
Phthalates											
Bis(2-ethylhexyl) phthalate	<	<	<	<	<	<	<	<	<	<	10
Butylbenzyl phthalate	<	<	<	<	<	<	<	<	<	<	10
Di-n-butyl phthalate	<	<	<	<	<	<	<	<	<	<	10
Di-n-Octyl phthalate	<	<	<	<	<	<	<	<	<	<	10
Diethyl phthalate	<	<	<	<	<	<	<	<	<	<	10
Dimethyl phthalate	<	<	<	<	<	<	<	<	<	<	10
Other SVOCs											
1,2-Dichlorobenzene	<	<	<	<	<	<	<	<	<	<	10
1,2,4-Trichlorobenzene	<	<	<	<	<	<	<	<	<	<	10
1,3-Dichlorobenzene	<	<	<	<	<	<	<	<	<	<	10
1,4-Dichlorobenzene	<	<	<	<	<	<	<	<	<	<	10
2-Nitroaniline	<	<	<	<	<	<	<	<	<	<	10
2,4-Dinitrotoluene	<	<	<	<	<	<	<	<	<	<	10
2,6-Dinitrotoluene	<	<	<	<	<	<	<	<	<	<	10
3-Nitroaniline	<	<	<	<	<	<	<	<	<	<	10
4-Bromophenylphenylether	<	<	<	<	<	<	<	<	<	<	10
4-Chloroaniline	<	<	<	<	<	<	<	<	<	<	10
4-Chlorophenylphenylether	<	<	<	<	<	<	<	<	<	<	10
4-Nitroaniline	<	<	<	<	<	<	<	<	<	<	10
Azobenzene	<	<	<	<	<	<	<	<	<	<	10
Bis(2-chloroethoxy)methane	<	<	<	<	<	<	<	<	<	<	10
Bis(2-chloroethyl)ether	<	<	<	<	<	<	<	<	<	<	10
Carbazole	<	<	<	<	<	<	<	<	<	<	10
Dibenzofuran	<	<	<	<	<	<	<	<	<	<	10
Hexachlorobenzene	<	<	<	<	<	<	<	<	<	<	10
Hexachlorobutadiene	<	<	<	<	<	<	<	<	<	<	10
Hexachlorocyclopentadiene	<	<	<	<	<	<	<	<	<	<	10
Hexachloroethane	<	<	<	<	<	<	<	<	<	<	10
Isophorone	<	<	<	<	<	<	<	<	<	<	10
N-nitrosodi-n-propylamine	<	<	<	<	<	<	<	<	<	<	10
Nitrobenzene	<	<	<	<	<	<	<	<	<	<	10
Notes											
< - Denotes Limit of Detection (LoD) not exceeded											

Table 3.4 Alcohol/Acetate Analysis											
Sample	S-1	S-2	S-3	S-4	S-5	S-6	S-7	S-8	S-9	S-10	LoD
Depth	0.3-1.0	0-1	0.4-1.0	0.5-1.0	0.2-1.0	0.5-1.0	0-1	0-1	0.5-1.0	0-1	
Parameter / Units	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l
Alcohols/Acetates											
Methyl Alcohol	<	<	<	<	<	<	<	<	<	<	<500
Ethyl Alcohol	<	<	<	<	<	<	<	<	<	<	<500
i-Propyl Alcohol	<	<	<	<	<	<	<	<	<	<	<100
n-Propyl Alcohol	<	<	<	<	<	<	<	<	<	<	<100
n-Butyl Alcohol	<	<	<	<	<	<	<	<	<	<	<100
n-Pentyl Alcohol	<	<	<	<	<	<	<	<	<	<	<100
n-Hexyl Alcohol	<	<	<	<	<	<	<	<	<	<	<100
n-Heptyl Alcohol	<	<	<	<	<	<	<	<	<	<	<100
Methyl Acetate	<	<	<	<	<	<	<	<	<	<	<100
Ethyl Acetate	<	<	<	<	<	<	<	<	<	<	<100
i-Propyl Acetate	<	<	<	<	<	<	<	<	<	<	<100
n-Propyl Acetate	<	<	<	<	<	<	<	<	<	<	<100
n-Butyl Acetate	<	<	<	<	<	<	<	<	<	<	<100
Acetone	<	<	<	<	<	<	<	<	<	<	<50
Cyclohexane	<	<	<	<	<	<	<	<	<	<	<50
Tetrahydrofuran	<	<	<	<	<	<	<	<	<	<	<50
Amyl Acetate	<	<	<	<	<	<	<	<	<	<	<100
Notes											
< - Denotes Limit of Detection (LoD) not exceeded											

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4 CONCLUSIONS

4.1 Conclusions

During the site investigation no evidence of soil contamination (staining or odours) was detected in any of the samples.

Laboratory analysis results indicate that the subsoils in the areas investigated are uncontaminated.

The site is underlain by up to 1.2m of fill material which is typically comprised of sand and gravel.

The fill is underlain by stiff slightly sandy slightly gravelly CLAY to the top of weathered bedrock which comprises weathered siltstone/mudstone.

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APPENDIX 1

Soil Boring Logs

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Borehole Number: S-1

Project: Soil Assessment 2014

Completion Depth: 2m

Client: Eli Lilly

Groundwater entry: None

Location: Dunderrow

SWL (m): N/A

Depth (m)	Lithology Description	VOCs (ppm)	Soil Sample Depth (m)	Lithology
		0 10 20 30 40 50		
0	Ground Surface			
	Topsoil Brown Topsoil			
	CLAY Light Brown mottled Grey slightly gravelly CLAY			
	GRAVEL Fine to Coarse GRAVEL		0-3 - 1m	
	CLAY Very light brown / grey slightly gravelly CLAY			
1				
			1-2m	
	BEDROCK Weathered BEDROCK: Clayey siltstone/mudstone			
2				
	EOB - No Penetration			

Excavation Method: Dando Competitor Percussion Rig

Geologist: Neil Sandes

Excavation Date: 9/7/14

Sheet: 1 of 1

Borehole Number: S-2

Project: Soil Assessment 2014

Completion Depth: 2m

Client: Eli Lilly

Groundwater entry: None

Location: Dunderrow

SWL (m): N/A

Depth (m)	Lithology Description	VOCs (ppm)	Soil Sample Depth (m)	Lithology
		0 10 20 30 40 50		
0	Ground Surface			
	TOPSOIL TOPSOIL			
	FILL Black Bitumen FILL	0-1m	0-1m	
1	CLAY Light grey very gravelly CLAY			
	BEDROCK Weathered clayey BEDROCK	1-2m	1-2m	
2	EOB - No Penetration			

Excavation Method: Dando Competitor Percussion Rig

Geologist: Neil Sandes

Excavation Date: 9/7/14

Sheet: 1 of 1

Borehole Number: S-3

Project: Soil Assessment 2014

Completion Depth: 2m

Client: Eli Lilly

Groundwater entry: None

Location: Dunderrow

SWL (m): N/A

Depth (m)	Lithology Description	VOCs (ppm)	Soil Sample Depth (m)	Lithology
		0 10 20 30 40 50		
0	Ground Surface			
	FILL Compact Gravel (Hardcore) FILL			
	CLAY Light grey mottled light brown gravelly CLAY		0.4 - 1m	
1				
	BEDROCK Weathered BEDROCK - Brown mottled dark brown very gravelly CLAY		1-2m	
2				
	EOB - No Penetration			

Excavation Method: Dando Competitor Percussion Rig

Geologist: Neil Sandes

Excavation Date: 9/7/14

Sheet: 1 of 1

Borehole Number: S-4

Project: Soil Assessment 2014

Completion Depth: 2m

Client: Eli Lilly

Groundwater entry: None

Location: Dunderrow

SWL (m): N/A

Depth (m)	Lithology Description	VOCs (ppm)	Soil Sample Depth (m)	Lithology
		0 10 20 30 40 50		
0	Ground Surface			
	FILL Compact Gravel (Hardcore) FILL			
	CLAY Very light brown / grey CLAY			
1			0.5 - 1m	
			1-2m	
2	EOB - No Penetration			

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Excavation Method: Dando Competitor Percussion Rig

Geologist: Neil Sandes

Excavation Date: 9/7/14

Sheet: 1 of 1



Completion Depth: 1.6m

Groundwater entry: None

SWL (m): N/A

Sheet: 1 of 1

Borehole Number: S-6

Project: Soil Assessment 2014

Completion Depth: 2m

Client: Eli Lilly

Groundwater entry: None

Location: Dunderrow

SWL (m): N/A

Depth (m)	Lithology Description	VOCs (ppm)	Soil Sample Depth (m)	Lithology
		0 10 20 30 40 50		
0	Ground Surface			
	TARMAC Rolled Tarmac			
	FILL Sandy gravel FILL			
		0-1m	0-1m	
1	CLAY Light grey brown very gravelly CLAY			
		1-2m	1-2m	
2	EOB - No Penetration			

Excavation Method: Dando Competitor Percussion Rig

Geologist: Neil Sandes

Excavation Date: 10/7/14

Sheet: 1 of 1

Borehole Number: S-7

Project: Soil Assessment 2014

Completion Depth: 2m

Client: Eli Lilly

Groundwater entry: None

Location: Dunderrow

SWL (m): N/A

Depth (m)	Lithology Description	VOCs (ppm)	Soil Sample Depth (m)	Lithology
		0 10 20 30 40 50		
0	Ground Surface			
	FILL Brown clayey sandy gravel FILL with occasional cobbles		0-1m	
1				
	CLAY Light brown occasionally light grey slightly gravelly CLAY		1-2m	
2				
	EOB			

Excavation Method: Dando Competitor Percussion Rig

Geologist: Neil Sandes

Excavation Date: 10/7/14

Sheet: 1 of 1

Borehole Number: S-8

Project: Soil Assessment 2014

Completion Depth: 2m

Client: Eli Lilly

Groundwater entry: None

Location: Dunderrow

SWL (m): N/A

Depth (m)	Lithology Description	VOCs (ppm)	Soil Sample Depth (m)	Lithology
0	Ground Surface	0 10 20 30 40 50		
	FILL Clayey sandy gravel FILL			
		0-1m	0-1m	
1				
	CLAY Light grey brown sandy CLAY			
		1-2m	1-2m	
2				
	EOB			

Excavation Method: Dando Competitor Percussion Rig

Geologist: Neil Sandes

Excavation Date: 10/7/14

Sheet: 1 of 1

Borehole Number: S-9

Project: Soil Assessment 2014

Completion Depth: 2m

Client: Eli Lilly

Groundwater entry: None

Location: Dunderrow

SWL (m): N/A

Depth (m)	Lithology Description	VOCs (ppm)	Soil Sample Depth (m)	Lithology
		0 10 20 30 40 50		
0	Ground Surface			
	TARMAC Rolled Tarmac			
	FILL Sandy gravel FILL			
		0-1m	0-1m	
1	CLAY Light grey brown gravelly CLAY			
		1-2m	1-2m	
2	EOB - No Penetration			

Excavation Method: Dando Competitor Percussion Rig

Geologist: Neil Sandes

Excavation Date: 10/7/14

Sheet: 1 of 1

Borehole Number: S-10

Project: Soil Assessment 2014

Completion Depth: 2m

Client: Eli Lilly

Groundwater entry: None

Location: Dunderrow

SWL (m): N/A

Depth (m)	Lithology Description	VOCs (ppm)	Soil Sample Depth (m)	Lithology
		0 10 20 30 40 50		
0	Ground Surface			
	FILL Subrounded gravel FILL			
	FILL Angular to subrounded cobbly gravel FILL			
	FILL Brown sandy gravelly clay FILL	0-1m	0-1m	
	FILL Angular clayey gravelly FILL			
1	FILL Sand Fill			
	FILL Brown slightly sandy slightly gravelly clay FILL			
	GRAVEL Light brown grey slightly sandy GRAVEL	1-2m	1-2m	
2	EOB			

Excavation Method: Dando Competitor Percussion Rig

Geologist: Neil Sandes

Excavation Date: 10/7/14

Sheet: 1 of 1

APPENDIX 2
OCM Sampling Protocol

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STANDARD OPERATING PROCEDURE

SOIL SAMPLING

The soil sampling technique described below will be followed to ensure that soil samples are representative of the environment which they are intended to characterise.

1.0 SAMPLING

- (A) Locate the soil sampling station in accordance with the workplan which will specify the number and type of samples to be taken. Place a wooden stake into the ground one metre from the sample location and record sample location on the stake.
- (B) Record the location in the field logbook and, if possible, photograph the location.
- (C) Collect soil samples from the depth specified in the workplan and record the depth in the field notebook. Describe the colour and texture of each sample and record in notebook.
- (D) Wear appropriate level of protection when taking samples (gloves, safety glasses, hard hat etc.) as specified in the workplan. Collect soil samples as specified in the workplan using decontaminated stainless steel trowel, soil corer, or similar device. Collect discrete soil samples from each station.
- (E) If required by the workplan, composite discrete soil samples by placing equal volumes of soil into the container and mixing thoroughly to a homogenous mixture. Samples may be hand picked, if necessary, to remove larger materials, such as leaves, sticks, gravel, rocks etc., if specified in the workplan. Record in notebook the nature of any materials removed from soil samples.
- (F) Deposit each soil sampled into a (clean, pre-washed) container. At the time of collection, the sample bottle will be filled to the top with soil sample.
- (G) Fill out labels with waterproof ink and attach to the sample container. The following information will be recorded on each sample label: -

Client/Site Name
Date Collected
Time Collected
Analysis
Preservative
Sample Identification Number

- (H) Decontaminate sampling equipment as described below unless otherwise specified in the site workplan. When using stainless steel sampling equipment: -
- wash with non-phosphate detergent in potable water,
 - rinse sequentially in potable water, methanol, acetone, methanol and D1 water and;
 - allow to air dry in a containment free area.
- (I) Wrap the decontaminated sampling equipment in aluminium foil which has been decontaminated in accordance with Section H.

2.0 FIELD DOCUMENTATION

Record sample information in the field notebook. Provide a complete description of the sample location, and a photograph, if necessary. Describe the soil appearance, especially if the presence of oil or an odour is noted. Document the sample bottle lot numbers in the field notebook. Record weather conditions at the time of sampling. The Field Team Leader will initial the logbook entries for correctness.

3.0 FIELD QA/QC SAMPLES

See the separate SOP on Field QA/QC samples for appropriateness and preparation of D1 Water Field Blanks, Cross-contamination Field Blanks, Trip Blanks and Field Duplicate Samples.

4.0 PACKAGING AND TRANSPORT

Check to be sure that all necessary information is on the sample container label. Complete the chain-of custody form. Package, label and transport the samples to the testing laboratory in accordance with requirements for packing, shipping and labelling environmental samples.

END.

APPENDIX 3

Laboratory Results

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Jones Environmental Laboratory

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Attention : Neil Sandes
Date : 22nd August, 2014
Your reference : 14-099-11
Our reference : Test Report 14/8074 Batch 1
Location : Eli Lilly
Date samples received : 15th July, 2014
Status : Final report
Issue : 2

Twenty samples were received for analysis on 15th July, 2014. Please find attached our Test Report which should be read with notes at the end of the report and should include all sections if reproduced. Interpretations and opinions are outside the scope of any accreditation, and all results relate only to samples supplied.

All analysis is carried out on as received samples and reported on a dry weight basis unless stated otherwise. Results are not surrogate corrected.

Compiled By:

Phil Sommerton BSc
Project Manager

Bob Millward BSc FRSC
Principal Chemist

Jones Environmental Laboratory

Client Name: O'Callaghan Moran & Associates
Reference: 14-099-11
Location: Eli Lilly
Contact: Neil Sandes
JE Job No.: 14/8074

Report : Solid

Solids: V=60g VOC jar, J=250g glass jar, T=plastic tub

J E Sample No.	1-3	7-8	12-14	15-17	21-23	27-29	33-35	39-41	45-47	51-53	Please see attached notes for all abbreviations and acronyms		
Sample ID	S-1	S-2	S-3	S-4	S-5	S-6	S-7	S-8	S-9	S-10			
Depth	0.3-1.0	0.0-1.0	0.4-1.0	0.5-1.0	0.2-1.0	0.5-1.0	0.0-1.0	0.0-1.0	0.5-1.0	0.0-1.0			
COC No / misc													
Containers	V J T	V J	V J T	V J T	V J T	V J T	V J T	V J T	V J T	V J T			
Sample Date	09/07/2014	09/07/2014	09/07/2014	09/07/2014	09/07/2014	10/07/2014	10/07/2014	10/07/2014	10/07/2014	10/07/2014			
Sample Type	Soil	Soil	Soil	Soil	Soil	Soil	Soil	Soil	Soil	Soil			
Batch Number	1	1	1	1	1	1	1	1	1	1			
Date of Receipt	15/07/2014	15/07/2014	15/07/2014	15/07/2014	15/07/2014	15/07/2014	15/07/2014	15/07/2014	15/07/2014	15/07/2014	LOD/LOR	Units	Method No.
PAH MS													
Naphthalene #	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	mg/kg	TM4/PM8
Acenaphthylene	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	mg/kg	TM4/PM8
Acenaphthene #	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	mg/kg	TM4/PM8
Fluorene #	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	mg/kg	TM4/PM8
Phenanthrene #	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	mg/kg	TM4/PM8
Anthracene #	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	mg/kg	TM4/PM8
Fluoranthene #	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	mg/kg	TM4/PM8
Pyrene #	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03	mg/kg	TM4/PM8
Benzo(a)anthracene #	<0.06	<0.06	<0.06	<0.06	<0.06	<0.06	<0.06	<0.06	<0.06	<0.06	<0.06	mg/kg	TM4/PM8
Chrysene #	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	mg/kg	TM4/PM8
Benzo(bk)fluoranthene #	<0.07	<0.07	<0.07	<0.07	<0.07	<0.07	<0.07	<0.07	<0.07	<0.07	<0.07	mg/kg	TM4/PM8
Benzo(a)pyrene #	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	mg/kg	TM4/PM8
Indeno(123cd)pyrene #	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	mg/kg	TM4/PM8
Dibenzo(ah)anthracene #	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	mg/kg	TM4/PM8
Benzo(ghi)perylene #	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	mg/kg	TM4/PM8
Coronene	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	<0.04	mg/kg	TM4/PM8
PAH 17 Total	<0.64	<0.64	<0.64	<0.64	<0.64	<0.64	<0.64	<0.64	<0.64	<0.64	<0.64	mg/kg	TM4/PM8
Benzo(b)fluoranthene	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	mg/kg	TM4/PM8
Benzo(k)fluoranthene	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	mg/kg	TM4/PM8
PAH Surrogate % Recovery	109	111	112	117	115	118	118	119	116	118	<0	%	TM4/PM8
Methyl Tertiary Butyl Ether #	<2	<2	<2	<2	<2	<2	<2	<2	<2	<2	<2	ug/kg	TM15/PM10
Benzene #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
Toluene #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
Ethylbenzene #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
p/m-Xylene #	<6	<6	<6	<6	<6	<6	<6	<6	<6	<6	<6	ug/kg	TM15/PM10
o-Xylene #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
Surrogate Recovery Toluene D8	107	106	107	109	108	107	103	109	109	103	<0	%	TM15/PM10
Surrogate Recovery 4-Bromofluorobenzene	104	105	110	110	110	108	96	102	112	90	<0	%	TM15/PM10
Mineral Oil (C10-C40)	<30	65	<30	<30	<30	88	<30	<30	<30	<30	<30	mg/kg	TM5/PM16
PCB 28 #	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	ug/kg	TM17/PM8
PCB 52 #	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	ug/kg	TM17/PM8
PCB 101 #	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	ug/kg	TM17/PM8
PCB 118 #	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	ug/kg	TM17/PM8
PCB 138 #	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	ug/kg	TM17/PM8
PCB 153 #	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	ug/kg	TM17/PM8
PCB 180 #	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	ug/kg	TM17/PM8
Total 7 PCBs #	<35	<35	<35	<35	<35	<35	<35	<35	<35	<35	<35	ug/kg	TM17/PM8

Please include all sections of this report if it is reproduced

Please see attached notes for all abbreviations and acronyms

Client Name: O'Callaghan Moran & Associates
Reference: 14-099-11
Location: Eli Lilly
Contact: Neil Sandes
JE Job No.: 14/8074

VOC Report : Solid

J E Sample No.	1-3	7-8	12-14	15-17	21-23	27-29	33-35	39-41	45-47	51-53	Please see attached notes for all abbreviations and acronyms		
Sample ID	S-1	S-2	S-3	S-4	S-5	S-6	S-7	S-8	S-9	S-10			
Depth	0.3-1.0	0.0-1.0	0.4-1.0	0.5-1.0	0.2-1.0	0.5-1.0	0.0-1.0	0.0-1.0	0.5-1.0	0.0-1.0			
COC No / misc Containers	V J T	V J	V J T	V J T	V J T	V J T	V J T	V J T	V J T	V J T			
Sample Date	09/07/2014	09/07/2014	09/07/2014	09/07/2014	09/07/2014	10/07/2014	10/07/2014	10/07/2014	10/07/2014	10/07/2014			
Sample Type	Soil	Soil	Soil	Soil	Soil	Soil	Soil	Soil	Soil	Soil			
Batch Number	1	1	1	1	1	1	1	1	1	1	LOD/LOR	Units	Method No.
Date of Receipt	15/07/2014	15/07/2014	15/07/2014	15/07/2014	15/07/2014	15/07/2014	15/07/2014	15/07/2014	15/07/2014	15/07/2014			
VOC MS													
Dichlorodifluoromethane	<2	<2	<2	<2	<2	<2	<2	<2	<2	<2	<2	ug/kg	TM15/PM10
Methyl Tertiary Butyl Ether #	<2	<2	<2	<2	<2	<2	<2	<2	<2	<2	<2	ug/kg	TM15/PM10
Chloromethane #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
Vinyl Chloride	<2	<2	<2	<2	<2	<2	<2	<2	<2	<2	<2	ug/kg	TM15/PM10
Bromomethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	ug/kg	TM15/PM10
Chloroethane #	<2	<2	<2	<2	<2	<2	<2	<2	<2	<2	<2	ug/kg	TM15/PM10
Trichlorofluoromethane #	<2	<2	<2	<2	<2	<2	<2	<2	<2	<2	<2	ug/kg	TM15/PM10
1,1-Dichloroethene (1,1 DCE) #	<6	<6	<6	<6	<6	<6	<6	<6	<6	<6	<6	ug/kg	TM15/PM10
Dichloromethane (DCM) #	<7	<7	<7	<7	<7	<7	<7	<7	<7	<7	<7	ug/kg	TM15/PM10
trans-1,2-Dichloroethene #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
1,1-Dichloroethane #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
cis-1,2-Dichloroethene #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
2,2-Dichloropropane	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	ug/kg	TM15/PM10
Bromochloromethane #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
Chloroform #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
1,1,1-Trichloroethane #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
1,1-Dichloropropene #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
Carbon tetrachloride #	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	ug/kg	TM15/PM10
1,2-Dichloroethane #	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	ug/kg	TM15/PM10
Benzene #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
Trichloroethene (TCE) #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
1,2-Dichloropropane #	<6	<6	<6	<6	<6	<6	<6	<6	<6	<6	<6	ug/kg	TM15/PM10
Dibromomethane #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
Bromodichloromethane #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
cis-1,3-Dichloropropene	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	ug/kg	TM15/PM10
Toluene #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
trans-1,3-Dichloropropene	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
1,1,2-Trichloroethane #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
Tetrachloroethene (PCE) #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
1,3-Dichloropropane #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
Dibromochloromethane #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
1,2-Dibromoethane #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
Chlorobenzene #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
1,1,1,2-Tetrachloroethane	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
Ethylbenzene #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
p/m-Xylene #	<6	<6	<6	<6	<6	<6	<6	<6	<6	<6	<6	ug/kg	TM15/PM10
o-Xylene #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
Styrene	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
Bromoform	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
Isopropylbenzene #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
1,1,2,2-Tetrachloroethane #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
Bromobenzene	<2	<2	<2	<2	<2	<2	<2	<2	<2	<2	<2	ug/kg	TM15/PM10
1,2,3-Trichloropropane #	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	ug/kg	TM15/PM10
Propylbenzene #	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	ug/kg	TM15/PM10
2-Chlorotoluene	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
1,3,5-Trimethylbenzene #	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
4-Chlorotoluene	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	<3	ug/kg	TM15/PM10
tert-Butylbenzene #	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	ug/kg	TM15/PM10
1,2,4-Trimethylbenzene #	<6	<6	<6	<6	<6	<6	<6	<6	<6	<6	<6	ug/kg	TM15/PM10
sec-Butylbenzene #	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	ug/kg	TM15/PM10
4-Isopropyltoluene #	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	ug/kg	TM15/PM10
1,3-Dichlorobenzene #	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	ug/kg	TM15/PM10
1,4-Dichlorobenzene #	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	ug/kg	TM15/PM10
n-Butylbenzene #	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	ug/kg	TM15/PM10
1,2-Dichlorobenzene #	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	ug/kg	TM15/PM10
1,2-Dibromo-3-chloropropane #	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	ug/kg	TM15/PM10
1,2,4-Trichlorobenzene #	<7	<7	<7	<7	<7	<7	<7	<7	<7	<7	<7	ug/kg	TM15/PM10
Hexachlorobutadiene	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	<4	ug/kg	TM15/PM10
Naphthalene	<27	<27	<27	<27	<27	<27	<27	<27	<27	<27	<27	ug/kg	TM15/PM10
1,2,3-Trichlorobenzene #	<7	<7	<7	<7	<7	<7	<7	<7	<7	<7	<7	ug/kg	TM15/PM10
Surrogate Recovery Toluene D8	107	106	107	109	108	107	103	109	109	103	<0	%	TM15/PM10
Surrogate Recovery 4-Bromofluorobenzene	104	105	110	110	110	108	96	102	112	90	<0	%	TM15/PM10

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Mass of sample taken (kg)	-	Moisture Content Ratio (%) =	20.7
Mass of dry sample (kg) =	0.09	Dry Matter Content Ratio (%) =	82.9
Particle Size <4mm =	>95%		
JEFL Job No	14/8074	Landfill Waste Acceptance Criteria Limits	
Sample No	3		
Client Sample No	S-1		
Depth/Other	0.3-1.0		
Sample Date	09/07/2014		
Batch No	1		
Solid Waste Analysis		Inert Waste Landfill	Stable Non-reactive Hazardous Waste in Non- Hazardous Landfill
Total Organic Carbon (%)	0.34	3	5
Loss on Ignition (%)	-	-	10
Sum of BTEX (mg/kg)	<0.018	6	-
Sum of 7 PCBs (mg/kg)	<0.035	1	-
Mineral Oil (mg/kg)	<30	500	-
PAH Sum of 17(mg/kg)	<0.64	100	-
pH (pH Units)	-	-	>6
ANC to pH 7 (mol/kg)	-	-	to be evaluated
ANC to pH 4 (mol/kg)	-	-	to be evaluated
Eluate Analysis	10:1 conc ⁿ leached		Limit values for compliance leaching test using BS EN 12457-2 at L/S 10 l/kg
	C ₁₀ mg/l	A ₁₀ mg/kg	
Arsenic	<0.0025	<0.025	0.5
Barium	0.010	0.10	20
Cadmium	0.0005	<0.005	0.04
Chromium	0.0026	0.026	0.5
Copper	<0.007	<0.07	2
Mercury	<0.001	<0.01	0.01
Molybdenum	<0.002	<0.02	0.5
Nickel	<0.002	<0.02	0.4
Lead	<0.005	<0.05	0.5
Antimony	<0.002	<0.02	0.06
Selenium	<0.003	<0.03	0.1
Zinc	0.006	0.06	4
Chloride	0.8	8	800
Fluoride	<0.3	<3	10
Sulphate as SO ₄	2.88	28.8	1000
Total Dissolved Solids	<35	<350	4000
Phenol	<0.01	<0.1	1
Dissolved Organic Carbon	4	40	500

Mass of sample taken (kg)	-	Moisture Content Ratio (%) =	7.3
Mass of dry sample (kg) =	0.09	Dry Matter Content Ratio (%) =	93.2
Particle Size <4mm =	>95%		
JEFL Job No	14/8074	Landfill Waste Acceptance Criteria Limits	
Sample No	8		
Client Sample No	S-2		
Depth/Other	0.0-1.0		
Sample Date	09/07/2014		
Batch No	1		
Solid Waste Analysis		Inert Waste Landfill	Stable Non-reactive Hazardous Waste in Non- Hazardous Landfill
Total Organic Carbon (%)	0.24	3	5
Loss on Ignition (%)	-	-	10
Sum of BTEX (mg/kg)	<0.018	6	-
Sum of 7 PCBs (mg/kg)	<0.035	1	-
Mineral Oil (mg/kg)	65	500	-
PAH Sum of 17(mg/kg)	<0.64	100	-
pH (pH Units)	-	-	>6
ANC to pH 7 (mol/kg)	-	-	to be evaluated
ANC to pH 4 (mol/kg)	-	-	to be evaluated
Eluate Analysis	10:1 conc ⁿ leached		Limit values for compliance leaching test using BS EN 12457-2 at L/S 10 l/kg
	C ₁₀ mg/l	A ₁₀ mg/kg	
Arsenic	<0.0025	<0.025	0.5
Barium	0.004	0.04	20
Cadmium	<0.0005	<0.005	0.04
Chromium	<0.0015	<0.015	0.5
Copper	<0.007	<0.07	2
Mercury	<0.001	<0.01	0.01
Molybdenum	<0.002	<0.02	0.5
Nickel	<0.002	<0.02	0.4
Lead	<0.005	<0.05	0.5
Antimony	<0.002	<0.02	0.06
Selenium	<0.003	<0.03	0.1
Zinc	0.004	0.04	4
Chloride	0.4	4	800
Fluoride	<0.3	<3	10
Sulphate as SO ₄	1.29	12.9	1000
Total Dissolved Solids	<35	<350	4000
Phenol	<0.01	<0.1	1
Dissolved Organic Carbon	6	60	500

Mass of sample taken (kg)	-	Moisture Content Ratio (%) =	13.9
Mass of dry sample (kg) =	0.09	Dry Matter Content Ratio (%) =	87.8
Particle Size <4mm =	>95%		
JEFL Job No	14/8074	Landfill Waste Acceptance Criteria Limits	
Sample No	14		
Client Sample No	S-3		
Depth/Other	0.4-1.0		
Sample Date	09/07/2014		
Batch No	1		
Solid Waste Analysis		Inert Waste Landfill	Stable Non-reactive Hazardous Waste in Non- Hazardous Landfill
Total Organic Carbon (%)	0.15	3	5
Loss on Ignition (%)	-	-	10
Sum of BTEX (mg/kg)	<0.018	6	-
Sum of 7 PCBs (mg/kg)	<0.035	1	-
Mineral Oil (mg/kg)	<30	500	-
PAH Sum of 17(mg/kg)	<0.64	100	-
pH (pH Units)	-	-	>6
ANC to pH 7 (mol/kg)	-	-	to be evaluated
ANC to pH 4 (mol/kg)	-	-	to be evaluated
Eluate Analysis	10:1 conc ⁿ leached		Limit values for compliance leaching test using BS EN 12457-2 at L/S 10 l/kg
	C ₁₀ mg/l	A ₁₀ mg/kg	
Arsenic	<0.0025	<0.025	0.5
Barium	0.011	0.11	20
Cadmium	<0.0005	<0.005	0.04
Chromium	0.0032	0.032	0.5
Copper	<0.007	<0.07	2
Mercury	<0.001	<0.01	0.01
Molybdenum	<0.002	<0.02	0.5
Nickel	<0.002	<0.02	0.4
Lead	<0.005	<0.05	0.5
Antimony	<0.002	<0.02	0.06
Selenium	<0.003	<0.03	0.1
Zinc	0.006	0.06	4
Chloride	0.8	8	800
Fluoride	<0.3	<3	10
Sulphate as SO ₄	2.75	27.5	1000
Total Dissolved Solids	<35	<350	4000
Phenol	<0.01	<0.1	1
Dissolved Organic Carbon	6	60	500

Mass of sample taken (kg)	-	Moisture Content Ratio (%) =	16.3
Mass of dry sample (kg) =	0.09	Dry Matter Content Ratio (%) =	86.0
Particle Size <4mm =	>95%		
JEFL Job No	14/8074	Landfill Waste Acceptance Criteria Limits	
Sample No	17		
Client Sample No	S-4		
Depth/Other	0.5-1.0		
Sample Date	09/07/2014		
Batch No	1		
Solid Waste Analysis		Inert Waste Landfill	Stable Non-reactive Hazardous Waste in Non- Hazardous Landfill
Total Organic Carbon (%)	0.16	3	5
Loss on Ignition (%)	-	-	10
Sum of BTEX (mg/kg)	<0.018	6	-
Sum of 7 PCBs (mg/kg)	<0.035	1	-
Mineral Oil (mg/kg)	<30	500	-
PAH Sum of 17(mg/kg)	<0.64	100	-
pH (pH Units)	-	-	>6
ANC to pH 7 (mol/kg)	-	-	to be evaluated
ANC to pH 4 (mol/kg)	-	-	to be evaluated
Eluate Analysis	10:1 conc ⁿ leached		Limit values for compliance leaching test using BS EN 12457-2 at L/S 10 l/kg
	C ₁₀ mg/l	A ₁₀ mg/kg	
Arsenic	<0.0025	<0.025	0.5
Barium	0.012	0.12	20
Cadmium	<0.0005	<0.005	0.04
Chromium	0.0035	0.035	0.5
Copper	<0.007	<0.07	2
Mercury	<0.001	<0.01	0.01
Molybdenum	<0.002	<0.02	0.5
Nickel	0.003	0.03	0.4
Lead	0.078	0.78	0.5
Antimony	<0.002	<0.02	0.06
Selenium	<0.003	<0.03	0.1
Zinc	0.010	0.10	4
Chloride	1.3	13	800
Fluoride	<0.3	<3	10
Sulphate as SO ₄	3.24	32.4	1000
Total Dissolved Solids	<35	<350	4000
Phenol	<0.01	<0.1	1
Dissolved Organic Carbon	4	40	500

Mass of sample taken (kg)	-	Moisture Content Ratio (%) =	17.5
Mass of dry sample (kg) =	0.09	Dry Matter Content Ratio (%) =	85.1
Particle Size <4mm =	>95%		
JEFL Job No	14/8074	Landfill Waste Acceptance Criteria Limits	
Sample No	23		
Client Sample No	S-5		
Depth/Other	0.2-1.0		
Sample Date	09/07/2014		
Batch No	1		
Solid Waste Analysis		Inert Waste Landfill	Stable Non-reactive Hazardous Waste in Non- Hazardous Landfill
Total Organic Carbon (%)	0.32	3	5
Loss on Ignition (%)	-	-	10
Sum of BTEX (mg/kg)	<0.018	6	-
Sum of 7 PCBs (mg/kg)	<0.035	1	-
Mineral Oil (mg/kg)	<30	500	-
PAH Sum of 17(mg/kg)	<0.64	100	-
pH (pH Units)	-	-	>6
ANC to pH 7 (mol/kg)	-	-	to be evaluated
ANC to pH 4 (mol/kg)	-	-	to be evaluated
Eluate Analysis	10:1 conc ⁿ leached		Limit values for compliance leaching test using BS EN 12457-2 at L/S 10 l/kg
	C ₁₀ mg/l	A ₁₀ mg/kg	
Arsenic	<0.0025	<0.025	0.5
Barium	<0.003	<0.03	20
Cadmium	<0.0005	<0.005	0.04
Chromium	<0.0015	<0.015	0.5
Copper	<0.007	<0.07	2
Mercury	<0.001	<0.01	0.01
Molybdenum	<0.002	<0.02	0.5
Nickel	<0.002	<0.02	0.4
Lead	<0.005	<0.05	0.5
Antimony	<0.002	<0.02	0.06
Selenium	<0.003	<0.03	0.1
Zinc	<0.003	<0.03	4
Chloride	0.8	8	800
Fluoride	0.4	4	10
Sulphate as SO ₄	6.85	68.5	1000
Total Dissolved Solids	74	740	4000
Phenol	<0.01	<0.1	1
Dissolved Organic Carbon	<2	<20	500

Mass of sample taken (kg)	-	Moisture Content Ratio (%) =	5.3
Mass of dry sample (kg) =	0.09	Dry Matter Content Ratio (%) =	94.9
Particle Size <4mm =	>95%		
JEFL Job No	14/8074	Landfill Waste Acceptance Criteria Limits	
Sample No	29		
Client Sample No	S-6		
Depth/Other	0.5-1.0		
Sample Date	10/07/2014		
Batch No	1		
Solid Waste Analysis		Inert Waste Landfill	Stable Non-reactive Hazardous Waste in Non- Hazardous Landfill
Total Organic Carbon (%)	0.11	3	5
Loss on Ignition (%)	-	-	10
Sum of BTEX (mg/kg)	<0.018	6	-
Sum of 7 PCBs (mg/kg)	<0.035	1	-
Mineral Oil (mg/kg)	88	500	-
PAH Sum of 17(mg/kg)	<0.64	100	-
pH (pH Units)	-	-	>6
ANC to pH 7 (mol/kg)	-	-	to be evaluated
ANC to pH 4 (mol/kg)	-	-	to be evaluated
Eluate Analysis	10:1 conc ⁿ leached		Limit values for compliance leaching test using BS EN 12457-2 at L/S 10 l/kg
	C ₁₀ mg/l	A ₁₀ mg/kg	
Arsenic	<0.0025	<0.025	0.5
Barium	<0.003	<0.03	20
Cadmium	<0.0005	<0.005	0.04
Chromium	<0.0015	<0.015	0.5
Copper	<0.007	<0.07	2
Mercury	<0.001	<0.01	0.01
Molybdenum	0.004	0.04	0.5
Nickel	<0.002	<0.02	0.4
Lead	<0.005	<0.05	0.5
Antimony	<0.002	<0.02	0.06
Selenium	<0.003	<0.03	0.1
Zinc	<0.003	<0.03	4
Chloride	3.6	36	800
Fluoride	0.5	5	10
Sulphate as SO ₄	2.73	27.3	1000
Total Dissolved Solids	<35	<350	4000
Phenol	<0.01	<0.1	1
Dissolved Organic Carbon	2	<20	500

Mass of sample taken (kg)	-	Moisture Content Ratio (%) =	12.4
Mass of dry sample (kg) =	0.09	Dry Matter Content Ratio (%) =	89.0
Particle Size <4mm =	>95%		
JEFL Job No	14/8074	Landfill Waste Acceptance Criteria Limits	
Sample No	35		
Client Sample No	S-7		
Depth/Other	0.0-1.0		
Sample Date	10/07/2014		
Batch No	1		
Solid Waste Analysis		Inert Waste Landfill	Stable Non-reactive Hazardous Waste in Non- Hazardous Landfill
Total Organic Carbon (%)	0.31	3	5
Loss on Ignition (%)	-	-	10
Sum of BTEX (mg/kg)	<0.018	6	-
Sum of 7 PCBs (mg/kg)	<0.035	1	-
Mineral Oil (mg/kg)	<30	500	-
PAH Sum of 17(mg/kg)	<0.64	100	-
pH (pH Units)	-	-	>6
ANC to pH 7 (mol/kg)	-	-	to be evaluated
ANC to pH 4 (mol/kg)	-	-	to be evaluated
Eluate Analysis	10:1 conc ⁿ leached		Limit values for compliance leaching test using BS EN 12457-2 at L/S 10 l/kg
	C ₁₀ mg/l	A ₁₀ mg/kg	
Arsenic	<0.0025	<0.025	0.5
Barium	<0.003	<0.03	20
Cadmium	<0.0005	<0.005	0.04
Chromium	<0.0015	<0.015	0.5
Copper	<0.007	<0.07	2
Mercury	<0.001	<0.01	0.01
Molybdenum	0.003	0.03	0.5
Nickel	<0.002	<0.02	0.4
Lead	<0.005	<0.05	0.5
Antimony	<0.002	<0.02	0.06
Selenium	<0.003	<0.03	0.1
Zinc	<0.003	<0.03	4
Chloride	0.6	6	800
Fluoride	0.3	3	10
Sulphate as SO ₄	1.95	19.5	1000
Total Dissolved Solids	66	660	4000
Phenol	<0.01	<0.1	1
Dissolved Organic Carbon	2	20	500

Mass of sample taken (kg)	-	Moisture Content Ratio (%) =	10.8
Mass of dry sample (kg) =	0.09	Dry Matter Content Ratio (%) =	90.2
Particle Size <4mm =	>95%		
JEFL Job No	14/8074	Landfill Waste Acceptance Criteria Limits	
Sample No	41		
Client Sample No	S-8		
Depth/Other	0.0-1.0		
Sample Date	10/07/2014		
Batch No	1		
Solid Waste Analysis		Inert Waste Landfill	Stable Non-reactive Hazardous Waste in Non- Hazardous Landfill
Total Organic Carbon (%)	0.20	3	5
Loss on Ignition (%)	-	-	10
Sum of BTEX (mg/kg)	<0.018	6	-
Sum of 7 PCBs (mg/kg)	<0.035	1	-
Mineral Oil (mg/kg)	<30	500	-
PAH Sum of 17(mg/kg)	<0.64	100	-
pH (pH Units)	-	-	>6
ANC to pH 7 (mol/kg)	-	-	to be evaluated
ANC to pH 4 (mol/kg)	-	-	to be evaluated
Eluate Analysis	10:1 conc ⁿ leached		Limit values for compliance leaching test using BS EN 12457-2 at L/S 10 l/kg
	C ₁₀ mg/l	A ₁₀ mg/kg	
Arsenic	<0.0025	<0.025	0.5
Barium	<0.003	<0.03	20
Cadmium	<0.0005	<0.005	0.04
Chromium	<0.0015	<0.015	0.5
Copper	<0.007	<0.07	2
Mercury	<0.001	<0.01	0.01
Molybdenum	0.003	0.03	0.5
Nickel	<0.002	<0.02	0.4
Lead	<0.005	<0.05	0.5
Antimony	0.003	0.03	0.06
Selenium	<0.003	<0.03	0.1
Zinc	<0.003	<0.03	4
Chloride	0.5	5	800
Fluoride	<0.3	<3	10
Sulphate as SO ₄	9.23	92.3	1000
Total Dissolved Solids	56	560	4000
Phenol	<0.01	<0.1	1
Dissolved Organic Carbon	<2	<20	500

Mass of sample taken (kg)	-	Moisture Content Ratio (%) =	17.6
Mass of dry sample (kg) =	0.09	Dry Matter Content Ratio (%) =	85.0
Particle Size <4mm =	>95%		
JEFL Job No	14/8074	Landfill Waste Acceptance Criteria Limits	
Sample No	47		
Client Sample No	S-9		
Depth/Other	0.5-1.0		
Sample Date	10/07/2014		
Batch No	1		
Solid Waste Analysis		Inert Waste Landfill	Stable Non-reactive Hazardous Waste in Non- Hazardous Landfill
Total Organic Carbon (%)	0.17	3	5
Loss on Ignition (%)	-	-	10
Sum of BTEX (mg/kg)	<0.018	6	-
Sum of 7 PCBs (mg/kg)	<0.035	1	-
Mineral Oil (mg/kg)	<30	500	-
PAH Sum of 17(mg/kg)	<0.64	100	-
pH (pH Units)	-	-	>6
ANC to pH 7 (mol/kg)	-	-	to be evaluated
ANC to pH 4 (mol/kg)	-	-	to be evaluated
Eluate Analysis	10:1 conc ⁿ leached		Limit values for compliance leaching test using BS EN 12457-2 at L/S 10 l/kg
	C ₁₀ mg/l	A ₁₀ mg/kg	
Arsenic	<0.0025	<0.025	0.5
Barium	0.005	0.05	20
Cadmium	<0.0005	<0.005	0.04
Chromium	<0.0015	<0.015	0.5
Copper	<0.007	<0.07	2
Mercury	<0.001	<0.01	0.01
Molybdenum	<0.002	<0.02	0.5
Nickel	<0.002	<0.02	0.4
Lead	<0.005	<0.05	0.5
Antimony	<0.002	<0.02	0.06
Selenium	<0.003	<0.03	0.1
Zinc	<0.003	<0.03	4
Chloride	1.2	12	800
Fluoride	<0.3	<3	10
Sulphate as SO ₄	4.80	48.0	1000
Total Dissolved Solids	<35	<350	4000
Phenol	<0.01	<0.1	1
Dissolved Organic Carbon	3	30	500

Mass of sample taken (kg)	-	Moisture Content Ratio (%) =	18.2
Mass of dry sample (kg) =	0.09	Dry Matter Content Ratio (%) =	84.6
Particle Size <4mm =	>95%		
JEFL Job No	14/8074	Landfill Waste Acceptance Criteria Limits	
Sample No	53		
Client Sample No	S-10		
Depth/Other	0.0-1.0		
Sample Date	10/07/2014		
Batch No	1		
Solid Waste Analysis		Inert Waste Landfill	Stable Non-reactive Hazardous Waste in Non- Hazardous Landfill
Total Organic Carbon (%)	1.07	3	5
Loss on Ignition (%)	-	-	10
Sum of BTEX (mg/kg)	<0.018	6	-
Sum of 7 PCBs (mg/kg)	<0.035	1	-
Mineral Oil (mg/kg)	<30	500	-
PAH Sum of 17(mg/kg)	<0.64	100	-
pH (pH Units)	-	-	>6
ANC to pH 7 (mol/kg)	-	-	to be evaluated
ANC to pH 4 (mol/kg)	-	-	to be evaluated
Eluate Analysis	10:1 conc ⁿ leached		Limit values for compliance leaching test using BS EN 12457-2 at L/S 10 l/kg
	C ₁₀ mg/l	A ₁₀ mg/kg	
Arsenic	<0.0025	<0.025	0.5
Barium	0.005	0.05	20
Cadmium	<0.0005	<0.005	0.04
Chromium	<0.0015	<0.015	0.5
Copper	<0.007	<0.07	2
Mercury	<0.001	<0.01	0.01
Molybdenum	<0.002	<0.02	0.5
Nickel	<0.002	<0.02	0.4
Lead	<0.005	<0.05	0.5
Antimony	<0.002	<0.02	0.06
Selenium	<0.003	<0.03	0.1
Zinc	0.003	0.03	4
Chloride	0.8	8	800
Fluoride	0.9	9	10
Sulphate as SO ₄	1.38	13.8	1000
Total Dissolved Solids	92	920	4000
Phenol	<0.01	<0.1	1
Dissolved Organic Carbon	<2	<20	500

Client Name: O'Callaghan Moran & Associates

Reference: 14-099-11

Location: Eli Lilly

Contact: Neil Sandes

Matrix : CEN 10:1 1 Batch

[illegible]

Please note that only samples that are deviating are mentioned in this report. If no samples are listed it is because none were deviating. Only analyses which are accredited are recorded as deviating if set criteria are not met.

Client Name: O'Callaghan Moran & Associates

Matrix : Solid

Reference: 14-099-11

Location: Eli Lilly

Contact: Neil Sandes

[illegible]

Please note that only samples that are deviating are mentioned in this report. If no samples are listed it is because none were deviating. Only analyses which are accredited are recorded as deviating if set criteria are not met.

NOTES TO ACCOMPANY ALL SCHEDULES AND REPORTS

JE Job No.: 14/8074

SOILS

Please note we are only MCERTS accredited for sand, loam and clay and any other matrix is outside our scope of accreditation.

Where an MCERTS report has been requested, you will be notified within 48 hours of any samples that have been identified as being outside our MCERTS scope. As validation has been performed on clay, sand and loam, only samples that are predominantly these matrices, or combinations of them will be within our MCERTS scope. If samples are not one of a combination of the above matrices they will not be marked as MCERTS accredited.

It is assumed that you have taken representative samples on site and require analysis on a representative subsample. Stones will generally be included unless we are requested to remove them.

All samples will be discarded one month after the date of reporting, unless we are instructed to the contrary. If we are instructed to keep samples, a storage charge of £1 (1.5 Euros) per sample per month will be applied until we are asked to dispose of them.

If you have not already done so, please send us a purchase order if this is required by your company.

Where appropriate please make sure that our detection limits are suitable for your needs, if they are not, please notify us immediately.

All analysis is reported on a dry weight basis unless stated otherwise. Results are not surrogate corrected. Samples are dried at 35°C ±5°C unless otherwise stated. Moisture content for CEN Leachate tests are dried at 105°C ±5°C.

Where Mineral Oil or Fats, Oils and Grease is quoted, this refers to Total Aliphatics C10-C40.

Where a CEN 10:1 ZERO Headspace VOC test has been carried out, a 10:1 ratio of water to wet (as received) soil has been used.

% Asbestos in Asbestos Containing Materials (ACMs) is determined by reference to HSG 264 The Survey Guide - Appendix 2 : ACMs in buildings listed in order of ease of fibre release.

WATERS

Please note we are not a Drinking Water Inspectorate (DWI) Approved Laboratory . It is important that detection limits are carefully considered when requesting water analysis.

UKAS accreditation applies to surface water and groundwater and one other matrix which is analysis specific, any other liquids are outside our scope of accreditation

As surface waters require different sample preparation to groundwaters the laboratory must be informed of the water type when submitting samples.

Where Mineral Oil or Fats, Oils and Grease is quoted, this refers to Total Aliphatics C10-C40.

DEVIATING SAMPLES

Samples must be received in a condition appropriate to the requested analyses. All samples should be submitted to the laboratory in suitable containers with sufficient ice packs to sustain an appropriate temperature for the requested analysis. If this is not the case you will be informed and any test results that may be compromised highlighted on your deviating samples report.

SURROGATES

Surrogate compounds are added during the preparation process to monitor recovery of analytes. However low recovery in soils is often due to peat, clay or other organic rich matrices. For waters this can be due to oxidants, surfactants, organic rich sediments or remediation fluids. Acceptable limits for most organic methods are 70 - 130% and for VOCs are 50 - 150%. When surrogate recoveries are outside the performance criteria but the associated AQC passes this is assumed to be due to matrix effect. Results are not surrogate corrected.

DILUTIONS

A dilution suffix indicates a dilution has been performed and the reported result takes this into account. No further calculation is required.

NOTE

Data is only reported if the laboratory is confident that the data is a true reflection of the samples analysed. Data is only reported as accredited when all the requirements of our Quality System have been met. In certain circumstances where all the requirements of the Quality System have not been met, for instance if the associated AQC has failed, the reason is fully investigated and documented. The sample data is then evaluated alongside the other quality control checks performed during analysis to determine its suitability. Following this evaluation, provided the sample results have not been effected, the data is reported but accreditation is removed. It is a UKAS requirement for data not reported as accredited to be considered indicative only, but this does not mean the data is not valid.

Where possible, and if requested, samples will be re-extracted and a revised report issued with accredited results. Please do not hesitate to contact the laboratory if further details are required of the circumstances which have led to the removal of accreditation.

ABBREVIATIONS and ACRONYMS USED

#	UKAS accredited.
B	Indicates analyte found in associated method blank.
DR	Dilution required.
M	MCERTS accredited.
NA	Not applicable
NAD	No Asbestos Detected.
ND	None Detected (usually refers to VOC and/SVOC TICs).
NDP	No Determination Possible
SS	Calibrated against a single substance
SV	Surrogate recovery outside performance criteria. This may be due to a matrix effect.
W	Results expressed on as received basis.
+	AQC failure, accreditation has been removed from this result, if appropriate, see 'Note' on previous page.
++	Result outside calibration range, results should be considered as indicative only and are not accredited.
*	Analysis subcontracted to a Jones Environmental approved laboratory.
AD	Samples are dried at 35°C ±5°C
CO	Suspected carry over
LOD/LOR	Limit of Detection (Limit of Reporting) in line with ISO 17025 and MCERTS
ME	Matrix Effect
NFD	No Fibres Detected
OC	Outside Calibration Range

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JE Job No: 14/8074

Test Method No.	Description	Prep Method No. (if appropriate)	Description	UKAS	MCERTS (soils only)	Analysis done on As Received (AR) or Dried (AD)	Reported on dry weight basis
PM4	Gravimetric measurement of Natural Moisture Content and % Moisture Content at either 35°C or 105°C. Calculation based on ISO 11465 and BS1377.	PM0	No preparation is required.				
TM4	16 PAH by GC-MS, modified USEPA 8270	PM8	In-house method based on USEPA 3510. ISO 17025 accredited extraction method for organic extraction from solid samples using an end over end agitator.			AR	Yes
TM4	16 PAH by GC-MS, modified USEPA 8270	PM8	In-house method based on USEPA 3510. ISO 17025 accredited extraction method for organic extraction from solid samples using an end over end agitator.	Yes		AR	Yes
TM5	In-House method based on USEPA 8015B. Determination of Extractable Petroleum Hydrocarbons (EPH) in the carbon chain length range of C8-40 by GC-FID. Accredited to ISO 17025 on soil and water samples and MCERTS (carbon banding only) on soils. All accreditation is matrix specific.	PM16	Aliphatic/Aromatic fractionation			AR	Yes
TM15	In-House method based on USEPA 8260. Determination of Volatile Organic compounds (VOCs) by Headspace GC-MS. Accredited to ISO 17025 for soils and waters and MCERTS for Soils. All accreditation is matrix specific. Quantification by Internal Standard method.	PM10	In-house method based on USEPA 5021. Preparation of solid and liquid samples for headspace analysis. Samples are spiked with surrogates to facilitate quantification. ISO 17025 accredited extraction method. All accreditation is matrix specific			AR	Yes
TM15	In-House method based on USEPA 8260. Determination of Volatile Organic compounds (VOCs) by Headspace GC-MS. Accredited to ISO 17025 for soils and waters and MCERTS for Soils. All accreditation is matrix specific. Quantification by Internal Standard method.	PM10	In-house method based on USEPA 5021. Preparation of solid and liquid samples for headspace analysis. Samples are spiked with surrogates to facilitate quantification. ISO 17025 accredited extraction method. All accreditation is matrix specific	Yes		AR	Yes
TM16	In-House method based on USEPA 8270. Determination of Semi-Volatile Organic compounds (SVOCs) by GC-MS. Accredited to ISO 17025 for waters. All accreditation is matrix specific. Quantification by Internal Standard method.	PM8	In-house method based on USEPA 3510. ISO 17025 accredited extraction method for organic extraction from solid samples using an end over end agitator.			AR	Yes
TM17	PCB 7 Congeners and WHO 12 PCBs by GC-MS	PM8	In-house method based on USEPA 3510. ISO 17025 accredited extraction method for organic extraction from solid samples using an end over end agitator.	Yes		AR	Yes
TM20	TDS, TSS and TS - gravimetric	PM0	No preparation is required.			AR	Yes
TM21	TOC and TC by Combustion	PM24	Eltra preparation	Yes		AD	Yes

JE Job No: 14/8074

Test Method No.	Description	Prep Method No. (if appropriate)	Description	UKAS	MCERTS (soils only)	Analysis done on As Received (AR) or Dried (AD)	Reported on dry weight basis
TM26	Phenols by HPLC	PM0	No preparation is required.			AR	Yes
TM27	In-House method based on USEPA 9056. Analysis of samples using a Dionex Ion-Chromatograph instrument.	PM0	No preparation is required.			AR	Yes
TM30	Trace Metal elements by ICP-OES (Inductively Coupled Plasma - Optical Emission Spectrometry) using Thermo iCAP 6000 series instrument. Accredited to ISO 17025 for soils and waters and MCERTS accredited for Soils. All accreditation is matrix specific.	PM17	CEN PR12457-2 10:1 1 batch leach	Yes		AR	Yes
TM38	Ionic analysis using the Thermo Aquakem Photometric Automatic Analyser. Accredited to ISO17025 and MCERTS for most analytes. All accreditation is matrix specific.	PM0	No preparation is required.	Yes		AR	Yes
TM60	TOC/DOC by NDIR	PM0	No preparation is required.			AR	Yes
TM83	Alcohols, acetates, VFAs, acetone and THF by GC-MS	PM10	In-house method based on USEPA 5021. Preparation of solid and liquid samples for headspace analysis. Samples are spiked with surrogates to facilitate quantification. ISO 17025 accredited extraction method. All accreditation is matrix specific			AR	Yes
NONE	No Method Code	PM4	Gravimetric measurement of Natural Moisture Content and % Moisture Content at either 35°C or 105°C. Calculation based on ISO 11465 and BS1377.			AR	

Appendix 4

Closure Restoration and Aftercare Management Plan (CRAMP) & Environmental Liabilities Risk Assessment

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CLOSURE, RESTORATION AND AFTERCARE MANAGEMENT PLAN (CRAMP)

AT ELI LILLY SA

ORIGINAL

JUNE 2012





CLOSURE, RESTORATION AND AFTERCARE MANAGEMENT PLAN (CRAMP)

AT ELI LILLY SA

COPY

AUGUST 2012



CLOSURE, RESTORATION AND AFTERCARE MANAGEMENT PLAN (CRAMP)

AT ELI LILLY SA

AUGUST 2012

User is Responsible for Checking the Revision Status Of This Document

Rev. Nr.	Description of Changes	Prepared by:	Checked by:	Approved by:	Date:
0	Issue to Client	TFM/MT	BR	BG	09.08.12

Client: Eli Lilly SA

Keywords: IPPC licence review, Closure Restoration Aftercare Management Plan (CRAMP)

Abstract: This report has been compiled in support of the IPPC licence review application.

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1 INTRODUCTION

This report has been compiled in support of Eli Lilly's Integrated Pollution Prevention and Control (IPPC) licence review application. This report has been prepared in accordance with the document "*Guidance on Environmental Liabilities Risk Assessment, Residuals Management Plans and Financial Provision*", EPA 2006. This report builds on previous Residual Management Plans and Environmental Liabilities Risk Assessments prepared, revised and submitted to the Agency under the current IPPC license for the site.

1.1 Environmental Liability Risk Assessment

Environmental Liabilities can be subdivided into **known** and **unknown liabilities**. Different financial instruments are appropriate depending on whether it is an anticipated liability, such as the ongoing environmental management of the closed site, or whether it is an unknown liability arising from accidental discharge, tank rupture or uncontrolled gas migration.

- The financial instruments most suited for the provision of known liabilities are cash based, such as Trusts, Cash funds or Escrow¹.
- The financial instruments most suited for the provision of unknown liabilities are Insurances, Bonds, Standby Letters of Credit and Guarantees.

The EPA (2006) has provided guidance's in the preparation of Environmental Liabilities Risk Assessment in the form of a document entitled '*Guidance on Environmental Liabilities Risk Assessment, Residuals Management Plans and Financial Provision*'.

The EPA guidance document states that "Closure Restoration Management Planning (CRAMP), Environmental Liabilities Risk Assessment (ELRA) and Financial Provision (FP) are mutually dependent. A systematic step-wise approach is in order to assess and quantify the risks and liabilities of a licensed facility recommended:

- Step 1: Initial Screening & Operational Risk Assessment
- Step 2: Preparation of a Closure, Restoration and Aftercare Management Plan (CRAMP) for known Liabilities
- Step 3: Environmental Liability Risk Assessment (ELRA) for unknown Liabilities
- Step 4: Identification of Financial Provisions (FP) and Instruments

This report forms step 1 and 2 of the process.

Step 1: Initial Screening & Operational Risk Assessment

Step 1 of the process involves a risk assessment decision matrix which is used to classify the Eli Lilly SA site into a Risk Category (1-3) and thereby select the specific CRAMP, ELRA and FP requirements that are required.

¹ Escrow - A financial instrument held by a third party on behalf of the other two parties in a transaction. The funds are held by the escrow service until it receives the appropriate written or oral instructions or until obligations have been fulfilled. Securities, funds and other assets can be held in escrow.

Step 2: Preparation of a Closure, Restoration and Aftercare Management Plan (CRAMP) for known Liabilities.

A CRAMP must include the following:

- Site evaluation - including description and history of activities on the site, compliance status with previous licence, facility processes and activities
- Closure considerations – plant decontamination, plant disposal/recovery, waste disposal, leachate recirculation, groundwater pumping, soil removal etc
- Criteria for successful closure
- Closure Plan costing (Financial Provision)
- Closure Plan update and review procedures
- Closure Plan implementation
- Closure Plan validation – auditing report and validation certificate

These requirements are based on the EPA document '*Guidance on Environmental Liability Risk Assessment, Residuals Management Plans and Financial Provision*'. The CRAMP was initially scoped using the Operational Risk Assessment process as outlined in the EPA reference document.

The CRAMP contains:

- A scope statement
- The criteria for successful decommissioning
- A programme to achieve stated criteria
- Details of how costs will be underwritten

Aftercare management is an integral part of the site restoration process and follows logically from the site restoration plan. The length of the aftercare period is one of the most critical components in the aftercare management plan and is related to the type of restoration required at the site. The aftercare management plan deals with restoration maintenance and environmental monitoring.

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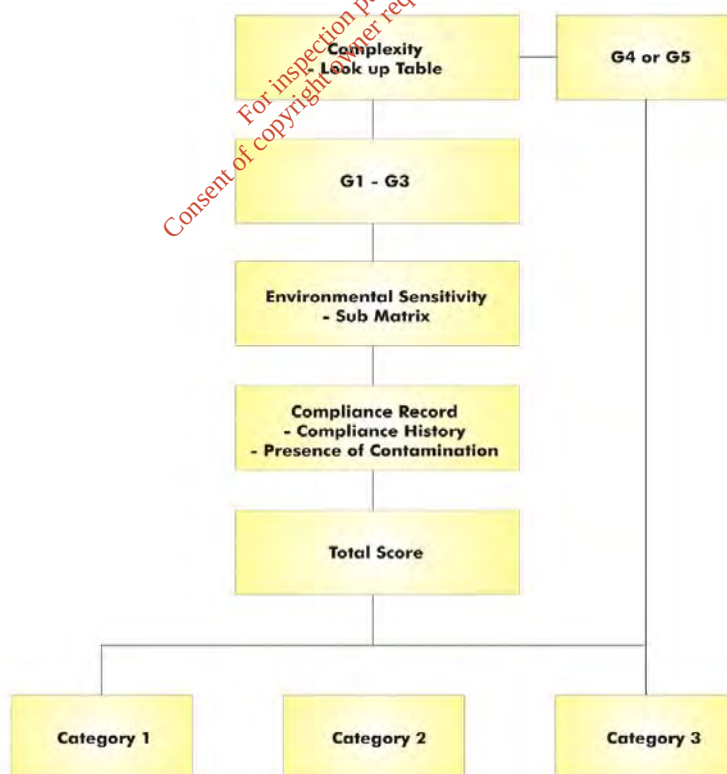
2 STEP 1 – INITIAL SCREENING AND OPERATIONAL RISK ASSESSMENT

The initial screening and operational risk assessment of the Eli Lilly SA site was carried to establish if the site was of Low, Medium or High risk. The risk assessment criteria are shown below:

- **Complexity** – the extent and magnitude of potential hazards present due to the operation of the facility (e.g. a function of the nature of the activity, the volumes of hazardous materials stored on site etc.). A Complexity Band (G1 least complex to G5 most complex) for each class of activity has been assigned and included in a Look-Up Table (Appendix B Appendix IPPC and Waste Activities Complexity Look-Up Tables of the EPA Guidance Document²). For activities with complexity G4 or G5, these facilities are automatically classified as Risk Category 3. For activities with complexity of G1, G2 or G3, these facilities must consider and evaluate their score using the Environmental Sensitivity and compliance record as outlined below:
 - o **Environmental Sensitivity** – the sensitivity of the receiving environment in the vicinity of the facility, with more sensitive locations given a higher score (e.g. the presence of aquifers below the site, groundwater vulnerability, the proximity to surface water bodies and their status, the proximity to sensitive human receptors, etc). The Environmental Sensitivity is calculated on a site-specific basis using a sub-matrix
 - o **Compliance Record** – the compliance history of the facility and whether soil and/or activities carried on are in compliance with licence requirements and emission limits.

Each aspect is multiplied to give the Total Score for the facility, and this was used to place the facility into an appropriate Risk Category (1-3). Once this is completed, the process proceeds through the relevant steps of CRAMP, ELRA and FP that are considered appropriate for the Risk Category. Figure 2.1 shows the overall Step 1 process.

Figure 2.1: Flow chart of Initial Screening and Operational Risk (EPA, 2006)



2.1 Complexity

The EPA Guidance (IPPC and Waste Activities Complexity Look-Up Tables, Appendix B) was used to determine the initial screening and operational risk assessment of the Eli Lilly facility in Dunderrow, Kinsale, Co. Cork.

There are five possible complexity bands for a facility, G1 to G5, with G5 being the most complex. These bands are used to determine the Risk Category. Table 2.1 summaries the complexity rating for the Kinsale facility based on the activities that occur on site.

Table 2.1: Complexity Rating

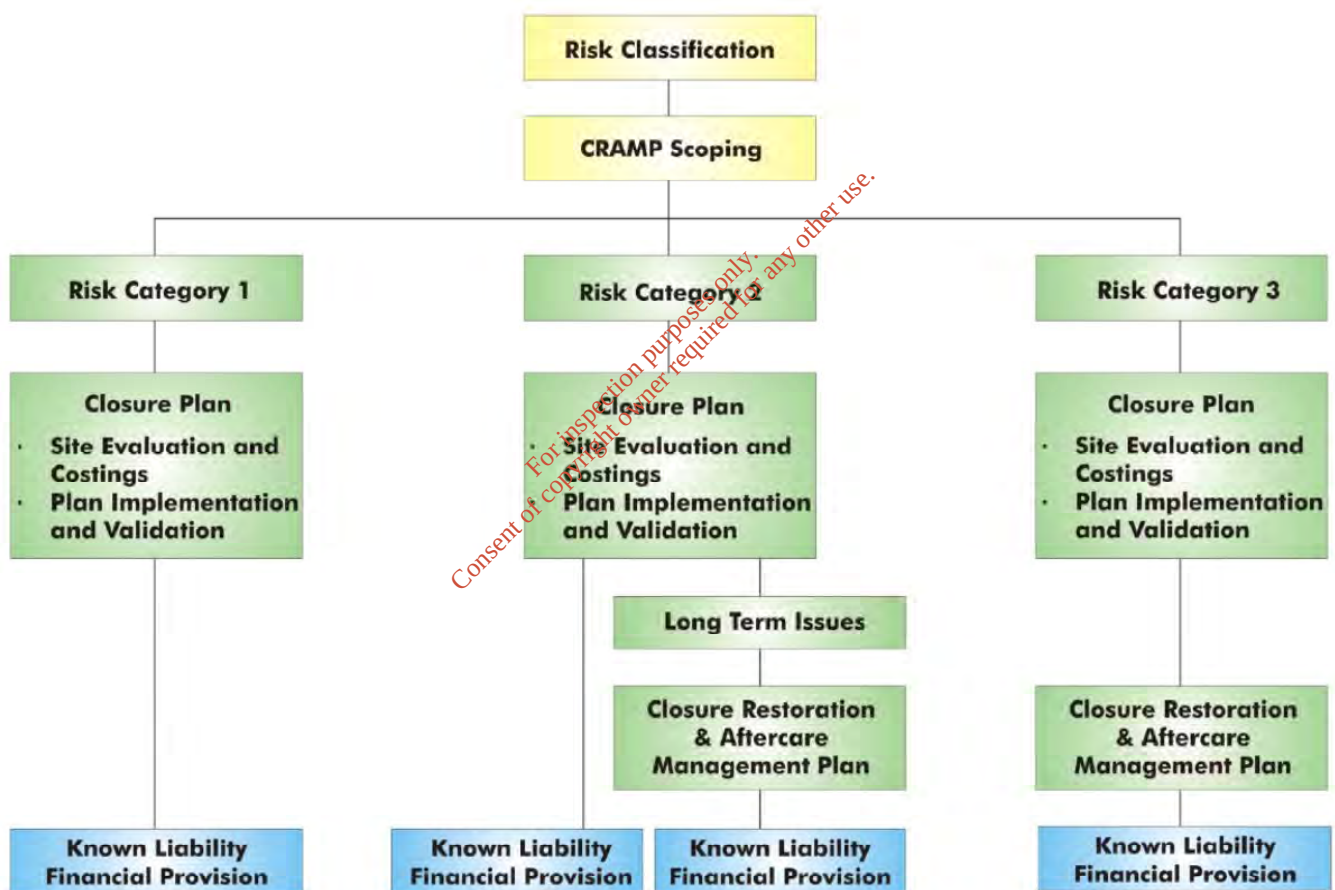
Complexity		Score	
Licensed Activity Class	Complexity Band	Operational Risk Assessments	Risk Category
11.1 The recovery or disposal of waste of waste in a facility, within the meaning of the Act of 1996, which facility is connected or associated with another activity specified in this schedule in respect of which a licence or revised licence under Part IV is in force or in respect of which a licence under the said Part is or will be required	G5	5	3
5.16 The use of a chemical or biological process for the production of basic pharmaceutical products annual production <2,000 Tonnes	G3	3	*

*Because the annual production volume for the licensed activity class 5.16 results in the classification of this activity to the G3 Complexity Band, further assessment related to the Environmental Sensitivity and the Compliance Record of the site would be typically required to determine if Risk Category 1 or 2 is appropriate as outlined above in Figure 2-1. However because the site is also licensed for activity class 11.1, it is automatically assigned to Risk Category 3 on the basis of 'Complexity' and therefore further is assessment on the basis of the 'Environmental Sensitivity' and 'Compliance Record' for the site is not an option.

3 STEP 2 - CLOSURE, RESTORATION AND AFTERCARE MANAGEMENT PLAN (CRAMP) - KNOWN LIABILITIES

As a result of the "Initial Screening" (Step 1 above) the Eli Lilly facility is a Category 3 facility. Therefore a Closure Plan and a Restoration and Aftercare Plan are required.

Figure 3.1: Closure, Restoration and Aftercare Management Plan Process (CRAMP) (EPA, 2006)



3.1 Closure Plan for Site

The Closure Plan for the site should include the following sections (as set out in Table 3-2 of the EPA Guidance document):

- Introduction
- Site Evaluation
- Closure Considerations
- Criteria for Successful Closure
- Closure Plan Costing
- Closure Plan Update and Review
- Closure Plan Implementation
- Closure Plan Validation

3.1.1 Introduction

In accordance with the facilities IPPC licence. Eli Lilly is licensed to carry out following activities listed in Table 2.1.

The Dunderrow facility is a subsidiary of the Eli Lilly International Corporation which has its headquarters in Indianapolis, Indiana. The parent Company has operations in 30 countries worldwide and markets products in more than 60 countries. There are approximately 40,000 employees worldwide with annual sales of \$22 billion (2010).

The Dunderrow facility is one of four Lilly bulk manufacturing plants worldwide whereby a range of products are manufactured and exported to finishing plants supplying worldwide markets.

3.1.2 Site Evaluation

The Eli Lilly SA site evaluation includes the following information:

- A description of the facility
- An inventory of site buildings, plant and equipment.

3.1.3 Description of the Facility

The Eli Lilly Kinsale facility supports the development, as well as manufacture and supply, of many of the medicines for the treatment of depression, schizophrenia, attention-deficit hyperactivity disorder, diabetes, osteoporosis, cancer and many other illnesses. The Kinsale facility has also been involved in the manufacture of animal health products in the past and such products may be developed and manufactured in Kinsale in the future.

The site uses advanced chemical and biological processes to produce a range of active pharmaceutical ingredients (API) that provide a medical benefit. These products are then further processed at various facilities to supply medicines to patients worldwide

Originally the Kinsale site's main focus was on manufacturing and supplying of medicines and while focus continues onsite, the facility is also expanding to develop of a centre of technical excellence in innovative new medicines. As a result Kinsale is now focused on three core business activities, namely:

- **Small Molecule Active Pharmaceutical Ingredient (API) Supply** – this is the sites traditional business being the most valued manufacturer and supplier of API for Lilly's launched products.

- **Small Molecule Commercialisation** - the Kinsale facility has become a centre of excellence for chemical synthesis and the commercialisation of new molecules. The site undergoes research and development work for new medicines as well as for new manufacturing technologies such as process analytics and continuous processing.
- **Biopharmaceutical Commercialisation and Supply** - In 2006 Lilly announced that Kinsale would become the main centre for the manufacture and supply of active ingredients for its new biopharmaceutical medicines. The site has invested in facilities and technologies to produce monoclonal antibodies (mAb's) and has the capability to further develop newly discovered medicines.

In addition to production facilities, there is a range of production support facilities including solvent storage, laboratories, warehousing, utility generation, waste water treatment facilities, maintenance, offices, staff facilities and a cafeteria. The three core unit operations and the support facilities are discussed further hereunder.

1. Small Molecule Active Pharmaceutical Ingredient (API) Supply & Small Molecule Commercialisation

The majority of the production buildings onsite are multipurpose buildings with the capability to manufacture various campaigned compounds for Lilly products. Each building consists of similar process equipment. The main buildings for the production of APIs are IE2, IE3, IE8, IE16 and IE30. These buildings are outlined in Figure 3.2 and summarised below.

- The **IE2 production facility** has been in operation since 1981. It was originally used for sterile manufacturing processes and was later modified for the production of a specific small scale product (Small Molecule Commercialisation). This facility has been largely transformed for use in product development/small scale manufacture in recent years. The facility is now divided into three main areas with a fourth area under consideration. The three areas currently developed are as follows:
 - o PMO Laboratory - This facility is used primarily for the review of development/optimisation opportunities for existing or proposed products.
 - o Fifty Gallon Production Facility (Engineering Laboratories) - This is a scale up from the PMO laboratory operation which again allows for flexible manufacturing arrangements up to a 50 gallon tank capacity. This facility provides the site with the capability of investigating early life cycle molecules, process improvement opportunities, trials of new or alternative types of equipment on existing or planned products and trials of vendor equipment.
 - o Two Hundred and Fifty Gallon Production Facility - This is essentially a pilot plant facility with a total reactor capacity of 1000 gallons (4* 250Gal), suitable for both wet and dry processing. This facility provides the site with a platform to generate a better understanding of new processes and products. As such, the facility provides the capability to:
 - o Produce clinical trial, registration stability, and validation material at appropriate scale
 - o Implement Alternative Reactor Technology platforms
 - o Transfer early life-cycle molecules
 - o Trial process improvements for site operations
 - o Trial new/alternative types of equipment on existing products
 - o Trial vendor equipment
 - o A proposed development of the last quadrant of the IE2 building is currently being considered. It is envisaged that this development will be on a similar scale to that already outlined above and will consist of either a fixed or flexible manufacturing equipment train. Details of the facility layout and proposed manufacturing operations will be outlined to the Agency as soon as the project is confirmed and prior manufacturing approval will be sought for intended product use.
- **IE3** production building has been in operation since 1981 and has manufactured human antibiotics and animal health products. This building is currently underutilised however; it can be used for human or veterinary product manufacturing in the future
- **IE8** production building was established in 1984 and is a multipurpose plant for intermediate and final bulk manufacture of various campaigned compounds
- **IE16** production building is a multipurpose plant comprising two production areas containing both large scale and small-scale production processes. The large scale production process in this building was proposed to be extended in 2007/2008. This did not occur to date however; the expansion may take place in the future

- **IE30** production facility is a dedicated clean manufacturing plant used to produce aseptic product. This process involves further processing of an active final bulk material. Such processes include dissolution, crystallisation, filtration, drying, milling and blending. This facility contains process areas, environmental monitoring laboratories, in and outbound shipping, warehouse space, general administrative and utility support areas.

2. Biopharmaceutical Commercialisation and Supply (IE42 and IE43)

Since 2009, the Kinsale facility has been manufacturing and supplying monoclonal antibodies (mAb's) for biopharmaceutical medicines. This new biotechnology process is currently operational in building IE42 and is to be extended to the IE43 facility once construction is completed. The location of these buildings is outlined in Drawing 001.

These facilities are designed to be multi-product and may be modified in the future in response to changes in product mix and market requirements. The typical generic process sequence for products that will be manufactured in IE42 and IE43 is as follows: cell culture, broth clarification, detergent inactivation, capture column purification step (chromatography), low-pH inactivation, intermediate purification step (chromatography), final polishing step (chromatography). The chromatography steps are followed by a nanofiltration step and a product concentration/diafiltration via a tangential flow filtration step. The process is water based as opposed to solvent based for traditional synthetic pharmaceutical manufacturing.

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3.1.4 Inventory of Site Buildings, Plant, and Equipment

The following is a brief overview of the key areas and functions of the site namely, Production facilities, Storage facilities, Environmental and Utilities, Maintenance Engineering, Administration and Security.

A. Production Facilities:

1. IE3 is a large 3-floor production facility which was used for the production of antibiotic intermediates and animal health products. The antibiotic portion of the facility was decommissioned over a period from 2000 to 2004. A small annex was added in 2001 with some specialist equipment for the manufacture of animal health products. A further smaller extension to this annex has been added in 2007 for the manufacture of an intermediate for a new product. The core equipment consisted of 24 reactors, 4 centrifuges, a dryer and ancillary equipment. This core equipment has been de-contaminated and left in a safe state. Most of the old process and solvent piping and equipment was decontaminated, removed and recycled to a smelter. The building is essentially decommissioned at this stage but may be used again in the future. (Ref: letter to Agency, Dec 21st, 2010).
2. IE8 is very similar to IE3 as outlined above in terms of equipment and layout but the operation is different as a number of different products are manufactured on a campaigned basis in the building. The core equipment is similar to IE3. A solvent recovery facility was de-commissioned in 2006. (Ref: letter to the Agency, dated October 19th, 2005). The production facility has been expanded into this vacated space containing a new filter dryer and associated equipment.
3. IE16 SS/LS. There are two sections in this production facility, IE16SS (small scale) and IE16LS (large scale). The IE16SS plant is used to manufacture small quantities (20-30kgs) of potent compounds. The IE16LS facility is very similar to the IE8 facility and is also run on a campaigned basis. Generally, new products have been introduced in this building.
4. IE30 is a new clean room type production facility which was commissioned in 2006. A small scale biotech product was manufactured here in late 2008 and Q1, 2009. The IE30 facility was originally designed to meet the requirements of a clean manufacturing environment to support the manufacture of the drug substance Olanzapine Pamotate Monohydrate (OPM). Subsequently, the facility was utilised to manufacture Teplizumab (TmAb) a low bioburden biological (Class 1 GMO) drug substance. OPM and Teplizumab were manufactured in the IE30 Facility on a campaigned basis with only one product being manufactured at any given time. Teplizumab manufacture has since ceased while OPM continues to be manufactured on an infrequent campaign basis. A small section of the building continues to supply utilities to the nearby IE42 biologics plant.
5. IE42 is a new biotech manufacturing facility. It is proposed to extend the operations of IE42 into the proposed IE43 building.

B. Storage Facilities:

1. IE1, IE1B, IE9B, IE9B (Cold Room) and IE14 (Cold Room) are all warehousing facilities in which key raw materials, intermediates and final products are stored. There are also significant quantities of packaging, safety and other materials stored in IE1. Both IE1B and IE9B were completely de-contaminated of antibiotic residues in 2003. This de-contamination was analytically verified. These warehouses are now used to store other materials.
2. IE14 is a new cold store, converted from an old engineering equipment store.
3. IE15 is an open warehouse for the storage of hazardous chemicals, generally in drums or small pails.
4. IE15B is a special warehouse for the storage of moisture sensitive materials.

5. The Bulk Storage Tank Farm consisted of 45 storage vessels. These vessels are used for the storage of organic solvents. The solvents can be virgin, spent, or recovered from a process for re-use. Due to the outsourcing of products and decommissioning of IE3, only 28 of the tanks are currently in use. The remainder are decontaminated and clean. Plans are in place to upgrade a number of these tanks over the coming years to provide improved containment by increasing the pressure relief settings for breathing loss vapours.
6. The waste solvent storage area comprises of a group of 7 tanks, which store liquid wastes for incineration. All of the tanks in the waste solvent tank farm were replaced with new tanks in 2007 built to a much higher specification than the original tanks. These are pressure rated vessels that can be operated at much higher pressure relief settings thus minimising vapour breathing losses. This has led to a significant reduction in fugitive emissions from these tanks. The original storage tanks were de-contaminated and removed in late 2010.

C. Environmental and Utilities:

1. IE4 is a single floor building which houses much of the utilities required to maintain the production operations. Utilities generated include steam, compressed air, refrigerant (-20 Deg C), nitrogen and process water. All of these services are distributed throughout the plant to the various points of use. Two of the older boilers are completely new units (replaced in 2010) and all three units have had the burners upgraded to low NO_x units and each boiler unit is now also fitted with an economiser to recover significant amounts of waste heat.
2. IE34 is a building (2005) which produces purified water.
3. IE7 is the environmental area control room and the environmental laboratory. The environmental area consists of incineration plant for the destruction of liquid, gaseous and solid waste generated from the production operations. There is, in addition, a biological waste water treatment plant for the treatment of all aqueous waste generated on site. This waste treatment plant has been significantly upgraded over the past few years. One of the incinerators has been upgraded and is now fully operational. This upgraded unit is equipped with a heat recovery boiler which should generate about a third of the site steam requirements at full capacity. A second incinerator on site is currently out of service.
4. IE6 houses the fire pumps which supply the site firewater ring main.
5. A storm water containment pond with a capacity of 6,110 m³ is located at the south end of the site with on-line TOC and pH monitoring at both inlet and outlet.

D. Maintenance and Engineering:

1. IE9 is the primary maintenance workshop for the site. The site engineering and maintenance area in IE9 consists of four groups. These include; Mechanical Fitters, Electricians, Instrumentation Technicians and Co-ordinators. Chemical, Mechanical, Instrumentation and Electrical engineers support the production buildings. Chemists and Process Engineers also provide technical support for the production areas, as well as maintaining quality control. Additional technical support personnel include the Environmental, Health and Safety departments.
2. IE21 is a complex of various workshops and temporary buildings used by contract engineering and construction staff. Large construction projects generally have separate temporary facilities.

E. Administration and Security:

1. IE28 is an analytical and development laboratory which also has extensive office space for technical support staff. This new laboratory replaced the old IE2 building and was occupied in late 2004. A further biotech development laboratory was added in 2007 and was occupied in 2008.
2. IE5 is the main administration office located at the site entrance. Administration includes Financial, Procurement and Personnel functions. This building also incorporates the cafeteria and locker rooms.
3. IE10 is the main security building at the site entrance. Temporary security facilities are generally used for large construction projects.

3.1.5 Closure Considerations

The scope of this Closure Plan addresses the key issues for an orderly shutdown of all the site activities on a phased basis over an estimated time period of 9 - 12 months. The approach taken is to present a broad overview of the major aspects of plan. The scope of the plan includes the following major activities:

- o Setting up a management structure to oversee the Closure Plan
- o Development of a comprehensive Safety and Containment plan covering the duration of the activity
- o Cessation of all production activities
- o Removal of all raw materials, intermediates and final products from the site
- o Cleaning and decontamination of all equipment and buildings
- o Secure archiving of all documentation
- o Shutting down of all environmental and utility systems
- o Production of a comprehensive status report on all aspects of the site at completion
- o Maintaining an ongoing security and monitoring service
- o Any further remediation activities deemed to be necessary.

The overall strategy adopted is to bring the facility to a safe and de-contaminated state with minimal services to maintain the facility in good order. It is not intended to remove equipment or systems from the site other than specialist items needed at other sites or items that are obsolete or non-serviceable. The approach taken is to manage and execute this plan using existing internal resources, supplemented where appropriate with outside resources. It is envisaged that a Closure Plan Team would be created to manage and execute this entire project. This internal team would need to be supplemented by considerable specialist outside resources both in terms of personnel, equipment and specialist skills. Outside resources used for cleaning, waste disposal, incineration or recycling activities would be bona fide contractors, fully approved and licenced by the EPA or other agencies. The estimated duration would be approximately 9-12 months but some specific portions of the plan may be completed sooner.

Closure Plan – A, Production Facilities:

The IE3 production facility is currently out of service. All product has been removed from the building and all equipment has been decontaminated and remains in a clean state. All unnecessary services to be building have been temporarily isolated. This facility may be upgraded or replaced, dependent on future site requirements.

The Closure Plan for the **IE8 / IE16 (LS & SS), IE30, IE42 and IE43** production units would consist of the following actions:

- o Cessation of all production other than the completion of work in progress. The facility will be brought to a safe state
- o Removal of all products or intermediates to the relevant warehouse for disposal or transfer to other facilities
- o Cleaning and decontamination of all reactors, pumps, transfer lines and any other equipment with product contact. Existing cleaning procedures are adequate for this purpose. Specific procedures may have to be developed for some ancillary areas or specialist equipment, (IE30). The cleanliness will be verified both visually and analytically
- o Shutting of all organic solvents, acids or bases supply lines to the building. Flushing the various supply lines back to the tank farm using nitrogen or water as appropriate, followed by decontamination
- o Shutting off unnecessary services to the building. Heating and ventilation capability would be maintained in a reduced fashion
- o Removal and destruction by incineration of all extract ventilation lines and filters or any other ducting or enclosure that would have product or other material contact
- o Maintenance of key instrumentation and computer systems deemed required for the ongoing monitoring of the status of the equipment. The remaining instrumentation and electrical systems should be disconnected and rendered safe
- o Cleaning and decontamination of all floor drains, sumps and bunded areas
- o Removal of any damaged or materials of no intrinsic value for disposal

- o Specialist equipment, once decontaminated, may be returned to other Lilly affiliates for use in similar or other processes.

The Closure Plan for the **IE2 Production and Laboratory Facility** was implemented during the period 2003 - 2005 and described in the 2007 AER submission. A small process development laboratory was subsequently retrofitted in this facility for commercialisation and process improvement activities in addition to pilot commercialisation manufacturing facilities from 5 to 250 gallon scale.

Closure Plan – B, Storage Facilities

Warehouses:

The warehouses, IE1, IE1B, IE9B and IE9B (Cold Room), IE14, IE15 and IE15B contain all the key raw materials, intermediates and final products produced at the site. The Closure Plan for these areas would incorporate the following specific action:

- o Cancellation of all incoming materials to the site. This would involve contacting a sizeable amount of vendors. Some key ingredients are supplied from other Lilly affiliates and any issues arising would be dealt with by the supply chain management. Intermediate products would be consigned to other Lilly sites for completion to final product form. Final bulk products would be dispatched to the relevant fill/finish facilities for completion into final dosage forms
- o Negotiation with relevant vendors with view to returning unused materials. This would include raw materials, packaging materials, safety materials and any other materials deemed appropriate.
- o Arrangement for the destruction of non-returnable or non-recyclable materials. This could be accomplished either on site or at a licenced approved contract disposal facility
- o Removal and destruction by incineration, of any filters, bag houses or any other medium that would have had contact with any product or raw material
- o Complete verifiable decontamination of all storage facilities to remove any possible residual product, raw material or intermediate
- o Inspection and verification that all sumps, drains and any other containment area is thoroughly clean and de-contaminated
- o The selective removal of services no longer required. Heating and ventilation would be maintained at an appropriate level to maintain the buildings in a good condition.

Main Tank Farm:

The main tank farm contains significant amounts of organic solvents. The Closure Plan for this area would incorporate the following specific actions:

- o Negotiation with relevant vendors with view to cancellation of all deliveries and the returning of unused virgin organic solvents
- o The destruction, by incineration of all used solvents, including those solvents that are recovered and deemed suitable for internal use
- o The verifiable decontamination of all the storage tanks, pumps and lines to ensure all traces of product and solvent have been removed. All storage vessels should be in a completely safe state, suitable for entry and inspection
- o The inspection and verification that all drains, sumps and bunds are completely free of any contamination
- o The disconnection of all electric supplies to pumps and the blanking of all lines into and out of the tank farm
- o Maintenance of routine groundwater checks in the vicinity to ensure no residual contamination exists
- o Caustic soda and acids would be passed through the waste treatment plant on a phased basis and the vessels decontaminated as outlined above.

Note: Some elements of this plan have been partially implemented as 20 storage tanks were taken out of service due to the cessation of antibiotic production. Some were thoroughly cleaned and decontaminated and have since been dedicated for other solvents. Others have been flushed and cleaned with water but not fully de-contaminated. Eight older tanks have been completely removed.

Closure Plan –C, Environmental and Utilities:

These would be the final areas to be de-commissioned due to ongoing needs for incineration and waste treatment capability until all materials and waste are removed from the plant.

The Closure Plan for the **Environmental Areas** would consist of the following actions:

- o Incineration of all remaining waste solvents and contaminated liquors in storage
- o Incineration of any remaining contaminated packaging or clothing
- o Cleaning and decontamination of all waste storage tanks. The tanks should be in a fit state to be entered and inspected
- o Cleaning, decontamination and inspection of all bunds, sumps and underground drains
- o When all incineration of onsite materials is complete, shut down and disconnection of the incinerators. All process and service lines to the units to be drained, cleaned and decontaminated. Ancillary equipment such as scrubbers, heat exchangers, on-line instrumentation would be similarly cleaned of all residual materials and left in a secure state
- o The associated clarifiers and holding tanks would be made completely free of solids. All remaining ash from the incineration operations would be disposed of in a licensed landfill
- o Continuation with the operation of the aqueous waste treatment facility to maintain ongoing capability for the collection treatment of rainwater (collecting in various site sumps and bunded areas) and any ongoing sanitary waste treatment requirements. Maintenance of routine pump-outs to the ocean outfall to maintain the system integrity
- o Removal of all residual sludges by centrifugation offsite treatment
- o Maintenance of key instrumentation and computer systems deemed required for the ongoing monitoring of the status of waste treatment facility. The remaining instrumentation and electrical systems should be disconnected and rendered safe
- o Maintenance of routine groundwater and other checks on site to ensure no residual contamination exists and that ongoing protection is maintained. This ongoing monitoring would be carried out by an outside contractor.

The Closure Plan for the **Utilities** area would consist of the following actions:

- o Shutting down of the following systems in a phased basis depending on plant status and requirements:
 - a. **Steam Boilers:** It is likely that only one of the three boilers would be required during decommissioning and subsequently for ongoing heating requirements. The two remaining units would be shut down and disconnected from the steam distribution system. The boilers would be cleared of all residues and the fuel lines cleaned and blanked off. Condensate systems would be drained, cleaned and left in a safe state
 - b. **Nitrogen:** Depending on the site requirements this unit would be shut down and disconnected at an appropriate time. The liquid nitrogen storage tank would be left empty.
 - c. **Chillers:** Shut down and disconnecting of all these units at an appropriate time. Removal of all Ammonia would be performed by specialist contractors
 - d. **Compressed Air:** Depending on site needs, these machines would be shutdown and disconnected at an appropriate time
 - e. **Cooling Water:** After all the utilities and production areas are taken out of service the cooling water systems should be shut down and decontaminated. All cooling water should be removed from the systems and all lines flushed to the waste treatment plant to ensure the removal of residual biocides.
- o Removal of any associated chemicals, oils, or any other materials used in the utilities area for secure storage or disposal
- o The water supply system may be maintained at status quo due to the ongoing needs for fire protection and sanitary services. The municipal supply line would probably be unnecessary in this scenario and may be disconnected.

Closure Plan – D, Maintenance and Engineering:

The Closure Plan for the **Maintenance and Engineering** area would include the following actions:

- o The secure archiving of all engineering documentation including drawings, process and instrumentation diagrams, validation documentation, vendor manuals and data, project files, maintenance records, inspection records and all other appropriate documentation

- o Disconnection of all maintenance equipment to a safe and secure state
- o Removal of all old and obsolete equipment and maintaining the workshop areas and maintenance stores in an orderly and safe state.

Closure Plan – E, Administration and Security

The Closure Plan for the **Administration and Security** area would include the following actions:

- o The secure archiving of all financial, procurement, personnel and all other relevant documentation pertaining to the site and its operations
- o Shutting down of all computer systems other than those necessary for ongoing monitoring and security
- o Maintenance of a security presence on site on a 24 hour basis for ongoing monitoring of the site from a safety, fire protection and environmental perspective.

The Closure Plan for the **IE28 Laboratory** area would consist of the following actions:

- o Completion of all necessary analytical assay work on production lots in progress and all final products before removal from the site
- o Completion of all necessary quality control and regulatory documentation for all intermediates and final products before removal from site
- o Shipping to a secure archive, (most likely at another Lilly facility) all historical records of all products produced on site. These would include analytical records of all raw materials, intermediates and final products, approval documentation, batch records, change control documentation, validation records, computer records, regulatory submissions and all other relevant documentation
- o Removal of all retention samples to a secure location for ongoing retention
- o Removal and destruction of all laboratory chemicals
- o Cleaning and decontamination of all laboratory analytical instruments
- o Cleaning and decontamination of all glassware, fume hoods, storage areas, waste systems, and any other equipment or systems
- o Shutting down of all computer systems other than those deemed necessary for ongoing monitoring of the area.

Closure Plan –Site-Wide Issues:

Other actions would include:

- o Cessation of all construction project work on site in such a way that the various sites are left in a safe and orderly condition
- o Disbandment of contract personnel, facilities and equipment
- o Termination of all non-essential maintenance or other contracts
- o Removal from site of any temporary offices or storage areas
- o Continuation of ongoing programmes to ensure the integrity of the groundwater, surface waters and the streams running through the site and at the boundary
- o Rationalisation of the site electrical supply. This would involve removing transformers from service, allowing the remaining site operations to run from one transformer. The redundant transformers would be made free of oils
- o Remediation of soils, if necessary would be based on a site specific risk analysis model
- o Maintenance of all necessary fire alarms and fire protection systems
- o Maintenance of standard security patrols, video monitoring and defined site access procedures
- o Any asbestos bearing materials would be disposed of as per the pertinent regulations
- o Small quantities of PCB's, mercury or any other controlled compounds would be disposed of in a manner consistent with current requirements and regulations
- o Contract facilities that may be used for handling of any material from the site would be subject to a prior due diligence audit

3.1.6 Criteria for Successful Closure

The Restoration and Aftercare Management Plan required to address this aspect is outlined in Section 3.2.

3.1.7 Closure Plan Costing

Appendix 1 shows a breakdown of the internal and external costs associated with the Closure Plan. The total cost associated with the Closure Plan at the Dunderrow site is estimated to be in the region of €20 - €25million. In addition, to maintain an ongoing security, safety and environmental monitoring presence at the site would cost approximately €2 million per annum.

3.1.8 Closure Plan Update and Review

The Closure Plan will be reviewed and updated as necessary. The updated plan will take into account any site process changes, technology changes and costing changes. Updates will be included as part of the relevant AER and submitted to the EPA for approval.

3.1.9 Closure Plan Implementation

The original residual management plan for the site was submitted to the Agency in October 2002 in accordance with Condition 14.2.1 of Licence 546. Some elements of the plan have been implemented over the past years as the focus of the site activities changed such as:

- o A new laboratory building has replaced the original laboratory which has recently been converted to a small development laboratory and a small scale production facility. (Ref: letter to Agency, August 4th, 2010)
- o Production activity has commenced in a new biopharmaceutical manufacturing facility, IE42
- o Solvent recovery facilities associated with older products have been de-commissioned and removed from site
- o Waste solvent storage tanks have been removed and replaced with a new waste solvent tank farm.

3.1.10 Closure Plan Validation

It is anticipated that the certification of the closure process will take place in following sequence:

- o Cessation of all production activities
- o Removal of all raw materials, intermediates and final products from the site
- o Cleaning and decontamination of all equipment and buildings
- o Shutting down of all environmental and utility systems
- o Production of a comprehensive status report on all aspects of the site at completion
- o Maintaining an ongoing security and monitoring service
- o Any further remediation activities deemed to be necessary

For each relevant closure step, Eli Lilly will retain a suitably qualified independent auditor to certify the process.

3.2 **Restoration and Aftercare Management Plan**

The Dunderrow facility will be restored in accordance with the site planning permissions and most recent IPPC licence.

3.2.1 Restoration and Remediation Proposal

The facility may require environmental monitoring for an extended period after the completion of the Closure Plan. The duration of this monitoring programme is currently envisaged to be up to 5 years but will be subject to agreement with the EPA and should be dependent on the situation at the time of closure and then on ongoing assessment of the results of any monitoring programme that may be required.

A Closure Plan is proposed for the potential non-clean closure of the facility. In addition to the closure actions described in the Closure Plan, Eli Lilly will continue to operate and maintain some key infrastructure for the aftercare period as required.

3.2.2 Aftercare Management Plan

The following plant and infrastructure will be maintained as required on site during the restoration and aftercare period:

- Environmental monitoring infrastructure
- Environmental monitoring equipment
- Laboratory equipment
- Roadways and drainage system
- Surface water retention pond
- Surface water collection system
- Groundwater control system
- Security system
- Access to monitoring locations

The timeframes for the maintenance and servicing of the above infrastructure is dependent on the operational timeframe for each, environmental monitoring shall continue until the EPA accepts the surrender of the IPPC licence.

A potentially significant consideration in the environmental monitoring programme will be in relation to Methyl Tert Butyl Ether (MTBE). In 2003 as part of the bi-annual groundwater sampling and analysis programme, 7 ppb (parts per billion) of MTBE was detected in supply Well 7. A more extensive sampling and analysis programme indicated that the MTBE impacts were concentrated in a localised area of the site aquifer a short distance to the southeast of the WWTP. A number of measures were immediately implemented to further investigate the issue and to ensure the situation did not escalate and to eventually remediate the impacted area. This area is now considered largely remediated but efforts are currently ongoing to further improve the groundwater quality at this location by continuing to pump groundwater from this area to the site wastewater treatment plant. (Further details of these can be in the most recent IPPC review application).

At this stage it is planned to continue this remediation pumping for at least one more year or until a point where MTBE is not detected in the well in consecutive months, (whichever comes first). At that stage, it is planned to shutdown the well for a sustained period but to continue monitoring the MTBE concentration on a monthly basis. If the MTBE concentration starts to rebound significantly, remediation pumping can be resumed. If the MTBE concentration measured in Well 18 remains under the IGVL of 30 µg/l for a sustained period (at least one year) without a significant rebound, this may be taken to indicate that the additional remediation efforts have been successful and a decision about the requirement for further remediation and monitoring would be taken at that stage. The success of the current remediation effort will clearly determine the future requirements to include these specific provisions for MTBE remediation and monitoring in the Aftercare Management Plan. Any related changes to the plan would be made in line with Agency requirements.

The wider environmental monitoring programme will continue in accordance with the licence conditions for the duration of the aftercare period.

3.2.3 Site Restoration and Aftercare Management Costs

The annual cost of this monitoring programme is estimated to be up to €50,000. Based on the current estimated 5 year extent of the restoration and aftercare period the total cost of the monitoring programme will be €250,000 over the period.

3.2.4 Conclusion – Known Liabilities and Financial Provisions

With regard to the known liabilities of the site, Eli Lilly recognises its responsibility to prevent or mitigate environmental emissions from the site. The salaries and costs will continue to be funded in full from the Eli Lilly revenue budget. Eli Lilly SA will make the necessary provisions to ensure that there is adequate funding for the management, restoration and aftercare at the Dunderrow facility. The current financial provisions that the company has in place and that are considered sufficient to cover the requirements for the closure, restoration and aftercare plan are further outlined in the correspondence dated May 11th 2012 from Eli Lilly & Company Corporate Treasury / Risk Management and included in Attachment K of the 2012 IPPC license review for the site.

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Appendix 1

Closure Plan Costs

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1. Internal Resource Requirements

It is envisaged that the maximum resources outlined below would be required for a period between 9-12 months depending on the actual extent and difficulties encountered in implementing the plan. The estimated maximum man-hours required could reach 100,000. The estimated cost associated with these resources is €10 - 15 million.

Category	No
Management	4
Administration	12
Staff	12
Operations	31
Laboratory	10
Craft	35
CAD Support	3

2. External Resource Requirements:

The following is an estimate of the costs associated with external contract support during the execution of the plan. The estimated cost associated with these requirements is 10.75 million euros.

Type of External Contract Support	Cost (Euros)
Contract Cleaning and Decontamination	5000k
Incineration and Disposal	700k
Civil, Structural and Demolition	1500k
Electrical, Instrumentation, IT Specialists	1000k
Logistics and Transport	500k
Others	500k
Total	9200k

Total Cost:

The total cost associated with a Residuals Management Plan at the Dunderrow site is estimated to be in the region of €20 - €25million. In addition, to maintain an ongoing security, safety and environmental monitoring presence at the site would cost approximately €2.0 million per annum.

Footnote:

In order to define the scope and estimate the costs involved, the approach used was to assume that the bulk of the activity would be accomplished by existing Lilly resources. However, if the project were to be executed largely by contractors, under a Lilly management structure, the costs and duration are unlikely to vary significantly.



ENVIRONMENTAL LIABILITIES RISK ASSESSMENT (ELRA) FOR P0009-03

ELI LILLY S.A

MARCH 2014 (updated May-15)



ENVIRONMENTAL LIABILITIES RISK ASSESSMENT (ELRA) FOR P0009-03

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Client: Eli Lilly S.A

Keywords: Environmental Liability Risk Assessment (ELRA)

Abstract: In response to a request from the Agency dated 15/04/2015, this document comprises a revised ELRA for the Eli Lilly S.A Dunderrow site, prepared in accordance with the relevant Agency guidance and addressing specifically the issues raised by the Agency in the review of the original submission

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1 INTRODUCTION

Eli Lilly S.A. has retained Fehily Timoney & Company (FTC) to prepare an environmental liabilities risk assessment (ELRA) in relation to its operation at Dunderrow, Kinsale. As an independent environmental consultancy, FTC is experienced in the preparation of ELRAs and CRAMPs and has prepared and submitted a number of these documents to the Agency in the past on behalf of various clients.

This document is prepared following a request from the Agency, dated 27 January 2014, as follows:

"I refer to your submission LR004119, "Environmental Liabilities Risk Assessment" received 31/03/2006. I wish to advise you that on the basis of the information provided, the Agency rejects your report on the following basis:

- (1) Significant changes at your facility that have taken place since the preparation of the report.*
- (2) Guidance published by the Agency in this area (most recently in 2013)*

In order to comply with Condition 12.2 of your licence, the Agency requires the following:-

A review of the ELRA shall be carried out which shall address the changes at your facility since 2006. The review shall be carried out in accordance with the guidance which is available on the Agency's website at the following link: <http://www.epa.ie/pubs/consultation/assessingenv/>

You are requested to submit the updated report by 28/02/2014"

Two guidance documents have been prepared by the EPA in relation to ELRA and related topics, these being:

- *Guidance on Environmental Liabilities Risk Assessment, Residuals Management Plans and Financial Provision – 2006*
- *Guidance on assessing and costing environmental liabilities (Draft) – July 2013*

It is understood that the 2013 guidance document is due for imminent formalisation.

These documents will be used as the basis for the preparation of this ELRA.

1.1 Environmental Liability Regulations

A relevant and related issue concerns the Environmental Liability Directive (2004/35/EC), which has been transposed into law through the European Communities (Environmental Liability) Regulations (2008) and the Environmental Liability Act. The Directive identifies activities for which 'strict liabilities' apply, for which waste management operations are identified. The Regulations place a number of responsibilities on operators i.e. the entity that controls an activity, namely:

- Prevention of environmental damage including taking measures to prevent (environmental) damage occurring when there is an imminent threat of damage
- Informing the EPA of the imminent threat of environmental damage where the preventative measures have not been successful in dispelling the threat
- Informing the EPA when environmental damage has occurred
- Complying with the EPA's direction in relation to where an imminent threat of damage has occurred
- Where damage has occurred, the operators shall take steps to control, contain, remove or manage the contaminants

Section 4.1 of the document 'Environmental Liabilities Regulations – Guidance Document, EPA 2011' identifies **proactive risk management** as a core principle by which these Regulations will be implemented by the EPA.

Section 4.3 of the Regulations identifies Environmental Liability Risk Assessment (ELRA) as being a good example of a methodology for environmental risk management. Therefore, the preparation of an ELRA can be considered as a means of implementation of these Regulations.

1.2 Environmental Liability Risk Assessment

As per the recent 2013 Agency Guidance Document, the ELRA to be prepared will have particular regard to accidents, emergencies, facilities activities or other incidents, which may have occurred in the past or could occur in the future and their effect on the environment, on the neighbours of the facility and on adjoining land-uses. The purpose of ELRA is:

- to identify and quantify environmental liabilities focusing on unplanned, but possible and plausible events occurring during the operational phase; and
- to provide a mechanism to encourage continuous environmental improvement through the management of potential environmental risks.

Environmental Liabilities can be subdivided into **known** and **unknown liabilities**. Different financial instruments are appropriate depending on whether it is an anticipated liability, such as the ongoing environmental management of a closed and restored landfill, or whether it is an unknown liability arising from, for example, accidental discharge or tank rupture or uncontrolled migration at a waste treatment facility. The most appropriate financial instrument to cover both known and unknown liabilities is to be agreed separately with the Agency.

The 2006 Agency Guidance Document states that "Closure Restoration Management Planning (CRAMP), Environmental Liabilities Risk Assessment (ELRA) and Financial Provision (FP) are mutually dependent".

The 2006 Guidance Document identifies a systematic step-wise approach to assess and quantify the risks and liabilities of a licensed facility as follows:

- Initial Screening & Operational Risk Assessment
- Preparation of a Closure, Restoration and Aftercare Management Plan (CRAMP) for known Liabilities
- Environmental Liability Risk Assessment (ELRA) for unknown Liabilities
- Identification of Financial Provision (FP) and Instruments

The 2013 Guidance amended this approach slightly to remove the requirement for initial screening for ELRA, while identifying revised procedures for preparing a CRAMP and an ELRA.

It should be noted that the preparation of a CRAMP is **not** within the scope of this document and a CRAMP has been submitted to the Agency under separate cover.

The 2013 guidance identifies the steps in ELRA as follows:

- **Step 1 - Scoping** to determine the type of environmental liabilities to be covered
- **Step 2 - Risk assessment** including the following stages:
 - o *Step 2a - Risk identification*, i.e. the systematic identification of plausible risks, the sensitivity of the receiving environment (receptor) and the potential pathway for the activity to impact on the environment.
 - o *Step 2b - Risk analysis* consists of determining the likelihood and consequences for identified risk events.
 - o *Step 2c - Risk evaluation* is the ranking and presentation of risks to allow for prioritisation of the risk treatment program.
- **Step 3 - Risk treatment** is a process to mitigate risks, e.g. by removing the risk or minimising the likelihood or consequences; and

- **Step 4** - *Identification, quantification and costing* worst case scenario for financial provision

Therefore, this document is structured in four sections, reflecting the ELRA steps identified.

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2 STEP 1: SCOPING

Condition 12.2 of licence P0009-03 requires the licensee to “*provide an annual statement as to the measures taken or adopted at the site in relation to the prevention of environmental damage, and the financial provisions to underwrite the costs of remedial actions following anticipated events or accidents/incidents, as may be associated with the carrying on of the activity*”.

Therefore, the scope of the ELRA is such that it should address potential liabilities associated with the “carrying on of the activity” i.e. liabilities that may have occurred since the commencement of operations at the site and until such time as operational activities at the site may cease.

However, at the time of writing, it is not possible to accurately forecast the nature of future development and/or activities at the facility and resulting potential liabilities that may arise until cessation of activities at the site.

In keeping with the requirements of Condition, 12.2, the licensee will provide an annual statement of measures adopted at the site to prevent environmental damage that will reflect any future activities or development at the site which may not be identified in this document. Therefore, this document addresses liabilities associated with historic activities at the facility up until current activities at the time of writing.

Activities associated with the closure of the site, and any subsequent remediation and/or aftercare requirements, and potential liabilities associated with these, are not considered within the scope of the ELRA and have been addressed in the separate CRAMP document submitted to the Agency.

The following sections present an overview of operations at the Dunderraw facility in order to inform the subsequent Step 2 – Risk Assessment.

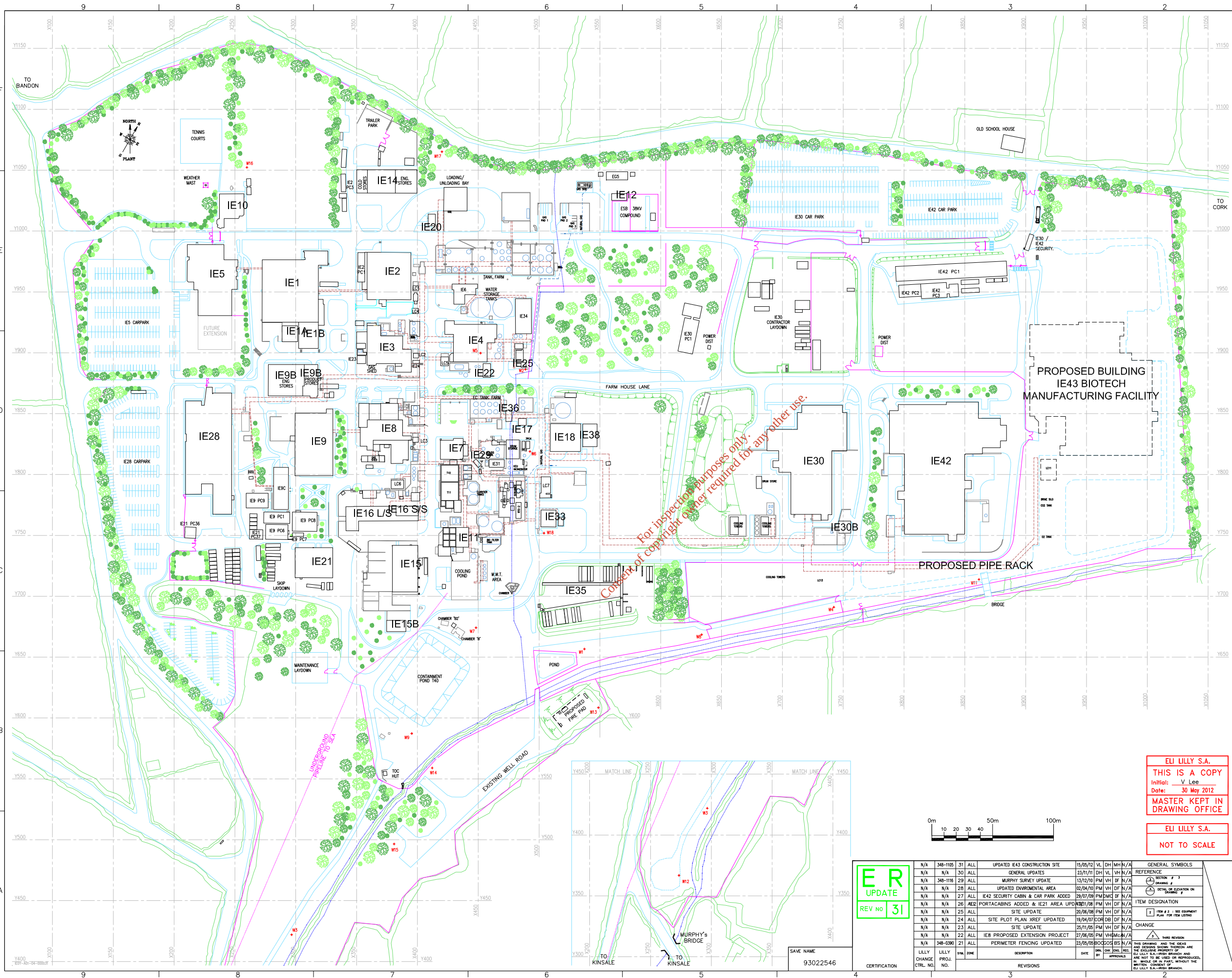
2.1 Overview of Operations

The Eli Lilly Kinsale facility supports the development, as well as manufacture and supply of many of the medicines for the treatment of depression, schizophrenia, attention-deficit hyperactivity disorder, diabetes, osteoporosis, cancer and many other illnesses. The Kinsale facility has also been involved in the manufacture of animal health products in the past and such products may be developed and manufactured in Kinsale in the future. The facility site layout is shown in the drawing overleaf.

The site uses advanced chemical and biological processes to produce a range of active pharmaceutical ingredients (API) that provide a medical benefit. These products are then further processed at various facilities to supply medicines to patients worldwide. Originally the Kinsale site's main focus was on manufacturing and supplying of medicines and while this focus continues onsite, the facility is also expanding to develop a centre of technical excellence in innovative new medicines. As a result Kinsale is now focused on three core business activities, namely:

- **Small Molecule Active Pharmaceutical Ingredient (API) Supply** – this is the sites traditional business being the most valued manufacturer and supplier of API for Lilly's launched products.
- **Small Molecule Commercialisation** - the Kinsale facility has become a centre of excellence for chemical synthesis and the commercialisation of new molecules. The site undergoes research and development work for new medicines as well as for new manufacturing technologies such as process analytics and continuous processing.
- **Biopharmaceutical Commercialisation and Supply** - In 2006 Lilly announced that Kinsale would become the main centre for the manufacture and supply of active ingredients for its new biopharmaceutical medicines. The site has invested in facilities and technologies to produce monoclonal antibodies (mAb's) and has the capability to further develop newly discovered medicines.

In addition to production facilities, there is a range of production support facilities including solvent storage, thermal oxidation, laboratories, warehousing, utility generation, waste water treatment facilities, maintenance, offices, staff facilities and a cafeteria. The three core unit operations and the support facilities are discussed further below.



REFERENCE DRAWINGS

1. XREF DRAWING No IE0Y-XRF-04-000001
(SAVE NAME: 92031861)

NOTES

1. PORTACABINS AND CONTAINERS (WITH *) LISTED IN THE CONTRACTORS COMPUND ARE NOT TO SCALE AND ARE FOR REFERENCE ONLY.
2. TO HIGHLIGHT THE GROUND ELEVATIONS AT EACH BUILDING AND BUILDING HEIGHT, TURN ON LAYER "ELEVATION"
3. TO SEE SITE STEEL COLUMN LOCATIONS, TURN ON LAYER "COLUMN"

LEGEND

IE1 WAREHOUSE BUILDING.(8E)
IE2 PMO LAB/ENGINEERING LAB/250GAL FACILITY.(7E)
IE3 PRODUCTION BUILDING.(7D)
IE4 POWERHOUSE & UTILITIES BUILDING.(6D)
IE5 ADMINISTRATION BUILDING.(8E)
IE6 PUMP HOUSE.(7E)
IE7 WASTE TREATMENT BUILDING.(7D)
IE8 PRODUCTION BUILDING.(7D)
IE9 ENGINEERING WORKSHOP/OFFICES.(7D)
IE9B ENGINEERING AND PRODUCT STORES.(8D)
IE9C ENGINEERING OFFICES.(8D)
IE10 PLANT PROTECTION BUILDING.(8E)
IE11 WASTE TREATMENT BUILDING.(7C)
IE12 38kv SUB-STATION.(6E)
IE14 COLD STORE/ERT BUILDING.(7E)
IE15 DRUM STORAGE BUILDING.(7C)
IE15B WATER REACTIVES STORE.(7C)
IE16 PRODUCTION BUILDING.(7C)
IE17 EC TANK FARM FOAM SUPPRESSION BUILDING.(6D)
IE18 WASTE TREATMENT/DRUM STORE BUILDING.(6D)
IE20 TANK FARM OPERATIONS BUILDING.(7E)
IE21 CONTRACTORS WORKSHOPS.(8C)
IE22 NITROGEN PLANT/COMPRESSOR HOUSE.(6D)
IE23 MECH. REFRIGE. COMPRESSOR HOUSE.(7D)
IE24 CARBON ADSORPTION CTR BUILDING.(7D)
IE25 WATER METERING HOUSE.(6D)
IE28 LABORATORY AND OFFICE BUILDING (8D)
IE29 ENVIRONMENTAL MONITORING STATION (ELEVATED) (6D)
IE30 PRODUCTION BUILDING (4D)
IE30B CHILLER BUILDING (C4)
IE31 M.C.C.- COMPRESSOR HOUSE.(6D)
IE33 M.C.C./CONTROL ROOM.(6C)
IE34 WATER GENERATION PLANT (6E)
IE35 CONTRACTORS LAYDOWN COMPOUND (6C)
IE36 ENVIRONMENTAL DECONTAMINATION STATION(6D)
IE37 RESERVED BUILDING NUMBER
IE38 ENVIRONMENTAL BRICK STORE BUILDING(6D)
IE42 PRODUCTION BUILDING(4C)
IE43 FUTURE PRODUCTION BUILDING

PORTACABINS (PC)

IE2 2PC No1. TEMPORARY LABS (7E)
IE7 7PC No2 SAFETY EQUIPMENT STORE.(6D)
7C No4 PPE CHANGING ROOM.(6D)
IE9 9PC No1 C&O. (8C)
9PC No6 DRAFTING OFFICE. (8C)
9PC No7 DRAWING ARCHIVE (8C)
9PC No8 PROCESS AUTOMATION (8C)
9PC No9 SMALL PROJECT GROUP (8C)
IE21 21PC No36 SECURITY/INDUCTION BUILDING (8C)
21PC No37 MEET ROOM/CANTEEN (8C)
IE30 30PC No1 PROJECT ENGINEERING OFFICES (5E)
IE42 42PC No1 IE43 CONSTRUCTION SUPPORT (3/4E)
42PC No2 DOCUMENT CONTROL (3/4E)

KEY

INTERNAL BOUNDARY FENCE

HEDGE ROW ELI LILLY SITE

PIPE ARBOUR

STREAM FLOWING THRU SITE

PROJECT NO. 3P14P0011

ELI LILLY S.A.-IRISH BRANCH
DUNDERROW, KINSALE, CO. CORK, IRELAND
SITE PLOT PLAN
ELI LILLY
KINSALE

DATE 27/09/1993
SCALE 1:3000
DRAWN JFD
CHECKED N/A
RECORDS CONTROL N/A
NEW DRAWING NO. 98/EE-73

FIGURE 3.2

REVISIONS

NO.	SYMBOL	DESCRIPTION	DATE	BY	CHK	ENG.	REC.
1		348-1105 31 ALL UPDATED IE43 CONSTRUCTION SITE	15/05/12	VL	DH	MH	N/A
2		N/A N/A 30 ALL GENERAL UPDATES	23/11/11	DH	VL	VH	N/A
3		N/A 348-1116 29 ALL MURPHY SURVEY UPDATE	13/12/10	PM	VH	DF	N/A
4		N/A N/A 28 ALL UPDATED ENVIRONMENTAL AREA	02/04/10	PM	VH	DF	N/A
5		N/A N/A 27 ALL IE42 SECURITY CABIN & CAR PARK ADDED	29/07/09	PM	DMC	DF	N/A
6		N/A 26 AER PORTACABINS ADDED & IE21 AREA UPD	03/01/08	PM	VH	DF	N/A
7		N/A N/A 25 ALL SITE UPDATE	20/06/08	PM	VH	DF	N/A
8		N/A N/A 24 ALL SITE PLOT PLAN XREF UPDATED	19/04/07	COR	DB	DF	N/A
9		N/A N/A 23 ALL SITE UPDATE	25/11/05	PM	VH	DF	N/A
10		N/A N/A 22 ALL IE8 PROPOSED EXTENSION PROJECT	27/06/05	PM	VH	MC	N/A
11		N/A 348-0390 21 ALL PERIMETER FENCING UPDATED	23/05/05	BOC	OS	BS	N/A

CERTIFICATION

ELI LILLY S.A. - IRISH BRANCH
LILLY CHANGE PROL. CTRL. NO. 93022546

GENERAL SYMBOLS

SECTION # 3
DRAWING # 3
TOTAL OF ELEVATION ON DRAWING #

ITEM DESIGNATION
ITEM # 2 : SEE EQUIPMENT PLAN FOR ITEM LISTING

THIRD REVISION
THIS DRAWING AND THE IDEAS AND DESIGNS SHOWN THEREON ARE THE EXCLUSIVE PROPERTY OF ELI LILLY S.A.-IRISH BRANCH AND MAY NOT BE USED OR REPRODUCED, IN WHOLE OR IN PART, WITHOUT THE WRITTEN CONSENT OF ELI LILLY S.A.-IRISH BRANCH.

ER UPDATE
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SAVE NAME 93022546

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2.1.1 Unit Operations

1. Small Molecule Active Pharmaceutical Ingredient (API) Supply & Small Molecule Commercialisation

The majority of the production buildings onsite are multipurpose buildings with the capability to manufacture various campaigned compounds for Lilly products. Each building consists of similar process equipment. The main buildings for the production of APIs are IE2, IE3, IE8, IE16 and IE30. These buildings are outlined in Drawing 001 and summarised below.

The **IE2** production facility has been in operation since 1981. It was originally used for sterile manufacturing processes and was later modified for the production of a specific small scale product.

This facility has been largely transformed for use in product development/small scale manufacture in recent years. The facility is now divided into three main areas with a fourth area under consideration.

The three areas currently developed in the IE2 production facility are as follows:

- *PMO Laboratory* - a laboratory scale operation involving reaction, crystallisation and filtration activities in vessels of less than 50 litre capacity.
- *Fifty Gallon Production Facility (Engineering Laboratories)* - this is a scale up from the PMO laboratory operation which again allows for flexible manufacturing arrangements up to a 50 gallon tank capacity.

The facility encompasses both wet end and dry end processing areas.

- *Two Hundred and Fifty Gallon Production Facility* - this is essentially a pilot plant facility with a total reactor capacity of 1000 gallons (4* 250Gal), suitable for both wet and dry processing.

A proposed development of the last quadrant of the IE2 building is currently being considered. It is envisaged that this development will be on a similar scale to that already outlined above and will consist of either a fixed or flexible manufacturing equipment train.

The **IE3** production building has been in operation since 1981 and has manufactured human antibiotics and animal health products. This building is currently underutilised however; it can be used for human or veterinary product manufacturing in the future.

The **IE8** production building was established in 1984 and is a multipurpose plant for intermediate and final bulk manufacture of various campaigned compounds.

The **IE16** production building is a multipurpose plant comprising two production areas containing both large scale and small-scale production processes. The large scale production process in this building was proposed to be extended in 2007/2008. This did not occur to date, however, the expansion may take place in the future.

The **IE30** production facility is a dedicated clean manufacturing plant used to produce aseptic product. This process involves further processing of an active final bulk material. This facility contains process areas, environmental monitoring laboratories, in and outbound shipping, warehouse space, general administrative and utility support areas.

2. Biopharmaceutical Commercialisation and Supply (IE42 and IE43)

Since 2009 the Kinsale facility has been manufacturing and supplying monoclonal antibodies (mAb's) for biopharmaceutical medicines. This new biotechnology process is currently operational in building **IE42** and is to be extended to the **IE43** facility once construction is completed.

These facilities are designed to be multi-product and may be modified in the future in response to changes in product mix and market requirements. The typical generic process sequence for products that will be manufactured in IE42 and IE43 is as follows: cell culture, broth clarification, detergent inactivation, capture column purification step (chromatography), low-pH inactivation, intermediate purification step (chromatography), final polishing step (chromatography).

The chromatography steps are followed by a nanofiltration step and a product concentration/diafiltration via a tangential flow filtration step. The process is water based as opposed to solvent based for traditional synthetic pharmaceutical manufacturing.

2.1.2 Support Facilities

In addition to production facilities described, there is a range of production support facilities onsite including:

- Bulk Solvent Storage and Tanker Unloading
- Waste Solvent Storage & Treatment
- Warehousing
- Utilities Area
- Wastewater Treatment Plant
- Engineering and Maintenance
- General Administration.

Bulk Storage and Tanker Unloading

The bulk solvent storage facility (tank farm) is designed to hold up to 45 tanks. The tank farm currently holds 28 tanks, including additional spare capacity. Plans are in place to upgrade a number of these tanks over the coming years to provide improved containment by increasing the pressure relief settings for breathing loss vapours.

The usage of bulk solvents on site has reduced by an estimated 40% over the past 4-5 year period as a result of the introduction of newer less solvent intensive manufacturing processes together with a move to aqueous based biotechnology manufacturing processes.

All the fixed bulk storage tanks are surrounded by contained bunds (meeting the 25% and 110% capacity requirements) that are designed to contain material in the event of flammable or toxic liquid spills. Fixed foam and firewater protection systems are installed in keeping with current standards and expectations.

Waste Solvent Storage

The waste solvent storage area comprises of a group of 7 tanks, which store liquid wastes for incineration. All of the tanks in the waste solvent tank farm were replaced with new tanks in 2007, built to a much higher specification than the original tanks. These are pressure rated vessels that can be operated at much higher pressure relief settings thus minimising vapour breathing losses. This has led to a significant reduction in fugitive emissions from these tanks.

Wastes stored here are segregated into primary waste, which is mostly organic solvent and secondary waste which is mostly water, contaminated with some solvent and other organic residues. All the waste solvent storage tanks are surrounded by contained bunds that meet the 25% and 110% capacity requirements. Fixed foam and firewater protection systems are installed around this area.

Warehousing

The main storage areas onsite are:

- **IE15** is used to store primarily liquid raw materials in drums, cylinders, IBC's etc.
- **IE1, IE14 and IE9B, IE30** are warehouses that are used to store dry goods, e.g. powders, some solvent-wet intermediates in flexible IBCs, dry intermediates and final products
- Bottled Gas Storage Pad (including Hydrogen, Helium, Nitrogen, Oxygen, Acetylene etc.)
- **IE8** Gas Storage Area is specifically designed for charging operations to reactor vessels
- **IE1B** Cold Storage Annex is used to store products from Biotech manufacturing
- **IE15B** Water Reactive Material Storage
- **IE42** Warehouse is used to store raw materials and consumables for biotech manufacturing.

Materials are delivered to warehouses IE15, IE1, IE9B or IE42. Warehouse personnel are responsible for accepting, storing and dispensing of all materials, other than the following materials:

- Organic solvents, which are delivered directly to the tank farm
- Gases which are directed to the hydrogen storage pad or IE8 gas storage area-

Utilities Area

The main utilities area onsite (**IE4**) includes three steam boilers, a purified water plant, a nitrogen plant, air compressors, two emergency generators, two chillers and four cooling water towers.

There is a site wide fire protection system and a retention pond to retain water used in firefighting, which may need to be treated prior to discharge.

IE30 has its own standalone utilities which support production in **IE30**, **IE42** and **IE43**. The utilities in IE30 consists of three clean steam generators, two purified water plants, a nitrogen storage tank, four air compressors, four chillers (R134a) and six cooling towers. Two standalone chillers (R134a) are located in IE42 exclusively for cooling that building. These standalone utilities will be replicated in the IE43 development.

The boiler system onsite has been upgraded in the past number of years. Saturated steam is now supplied by three fire-tube boilers located in IE4. Two of these are completely new units and all three units have had the burners upgraded to low NO_x units and each boiler unit is now also fitted with an economiser to recover significant amounts of waste heat. The boilers run on natural gas, each with a nominal capacity of 9 tonnes. Normal demand is met by running two boilers simultaneously, with the third boiler on standby.

Demand is also supplemented by the steam generated from the waste heat boiler on the John Zink (KEU) thermal oxidiser. This waste heat boiler provides approximately 30% of the daily site steam demand.

The boiler emission generated is primarily carbon dioxide, which is released to atmosphere through a single stack, which is a licensed emission point. Current expansion of the Biotech manufacturing capacity (IE43) will lead to increased steam demand. This may necessitate the installation of an additional boiler or CHP Plant, which in turn may lead to an additional, or larger existing, boiler emission stack.

Process reaction vessels and equipment are heated by means of temperature controlled ethylene glycol loops, where steam is indirectly used for heating duty, and chilled glycol at -17 °C is used for cooling. De-aerated water is fed to the boiler by a feed pump to a pre-determined level. Water level within the boiler is controlled by means of a modulating control valve. This valve also controls the steam pressure of the boiler over a pressure range. Condensate is collected and returned to IE4 via the steam distribution system.

Engineering and Maintenance

The site engineering and maintenance area in **IE9** consists of four groups. These include; Mechanical Fitters, Electricians, Instrumentation Technicians and Co-ordinators. Chemical, Mechanical, Instrumentation and Electrical engineers support the production buildings. Chemists and Process Engineers also provide technical support for the production areas, as well as maintaining quality control. Additional technical support personnel include the Environmental, Health and Safety departments.

General Administration and Laboratories

The general administrative functions are located in **IE5**. Functions include procurement, financial, HR and training. The site cafeteria is also located here. Adjoining IE5 is a smaller building, **IE10**, which is the Security and conference facility for the site. The IE28 building houses both the site's laboratories and office space for various support functions.

2.2 Development history

A summary of the developmental history of the site is presented as follows:

- 1976 - Eli Lilly and Co. purchased a 112 acres site in Dunderrow, Kinsale Co. Cork
 - o since 1976, a further 40 acres has been purchased
 - o currently, c. 80% of the site is occupied by development
- 1978 - construction began on-site
- 1979 - the IE2 Laboratory was built & production commenced at this facility in 1981
- 1984 - IE8, the second production facility was added as well as IE2, a small production facility
- 1988 - the IE8 production facility was expanded
- 1999 - IE16 small scale, high containment facility was commissioned
- 2000 - IE16 a large scale facility was constructed
- 2002 - a new laboratory and office (IE28) was constructed
- 2004 - a new clean manufacturing facility (IE30) was constructed
- 2007 - the IE30 facility achieved complete validation
- 2009 - biopharmaceutical manufacturing, commercialisation facilities and engineering laboratories (Building IE42) were commissioned
- 2011 - Lilly announced the expansion of the production capacity for biopharmaceutical products at the Kinsale plant with the addition of a new biotechnology manufacturing facility (Building IE43)

There are no disused over or underground storage tanks or waste disposal/treatment areas onsite.

All relevant incidents onsite have been notified to the Agency and are recorded on file. There is one known pollution incident with residual impacts onsite which is confined to a localised area of the site groundwater aquifer at Well 18 (previously named RW-1), in which residual levels of the Methyl Tertiary Butyl Ether (MTBE) continue to be detected, now at low levels below the Agency's Groundwater Interim Guideline Value of 30 µg/l.

The presence of MTBE in this area relates to an historic incident that occurred in 2003 in the IE8 production building. The MTBE impacts in the groundwater are now considered largely remediated, however remediation efforts are ongoing to further improve and sustain the quality of the groundwater at this localised area of the site aquifer.

3 STEP 2: RISK ASSESSMENT

As identified previously, the Risk Assessment step of the ELRA process comprises a number of sub-steps as follows:

- *Risk identification*, i.e. the systematic identification of plausible risks, the sensitivity of the receiving environment (receptor) and the potential pathway for the activity to impact on the environment.
- *Risk analysis* consists of determining the likelihood and consequences for identified risk events.
- *Risk evaluation* is the ranking and presentation of risks to allow for prioritisation of the risk treatment program.

The following sections follow these sub-steps through the Risk Assessment stage of the ELRA process.

3.1 Risk Identification – Key Information

The 2013 Guidance requires that “a list of plausible risks for the activity must be identified” that focus on “abnormal but possible and plausible **incidents** that could result in liabilities”. Environmental risks are identified as including “all impacts to surface water, groundwater, atmosphere, land, human health, natural habitats and protected species”.

Incidents are identified in the 2013 Guidance as:

- an emergency
- an accident
- an abnormal operation
- a breakdown
- any emission/discharge which does not comply with the requirements of an authorisation
- any exceedance of the daily duty capacity of waste handling equipment
- any trigger level which is attained or exceeded
- any compliance value which is attained or exceeded
- any indication that environmental pollution has, or may have, taken place
- any loading or dumping activity which does not comply with the requirements of an authorisation (Dumping at Sea)
- an incident with the potential for environmental contamination of surface water or groundwater or posing an environmental threat to land or requiring an emergency response by the relevant water services authority (Wastewater Discharge Authorisations).

In order to accurately identify a set of risks, the 2013 Guidance requires the provision of detail in relation to site operation, operator performance and environmental sensitivity, as shown in Figure 3.1 (derived the 2013 Guidance)

Table 3-1: Key Information required for the Risk Identification process

Parameter	Data Requirement
Site Operation	Size and nature of the activity Age of the activity and previous site uses Details of licence/permit Overview of site infrastructure Details on fuel and other materials storage and handling Details on the scale and nature of all environmental emissions Overview of abatement plant Overview of the nature and volumes of waste generated
Operator Performance	Environmental Management Systems Compliance History Enforcements History Incidents History
Environmental Sensitivity	Details on the underlying geology/hydrogeology, coupled with any historic soil or groundwater monitoring or known contamination Proximity to identified surface water bodies, their Water Framework Directive status and identification of scheduled or unscheduled discharges to these water bodies from the activity Proximity to sensitive human receptors and potential for nuisance or health impacts to these receptors Details on the nearest EU or National protected site, natural habitat or protected species and potential pathways for the activity to impact these habitats and species

3.1.1 Site Operation

Size & Nature of the activity

The Dunderrow site covers an area of approximately 150 acres. The facility is operated under an Integrated Pollution Control (IPC) licence (EPA Licence Ref No P0009-03) for the manufacture of pharmaceutical and veterinary products as well as the recovery and disposal of waste.

Age of the activity and previous site uses

The Dunderrow site was used primarily for agricultural purposes prior to its purchase by Eli Lilly in 1981.

Details of Licence

The facility operates under EPA licence P0009-03. At the time of writing, a review of the facility licence is being considered by the Agency under application number P0009-04. In addition, P0009-03 was amended in January 2014 in order to bring it in line with the requirements of the Directive 2010/75/EU (Industrial Emissions Directive).

Overview of site infrastructure

An overview of facility infrastructure has been provided in Section 2.1.1 & 2.1.2.

Details on fuel and other materials storage and handling

Details on the raw materials, intermediates or products used or generated on the site are included in Appendix 1.

There are a large number of different chemicals used on site as part of the process operations. For tabulation purposes, they are divided into the following categories:

- Bulk materials
- Reagents
- Products and intermediates
- Processing aids
- Cleaning and maintenance materials.

Due to the flexible nature of the production process, and the variation in the use of equipment across the site, it is not practical to detail exactly what can be found in a typical reactor, filter etc. For this reason, the category of material likely to be found is given in many cases, unless there are a small number of materials which are usually found in such equipment.

These are described in Tables 3.2 – 3.4 below.

Table 3-2: Materials Involved In Small Molecule Active Pharmaceutical Ingredient (API) Supply and Small Molecule Commercialisation Unit Operations

Operation	Materials Usually Found	Other Materials Likely
Reactions	Bulk Solvents, Reagents, Solids, Liquids, Gases	Processing Aids (Catalysts, Filter Aids), Intermediates
Distillations	Bulk Solvents	Products/Intermediates, Reagents
pH Adjustment	Acids/Bases from Bulk Stock, Acids/Bases from Reagent Stock	Products / Intermediates, Reagents
Liquid/Liquid Extraction	Water, Solvents	Reagents
Crystallisation	Products / Intermediates	Solvents, Reagents
Equipment Cleaning	Solvents, Water, Sodium Hydroxide	Detergents
Inerting	Nitrogen	Any Other
Solids Charging	Products/ Intermediates, Solid Reagents	Solid Processing Aid, Bulk Solvent
Transfers	Bulk Materials, Reagents, Products / Intermediates	Processing Aids
Vacuum Operations	Solvent, Water	Products / Intermediates, Reagents
Centrifuging	Solvent, Water, Products/Intermediates	Reagents
Filtering	Solvent, Water, Products/Intermediates	Reagents, Processing Aids
Drying	Products / Intermediates, Solvent, Water	-
Milling	Product / Intermediate, Solvent, Water	-
Bagging/Drumming	Products / Intermediates	-

Table 3-3: Materials Involved In Biopharmaceutical Commercialisation and Supply Unit Operation

Operation	Materials Usually Found	Other Materials Likely
Cell Culture	Water, Media, Nutrients	Inorganic solutions
Cell Cultural Clarification	Water, product	Inorganic solutions
Detergent Inactivation Operations	Water, product, detergent	-----
Purification Operations	Product	Organic/inorganic impurities Buffers/ salts, dilute acid/base Filter media, chromatography resins
Final Product Packaging	Product	Detergent

Table 3-4: Ancillary Materials Involved in Support of Unit Operations

Operation	Materials Usually Found	Other Materials Likely
Boilers	Water, Natural Gas, Processing Aids, Steam	Oxygen Scavengers, Corrosion Inhibitors
Thermal oxidisers	Primary and Secondary liquid waste, Process vapours	Corrosion Inhibitors
Wastewater treatment plant/ Membrane Filtration Plant	Aqueous waste	Flocculant, acids, alkali, surfactant
Compressed Air	Air	-
Nitrogen	Nitrogen, Oxygen	Resin
Heat Transfer	Ethylene Glycol, Dowtherm, Methanol, Water/Steam/ Ammonia	Processing Aids (e.g. Biocides)
Cooling water	Biocides	-
Water Purification	Anionic and Cationic resins	Inorganic salts

Details of energy resources used on site are presented in Table 3.5.

Table 3-5: Energy Usage on-Site 2013

Energy usage on site		
Energy Use	Previous year	Current year
Total MWh	119, 812	112,584
Electricity MWh	47,724	46,507
Fossil Fuels:		
Heavy Fuel Oil (m ³)	0	0

Energy usage on site		
Energy Use	Previous year	Current year
Light Fuel Oil (m ³)	24	120
Natural gas (CMN)	6,280,965	5,974,454
Coal/Solid fuel (metric tonnes)	0	0
Renewable energy generated on site kWh	18,000	18,000

The vast bulk of the energy consumed at the site is now supplied in two main forms namely:

1. Natural gas supplied via a low pressure gas pipeline to site
2. Electricity from the national grid

The current annual energy demand at the site amounts to almost 120 GWhr, with approximately 40% of the energy demand accounted for by the consumption of electricity and the bulk of the remaining energy demand is primarily supplied by natural gas.

The main energy using aspects at the site are listed below:

- Heating, Ventilation and Air Conditioning (HVAC) Systems
- Steam Production (primarily for HVAC and process heating applications)
- Waste Treatment Systems
- Cooling Towers
- Refrigeration
- Compressed Air Systems

Natural Gas is primarily consumed in the first three energy using aspects listed above whilst a significant quantity of electrical energy is consumed across all the energy using aspects with the exception of steam production.

Small quantities of diesel are available for use in the site firewater pumps, the site emergency electrical generators and in a limited range of site transport vehicles. Diesel is also available as the back-up fuel alternative to natural gas but this fuel would only be used in exceptional circumstances. . Therefore the consumption of diesel on an ongoing basis is typically limited to short weekly tests of the site emergency electrical generators, short weekly tests of the site firewater pumps and in a small number of site transport vehicles. There is also potential for the use of diesel in the site emergency generators during electrical power outages to the facility but such events are relatively rare.

Renewable energy is generated at the site through the use of solar water heating panels for two of the site buildings (IE7 and IE9). This does offset some natural gas consumption at the site steam boilers but the quantity of renewable energy generated by these solar water heating panels is relatively insignificant.

Therefore, because the use of diesel at the site is quite limited and as the generation of renewable energy is relatively insignificant, energy consumption at site can be considered to be largely restricted to the two main forms outlined above i.e. natural gas and electrical energy from the national grid.

Prior to the installation of the natural gas supply to the site in 2011, significant volumes of Heavy Fuel Oil (HFO), diesel and propane were used at the site. The introduction of natural gas to the facility was part of the site's overall programme to improve the sustainability and reduce the environmental footprint of the site operations, whilst also delivering significant energy efficiency, economic and reliability benefits.

Details on the scale and nature of all environmental emissions

Emissions to Atmosphere

Atmospheric emissions from the site can be categorised into:

- Boiler emissions
- Main emissions
- Minor Emissions
- Potential emissions

The emission points to atmosphere are outlined in Appendix 2.

Under Condition 6.7 of the facilities IPPC licence, the licensee shall maintain a programme for the identification and reduction of fugitive emissions. Sources of fugitive emissions onsite include:

- RTO duct trips
- Building ventilation fans
- Solvent storage tank breathing losses
- Leaks from valves/pump seals / flanges
- Spills
- Emissions from wastewater treatment (e.g. volatile organics).

A programme is in place for the evaluation of fugitive emissions from both production building air exhaust systems and site bulk solvent and waste solvent storage tanks. Storage tank working and breathing VOC losses are calculated using recognised modelling techniques taking into account both ambient conditions and annual solvent throughput for each vessel. Fugitive VOC losses from production buildings (seal/flange leaks etc.) are calculated by monitoring VOC emissions from the building exhaust fans. Data is compiled into an annual fugitive emission total for each solvent.

Emissions to Surfacewater

Emissions to surfacewater originate from:

- Treated effluent from the facility
- Wastewater from incineration
- Site stormwater run-off

Emissions to Sewer

There are no emissions to sewer from the facility.

Emissions to Ground

There are no direct emissions to ground from the facility.

Noise Emissions

Historical noise surveys have shown that noise emissions from the site are not outside the relevant conditions.

Overview of abatement plant

Air

Air abatement and control systems on-site consist of:

- Fume thermal oxidiser (RTO or Reeco unit)
- Scrubbers
- Carbon absorbers
- Filters (bag and HEPA filters) and Glove Bag containment technology

Wastewater

The main sources of wastewater effluent on site are:

- Process wastewater arising directly and indirectly (equipment cleaning, floor washing, abatement systems etc.) from manufacturing
- Utility wastewater (steam and hot water generation, purified water production and cooling systems)
- Sanitary/foul wastewater (canteen, washrooms and toilets and is similar in composition to normal domestic sewage)
- Contaminated surface water
- Incinerator quench water (thermal oxidiser)

Wastewater Treatment Plants

There are currently two waste water treatment plants (WWTP) on-site namely:

- Biological WWTP
- Incineration process WWTP

Both of these plants have undergone upgrade work in the past number of years. Works to the incineration process WWTP were completed in 2005 and included changes to the management of the hydraulic loads associated with the inorganic treatment system. This was achieved through the addition of an extra clarifier and sand filter which enhanced the solids removal capability of the plant.

Over the past 5 year period a significant investment has been made in upgrading the existing biological WWTP facility to increase the capability of the plant while also improving effluent quality and providing additional groundwater protection thorough secondary containment measures.

A summary of the works carried out include:

- Installation of mechanical mixing devices in the final effluent holding tank to aerate tank contents and promote oxidation of residual salts (e.g. sulphite to sulphate) thus reducing potential impact on the receiving waters.
- Lining of concrete effluent holding tanks with a high density polyethylene (HDPE) material to minimise risk of leakage to ground/groundwater.
- General piping refurbishment within the area and installation of additional hard surface area under pipe racks to prevent soil or groundwater contamination.
- Upgrade of the WWTP odour abatement device (Biofilter) and installation of new Monoshell media.
- Upgrade of the WWTP sludge holding tanks including replacement of air sparge mixing with mechanical mixers and the replacement of the tank roofing system and associated venting arrangement to the Biofilter.

In all approximately €5 million has been spent on these upgrade works over the period.

In 2006 a Membrane Filtration Plant was installed to pre-treat a high volume process waste stream so as to render it suitable for biodegradation. The process was quite successful and resulted in a significant diversion of material to biological treatment and away from the historical incineration route. However the associated manufacturing process has now ceased and the Membrane Filtration plant is no longer in use. An alternative use for this equipment in the treatment of grey utilities water is currently being evaluated and if successful will lead to significant savings in site water use.

Incineration Process WWTP – quench water and scrubber blow down from the incineration process is routed through a separate treatment system before being combined with the biological WWTP effluent prior to discharge. The plant consists of two clarifiers (T49/50) operated in parallel and designed for a throughput of 1500 m³/day each. A pre clarifier polymer dosing system is in place to assist with suspended solids coagulation and flocculation. pH adjustment can also be carried out pre clarification. The effluent from the clarifiers is then routed to a three bed (T 64/65/66) polishing sand filter to achieve licence compliance for suspended solids concentration in this effluent stream.

Utility 'clean' wastewater and treated incinerator effluent is combined in the cooling ponds. A portion of this is then recycled back through the clarifiers and sand filters to act as make up water for the system. The remaining portion is then combined with the biological treatment plant final effluent and discharged to the ocean outfall off Sandy Cove in the outer Kinsale Harbour.

Storm Water

The storm water run-off is essentially uncontaminated (comprising precipitation runoff from roadways, roofs and hard standing areas not associated with production).

The containment pond (T-40) is designed to retain potentially contaminated fire water or storm water which is collected in the storm water drainage system across the site. The pond has a capacity of 6,110 m³ and is lined with high-density polyethylene. Since the pond was installed at the site in 1987, the time period required for the pond to reach full capacity during various worst case firefighting and rainfall scenarios (0.5 year to 100 year return periods) has been reassessed in line with the Agency guidance note on Firewater Retention Facilities.

Run off from the site is collected via two separate systems, one collecting run off from the West side of the site and the other from the East side.

In the event of a fire or a spillage to the surface water drainage system, the relevant site surface water shall be retained in the containment pond. The site surface water drainage system consists of two separate systems, the West Site (IE3/IE8/IE16) and the East Site (IE30/IE42) controlled by valving arrangements in Chambers A and B.

In the event of a firewater event on one side of the site, it is possible to divert the other around the containment pond to ensure that maximum fire water capacity is available to contain the surface water run-off. Contaminated storm water collected in the containment pond can be pumped back to the waste water treatment plant for further treatment.

Under normal conditions the site storm water flows through the pond and discharges through the open outlet valve provided that pH and TOC values are within programmed limit values.

Overview of the nature and volumes of waste generated

Waste Arisings

The following quantities of waste were generated on site in 2013:

- Hazardous – 5,324 tonnes
- Non-hazardous – 3,662 tonnes

Waste Disposal Arrangements

A number of different types of wastes are generated onsite. Wastes are primarily solid or liquid wastes (solvent/aqueous). Any gaseous waste streams generated onsite are treated in onsite abatement systems. Wastes generated onsite can either be hazardous or non-hazardous. Some waste streams are recovered, recycled, treated or disposed of onsite and other wastes are recovered, recycled, treated or disposed offsite. Offsite treatment or disposal of waste only occurs where there is no onsite capacity to treat it.

Wastes are classified as hazardous or non-hazardous. Hazardous liquid wastes (solvent based) are recovered where possible onsite or if not are incinerated onsite. This waste may be routed for offsite treatment if the onsite incinerator has reached its capacity or if the incinerator is out of service.

Waste oils and oil filters are stored in a designated waste oil holding tank/designated bin onsite and is removed offsite by an approved waste contractor.

All hazardous solid waste is sent offsite for incineration. Hazardous solid waste generated onsite includes:

- Empty unclean raw material packaging
- Fibre/Plastic drums and IBC's containing used PPE, wipes, packaging etc.
- Waste paint
- Florescent tubes/batteries
- WEEE
- Rejected solid material
- General laboratory waste
- Discarded lab chemicals and product samples
- Catalyst material
- Hazardous incinerator brick/slag

All this waste is segregated and stored in appropriate containers in dedicated locations prior to being removed offsite for incineration.

Non-hazardous waste generated onsite includes:

- General municipal solid waste – compacted prior to transport offsite – sent to an MRF facility for further segregation of recyclable and disposable fractions.
- Commercial and industrial material – plastics, mixed dry recyclables – baled/compacted prior to transport offsite – again sent to an MRF facility for further segregation of recyclable and disposable fractions.
- Mixed packaging – baled/compacted prior to transport offsite – sent for offsite recovery/disposal
- Food waste – sent for composting offsite
- Waste wood material– sent for offsite recovery
- Waste metal material– sent for offsite recovery/disposal
- Construction and demolition waste - sent for offsite recovery/disposal
- WWTP sludge's – sent to a sludge drying facility
- Non-hazardous incinerator brick – sent offsite for disposal
- Waste cooking oil - sent for offsite recovery/disposal
- Glass - sent for offsite recovery
- Confidential paper - sent for offsite for shredding and re-use

All these wastes are managed by a dedicated waste contractor onsite who collects, segregates and transports off-site as appropriate.

Wastes arising from the biotechnology facility can be broken down into cell contact/non-cell contact wastes which include:

- Cell contacted solids
- Cell containing liquid
- Non-cell contacted solids
- Non- cell containing liquid
- General waste

Waste that contains or has been in direct contact with cell material will be inactivated by chemical/heat treatment onsite or sent directly to bio-waste containers for offsite disposal. All bio-waste transported offsite is incinerated irrespective of how it has been treated or inactivated onsite.

Non cell-contacted solid waste is placed in clear waste liners provided within each area and is taken off-site for incineration. Non-cell contacted liquid waste from the cell culture and purification processes will be emptied to the aqueous waste system via aqueous waste floor drains and will be treated in the onsite waste water treatment plant.

A baler has been installed on-site to maximise the quantity per load of the above types of solid hazardous waste streams that are being removed off site. This will provide significant environmental benefits to the site both in terms of the reduction in outer packaging volumes and also the reduction in carbon footprint associated with reduced transport movements. The baler is located in the IE18 hazardous waste drum store.

General waste such as warehouse packaging waste or plastic containers is segregated and recycled as appropriate.

Only approved waste contractors who have appropriate waste permits and licences will be hired to transport, recover or dispose of Eli Lilly waste offsite. A database has been set up to log all waste movements offsite.

3.1.2 Operator Performance

Environmental Management Systems

Eli Lilly has developed and implemented an Environmental Management System (EMS) for the Kinsale site. The main objectives of this EMS are:

- To develop Eli Lilly's Environmental Policy Statement
- To implement an effective programme of environmental protection and conservation measures to meet the objectives of the Environmental Policy
- To set targets to improve its environmental performance. This is done through the implementation of the annual Environmental Management Programme.

To maintain this certification status, Eli Lilly strives to make continual improvements in waste minimisation and recycling efforts, undertakes ongoing development of the environmental management system, carries out regular internal audits and frequently reviews operating procedures.

Enforcement History

There have been no environmental prosecutions associated with the site.

Compliance & Incidents History

All minor incidents onsite have been notified to the Agency and are recorded on file. A summary of minor incidents are shown in the following table.

Year	Nature of Incident	Scale
2013	1 x instrumentation failure 1x uncontrolled release to atmosphere 1x trigger level exceedance on storm water	Minor
2012	2 x uncontrolled release to atmosphere	Minor
2011	2 x uncontrolled release to atmosphere	Minor
2010	1 x instrumentation failure	Minor
	1 x power failure to RTO	Minor

Year	Nature of Incident	Scale
2009	Tripping of fume duct in IE8 and subsequent bypass	Minor
	Daily average NO2 exceedance in Thermall unit	Minor
	RTO tripping on 3 no. occasions	Minor

There have been four complaints since 2009 relating to noise. No incidents relating to noise have occurred over this period. In each case, the engineering issue relating to the noise complaint was identified and rectified quickly. No complaints were received in 2013.

Date	Description	Cause	Outcome
09/11/2009	Complaint of low intensity humming noise from plant over 3 to 4 nights	Humming noise was identified as coming from the incinerator	Root cause identified and addressed through plant operational and engineering adjustment
25/12/09	Complaint of unusual noise from plant	Cause was unusually cold weather led to failure of pressure transmitter which led to opening of steam relief valve	Corrected by de-icing the transmitter
21/09/2011	Unusual vibrating sound emanating from the site	Source was a loose fan housing on air intake.	Housing repaired and noise eliminated
04/10/2012	Complaint regarding the frequency of use and the noise level of the site Public Address (PA) system	PA System	The PA system in a new construction area was identified as the cause of the complaint. The volume of the system was reduced.

There is one known pollution incident with residual impacts onsite which is confined to a localised area of the site groundwater aquifer at Well 18 (previously named RW-1), in which residual levels of the Methyl Tertiary Butyl Ether (MTBE) continue to be detected, now at low levels below the Agency's Groundwater Interim Guideline Value of 30 µg/l. The presence of MTBE in this area relates to an historic incident that occurred in 2003 in the IE8 production building. The MTBE impacts in the groundwater are now considered largely remediated, however remediation efforts are ongoing to further improve and sustain the quality of the groundwater at this localised area of the site aquifer.

3.1.3 Environmental Sensitivity

Much of the information provided in terms of the environmental sensitivity has been sourced from the EIS prepared by ARUP in December 2011 in relation to the proposed development of the IE43 manufacturing facility and from a licence revision application undertaken by FTC in 2012.

Details on the underlying geology/hydrogeology

Regional & Local Geology

The bedrock underlying the site is of Lower Carboniferous age, and is thought to belong to the Kinsale and the Courtmacsherry Formations. The Kinsale Formation consists mainly of calcareous mudstones or muddy limestones, while the Courtmacsherry Formation comprises calcareous mudstone, calcareous siltstone and limestone. These formations are known collectively as the Cork beds and were deposited in deep waters in the Munster basin some 360 million years ago.

After deposition, the mudstones were subject to faulting and folding. Because of the lack of outcrop in this area, there is little information on the extent of folds or faults. However in general, the faults and fold axes tend to strike east-north-east-west-south-west. The quaternary deposits consist of glacial sands, gravels and tills whilst the soils are principally brown podzolics and acid brown earths. Brown podzolics soil is generally well drained, with good moisture holding capacity. The lime-deficient acid brown earth is also free draining with good moisture holding capacity. The soil originates from glacial drift of sandstone-limestone mix, and is generally of good structure.

Geotechnical investigatory works undertaken in December 2010 have revealed the ground conditions at the proposed site of the IE43 facility is comprised of:

- Made ground.
- Glacial deposits
- Siltstone, shale, calcareous siltstone and limestone bedrock units.

Made ground was encountered in the majority of the boreholes and has a thickness of up to 3.60m. It comprises a reworked grey or grey brown sandy clayey gravel or gravelly clay with concrete constituents.

The indigenous soils comprise grey brown and reddish brown, sandy gravelly clay with medium to high cobble content. It is thought that these soils represent heavily over consolidated ablation till with local fluvio-glacial outwash deposits. The glacial till matrix is predominantly clay in nature but silt dominant till is also known to occur at the site, and was as identified during the earthworks phase of IE 42.

The rock cores taken during the site investigation confirm that bedrock in the area of the IE43 facility consists of a complex sequence of laminated siltstone, calcareous siltstone, shale and mudstone.

Surfacewater

A stream flows in an approximate northeast-southwest direction through the Lilly site. This stream originates in the hills of Clogheen and Tuckene, several kilometres to the northeast of the site, and enters the River Bandon at Doon Creek, approximately 1km to the southwest of the site.

A small tributary stream has been culverted throughout the length of the plant site. The culverted stream flows in as approximately north-south direction through the site and discharges into the larger stream at the south eastern site perimeter.

Groundwater

The site is located within the South Western River Basin District which covers most of counties Cork and Kerry, parts of Limerick, South Tipperary and Waterford and all of Cork City. The main aquifers in the southwest Cork region are isolated sand and gravel deposits. These predominantly occupy narrow stretches along the rivers, including the Bandon River.

The Geological Survey of Ireland has devised a system for classifying the aquifers in Ireland based on the hydrogeological characteristics, size and productivity of the groundwater resource. The three main classifications are Regionally Important Aquifers (RI), Locally Important Aquifers (LI) and Poor Aquifers (P).

The Geological Survey of Ireland aquifer classification for the site and surrounds is (PI) Poor Aquifer – bedrock which is Generally Unproductive except for Local Zones.

Groundwater movement in the bedrock is concentrated in fractures and fissures, and along bedding planes. These occur predominantly close to the bedrock surface. Ground water movement beneath the site has been interpreted as being in a south westerly direction. Groundwater was not encountered in any of the boreholes drilled during the December 2010 site investigation and groundwater in the bedrock appears to be confined by the overlying low permeability glacial till.

Groundwater Vulnerability

The vulnerability of a groundwater body is the term used to describe the ease with which the groundwater in the area can be contaminated by human activities.

The Geological Survey of Ireland groundwater vulnerability maps show that the main vulnerability rating in the site is 'High (H)'. The combination of poor aquifer and high vulnerability gives a resource protection zone rating of PI/H.

Groundwater Abstraction

A substantial proportion of the water used in the Lilly plant is supplied by ground water from a series of onsite boreholes. In 2013, 248,152 m³ of groundwater was used in the plant. The IPPC Licence conditions require monitoring of five ground water wells on site.

Known Incident of Groundwater Contamination

Details of a groundwater contamination incident with MTBE which occurred at the site in 2003 have been identified. The residual impacts from this incident are localised to a confined area of the site aquifer and are now considered largely remediated. Detailed information related to this incident has been previously reported in formal correspondences to the Agency and during Agency visits to the site. In addition, yearly remediation updates have been included in the Annual Environmental Reports submitted to the Agency since the incident occurred and during Agency visits to the site.

A summary of the impact of the incident, the mitigation measures that were undertaken in response to the incident and the current status of the residual groundwater impacts is provided below.

Impact of MTBE in Groundwater and Compliance with the EC Environmental Objectives (Groundwater) Regulations 2010 (S.I. No. 9 of 2010):

The following points should be considered when assessing the impact and significance of the level of MTBE in groundwater;

- The zone of residual MTBE impacts is confined to a localised area of the site aquifer with limited migration potential and no offsite impacts.
- MTBE is classified as a 'Non-Hazardous' substance in groundwater (EPA, 2010).
- A Groundwater Threshold Value for MTBE is not specified in the EC Environmental Objectives (Groundwater) Regulations 2010 (S.I. No. 9 of 2010) and therefore the presence of the compound in groundwater does not impact compliance with these regulations.
- The Agency has assigned an Interim Groundwater Guideline Value (IGV) of 30µg/l to MTBE (EPA, 2003).
- The MTBE concentration at the impacted area of the site aquifer is now being sustained in an overall downward trend below the Agency IGV of 30µg/l.

Mitigation Measures Undertaken in Response to the Presence of MTBE in Groundwater:

The following is an outline of the various mitigation measures that were implemented at the site in response to the detection of MTBE in the impacted area of the site aquifer. This includes measures that were implemented immediately after detecting the presence of the MTBE in the aquifer and in the intervening period since then in order to remediate the impacted area. The measures implemented are detailed in various reports, which are retained onsite.

- All production groundwater wells down gradient of the impacted zone were shutdown to minimise the potential for plume migration and/or expansion.
- Local and international hydro-geological consultants were retained to advise the site on an appropriate strategy to manage the issue and mitigate any immediate risks.
- A comprehensive groundwater sampling and analysis programme was implemented to characterise the nature and extent of the impacted zone.

- Further to this, the hydro-geological consultants that had been retained by the site undertook a series of comprehensive studies of the site hydrogeology throughout 2004 in order to fully understand the nature and extent of the contamination issue. This included the deployment of various advanced geophysical surveying techniques, chemical sampling and analysis and extended well pump testing.
- Based on the data gathered during the studies of the site hydrogeology, an appropriate remediation strategy was designed by the consultants that would be implemented in order to remove the bulk of the MTBE from the groundwater and sustain the concentration within acceptable levels.
- The remediation strategy required the drilling and installation of a remedial well (now renamed Well 18) in December 2004 from which to pump and remove the MTBE impacted groundwater from the aquifer for discharge to the site wastewater treatment plant. The optimal location for this remediation well was based on the information gathered during the hydro-geological studies of the site. Similarly, six optimally located sentinel wells were drilled and installed up gradient and down gradient of the remedial well in order to monitor the success of the remediation efforts.
- Pumping of the remediation well to the site wastewater treatment plant commenced in December 2004 with an immediate and significant reduction in the measured MTBE concentration in the impacted area achieved.

Current Status of the MTBE in Groundwater at the site:

- The MTBE concentration in the impacted area has fluctuated to a certain extent in the intervening years as influenced by seasonal factors (i.e. rainfall and groundwater level) and by the rate of remediation pumping.
- However, the issue is now considered largely remediated with the measured concentration at the impacted area currently being sustained below the Agency's IGV of 30µg/l and the area of MTBE impacts significantly contracted and confined to the localised zone of the site aquifer at Well 18.
- The site continues to pump groundwater from Well 18 to the site wastewater treatment plant. This includes an enhanced effort commencing in quarter one of 2012 to further improve and sustain the quality of the groundwater at this location by increased well pumping.

Proximity to identified surface water bodies

There are two surface water discharges from the site namely:

- Treated wastewater effluent discharge to coastal waters
- Storm water run-off to Doon Creek

Treated waste water emissions from the Eli Lilly site are discharged via a 9 km purpose built pipeline of approximately 25 cm in diameter. It is discharged from a multiport subtidal diffuser to coastal water east of Sandy Cove Island, outside Kinsale Harbour and south of Money Point, designated as the end of the Bandon Estuary by the EPA.

Surface water from the Eli Lilly plant discharges to the Doon (Creek) River which in turn outfalls to a transitional waterbody (Bandon River) prior to outfalling to a coastal water body (Kinsale Harbour).

The Doon Creek is not monitored as part of the Water Framework Directive (WFD), however, it outfalls to the Bandon River and Kinsale Harbour which have moderate status with the aim to achieve good status.

Proximity to sensitive human receptors

The site is located within a rural area, surrounded by fields. There are plantings around the boundary providing visual and noise screening from the site.

Sensitive receptors are once-off residential properties located on the roads along the northern and western boundaries of the site. The area to the south of the site is largely agricultural land. The wind direction is predominantly south-western.

The closest sensitive receptors are the residential properties around the site. There are no other types of sensitive receptors around the site.

There are 42 no. occupied residences within 500 m of the site boundary. The majority of these dwellings are in cluster developments to the northwest and southwest of the site. These include 3 no. dwellings to the northeast near the former Dunderrow School, two dwellings to the northwest and a cluster of dwellings to the southwest.

Details on the nearest EU or National protected site

The Dunderrow site does not form part of, nor is it in the vicinity of any Special Area of Conservation (SAC), Natural Heritage Area (NHA) or Special Protection Area (SPA). There are seven proposed designated areas within 10km of the site.

- Bandon Valley Below Innishannon pNHA (1515)
- Bandon Valley Above Innishannon pNHA (1740)
- James Fort pNHA (1060)
- Garrettstown Marsh pNHA (1053)
- Garrylucas Marsh pNHA (0087)
- Courtmacsherry Estuary pNHA (1230), SAC and SPA
- Sovereign Islands pNHA (0105) & pSPA (124)
- Bandon Valley West of Bandon pNHA (1034)

The nearest of these, 'Bandon Valley below Innishannon pNHA', site code 1515 is 3km to the west of the Lilly site.

A Natura Impact Statement Stage 1 Screening report was prepared to determine the likely impact on Special Areas of Conservation (SACs) and Special Protection Areas (SPAs) which could potentially be affected by the development of the proposed IE43 biotech manufacturing facility. This report concluded that no significant impacts are expected to occur.

3.2 Risk Identification – Risk Workshop

A risk work shop was held on February 25th 2014 at the Eli Lilly facility attended by representatives from the environmental, process and health and safety teams in Eli Lilly, as well as FTC personnel. This process facilitated the identification of plausible risks at the Eli Lilly facility, as presented in Table 3.6 following.

Table 3-6: Identified Plausible Risks at Eli Lilly S.A

Risk ID	Unit Operation	Potential Hazard	Potential Impact on Environment (HH – Human Health; AT – Atmosphere; GW – Groundwater; SW – Surfacewater; LD –Land)
1	API & Small Molecule Commercialisation – Buildings IE2, IE3 Annex, IE8, IE16, IE30	Failure of primary & secondary dust abatement systems resulting in dust release	AT – emission to atmosphere
2	API & Small Molecule Commercialisation – Buildings IE2, IE3 Annex, IE8, IE16, IE30	Failure of hydrogen system resulting in hydrogen release and ignition resulting in fire/explosion	AT – emission to atmosphere ; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater
3	API & Small Molecule Commercialisation – Buildings IE2, IE3 Annex, IE8, IE16, IE30	Solvent emission release through building ventilation system	AT – emission to atmosphere
4	API & Small Molecule Commercialisation – Buildings IE2, IE3 Annex, IE8, IE16, IE30	Solvent liquid release that escapes beyond building envelope	SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater
5	Segregated Boron Trichloride and Oxalyl Chloride gas cylinder storage area	Loss of containment of Boron Trichloride or Oxalyl chloride from storage cylinder resulting in release to atmosphere	AT – emission to atmosphere; HH – potential impact on human health
6	Biopharmaceutical Commercialisation & Supply – Buildings IE42, IE43	Accidental spill/leak within building	SW – potential contamination of surface water collection system leading to receiving water impact ; GW- potential discharge to groundwater
7		Uncontrolled release of oxygen resulting in fire/explosion	AT – emission to atmosphere ; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater
8		Uncontrolled release of GMM (genetically modified micro-organisms)	HH – potential impact on human health; SW – potential aquatic environment impact
9	Bulk Storage & Tanker Unloading – Bulk Storage (Tank Farm), Tanker Loading & Unloading, Piping to Usage point	Significant leak within tank farm	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater
10		Ignition of stored material leading to fire and/or explosion	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater
11		Spillage/loss of liquid material during loading or unloading	HH – potential impact on human health; SW – potential contamination of surface water collection system and WWTP leading to receiving water impact ; GW- potential discharge to groundwater
12		Rupture of pipeline or flange leak in piping lines originating in tank farm	SW – potential contamination of surface water collection system leading to receiving water impact
13	Waste Solvent Storage	Significant leak within storage tanks	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater
14		Ignition of stored material leading to fire and/or explosion	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater
15		Spillage/loss of liquid material during loading or unloading	HH – potential impact on human health; SW – potential contamination of surface water collection system and WWTP leading to receiving water impact ; GW- potential discharge to groundwater
16		Rupture of pipeline leading to storage tanks	SW – potential contamination of surface water collection system leading to receiving water impact
17		Uncontrolled reaction of waste materials within storage tanks leading to gaseous build up and release and liquid release	AT- impact on air quality; SW – potential contamination of surface water collection system leading to receiving water impact;
18	Warehousing – Dry Goods Storage	Dry Goods Storage - Ignition of stored material leading to fire and/or explosion	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater

Risk ID	Unit Operation	Potential Hazard	Potential Impact on Environment (HH – Human Health; AT – Atmosphere; GW – Groundwater; SW – Surfacewater; LD – Land)
19	Liquid Raw Materials Storage: Segregated into tank farm bulk storage and IE15 drum store liquid storage	Liquid Raw Materials Storage - Ignition of stored material leading to fire and/or explosion	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater
20	Gas cylinder storage pad (Hydrogen, Helium, Nitrogen, Oxygen etc.)	Bottled Gas Storage (excl Boron Trichloride & Oxalyl Chloride) - Ignition of stored material leading to fire and/or explosion	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater
21	Segregated Boron Trichloride and Oxalyl Chloride process use Gas Shed (IE8)	Boron Trichloride & Oxalyl Chloride operational use area- Ignition of stored material leading to fire and/or explosion	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater
22	Non-hazardous material storage area	Consumables Storage - Ignition of stored material leading to fire and/or explosion	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surfacewater collection system leading to receiving water impact; GW- potential discharge to groundwater
23	Utilities – IE4, IE30, IE 42 & IE 43	Ignition of natural gas boiler fuel leading to fire and/or explosion	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater
24		Uncontrolled ethylene glycol release that escapes beyond building envelope	SW – potential contamination of surface water collection system leading to receiving water impact ; GW- potential discharge to groundwater
25		Loss of ammonia to atmosphere from ammonia chillers	AT- impact on air quality; HH – potential impact on human health;
26		Loss of refrigerant to atmosphere from chillers	AT- impact on air quality
27	Engineering & Maintenance (IE9), General Administration (IE5) & Laboratory (IE28)	Fire within buildings	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater
28		Mis-classification of material being sent offsite	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water dependent on manner of treatment/disposal ; GW- potential contamination of groundwater dependent on manner of treatment/disposal
29	Emissions Abatement & Control – Fume Thermal & Liquid Oxidisers, Carbon Absorbers (decommissioned), Scrubbers, WWTPs, Membrane Filtration Plant (not in use at time of writing)	By-pass of Oxidiser leading to uncontrolled emissions	AT- impact on air quality
30		Sub- optimal performance of thermal oxidiser and/or failure of monitoring/control system on emission point, resulting in emission	AT- impact on air quality
31		Leak of caustic/acidic liquid from scrubber system	AT- impact on air quality; HH – potential impact on human health
32		Inhibition of biological process resulting in sub-optimal WWTP performance and elevated (non-compliant) discharge to receiving surface waters	SW – potential impact on receiving water due to elevated emission characteristics
33		Leaks/overflow from WWTP tanks	SW – potential contamination of surface water collection system resulting in receiving SW contamination
34		Leak from over-ground or underground pipes	SW – potential contamination of surface water collection system resulting in receiving SW contamination or GW - - potential discharge to groundwater
35		Failure or sub-optimal performance of WWTP bio-filter system	AT- release of odorous compounds impacting on air quality
36		Failure of storm water containment pond monitoring equipment resulting in elevated (non-compliant) discharge to receiving surface waters (separate from a fire event)	SW – potential receiving SW contamination

Risk ID	Unit Operation	Potential Hazard	Potential Impact on Environment (HH – Human Health; AT – Atmosphere; GW – Groundwater; SW – Surfacewater; LD –Land)
37		Overheating of Carbon Absorbers (currently decommissioned) leading to localised fire	AT- impact on air quality; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater
38		Bypass of membrane filtration plant (currently not in use) leading to active pharmaceutical ingredients (API) discharge to WWTP and receiving surface water	SW – potential contamination of surface water collection system resulting in receiving SW contamination
39	Legacy Issues – MTBE to groundwater	Failure of ongoing remediation efforts	GW- deterioration of groundwater quality
40	Operational Issues – Traffic, Power	Loss to environment of waste/raw materials due to vehicle collisions (forklifts, trucks etc.)	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system and receiving surface waters ; GW- potential discharge to groundwater
41		Power failure resulting in process shutdown/inhibition resulting in failure in one or a number of abatement plant failures	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system and receiving surface waters ; GW- potential discharge to groundwater
42		Rupture of onsite natural gas supply network	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system and receiving surface waters ; GW- potential discharge to groundwater

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3.3 Risk Analysis

In order to analyse the degree of risk, it is necessary to classify identified risks according to certain criteria, and then analyse each risk based on these criteria.

3.3.1 Risk Classification

The risk classification is based on an assessment of the probability or likelihood of occurrence of an event and following on from that, the likely severity or consequence if an event does occur. The combination of the likelihood of occurrence and likely consequence determines the Risk Score and consequently informs the assessment of worst case scenario.

$$\text{Likelihood of Event Occurrence} \times \text{Event Severity} = \text{Risk Score}$$

A 'Risk Classification Table – Likelihood' and 'Risk Classification Table – Consequence', as per the 2013 Guidance Document, are presented in Tables 3.7 and 3.8.

Table 3-7: Risk Classification Table – Likelihood (EPA, 2013)

Rating	Likelihood	
	Category	Description
1	Very Low	Very low chance of hazard occurring
2	Low	Low chance of hazard occurring
3	Medium	Medium chance of hazard occurring
4	High	High chance of hazard occurring
5	Very High	Very high chance of hazard occurring

Table 3-8: Risk Classification Table – Consequence (EPA, 2013)

Rating	Consequence	
	Category	Description
1	Trivial	No damage or negligible change to the environment
2	Minor	Minor impact/ localised or nuisance
3	Moderate	Moderate damage to environment
4	Major	Severe damage to local environment
5	Massive	Massive damage to a large area, irreversible in medium term

3.3.2 Risk Analysis

The risks identified in Table 3.6 are classified in terms of Likelihood and Consequence in accordance with Tables 3.7 and 3.8 and presented in Table 3.9.

Table 3-9: Risk Analysis Table

Risk ID	Unit Operation	Potential Hazard	Potential Impact on Environment (HH – Human Health; AT – Atmosphere; GW – Groundwater; SW – Surfacewater; LD –Land)	Consequence Rating	Basis of Consequence	Likelihood Rating	Basis of Likelihood	Risk Score
1	API & Small Molecule Commercialisation – Buildings IE2, IE3 Annex, IE8, IE16, IE30	Failure of primary & secondary dust abatement systems resulting in dust release	AT – emission to atmosphere	1	Dispersion of dust and very short duration likely before detection and remedy	1	Primary and secondary abatement system is use, overall operation monitoring control with Foxboro Distributed Control system	1
2	API & Small Molecule Commercialisation – Buildings IE2, IE3 Annex, IE8, IE16, IE30	Failure of hydrogen system resulting in hydrogen release and ignition resulting in fire/explosion	AT – emission to atmosphere ; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater	3	Moderate impact resulting from combustion products releases to atmosphere, and potential firewater release to receiving surface water and groundwater. Low expectation of firewater for significant contamination.	1	Overall process monitoring control with Foxboro Distributed Control system including audible alarm and screen messaging. Fire protection deluge system in place. Emergency Response Procedures in place	3
3	API & Small Molecule Commercialisation – Buildings IE2, IE3 Annex, IE8, IE16, IE30	Solvent emission release through building ventilation system	AT – emission to atmosphere	1	Dispersion of emission and very short duration likely before detection and remedy.	1	Overall process monitoring control with Foxboro Distributed Control system including audible alarm and screen messaging.	1
4	API & Small Molecule Commercialisation – Buildings IE2, IE3 Annex, IE8, IE16, IE30	Solvent liquid release that escapes beyond building envelope	SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater	2	Potential capture in SW collection system or leak to non hard standing area to impact GW (extensive hard standing areas in place across the site). Bulk solvents in use at the site are generally classified as WHC1 (Low Hazard to Waters).	1	Necessary for solvent to leak beyond the building envelope – catchment systems, cleaning and operational SOPs in place. Extensive site CCTV feed to constantly manned screens in Security. Regular security patrols of the site. Availability of site Emergency Response Team. Surface water collection system alarms in place.	2
5	Segregated Boron Trichloride and Oxalyl Chloride gas cylinder storage area	Loss of containment of Boron Trichloride or Oxalyl Chloride from storage cylinder resulting in release to atmosphere	AT – emission to atmosphere; HH – potential impact on human health	3	Moderate human health impact dependent on extent/quantity of release. Expect release to be rapidly dispersed with no lasting consequences for air quality.	1	Secure open area storage of cylinders. Availability of site Emergency Response Team. Very low probability of cylinder failures as per CPR 18E	3
6	Biopharmaceutical Commercialisation & Supply – Buildings IE42, IE43	Accidental spill/leak within building	SW – potential contamination of surface water collection system leading to receiving water impact ; GW- potential discharge to groundwater	1	Low hazard materials within the Biopharma unit operation, capture in internal pipe work to WWTP for treatment	1	Cleaning and operational SOPs in place	1
7		Uncontrolled release of oxygen resulting in fire/explosion	AT – emission to atmosphere; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater	2	Localised impact resulting from short term combustion product releases to atmosphere, and potential firewater release to receiving surface water and groundwater	1	Ignition source & combustibles also be required to result in fire, which limits event probability. Overall process monitoring control with Foxboro Distributed Control system including audible alarm and screen messaging Emergency Response Procedures in place	2

Risk ID	Unit Operation	Potential Hazard	Potential Impact on Environment (HH – Human Health; AT – Atmosphere; GW – Groundwater; SW – Surfacewater; LD –Land)	Consequence Rating	Basis of Consequence	Likelihood Rating	Basis of Likelihood	Risk Score
8		Uncontrolled release of GMM (genetically modified micro-organisms)	HH – potential impact on human health; SW – potential aquatic environment impact	1	Currently use only of Class 1 GMM (as per Genetically Modified Organisms (Contained Use) Organisms Regulations) at Eli Lilly. Highly sensitive cellular material that will not survive in the environment.	1	Overall process monitoring control with Foxboro Distributed Control system. Would require bypass or failure of multiple systems for an environmental release to occur (e.g. waste inactivation system at source followed by central site wastewater treatment plant).	1
9	Bulk Storage & Tanker Unloading – Bulk Storage (Tank Farm), Tanker Loading & Unloading, Piping to Usage point	Significant leak within tank farm	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater	3	Moderate impact if accompanied by bund failure/leak/overflow from potential receiving surfacewater and/or groundwater contamination. Bulk solvents stored in tank farm are generally classified as WHC 1 or 2 (Low to Medium Hazard to Waters). Remediation activities can be readily deployed at site in response to an event to limit consequences (e.g. use of remediation wells etc.).	1	Overall process monitoring control with Foxboro Distributed Control system; bund integrity testing in accordance with licence conditions. Unless there is significant bund failure, it is likely to retain the bulk of a leak. Storm water capture system, containment pond and online TOC monitoring will limit probability of significant leak escaping to surface & groundwater. PM testing program for tank farm vessels limits probability of leaks and catastrophic tank failures.	3
10		Ignition of stored material leading to fire and/or explosion	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater	3	Moderate impact resulting from combustion product releases to atmosphere, and potential firewater release to receiving surfacewater and groundwater	1	Overall process monitoring control with Foxboro Distributed Control system; IR fire detection and fire protection deluge system in place; operational SOPs in place to mitigate potential; no previous occurrence; Emergency Response Procedures in place. Storm water capture system, containment pond & continuous online TOC monitoring will limit probability of firewater escaping to surface and groundwater.	3
11		Spillage/loss of liquid material during loading or unloading	HH – potential impact on human health; SW – potential contamination of surface water collection system and WWTP leading to receiving water impact; GW- potential discharge to groundwater	2	Negligible impact as quantities that could be spilled before intervention to stop spill is likely to be very low as loading and unloading is a supervised procedure.	1	All loading and unloading takes place within a contained area that is integrity tested; loading and unloading a supervised procedure with SOP. Availability of site Emergency Response Team	2
12		Rupture of pipeline or flange leak in piping lines originating in tank farm	SW – potential contamination of surface water collection system leading to receiving water impact	3	Moderate impact possible dependent on quantity and location of rupture and leak	1	Extensive site CCTV feed to constantly manned screens in Security. Regular area operations and security patrols of the site and pipeline routes. Availability of site Emergency Response Team. Surface water collection system alarms in place. PM inspection programme of tank farm overhead pipelines.	3

Risk ID	Unit Operation	Potential Hazard	Potential Impact on Environment (HH – Human Health; AT – Atmosphere; GW – Groundwater; SW – Surfacewater; LD –Land)	Consequence Rating	Basis of Consequence	Likelihood Rating	Basis of Likelihood	Risk Score
13	Waste Solvent Storage	Significant leak within storage tanks	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater	3	Moderate impact if accompanied by bund failure/leak/overflow from potential receiving surface water and/or groundwater contamination. Bulk solvents routed to waste tank farm are generally classified as WHC 1 or 2 (Low to Medium Hazard to Waters).	1	Overall process monitoring control with Foxboro Distributed Control system; bund integrity testing in accordance with licence conditions. Storm water capture system, containment pond and online TOC monitoring will limit probability of significant leak escaping to surface & ground water. PM testing programme tank farm tanks limits probability of leaks and catastrophic tank failures.	3
14		Ignition of stored material leading to fire and/or explosion	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater	3	Moderate impact resulting from combustion product short term releases to atmosphere, and potential firewater release to receiving surface water and groundwater	1	Overall process monitoring control with Foxboro Distributed Control system; IR fire detection and fire protection deluge system in place; operational SOPs in place to mitigate potential; no previous occurrence; Emergency Response Procedures in place. Storm water capture system, containment pond & continuous online TOC monitoring will limit probability of firewater escaping to surface & groundwater.	3
15		Spillage/loss of liquid material during loading or unloading	HH – potential impact on human health; SW – potential contamination of surface water collection system and WWTP leading to receiving water impact ; GW- potential discharge to groundwater	2	Negligible impact as quantities that could be spilled before intervention to stop spill is likely to be very low as loading and unloading is a supervised procedure.	1	All loading and unloading takes place within a contained area that is also integrity tested; loading and unloading a supervised procedure with SOP. Availability of site Emergency Response Team	2
16		Rupture of pipeline leading to storage tanks	SW – potential contamination of surface water collection system leading to receiving water impact	3	Moderate impact possible dependent on quantity and location of rupture and leak	1	Extensive site CCTV feed to constantly manned screens in Security. Regular area operations and security patrols of the site and pipeline routes. Availability of site Emergency Response Team. Surface water collection system alarms in place. PM inspection programme of tank farm overhead pipelines.	3
17		Uncontrolled reaction of waste materials within storage tanks leading to gaseous build up and release and liquid release	AT- impact on air quality; SW – potential contamination of surface water collection system leading to receiving water impact;	2	Potential localised impact from short term atmospheric release. Liquid release would be retained in surrounding bund.	1	Overall process monitoring control with Foxboro Distributed Control system; fire protection deluge system in place. Process safety & environmental assessments of waste streams for new processes is likely to highlight and prevent potential waste incompatibility issues.	2

Risk ID	Unit Operation	Potential Hazard	Potential Impact on Environment (HH – Human Health; AT – Atmosphere; GW – Groundwater; SW – Surfacewater; LD –Land)	Consequence Rating	Basis of Consequence	Likelihood Rating	Basis of Likelihood	Risk Score
18	Warehousing – Dry Goods Storage	Dry Goods Storage - Ignition of stored material leading to fire and/or explosion	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater	3	Moderate impact due to nature of material - resulting from short term combustion product releases to atmosphere, and potential firewater release to receiving surface water and groundwater	1	Extensive site CCTV feed to constantly manned screens in Security. Regular security patrols of the site. Availability of site Emergency Response Team Operational SOPs in place to mitigate potential; Emergency Response Procedures in place; *Storm water capture system, containment pond & continuous online TOC monitoring will limit probability of firewater escaping to surface/groundwater.	3
19	Liquid Raw Materials Storage: Segregated into tank farm bulk storage and IE15 drum store liquid storage	Liquid Raw Materials Storage - Ignition of stored material leading to fire and/or explosion	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater	2	Localised impact due to quantity of material - resulting from short term combustion product releases to atmosphere, and potential firewater release to receiving surface water and groundwater	1	Extensive site CCTV feed to constantly manned screens in Security. Regular security patrols of the site. Availability of site Emergency Response Team Operational SOPs in place to mitigate potential; Emergency Response Procedures in place *As above regarding limited probability of firewater escape.	2
20	Gas cylinder storage pad (Hydrogen, Helium, Nitrogen, Oxygen etc.)	Bottled Gas Storage (excl Boron Trichloride & Oxalyl Chloride) - Ignition of stored material leading to fire and/or explosion	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater	2	Localised impact due to quantity of material - resulting from short term combustion product releases to atmosphere, and potential firewater release to receiving surface water and groundwater	1	Operational SOPs in place to mitigate potential; Emergency Response Procedures in place. Availability of site Emergency Response Team *As above regarding limited probability of firewater escape.	2
21	Segregated Boron Trichloride and Oxalyl Chloride process use Gas Shed (IE8)	Boron Trichloride & Oxalyl Chloride operational use area - Ignition of stored material leading to fire and/or explosion	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater	4	Potential major consequence due to toxic plume formation and movement offsite - a potential firewater release to receiving surface water and groundwater	1	Overall process monitoring control with Foxboro Distributed Control system; operational SOPs in place to mitigate potential; Emergency Response Procedures in place. Availability of site Emergency Response Team *As above regarding limited probability of firewater escape.	4
22	Non-hazardous material storage area	Consumables Storage - Ignition of stored material leading to fire and/or explosion	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surfacewater collection system leading to receiving water impact; GW- potential discharge to groundwater	2	Localised impact due to nature of material - resulting from short term combustion product releases to atmosphere, and potential firewater release to receiving surface water and groundwater	1	Extensive site CCTV feed to constantly manned screens in Security. Regular security patrols of the site. Availability of site Emergency Response Team. Operational SOPs in place to mitigate potential; Emergency Response Procedures in place *As above regarding limited probability of firewater escape.	2
23	Utilities – IE4, IE30, IE 42 & IE 42	Ignition of natural gas boiler fuel leading to fire and/or explosion	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater	2	Localised impact - resulting from short term combustion product releases to atmosphere, and potential firewater release to receiving surface water and groundwater	1	Overall process monitoring control with Foxboro Distributed Control system; mechanical controls in place to mitigate potential; Emergency Response Procedures in place; Availability of site Emergency Response Team	2

Risk ID	Unit Operation	Potential Hazard	Potential Impact on Environment (HH – Human Health; AT – Atmosphere; GW – Groundwater; SW – Surfacewater; LD –Land)	Consequence Rating	Basis of Consequence	Likelihood Rating	Basis of Likelihood	Risk Score
							*Storm water capture system, containment pond & continuous online TOC monitoring will limit probability of firewater escaping to surface & groundwater.	
24		Uncontrolled ethylene glycol release that escapes beyond building envelope	SW – potential contamination of surface water collection system leading to receiving water impact ; GW- potential discharge to groundwater	2	Localised impact – very low quantities and short duration likely before detection. Ethylene glycol is a WHC 1 material (i.e. low hazard to waters).	1	Necessary for coolant to leak beyond the building envelope – cleaning, catchment systems and operational SOPs in place. Storm water capture system, containment pond & continuous online TOC monitoring will limit probability of substance escaping to surface & groundwater.	2
25		Loss of ammonia to atmosphere from ammonia chillers	AT- impact on air quality; HH – potential impact on human health;	2	Localised short term impact – very low quantities and short duration likely before detection	1	Overall process monitoring control with Foxboro Distributed Control system; mechanical controls and gas sensors in place to mitigate potential	2
26		Loss of refrigerant to atmosphere from chillers	AT- impact on air quality	2	Localised short term impact – very low quantities and short duration likely before detection	1	Overall process monitoring control with Foxboro Distributed Control system; mechanical controls and regular preventative maintenance in place to mitigate potential	2
27	Engineering & Maintenance (IE9), General Administration (IE5) & Laboratory (IE28)	Fire within buildings	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater	2	Localised impact due to scale of building - resulting from combustion product releases to atmosphere, and potential firewater release to receiving surface water and groundwater	1	Operational, H&S SOPs & Emergency Response Procedures in place. Smoke detector and fire protection sprinkler system in place. Availability of site Emergency Response Team *As above regarding limited probability of firewater escape.	2
28		Mis-classification of material being sent offsite	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water dependent on manner of treatment/disposal ; GW- potential contamination of groundwater dependent on manner of treatment/disposal	1	Trivial impact given management by an approved waste contractor	1	Written SOPs in place for waste control (KIN-ED005, KIN-ED008, KIN-ED013, KIN-ED016, KIN-OVR-40304)	1
29	Emissions Abatement & Control – Fume Thermal & Liquid Oxidisers, Carbon Absorbers (decommissioned), Scrubbers, WWTPs, Membrane Filtration Plant (not in use at time of writing)	By-pass of Oxidiser leading to uncontrolled emissions	AT- impact on air quality	1	Negligible impact on air quality due to quantity of emission, typically short duration of emission and response procedures to minimise emissions.	3	Has occurred in past	3
30		Sub- optimal performance of thermal oxidiser and/or failure of monitoring/control system on emission point, resulting in emission	AT- impact on air quality	1	Negligible impact on air quality due to quantity of emission	1	Overall process monitoring control with Foxboro Distributed Control system; TALAS environmental reporting and monitoring system with controlled shutdowns etc.	1

Risk ID	Unit Operation	Potential Hazard	Potential Impact on Environment (HH – Human Health; AT – Atmosphere; GW – Groundwater; SW – Surfacewater; LD –Land)	Consequence Rating	Basis of Consequence	Likelihood Rating	Basis of Likelihood	Risk Score
31		Leak of caustic/acidic liquid from scrubber system	AT- impact on air quality; HH – potential impact on human health	1	Negligible impact on SW or GW quality due to quantities & type of materials (WHC1). Likely to be confined by secondary containment.	1	Overall process monitoring control with Foxboro Distributed Control system; mechanical controls in place to mitigate potential	1
32		Inhibition of biological process resulting in sub-optimal WWTP performance and elevated (non-compliant) discharge to receiving surface waters	SW – potential impact on receiving water due to elevated emission characteristics	2	Localised impact – very low quantities and short duration likely before detection, dilution effect of receiving water. Effluent routed to biological WWTP is of low polluting potential.	1	Overall process monitoring control with Foxboro Distributed Control system; Daily analysis of key control parameters.	2
33		Leaks/overflow from WWTP tanks	SW – potential contamination of surface water collection system resulting in receiving SW contamination	2	Localised impact – very low quantities and short duration likely before detection and remedy. Effluent routed to & through WWTP is of low polluting potential.	1	Operational management & written procedures; mechanical controls in place to mitigate potential; Extensive site CCTV feed to constantly manned screens in Security. Regular area operations and security patrols of the site.	2
34		Leak from over-ground or underground pipes	SW – potential contamination of surface water collection system resulting in receiving SW contamination or GW - - potential discharge to groundwater	2	Localised impact – very low quantities and short duration likely before detection and remedy. Effluent routed to & through WWTP is of low polluting potential.	1	Operational management & written procedures; mechanical controls in place to mitigate potential; Pipeline inspections etc. Extensive site CCTV feed to constantly manned screens in Security. Regular area operations and security patrols of the site.	2
35		Failure or sub-optimal performance of WWTP bio-filter system	AT- release of odorous compounds impacting on air quality	2	Localised impact – short duration likely before detection and remedy	1	Overall process monitoring control with Foxboro Distributed Control system; Regular area operations and security patrols of the site.	2
36		Failure of storm water containment pond monitoring equipment resulting in elevated (non-compliant) discharge to receiving surface waters (separate from a fire event)	SW – potential receiving SW contamination	2	Localised impact – very low quantities and short duration likely before detection, dilution effect of receiving water.	1	Overall process monitoring control with Foxboro Distributed Control system; Dual monitoring system in place; Very low probability of a failure & contamination incident coinciding.	2
37		Overheating of Carbon Absorbers (currently decommissioned) leading to localised fire	AT- impact on air quality; SW – potential contamination of surface water collection system leading to receiving water impact; GW- potential discharge to groundwater	1	Negligible impact due to scale of plant	1	Operational management & written procedures; mechanical controls in place to mitigate potential	1
38		Bypass of membrane filtration plant (currently not in use) leading to active pharmaceutical ingredients (API) discharge to WWTP and receiving surface water	SW – potential contamination of surface water collection system resulting in receiving SW contamination	2	Localised impact – very low quantities and short duration likely before detection, dilution effect of receiving water	1	Overall process monitoring control with Foxboro Distributed Control system; Operational management & written procedures; mechanical controls in place to mitigate potential	2
39	Legacy Issues – MTBE to groundwater	Failure of ongoing remediation efforts	GW- deterioration of groundwater quality	1	Existing remediation efforts are carried on as best practice to further improve groundwater – cessation of existing efforts will not result in deterioration of overall	1	Legacy issue is closed off	1

Risk ID	Unit Operation	Potential Hazard	Potential Impact on Environment (HH – Human Health; AT – Atmosphere; GW – Groundwater; SW – Surfacewater; LD –Land)	Consequence Rating	Basis of Consequence	Likelihood Rating	Basis of Likelihood	Risk Score
					aquifer GW quality resulting from legacy issues			
40	Operational Issues – Traffic, Power	Loss to environment of waste/raw materials due to vehicle collisions (forklifts, trucks etc.)	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system and receiving surface waters; GW- potential discharge to groundwater	3	Moderate impact due to nature of material - potential release to receiving surfacewater, groundwater and atmosphere	1	Site wide speed limit strictly enforced, speed camera use, appropriate logistics procedures in place onsite	3
41		Power failure resulting in process shutdown/inhibition resulting in failure in one or a number of abatement plant failures	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system and receiving surface waters; GW- potential discharge to groundwater	2	Localised impact given very short duration before backup power or ordered shutdown is implemented	1	Backup power plant availability which returns power after 1 minute; Control systems running on Uninterruptible Power Supplies (UPS)	2
42		Rupture of onsite natural gas supply network	AT- impact on air quality; HH – potential impact on human health; SW – potential contamination of surface water collection system and receiving surface waters; GW- potential discharge to groundwater	2	Localised impact due to likely short duration- resulting from combustion product/gas releases to atmosphere, and potential firewater release to receiving surface water and groundwater	1	Mechanical controls in place to mitigate potential; system design. Storm water capture system, containment pond & continuous online TOC monitoring will limit probability of firewater escaping to surface & groundwater.	2

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3.4 Risk Evaluation

Table 3.9 presents the evaluation of each risk, in terms of consequence and likelihood. Based on these evaluations, Table 3.10 presents a table of risks to enable prioritisation of same.

Table 3-10: Risk Register Assessment – by Ranking

Risk ID	Potential Hazard	Risk Score
21	Boron Trichloride & Oxalyl Chloride Storage - Ignition of stored material leading to fire and/or explosion	4
2	Failure of hydrogen system resulting in hydrogen release and ignition resulting in fire/explosion	3
5	Loss of containment of Boron Trichloride from storage cylinder resulting in release to atmosphere	3
9	Significant leak within tank farm	3
10	Ignition of stored material leading to fire and/or explosion	3
12	Rupture of pipeline or flange leak in piping lines originating in tank farm	3
13	Significant leak within storage tanks	3
14	Ignition of stored material leading to fire and/or explosion	3
16	Rupture of pipeline leading to storage tanks	3
18	Dry Goods Storage - Ignition of stored material leading to fire and/or explosion	3
29	By-pass of Oxidiser leading to uncontrolled emissions	3
40	Loss to environment of waste raw materials due to vehicle collisions (forklifts, trucks etc.)	3
4	Solvent liquid release that escapes beyond building envelope	2
7	Uncontrolled release of oxygen resulting in fire/explosion	2
17	Uncontrolled reaction of waste materials within storage tanks leading to gaseous build up and release and liquid release	2
19	Liquid Raw Materials Storage - Ignition of stored material leading to fire and/or explosion	2
20	Bottled Gas Storage (excl Boron Trichloride & Oxalyl Chloride) - Ignition of stored material leading to fire and/or explosion	2
22	Consumables Storage - Ignition of stored material leading to fire and/or explosion	2
23	Ignition of natural gas boiler fuel leading to fire and/or explosion	2
24	Uncontrolled ethylene glycol release that escapes beyond building envelope	2
25	Loss of ammonia to atmosphere from ammonia chillers	2
26	Loss of refrigerant to atmosphere from chillers	2
27	Fire within buildings	2

Risk ID	Potential Hazard	Risk Score
32	Inhibition of biological process resulting in sub-optimal WWTP performance and elevated (non-compliant) discharge to receiving surface waters	2
33	Leaks/overflow from WWTP tanks	2
34	Leak from over ground or underground pipes	2
35	Failure or sub-optimal performance of WWTP bio-filter system	2
36	Failure of storm water containment pond monitoring equipment resulting in elevated (non-compliant) discharge to receiving surface waters (separate from a fire event)	2
38	Bypass of membrane filtration plant (currently not in use) leading to active pharmaceutical ingredients (API) discharge to WWTP and receiving surface water	2
41	Power failure resulting in process shutdown/inhibition resulting in failure in one or a number of abatement plant failures	2
42	Rupture of onsite natural gas supply	2
11	Spillage/loss of liquid material during loading or unloading	2
15	Spillage/loss of liquid material during loading or unloading	2
1	Failure of primary & secondary dust abatement systems resulting in dust release	1
3	Solvent emission release through building ventilation system	1
6	Accidental spill/leak within building	1
8	Uncontrolled release of GMM (Genetically modified micro-organisms)	1
28	Mis-classification of material being sent offsite	1
30	Sub- optimal performance of thermal oxidiser and/or failure of monitoring/control system on emission point, resulting in emission	1
31	Leak of caustic/acidic solvent from scrubber system	1
37	Overheating of Carbon Absorbers (currently decommissioned) leading to localised fire	1
39	Failure of ongoing remediation efforts	1

Based on this, a risk matrix has been developed to allow the risks to be easily displayed and prioritised.

The risks are colour coded to provide a broad indication of the critical nature of each task, using the following colour code:

- Red – risks highlighted in red are considered to be high level risks requiring priority attention
- Amber – these risks are considered medium level risks requiring mitigation and/or management
- Green – (light and dark) these are identified as low level risks, however, they still require continuing awareness and monitoring on a regular basis.

Table 3-11: Risk Matrix

Likelihood	V. High	5					
	High	4					
	Medium	3	29				
	Low	2					
	V. Low	1	1, 3, 6, 8, , 28, 30, 31, 37, 39,	4, 7, 17, 19, 20, 22, 23, 24, 25, 26, 27, 32, 33, 34, 35, 36, 38, 41, 42 11, 15	2, 5, 9, 10, 12, 13, 14, 16, 18, 40	21	
			1	2	3	4	5
			Trivial	Minor	Moderate	Major	Massive
			Consequence				

4 STEP 3 - RISK TREATMENT

Risk treatment is the process to mitigate risks, e.g. by removing the risk or minimising the likelihood or consequences.

The output from this step is the preparation of a Statement of Measures to be taken in relation to the prevention of impact on the environment, which is presented in Table 4-1.

Responsibility for the carrying out of such measures is assigned in Table 4-1 to the relevant person within the Eli Lilly organisation.

As per the requirement of Condition 12.2, this Statement of Measures will be updated on an annual basis to include new risks or remove existing risk, based on the status of development or production at the facility.

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Table 4-1: Statement of Measures

Risk ID	Potential Hazard	Risk Score	Mitigation Measure	Action	Completion Date	Owner
21	Segregated Boron Trichloride and Oxalyl Chloride process use Gas Shed (IE8) Ignition of stored material leading to fire and/or explosion	4	Overall process monitoring control with Foxboro Distributed Control system; operational SOPs in place to mitigate potential; Emergency Response Procedures in place. Availability of site Emergency Response Team Area surrounding the building is hard surfaced with drainage routed to a firewater retention pond therefore minimal potential for surface water or groundwater contamination. The retention pond discharge is continuously monitored with a signal linked to the pond discharge valve which closes automatically on activation of an Agency agreed trigger limit. All site drainage systems are on an integrity test programme as per licence requirements. A groundwater pump and treat system is in place to handle any potential ground water contamination from containment system failures.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
2	Failure of hydrogen system resulting in hydrogen release and ignition resulting in fire/explosion	3	Overall process monitoring control with Foxboro Distributed Control system including audible alarm and screen messaging. Fire protection deluge system in place. Emergency Response Procedures in place.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
5	Loss of containment of Boron Trichloride or Oxalyl Chloride from storage cylinder resulting in release to atmosphere	3	Availability of site Emergency Response Team to quench gaseous release with water. Cylinders stored in hard surface area with drainage routed to firewater retention pond therefore minimal risk of surface water or groundwater contamination for the reasons outlined in risk ID 21 above. Very low probability of cylinder failures as per CPR 18E	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
9	Significant leak within tank farm	3	Overall process monitoring control with Foxboro Distributed Control system; bund integrity testing in accordance with licence conditions. Unless there is significant bund failure, it is likely to retain the bulk of a leak. Storm water capture system, containment pond and online TOC monitoring will limit probability of significant leak escaping to surface & groundwater. PM testing program for tank farm vessels limits probability of leaks and catastrophic tank failures.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
10	Ignition of stored material leading to fire and/or explosion	3	Overall process monitoring control with Foxboro Distributed Control system; IR fire detection and fire protection deluge system in place; operational SOPs in place to mitigate potential; no previous occurrence; Emergency Response Procedures in place. Availability of site Emergency Response Team. Storm water capture system, containment pond & continuous online TOC monitoring will limit probability of firewater escaping to surface and groundwater.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
12	Rupture of pipeline or flange leak in piping lines originating in tank farm	3	Extensive site CCTV feed to constantly manned screens in Security. Regular area operations and security patrols of the site and pipeline routes. Availability of site Emergency Response Team. Surface water collection system alarms in place. PM inspection programme of tank farm overhead pipelines.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management

Risk ID	Potential Hazard	Risk Score	Mitigation Measure	Action	Completion Date	Owner
13	Significant leak within storage tanks	3	Overall process monitoring control with Foxboro Distributed Control system; bund integrity testing in accordance with licence conditions Storm water capture system, containment pond and online TOC monitoring will limit probability of significant leak escaping to surface & ground water. PM testing programme tank farm tanks limits probability of leaks and catastrophic tank failures.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
14	Ignition of stored material leading to fire and/or explosion	3	Overall process monitoring control with Foxboro Distributed Control system; IR fire detection and fire protection deluge system in place; operational SOPs in place to mitigate potential; no previous occurrence; Emergency Response Procedures in place; Availability of site Emergency Response Team. Storm water capture system, containment pond & continuous online TOC monitoring will limit probability of firewater escaping to surface & groundwater.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
16	Rupture of pipeline leading to storage tanks	3	Extensive site CCTV feed to constantly manned screens in Security. Regular area operations and security patrols of the site and pipeline routes. Availability of site Emergency Response Team. Surface water collection system alarms in place. PM inspection programme of tank farm overhead pipelines.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
18	Dry Goods Storage - Ignition of stored material leading to fire and/or explosion	3	Extensive site CCTV feed to constantly manned screens in Security. Regular security patrols of the site. Availability of site Emergency Response Team Operational SOPs in place to mitigate potential; Emergency Response Procedures in place; *Storm water capture system, containment pond & continuous online TOC monitoring will limit probability of firewater escaping to surface/groundwater.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
29	By-pass of Oxidiser leading to uncontrolled emissions	3	Primary abatement systems in place to reduce potential emission. Overall process monitoring control with Foxboro Distributed Control system provides instant alert of bypass event. Emission minimisation response procedure activated immediately. Backup abatement system in place for specific process.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
40	Loss to environment of waste/raw materials due to vehicle collisions (forklifts, trucks etc.)	3	Site wide speed limit strictly enforced, speed camera use, appropriate logistics procedures in place onsite	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
4	Solvent liquid release that escapes beyond building envelope	2	Necessary for solvent to leak beyond the building envelope – catchment systems, cleaning and operational SOPs in place. Extensive site CCTV feed to constantly manned screens in Security. Regular security patrols of the site. Availability of site Emergency Response Team. Surface water collection system alarms in place.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
7	Uncontrolled release of oxygen resulting in fire/explosion	2	Ignition source & combustibles also be required to result in fire, which limits event probability. Overall process monitoring control with Foxboro Distributed Control system including audible alarm and screen messaging. Emergency Response Procedures in	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management

Risk ID	Potential Hazard	Risk Score	Mitigation Measure	Action	Completion Date	Owner
			place together with the availability of the site Emergency Response Team			
17	Uncontrolled reaction of waste materials within storage tanks leading to gaseous build up and release and liquid release	2	Overall process monitoring control with Foxboro Distributed Control system; fire protection deluge system in place. Process safety & environmental assessments of waste streams for new processes is likely to highlight and prevent potential waste incompatibility issues.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
19	Liquid Raw Materials Storage - Ignition of stored material leading to fire and/or explosion	2	Extensive site CCTV feed to constantly manned screens in Security. Regular security patrols of the site. Availability of site Emergency Response Team. Operational SOPs in place to mitigate potential; Emergency Response Procedures in place. Hard surfaced area with drainage routed to firewater retention pond therefore minimal risk of surface water or groundwater contamination for the reasons outlined in risk ID 21 above.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
20	Bottled Gas Storage (excl Boron Trichloride & Oxalyl Chloride) - Ignition of stored material leading to fire and/or explosion	2	Operational SOPs in place to mitigate potential; Emergency Response Procedures in place. Availability of site Emergency Response Team. Hard surfaced area with drainage routed to firewater retention pond therefore minimal risk of surface water or groundwater contamination for the reasons outlined in risk ID 21 above.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
22	Consumables Storage - Ignition of stored material leading to fire and/or explosion	2	Extensive site CCTV feed to constantly manned screens in Security. Regular security patrols of the site. Availability of site Emergency Response Team. Operational SOPs in place to mitigate potential; Emergency Response Procedures in place. Hard surfaced area with drainage routed to firewater retention pond therefore minimal risk of surface water or groundwater contamination for the reasons outlined in risk ID 21 above.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
23	Ignition of natural gas boiler fuel leading to fire and/or explosion	2	Overall process monitoring control with Foxboro Distributed Control system; mechanical controls in place to mitigate potential; Emergency Response Procedures in place; Availability of site Emergency Response Team. Hard surfaced area with drainage routed to firewater retention pond therefore minimal risk of surface water or groundwater contamination for the reasons outlined in risk ID 21 above.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
24	Uncontrolled ethylene glycol release that escapes beyond building envelope	2	Necessary for coolant to leak beyond the building envelope – cleaning, catchment systems and operational SOPs in place. Areas surrounding production buildings are hard surfaced with drainage routed to firewater retention pond therefore minimal risk of surface water or groundwater contamination for the reasons outlined in risk ID 21 above.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management

Risk ID	Potential Hazard	Risk Score	Mitigation Measure	Action	Completion Date	Owner
25	Loss of ammonia to atmosphere from ammonia chillers	2	Overall process monitoring control with Foxboro Distributed Control system; mechanical controls and gas sensors in place to mitigate potential. PM service contract in place on the equipment.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
26	Loss of refrigerant to atmosphere from chillers	2	Overall process monitoring control with Foxboro Distributed Control system; mechanical controls and regular preventative maintenance in place to mitigate potential. PM service contract in place on the equipment.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
27	Fire within buildings	2	Operational, H&S SOPS & Emergency Response Procedures in place. Smoke detector and fire protection sprinkler system in place. Availability of site Emergency Response Team. Areas surrounding production buildings are hard surfaced with drainage routed to firewater retention pond therefore minimal risk of surface water or groundwater contamination for the reasons outlined in risk ID 21 above.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
32	Inhibition of biological process resulting in sub-optimal WWTP performance and elevated (non-compliant) discharge to receiving surface waters	2	Overall process monitoring control with Foxboro Distributed Control system; Daily analysis of key control parameters.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
33	Leaks/overflow from WWTP tanks	2	Operational management & written procedures; mechanical controls in place to mitigate potential; Extensive site CCTV feed to constantly manned screens in Security. Regular area operations and security patrols of the site. Areas surrounding the WWTP are hard surfaced with drainage routed to firewater retention pond therefore minimal risk of surface water or groundwater contamination for the reasons outlined in risk ID 21 above.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
34	Leak from over ground or underground pipes	2	Operational management & written procedures; mechanical controls in place to mitigate potential; Pipeline inspections etc. Extensive site CCTV feed to constantly manned screens in Security. Regular area operations and security patrols of the site. Hard surfaced areas underneath all pipe arbours carrying hazardous materials with monitored run off to the firewater retention pond therefore minimal risk of surface water or groundwater contamination for the reasons outlined in risk ID 21 above. No underground pipes carrying hazardous materials. All underground pipes are on an integrity test programme as per licence requirements.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
35	Failure or sub-optimal performance of WWTP biofilter system	2	Overall process monitoring control with Foxboro Distributed Control system; Regular area operations and security patrols of the site.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management

Risk ID	Potential Hazard	Risk Score	Mitigation Measure	Action	Completion Date	Owner
36	Failure of storm water containment pond monitoring equipment resulting in elevated (non-compliant) discharge to receiving surface waters (separate from a fire event)	2	Overall process monitoring control with Foxboro Distributed Control system; Dual monitoring system in place; Very low probability of a failure & contamination incident coinciding. PM service contract in place on the equipment with weekly checks completed.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
38	Bypass of membrane filtration plant (currently not in use) leading to active pharmaceutical ingredients (API) discharge to WWTP and receiving surface water	2	Overall process monitoring control with Foxboro Distributed Control system; Operational management & written procedures; mechanical controls in place to mitigate potential	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
41	Power failure resulting in process shutdown/inhibition resulting in failure in one or a number of abatement plant failures	2	Backup power plant availability which returns power after 1 minute; Control systems running on Uninterruptible Power Supplies (UPS)	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
42	Rupture of onsite natural gas supply	2	Mechanical controls in place to mitigate potential; system design. Storm water capture system, containment pond & continuous online TOC monitoring will limit probability of firewater escaping to surface & groundwater.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
11	Spillage/loss of liquid material during loading or unloading	2	All loading and unloading takes place within a contained area that is integrity tested; loading and unloading a supervised procedure with SOP. Availability of site Emergency Response Team	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
15	Spillage/loss of liquid material during loading or unloading	2	All loading and unloading takes place within a contained area that is also integrity tested; loading and unloading a supervised procedure with SOP. Availability of site Emergency Response Team	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
1	Failure of primary & secondary dust abatement systems resulting in dust release	1	Primary and secondary abatement system is use, overall operation monitoring control with Foxboro Distributed Control system	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
3	Solvent emission release through building ventilation system	1	Overall process monitoring control with Foxboro Distributed Control system including audible alarm and screen messaging.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
6	Accidental spill/leak within building	1	Cleaning and operational SOPs in place. Availability of site Emergency Response Team	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
8	Uncontrolled release of GMM (genetically modified micro-organisms)	1	Overall process monitoring control with Foxboro Distributed Control system. Would require bypass or failure of multiple systems for an environmental release to occur (e.g. waste inactivation system at source followed by central site wastewater treatment plant).	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
28	Mis-classification of material being sent offsite	1	Written SOPs in place for waste control (KIN-ED005, KIN-ED008, KIN-ED013, KIN-ED016, KIN-OVR-40304). Waste shipments managed by experienced Waste Management Contractor.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
30	Sub- optimal performance of thermal oxidiser and/or failure of monitoring/control system on emission point, resulting in emission	1	Overall process monitoring control with Foxboro Distributed Control system; TALAS environmental reporting and monitoring system with controlled shutdowns etc.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management

Risk ID	Potential Hazard	Risk Score	Mitigation Measure	Action	Completion Date	Owner
31	Leak of caustic/acidic liquid from scrubber system	1	Overall process monitoring control with Foxboro Distributed Control system; mechanical controls in place to mitigate potential. Regular area operations and security patrols of the site.	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
37	Overheating of Carbon Absorbers (currently decommissioned) leading to localised fire	1	Operational management & written procedures; mechanical controls in place to mitigate potential. Availability of site Emergency Response Team	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management
39	Failure of ongoing remediation efforts	1	Legacy issue is closed off	Mitigation measure to be maintained on an ongoing basis	Mitigation measures already in place	Site Management

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5 STEP 4: IDENTIFICATION, QUANTIFICATION AND COSTING FOR WORST CASE SCENARIO

The 2013 Guidance Document requires that the costing of the required ELRA financial provision is based on the “*worst case scenario*” and that the worst case scenario refers to the event that “*poses the maximum environmental liability.*”

In this context, the worst case can be represent by the risk with the highest **consequence** rating, with the likelihood not being taken into account in the analysis.

The plausible risks identified with the highest consequence rating is Risk ID 21 – “boron trichloride & oxaly chloride storage - ignition of stored material leading to fire and/or explosion” with a consequence impact of “potential major consequence due to toxic plume formation and movement offsite - a potential firewater release to receiving surfacewater and groundwater”.

5.1 Risk ID 21

Costs provided in Table 5-1, as per the 2013 Guidance, provide, insofar as can be identified at this juncture, for all activities involved in the control and remediation of the relevant incident.

In attempting to provide a cost for the control and remediation of this risk, a number of assumptions must be made to “frame” the activity that must be addressed. To this end, we assume:

- Explosion/fire in the IE8 Gas Shed causing significant damage to the shed requiring decontamination, demolition, rebuild and commissioning.
- Damage to adjacent building housing electrical control panels and emergency generator resulting in decontamination, demolition, rebuild and commissioning. Minor structural damage to the south side of the IE8 production building, not affecting building equipment or operations.
- Minor damage to the west side of the IE9 building requiring window and door glass replacement.
- Requirements for 4 no. external fire tenders in addition to the onsite ERT fire tender
- Requirement to transport and incinerate firewater (hazardous waste) captured in firewater retention pond (FWRP). The FWRP, with a capacity of 6000 cubic metres, is designed for a worst case fire scenario.
- Intensive period of monitoring required by the Agency after incident

Table 5-1: Quantification and Costing of Risk ID 21

Task	Activity Description	Quantity	Unit	Rate, €	Cost, €	Source of Unit rates
Response to Risk ID 21	Fire					
	Firefighting – 4 no. external tenders	48	hour	480.00	23040	Note 1
	Firewater Transportation	6,000	cu.m	100.00	600,000	Note 2
	Firewater Disposal	6,000	cu.m	214.00	1,284,000	Note 3
	Tanker Hire	1200	day	55.00	66,000	Note 8
	Tanker Cleaning	240	tanks	250	60,000	Note 9
	Analytical testing of firewater	240	samples	150	36,000	Note 6
	Tanker loading operational costs	1152	hour	50	57,600	Note 10
	Decontamination and demolition					

Decontamination of the affected areas	480	hour	40	19,200	Note 4
Electrical and Utility isolation to the affected areas	64	hour	50	3,200	Note 13
Demolition man hours	640	hour	40	25,600	Note 11
Demolition support equipment (Crane hire)	20	days	1000	20,000	Note 14
Demolition waste disposal	20	tonnes	180	3,600	Note 12
Hazardous waste disposal (from decontamination process)	10	tonnes	1000	10,000	Note 9
Event management support					
External consultancy support	25	days	750	18,750	Note 5
Engineering management costs	30	days	750	22,500	Note 5
Monitoring					
Groundwater sampling and analysis @ 4 no. existing locations - daily for 3 months, weekly for 9 months	504	sample	150.00	75,600.00	Note 6
Surface water sampling and analysis @ 3 no. existing locations - daily 3 month, weekly 9 months	378	sample	150.00	56,700.00	Note 6
Sub-total				2,381,790	
Plus contingency @ 25%				595,448	
Plus VAT @ 23%				n/a	Note 7
Total				2,977,238	

Note 1 – Cork County Council hourly rate per tender

Note 2 – Based on waste contractor tender pricing for international transport of low CV hazardous waste for incineration (€2500 per 25 cubic metre tanker)

Note 3 – Based on waste contractor tender pricing for disposal of low CV hazardous waste by incineration

Note 4 – Based on 6 contract personnel, 8H day, for 10 days to decontaminate a building footprint of 125 square metres

Note 5 – Based on 4 contract personnel, 8H day, for 2 days

Note 6 – Laboratory rate

Note 7 – Eli Lilly S.A are VAT exempt

Note 8 – Based on an average 5 day hire period for a total of 240 tankers

Note 9 - Based on waste contractor tender pricing

Note 10- Based on 4 operators, working 12H shift, filling 240 tankers over a 24 day period.

Note 11 – Based on 4 contract personnel, 8H day, over a 20 day period

Note 12 – Based on current cost of transport and disposal of non-hazardous waste. The majority of the waste (metals) will be recoverable at zero cost.

Note 13 – Based on 4 contract personnel, 8H day, for 2 days

Note 14 – Average industrial rate

5.2 Financial Provision

The required financial provision for worst case scenario unknown environmental liability is thus based on Risk ID21 and is deemed to total **€2,977, 238**.

Eli Lilly's global property insurance policy provides significant coverage for unknown environmental liabilities that may arise at the Kinsale site.

In addition, the site also relies on the 'parental company guarantee' type financial provision to meets its obligations to cover unknown liabilities at the site. This parental company guarantee is based on the company's policy of 'self insurance' for such liabilities and relies on the strength of the company's balance sheet and its strong credit rating to confidently provide assurance of its ability to meet the known unknown liabilities for the Kinsale site.

A letter outlining this position is included in Appendix 3 to this document.

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Appendix 1

Detail on Raw Materials, Products & Intermediates

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Details of Process related Raw Materials, Intermediates, Products, etc., used or generated on the site

Ref. No. or Code	Material/ Substance(1)	CAS Number	Danger ⁽²⁾ Category	Amount Stored (tonnes)	Annual Usage (tonnes)	Nature of Use	R ⁽³⁾ - Phrase	S ⁽³⁾ - Phrase	Hazard Statement ⁽⁴⁾
	2-PROPANOL	67-63-0	F,Xi	0.1	0.5	Laboratory	11,36,67	S7,S16,S24,S25,S26	H225, H319, H336
QA384G	1,3-dimethyl-2-imidazolidinone	80-73-9	Xn (Harmful), Xi (Irritant), Reproductive Category 3	10	5	Production raw material	R21/22, R36/37, R41, R63	S26,S36,S37, S39,S45	H302, H311, H315, H318
QA528X	10% Benzyl Alcohol in Toluene (2191308)	426831-32-5 108-88-3	F (Highly Flammable), Xn (Harmful), Xi (Irritant), Reproductive Category 3	5	5	Production intermediate material	R11, R38, R48/20, R63, R65, R67, R41	S36/37, S46, S62	H225; H361d; H304; H373; H315; H336; H318
QA461M	2-(N-MORPHOLINO)ETHANE SULFACID SOD SALT	71119-23-8	Not classified as a hazardous substance.	1	0.5	Production raw material	none	none	none
QA525L	2-(N-MORPHOLINO)ETHANE SULFONIC ACID	4432-31-9	Not classified as a hazardous substance.	0.5	0.5	Production raw material	none	none	none
QA338C	2,4-DIAMINO-6-HYDROXYPYRIMIDINE	56-06-4	Not classified as a hazardous substance.	0.2	2	Production raw material	none	none	none
QA529A	20% Diisobutylaluminum Hydride in Toluene	1191-15-7, (20%) 108-88-3, (80%)	F (Highly Flammable), C (Corrosive)	0.1	0.1	Production raw material	R11; R38; R48/20; R63; R65; R67; R14/15; R17; R35	S36/37, S46, S62	H225; H304; H315; H336; H361; H362; H373A; H250; H260; H314
QD510Q	2-CHLOROETHANESULFONYL CHLORIDE	1622-32-8	T+ (Very Toxic)	Note 1	Note 1	Production raw material	R22; R26; R34	S26, S28, S36, S37, S39, S45	H301, H314, H330
QD481K	2-ETHYL-1-BUTANOL	97-95-0	Xn (Harmful)	3	6	Production raw material	R21/22	none	H312; H302
QA450U	2-Fluorotoluene	95-52-3	F (Highly Flammable), Xi (Irritant)	15	20	Production raw material	R11, R36/37/38	S23,S24,S25, S26	H225; H301; H315; H319; H335; H412

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QD506S	2-METHYLTETRAHYDROFURAN	96-47-9 (99.975%) / 128-37-0 (0.025%)	F (Highly Flammable)	3	12	Production raw material	R11; R19; R22; R36/38	none	H225
QA293L	4-(P-Hydroxyphenyl)-Butan-2-one	5471-51-2	Xn (Harmful), Xi (Irritant)	0.5	1	Starting Material	R22, R36	None	None
QA529T	5% Palladium on Carbon	7440-05-3 / 7440-44-0 / 7732-18-5	Not classified as a hazardous substance.	Note 1	Note 1	Production raw material	none	none	none
	ACETIC ACID 100 %	64-19-7	Flammable, Corrosive	1	14	Production raw material	R10, R35	S23, S26, S45	H226, H314
QA009J	Acetone	67-64-1	F (Highly Flammable), Xi (Irritant)	50	150	Production raw material / laboratory	R11, R36, R66, R67	S9,S16,S26	H225; H319; H336
QA129D	Acetonitrile	75-05-8	F (Highly Flammable), Xn (Harmful), Xi (Irritant)	50	80	Production raw material / laboratory	R11, R20/21/22, R36	S16,27,35	H225; H332; H312; H302; H319
QD477T	ACETYL CHLORIDE	75-36-5	F (Highly Flammable), C (Corrosive)	Note 1	Note 1	Production raw material	R11; R14; R34	S9, S16, S26, S45	H225; H314
QD531X	Activated Carbon (Ecosorb C947)	7440-44-0 / 9002-88-4	Not classified as hazardous	Note 1	Note 1	Production raw material	none	none	none
QA014N	Alcohol s d no. 3a absolute	64-17-5	F(Highly Flammable), Xn (Harmful)	50	350	Production raw material	R11	S7, S16	H225
QA432P	Amberlyst 15 Resin	39389-20-3	Not assigned an overall EC classification.	0.5	2	Production raw material	R36	S26, S36	H319
	Anhydrous Ammonia	7664-41-7	Toxic, corrosive, dangerous for the environment	6	30	Utilities	R10, R23, R34, R50	S9, S16, S26, S36/37/39, S45, S61	H221, H280, H314, H331, H400
QA098M	Amyl Acetate (98%)	628-63-7	Flammable	40	100	Production raw material	R10, R66	S23,S25	H226

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QA241V	ANTIFOAM C EMULSION	63148-62-9/ 556-67-2/ 541-02-6/ 9004-67-5/ 67762-90-7	Xn (Harmful)	0.025	0.1	Production raw material	R50, R53, R62		H319; H335
QA440Y	Atomoxetine Hydrochloride	82248-59-7	T (Toxic), Xi (Irritant), N (Dangerous for the Environment)	5	20	Production final material	R23/25, R41, R50/53	S26,S28,S36, S37,S39,S45	H330; H301; H318; H336; H373; H400; H410
QA455S	Atomoxetine Mandelate	83113-55-7	T (Toxic), Xi (Irritant), Xn (Harmful), N (Dangerous for the Environment)	0.25	20	Production intermediate material	R22, R23, R41, R50/53	S26,S28,S36, S37,S39,S45	H330; H302; H318; H336; H373; H400; H410
QA176V	Bentonite clay	1302-78-9	Not a hazardous substance or mixture	2.5	5	Production raw material	none	none	none
QA408D	Benzodiazepine Hydrochloride	138564-60-0	Xn (Harmful), Xi (Irritant)	1	50	Production intermediate material	R20/22, R41	none	H302; H332; H318
QA508W	Benzoic acid tech	65-85-0	Xn (Harmful), Xi (Irritant)	1.5	6	Production raw material	R37, R41	S26, S39	H318, H335
QD515T	BENZOTETRAZOLE	503293-47-8	Xi (Irritant)	Note 1	Note 1	Production intermediate material	R22, R36/37/38	S26	H302, H315, H319, H335, H336
QA440C	Benzothiophene	63675-74-1	Not assigned an overall EC classification.	20	50	Production intermediate material	none	none	none
QA543H	Benzyl Edivoxetine Fumarate (LSN2398789)	None available	Not assigned an overall EC classification.	0.025	0.1	Production intermediate material			H318
QA421J	Beta Ketosulfide	63675-73-0	N (Dangerous for the Environment)	30	60	Starting Material	R51/53		H411

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QA417G	Boron trichloride	10294-34-5	T+ (Very Toxic), C (Corrosive)	20	70	Production raw material	R14, R26/28, R34	S9,S26,S28,S36,S37,S39,S45	H280, H300, H314, H330
QA178R	Bromine	7726-95-6	T+ (Very Toxic), C (Corrosive), N(dangerous to the environment)	0.5	1	Production raw material	R26, R35, R50	S7/9, S26, S45, S61	H330; H314; H400
QA518Y	CARBON DIOXIDE GAS	124-38-9	Not classified as a hazardous substance.	0.5	2	Production raw material	none	none	none
QA292B	Caustic Soda 25%	1310-73-2 7732-18-5	Contains Sodium Hydroxide (C = 7.4 - 25%), C (Corrosive)	20	400	Production raw material	R35	S26, S37, S39, S45	H314
QA521L	CD-17 MEDIA	None available	Not classified as a hazardous substance.	0.25	4	Production raw material	none	none	none
QA525T	CHEMATIC 1700CL	1310-58-3 (10-30%) 7681-52-9 (1-5%)	C (Corrosive), Xn (Harmful)/ C (Corrosive), N (Dangerous to the environment)	0.5	8	Production raw material	R22, R35/ R31, R34, R50	S26, S36/37/39, S45	H302, H314
QA428V	Chlorodimethoxy triazine	3140-73-6	Xn (Harmful), C (Corrosive)	0.25	1.5	Production raw material	R20/22, R 34, R 41	S26, S36/37	H302; H315; H318; H317; H411
QA525D	CHO CELL CUSTOM ACID FEED	None available	Not classified as a hazardous substance.	0.01	0.2	Production raw material	none	none	none
QA525C	CHO CELL CUSTOM NEUTRAL FEED	None available	Not classified as a hazardous substance.	0.65	2	Production raw material	none	none	none
QA525K	CHO CUSTOM ACID FEED W/O TYROSINE	None available	Not classified as a	0.075	0.5	Production raw material	none	none	none

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			hazardous substance.						
QA525G	CHT HYDROXYAPATITE RESIN	1306-06-5	Not classified as a hazardous substance.	0.075	0.6	Production raw material	none	none	none
QA470J	CIP100	1310-58-3 64-02-8	C, Xn	15	40	Production raw material	R22, R35	2,24,25,26,3 6,37,39	
QA470J	CIP200	1310-58-3, 64-02-8	C, Xn	15	60	Production raw material, Maintenance & Utilities	R22, R35	2,24,25,26,3 6,37,39	
QA300L	Cis-3,5-dimethylpiperidine	35794-11-7	T (Toxic), C (Corrosive)	Note 1	Note 1	Production raw material	R10, R24/25, R34, R41	S26, S28, S36, S37, S39, S45	H226, H315, H319, H335
QA525W	CITRIC ACID ANHYDROUS POWDER 60 GU	77-92-9	Xi (Irritant)	0.01	0.2	Production raw material	R36	S26	H319
QA525H	CUSTOM NEUTRAL FEED W/O GLUCOSE	None available	Not classified as a hazardous substance.	0.25	0.5	Production raw material	none	none	none
QA360F	D, l-Octopamine hydrochloride	770-05-8	Xn (Harmful), Xi (Irritant)	0.25	1.5	Starting Material	R22, R36	S22,S36,S37	H302, H312, H332
QD504K	Darco G60	99439-28-8	Not classified	0.15	0.5	Production raw material			
QA452H	Deazaguanine acid	137281-39-1	Not assigned an overall EC classification.	0.15	0.5	Production intermediate material	Not assigned an overall EC classification.	Not listed	
QA511X	DEC-Bromosulfoxide (DBS)	None available	Xn (Harmful)	Note 1	Note 1	Production intermediate material	R62, R63		
QA521D	DEXTROSE (GLUCOSE ANHYDROUS)	50-99-7	Not classified as a hazardous substance.	0.75	1.5	Production raw material	none	none	none
QA048G	DIBASIC SODIUM PHOSPHATE CRYSTALS	7782-85-6	Not classified as a	0.5	2	Production raw material	none	none	none

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			hazardous substance.						
	Dichloromethane	75-09-2	Xn (Harmful)	Note 1	Note 1	Laboratory	R40	S23, S24/25, S36/37	H351
	Diesel	68476-34-6	Carcinogen, dangerous for the environment, flammable	20	40	Utilities, Maintenance & Utilities	R20, R38, R40, R51/53, R65	S2, S24, S36/37, S61, S62	H304, H315, H332, H351, H373, H411
QA509D	Dimethyl sulfoxide high purity grade	67-68-5	Xi (Irritant)	5	100	Production raw material, Laboratory	R36/37/38	S23,S24,S25, S26	
QA066F	Dimethylformamide	68-12-2	T (Toxic), Xn (Harmful), Xi (Irritant), Reproductive Category 2	15	100	Production raw material	R20/21, R36, R61	S45, S53	H226, H312,H319,H332, H360
QD531U	DPEPhos	166330-10-5	Not classified as hazardous	0.005	0.1	Production raw material	none	none	none
QD498S	ETHANOL 70% SOLUTION	64-17-5	F (Highly Flammable)	20	20	Production raw material	R10	none	H225
QA025Q	Ethyl acetate	141-78-6	F (Highly Flammable), Xi (Irritant)	50	200	Production raw material, Laboratory	R11, R36, R66, R67	S16,S26,S33	H225; H319; H336
QD508S	ETHYLAMINE (70% SOLUTION)	75-04-7 (70%) 7732-18-5 (30%)	F+ (Extremely Flammable); Xi (Irritant)	Note 1	Note 1	Production raw material	R11, R35, R37	S16, S26, S36/37/39, S45	H225, H314, H335
QA014C	Ethylene Dichloride	107-06-2	F (Highly Flammable), T (Toxic), Xn (Harmful), Xi (Irritant), Carcinogen Category 2	75	250	Production raw material	R11, R 22, R 36/37/38, R45	S45,S53	H225; H350; H302; H319; H335; H315

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N/A	Ethylene Glycol (Dowcal 10)	107-21-1	Xn (Harmful)	25	10	Maintenance & Utilities	22	none	H302
QA107D	Formic acid 98 percent	64-18-6	C (Corrosive)	Note 1	Note 1	Production raw material	R10, R35	S23, S26, S45	H226, H314
QD501L	FUMARIC ACID	110-17-8	Xi (Irritant)	0.01	0.5	Production raw material	R36	S26	H319
QA008H	GLACIAL ACETIC ACID	64-19-7	C (Corrosive)	0.1	1	Production raw material	R10, R35	S23, S26, S45	H226; H314
QA525Z	GLP FC	None available	Classification Pending	0.6		Production final material			
	Glycol	107-21-1	Xn (Harmful)	27	27	Utilities	R22	none	H302
NA	Granular Salt	7647-14-5	None	6	50	Maintenance & Utilities	none	none	none
QA521M	GSEM SUPPLEMENT	None available	Not classified as a hazardous substance.	Note 1	Note 1	Production raw material	none	none	none
QA525A	HEPES BUFFER	7365-45-9	Not classified as a hazardous substance.	0.02	0.2	Production raw material	none	none	none
QA172G	Heptane	142-82-5	F (Highly Flammable), Xn (Harmful), Xi (Irritant), N (Dangerous for the Environment)	50	50	Production raw material	R11, R38, R50/53, R65, R67	S9, S16, S29, S33, S60, S61, S62	H225; H304; H315; H336; H410
QD518T	HY10275 PHOSPHATE MICRONISED		Not classified as a hazardous substance according to Directive 67/548EEC	Note 1	Note 1	Production			

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QD515BSEED	HY10275 PHOSPHATE SEED	1097939-06-4	Not classified as a hazardous substance according to Directive 67/548EEC	0.15	0.5	Production final material			
	HYDRANAL-COMPOSITE 5 K ONE			Note 1	Note 1	Laboratory			
	HYDRANAL-COULOMAT AG			Note 1	Note 1	Laboratory			
	HYDRANAL-WORKING MEDIUM K SOLVENT			Note 1	Note 1	Laboratory			
QA093U	Hydrobromic Acid	10035-10-6 (HBr) 7732-18-5 (H2O)	C (Corrosive); Xi (Irritant)	1	4	Production raw material	R34; R37	S7/9, S26, S45	H314; H335
QA189B/QA512A	Hydrochloric Acid	7647-01-0	C (Corrosive)	20	100	Maintenance & Utilities	R34, R37	S26,S45	H314; H335; H290
QA030N	Hydrogen	1333-74-0	F+ (Extremely Flammable)	0.25	25	Production raw material	R12	S9, S16, S33	H280; H220
QD516V	HYDROXYQUINOLINE	503293-98-9	Not classified as a hazardous substance.	Note 1	Note 1	Production intermediate material			
QA171H	Isobutanol	78-83-1	Xi (Irritant)	40	50	Production raw material	R10; R37/38; R41; R67	S7/9, S13, S26	H226; H315; H318; H335; H336
QA028J	Isopropyl alcohol	67-63-0	F (Highly Flammable), Xi (Irritant)	45	100	Production raw material	R11, R36, R67	S7, S16, S24/25, S26	H225; H319; H336
QA516Q	K-tBuO in Tetrahydrofluoride (KTB in THF)	865-47-4 109-99-9	F (Highly Flammable), C (Corrosive), Xn (Harmful)	0.5	2	Production raw material	R11, R14, R19, R35, R36/37	S7/9, S16, S26, S29, S33,S36/37/39, S45	H225, H319,H228, H252, H314, H335
QA521F	L METHIONINE SULFOXIMINE	15985-39-4	Xi (Irritant)	0.01	0.1	Production raw material	R36/37/38	S26, S36	H315; H319; H335
QA292T	L(+)mandelic acid	17199-29-0	Xi (Irritant)	0.075	5	Production raw material	R37, R41		H315; H318; H335

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QD520J	LACTAM 55962	No info available	Classification Pending	Note 1	Note 1	Production intermediate material			
QA521J	L-ASPARAGINE MONOHYDRATE	70-47-3	Not classified as a hazardous substance.	Note 1	Note 1	Production raw material	none	none	none
QA521K	L-ASPARTIC ACID	56-84-8	Xi (Irritant)	Note 1	Note 1	Production raw material	R36	S26	H319
QA521E	L-CYSTINE	56-89-3	Not classified as a hazardous substance.	Note 1	Note 1	Production raw material	none	none	none
QA434B	LGlutamic acid diethyl ester hydrochloride	1118-89-4	Not classified as a hazardous substance.	1.5	2.5	Production raw material	none	none	none
QA446V	Liquid nitrogen	7727-37-9	Not assigned an overall EC classification.	25	500	Production raw material	none	none	none
QA525E	L-proline	147-85-3	Xi (Irritant)	0.1	0.1	Production raw material	none	none	none
QD530S	LSN 2808053	n/a	Not classified as hazardous	Note 1	Note 1	Production intermediate material			H318
QD531P	LSN 417420	n/a	Xn (Harmful)	0.225	1	Production intermediate material	R22		H302; H318
QD532N	LSN2963227	n/a	T (Toxic); Repr. Cat 2	0.015	0.5	Production intermediate material	R25; R61		H301; H361; H373
QA521G	L-TYROSINE	60-18-4	Xi (Irritant)	Note 1	Note 1	Production raw material	R36/37/38	S26	H315; H319; H335
QA525R	L-TYROSINE DISODIUM DIHYDRATE	122666-87-9	Xi (Irritant)	0.01		Production raw material	R36/37/38	S26	H315, H319, H335
QD509S	LY2523301 - 'BOC-SM'	No info available	Classification Pending	Note 1	Note 1	Production intermediate material			

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QD508W	LY2523303 - HCl SALT	910788-86-2	Classification Pending	Note 1	Note 1	Production intermediate material			
QD507D	LY2523355 - EG5	No info available	T+ (Very Toxic); Mutagen Cat. 2; Reprotoxin Cat. 2	Note 1	Note 1	Production final material	R28; R46; R60; R61		H300; H341; H360; H370; H372
QD518H	LY2553929 FUMARIC ACID SALT	No info available	Classification Pending	Note 1	Note 1	Production intermediate material			
QD518HSEED	LY2553929 FUMARIC ACID SALT SEED	No info available	Classification Pending	Note 1	Note 1	Production intermediate material			
QD519M	LY2784544	n/a	Xn (Harmful); T (Toxic)	0.01	0.1	Production final material	R22; R61		H302; H361; H373
	LY2189265 (Glp-Fc)			0.1	0.5				
	LY2127399 (LA294)			0.1	0.5				
	LY2439821 (LA426)			0.1	0.5				
	LY3009806 (IMC-1121B)			0.1	0.5				
QA521H	MAB SELECT RESIN	64-17-5 (Ethanol) 9012-36-6 (Agarose)	F (Highly Flammable)	0.1	1	Production raw material	R10		
QA408U	Magnesium Turnings	10035-10-6	F (Highly Flammable)	0.025	0.1	Production raw material	R11; R15		H228; H252; H261
QA525F	MEDIUM R ACIDIFIED	None available	Not classified as a hazardous substance.	0.65	1	Production raw material			
QA521C	MEM AMINO ACID SOLUTION	None available	C (Corrosive)	0.01	0.1	Production raw material	R34, R41		
QA157J	Methanesulfonic acid Technical	75-75-2	C (Corrosive)	0.5	15	Production raw material	R34		H314

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QA043W	METHANOL	67-56-1	F (Highly Flammable), T (Toxic)	50	1000	Production raw material, Laboratory	R11, R23/24/25 - R39/23/24/25		H225; H331; H311; H301; H370
QA082D	Methyl Ethyl Ketone	78-93-3	F (Highly Flammable), Xi (Irritant)	Note 1	Note 1	Production raw material	R11, R36, R66, R67		H225; H319; H336
QA507F	Methylglyoxylate	616898-64-7	Xi (Irritant)	Note 1	Note 1	Production intermediate material	R36		
QA415M	Methylparaben	99-76-3	Xi (Irritant)	15	45	Production raw material	R36/37/38	S26, S36	H315, H319, H335
QA533G	MTA ALDEHYDE	908145-87-9	Not classified as a hazardous substance	0.5	5	Production intermediate material			
QA454C	MTA Glutamate	165049-28-5	Not assigned an overall EC classification	3	5	Production intermediate material	Not assigned an overall EC classification.	Not listed	
	N,N-DIMETHYLFORMAMIDE	68-12-2		Note 1	Note 1	Laboratory	R61, R20/21, R36	S53, S45	H226, H312, H319, H332, H360D
NA	Nalco 77261	1310-73-2, 7757-83-7		5	12	Maintenance & Utilities			
	Nalco Water Treatment 1318			2	3	Utilities			
	Nalco Water Treatment 22310			0.5	2	Utilities			
	Nalco Water Treatment 3DT289			2	6	Utilities			
	Nalco Water Treatment 77211			0.5	2	Utilities			
	Nalco Water Treatment 77393	68515-73-1		1	1	Utilities			
	Nalco Water Treatment 93033			5	12	Utilities			
n/a	Natural Gas				7*10 ⁶ m3	Maintenance & Utilities			
QA009H	N-Butanol	71-36-3	Xn Harmful, Xi Irritant	25	50	Production raw material	R10, R22, R37/38, R41, R67		H226; H302; H335; H315; H318; H336

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	N-HEXANE	110-54-3	F (Flammable), Xn (Harmful), N (Dangerous for the Environment)	0.01	0.1	Laboratory	R11, R38, R48/20, R62, R65, R67, R51/53	S9, S16, S29, S33, S36/37, S61, S62	H225, H304, H315, H336, H361F, H373, H4113
NA	Nitric Acid	7697-37-2		0.01	0.1	Maintenance & Utilities			
QA209B	Nitrogen (oxygen free)	7727-37-9		50	1750	Production raw material, Maintenance & Utilities			
QA506Z	N-methylindole-acetamide	150114-41-3	Not assigned an overall EC classification.	0.1	0.5	Starting Material	Not assigned an overall EC classification.		
QA290M	N-methylmorpholine	109-02-4	F (Highly Flammable), Xn (Harmful), C (Corrosive)	0.5	3	Production raw material	R11, R22, R34	S9, S16, S26, S36, S37, S39, S45	H225; H314; H318; H302; H312; H332
QA380P	N-methylpiperazine	109-01-3	C (Corrosive)	3.5	15	Production raw material	R10, R34	9, 16, 26, 36, 37, 39, 45	H226; H312; H314
QD514D	N-TETRABUTYLAMMONIUM HYDROXIDE	2052-49-5	C (Corrosive)	0.01	0.1	Production raw material	R35		
QA402E	Olanzapine	132539-06-1	T (Toxic), Xi (Irritant)	6.5	15	Production final material	R25, R36, R43, R52	26, 28, 36	H310; H319; H317; H336; H373; H411
	ORTHO-PHOSPHORIC ACID 85%	7664-38-2	C (Corrosive)	0.25	1	Laboratory	R34	S26, 45, 24/25, 36/37/39,	
QA226P	Oxalyl chloride	79-37-8/75-44-5/76-02-8	T+ (Very Toxic), C (Corrosive)	2	20	Production raw material	R14/15, R20/22, R29, R35, R37	S8, S26, S28, S36/37/39, S43, S45	H260; H310; H331; H314; H335; H373; EUH059

Ref. No. or Code	Material/ Substance(1)	CAS Number	Danger ⁽²⁾ Category	Amount Stored (tonnes)	Annual Usage (tonnes)	Nature of Use	R ⁽³⁾ - Phrase	S ⁽³⁾ - Phrase	Hazard Statement ⁽⁴⁾
QD518N	OXAZEPINE METHYL ESTER 2629863	No info available	Classification Pending	Note 1	Note 1	Production intermediate material			
QD518NSEED	OXAZEPINE METHYL ESTER 2629863 SEED	No info available	Classification Pending	Note 1	Note 1	Production intermediate material			
QA511Q	Palladium 10% on carbon	7440-05-3/7440-44-0	F (Highly Flammable)	0.025	0.5	Production raw material	R11		
QA459J	Pamoic acid	130-85-8	Xi (Irritant)	0.65	1	Production raw material	R36/37/38		H302; H319; H400
QA449E	Pemetrexed Disodium Heptahydrate	150399-23-8/357166-29-1	T (Toxic), Xi (Irritant), Xn (Harmful) Mutagen Category 3, Reproductive Category 1	0.75	1	Production final material	R36/38, R60, R61, R68		H315; H341; H360; H372
QA337V	Phenyl Methyl Amino Propanol	42142-52-9	Xi (Irritant)	5	14	Starting Material	R38, R41		H315; H318
QA053Y	PHOSPHORIC ACID	7664-38-2	C (Corrosive)	0.5	5	Production raw material	R34	S26,S45	H314
QD523L	PHOSPHORUS OXYCHLORIDE	10025-87-3	T+ (Very Toxic), T (Toxic), Xn (Harmful), C (Corrosive)	Note 1	Note 1	Production raw material	R14, R22, R23, R26, R29, R35, R48		H330; H372; H302; H314
QA380W	Piperidinoethylchloride (hcl)	2008-75-5	T+ (Very Toxic), C (Corrosive), Mutagen Category 3	25	40	Production raw material	R26/28, R34, R68		H300; H314; H341
QA413P	Piperidinyl Ethoxy Benzoic Acid	84449-80-9	Xi (Irritant),	20	40	Production intermediate material	R36	25, 26	H319
QA460F	PiperidinylEthoxyPhenol (PEP)	100238-42-4	Xn Harmful, Xi Irritant	Note 1	Note 1	Starting Material	R22, R37/38, R41		
QA375N	Platinum 5% on carbon, water wet	7440-06-4/7440-44-0	Not assigned an overall EC classification.	0.1	1	Production raw material	36/37/38	S22,S24,S25, S26	

Ref. No. or Code	Material/ Substance(1)	CAS Number	Danger ⁽²⁾ Category	Amount Stored (tonnes)	Annual Usage (tonnes)	Nature of Use	R ⁽³⁾ - Phrase	S ⁽³⁾ - Phrase	Hazard Statement ⁽⁴⁾
QA455L	POLYSORBATE 80 VEGETABLE	9005-65-6	Xi (Irritant)	Note 1	Note 1	Production raw material	R36/38		
QD518F	POTASSIUM BICARBONATE	298-14-6	Not classified as a hazardous substance.	Note 1	Note 1	Production raw material			
QA051U	Potassium Carbonate	584-08-7	Xn (Harmful), Xi (Irritant)	5	60	Production raw material	R22, R37/38, R41		H319; H315; H335
QD518B	POTASSIUM CHLORIDE	7447-40-7	Not classified as a hazardous substance.	1	15	Production raw material			
QD518B	Potassium hydroxide	1310-58-3	Xn (Harmful), C (Corrosive)	1	15	Production raw material	R22, R35	26,27,39,45	H302, H314
	POTASSIUM PHOSPHATE MONOBASIC	7778-77-0		Note 1	Note 1	Laboratory			
QA508Z	Potassium t-amylate in toluene	41233-93-6/108-88-3	C (Corrosive), F (Highly Flammable), Xn (Harmful)	Note 1	Note 1	Production raw material	R11, R14/15, R20, R35		
QA307V	Potassium tert-butoxide	865-47-4	C (Corrosive)	2.5	5	Production raw material	R14, R35		
	Propanol	71-23-8		0.01	0.5	Laboratory			
QA144S	P-Toluene sulfonic acid 96%	104-15-4	Xi (Irritant)	2.5	8	Production raw material	R36/37/38		H319; H335; H315
QA525J	Q SEPHAROSE HIGH PERFORMANCE RESIN	64-17-5 (18-24%)	F (Highly Flammable)	0.1	0.5	Production raw material	R11		
QA420Y	Raloxifene Hydrochloride	82640-04-8	T (Toxic), Reproductive Category 1, Carcinogen Category 3, N (Dangerous to the Environment)	20	40	Production final material	R40, R50/53, R60, R61	22,36,37,57	H360; H351; H410

Ref. No. or Code	Material/ Substance(1)	CAS Number	Danger ⁽²⁾ Category	Amount Stored (tonnes)	Annual Usage (tonnes)	Nature of Use	R ⁽³⁾ - Phrase	S ⁽³⁾ - Phrase	Hazard Statement ⁽⁴⁾
N/A	Sabre P1074XL	NA		Note 1	Note 1	Maintenance & Utilities			
	Salt	7647-14-5		6	50	Utilities			
QA528Z	S-Benzylmorpholine Mesylate (Production intermediate material 2463667)	1120335-14-9	Xn (Harmful), Xi (Irritant),	0.175	1	Production intermediate material	R22, R36		H302; H318
QA523U	SERINE	56-45-1		Note 1	Note 1	Production raw material			
QD521V	SIDCHAIN 2800797	No info available	Classification Pending	0.01	0.1	Production intermediate material			
QA525U	SOD PHOSPHATE MONOBASIC MONOHYDRATE GU	7558-80-7	Not classified as a hazardous substance.	0.03	0.5	Production raw material			
QA121Z	SODIUM ACETATE ANHYDROUS	127-09-3	Not classified as a hazardous substance.	0.01	0.1	Production raw material			
QA476V	SODIUM BICARBONATE - CELL CULTURE GRADE	144-55-8	Not classified as a hazardous substance.	0.01	0.1	Production raw material			
QA052N	SODIUM BISULFITE	7631-90-5	Xn (Harmful)	Note 1	Note 1	Production raw material	R22, R31		H302
QA058U	Sodium Carbonate	497-19-8	Xi (Irritant)	0.01	0.2	Production raw material	R36		H319
QD515H	SODIUM CHLORIDE	7647-14-5	Not classified as a hazardous substance.	0.1	2	Production raw material			
QA044D	SODIUM CITRATE GRANULAR	6132-04-3	Not classified as a hazardous substance.	0.1	1	Production raw material			
QD520S	SODIUM HYDROXIDE	1310-73-2	C (Corrosive)		20	Production raw material	R35		H314

Ref. No. or Code	Material/ Substance(1)	CAS Number	Danger ⁽²⁾ Category	Amount Stored (tonnes)	Annual Usage (tonnes)	Nature of Use	R ⁽³⁾ - Phrase	S ⁽³⁾ - Phrase	Hazard Statement ⁽⁴⁾
QA188K	Sodium Hypochlorite	7681-52-9		1	5	Maintenance & Utilities	31,34	S28,S45,S50	
	Sodium Meta Bi Sulphite			6	20	Utilities	37/38,41,42,43	S26,S36,S37,S39	
QA523W	SODIUM PHOSPHATE DIBASIC	7558-79-4		Note 1	Note 1	Production raw material			
QA520Y	SODIUM PHOSPHATE MONOBASIC MONOHYDRATE	10049-21-5		Note 1	Note 1	Production raw material			
QA307D	Sulfuric acid 50%	7664-93-9	Contains sulfuric acid (C = 10 to 51%), C (Corrosive)	4	15	Production raw material	R35	S26,S30,S45	H314
	Sulphuric Acid 96% Bulk	7664-93-10	Contains sulfuric acid (C = 10 to 51%), C (Corrosive)	20	50	Utilities	R36	S26,S30,S46	H315
QD530H	t-Amyl Alcohol	75-84-4	F (Highly Flammable); Xn (Harmful); Xi (Irritant)	Note 1	Note 1	Production raw material	R11; R20; R37/38; R41		H318; H315; H312; H332; H225; H335
QA329E	T-butyl methyl ether	1634-04-4	F (Highly Flammable); Xi (Irritant)	25	100	Production raw material	R11, R38		H225; H315
QA405K	TCN Production intermediate material	138564-59-7	N (Dangerous for the Environment)	1	7	Starting Material	R50/53	S61	H410
QD294Y	TERTIARY BUTANOL	75-65-0	F (Highly Flammable); Xn (Harmful); Xi (Irritant)	0.01	0.2	Production raw material	R11, R20, R36/37		H225; H332
	TETRADECYLTRIMETHYLAMMONIUM BROMIDE			Note 1	Note 1	Laboratory			
QD485V	TETRAHYDROFURAN ANHYDROUS	109-99-9	F (Highly Flammable); Xi (Irritant)	6	10	Production raw material	R11-19, R36/37	16,29,33	H225; H319; H335
QA375B	Tin (ii) chloride anhydrous	7772-99-8	Xn (Harmful); Xi (Irritant)	2.5	20	Production raw material	R22, R36/37/38		

Ref. No. or Code	Material/ Substance(1)	CAS Number	Danger ⁽²⁾ Category	Amount Stored (tonnes)	Annual Usage (tonnes)	Nature of Use	R ⁽³⁾ - Phrase	S ⁽³⁾ - Phrase	Hazard Statement ⁽⁴⁾
QA071Y	Toluene	108-88-3	F (Highly Flammable), Xn (Harmful), Xi (Irritant), Reproductive Category 3	50	150	Production raw material	R11, R38, R48/20, R63, R65, R67	S16,S25,S29, S33	H225; H361d; H304; H373; H315; H336
QD498N	TRIETHYLAMINE	121-44-8	F (Highly Flammable), Xn (Harmful), C (Corrosive)	Note 1	Note 1	Production raw material	R11, R20/21/22, R35		H225; H332; H312; H302; H314
QA414P	TRIS BASE	77-86-1	Not classified as a hazardous substance.	0.5	1.5	Production raw material			
QA428E	TRIS HYDROCHLORIDE	1185-53-1	Xi (Irritant)	0.5	3	Production raw material	R36/37/38		
QA289D	TRITON X-100	25322-68-3/ 9036-19-5	Xn (Harmful), Xi(Irritant), N (Dangerous to the Environment)	0.1	1	Production raw material	R22, R37/38, R41, R51		H302; H318
QA521B	YEASTOLATE MEDIA - ULTRAFILTRATE (50x)	None available	Not classified as a hazardous substance.	0.01	0.5	Production raw material			

Appendix 2

Emission Point Details

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Emissions to Atmosphere

Atmospheric emissions from the site can be categorised into:

- Boiler emissions
- Main emissions
- Minor Emissions
- Potential emissions

The following tables outline the emission point's onsite under these categories.

Main Atmospheric Emission Points

Main Emission Point	Current label	Proposed Label
Boilers	4-1	A1-1
Proposed CHP boiler	N/A	A1-2
Proposed CHP engine *	N/A	A1-3
Proposed additional boiler *	N/A	A1-4
Reeco (RTO)	7-1 (a)	A2-1
John Zink (KEU) Thermal oxidiser	7-1 (b)	A2-2
Thermal thermal oxidiser	7-1 (c)	A2-3
Proposed Carbon absorber IE3	A3-24	A2-4
Proposed Carbon absorber IE16	A3-30	A2-5

* Either the CHP plant or an additional boiler will be developed, not both.

Minor Atmospheric Emission Points

Minor Emission Point	Current label	Proposed Label
Extract from dispensing room	IE1-V1	A3-01
Biofilter WWTP	----	A3-02
EF23 Exhaust Fan-IE2	IE02-V1	A3-03
EF24 Exhaust Fan-IE2	IE02-V5	A3-04
EF25 Exhaust Fan-IE2	IE02-V100	A3-05
EF26 Exhaust Fan-IE2	IE02-V4	A3-06
EF27 Exhaust Fan-IE2	IE02-V3	A3-07
EF29 Exhaust Fan-IE2	IE02-V2	A3-08
		*
EF7A Exhaust Fan-IE28	IE28-V1	A3-31
EF7B Exhaust Fan-IE28	IE28-V2	A3-32
EF7C Exhaust Fan-IE28	IE28-V3	A3-33
EF7D Exhaust Fan-IE28	IE28-V28	A3-34
EF32A Exhaust Fan-IE28	IE28-V29	A3--35

Minor Emission Point	Current label	Proposed Label
EF32B Exhaust Fan-IE28	IE28-V30	A3--36
		*
IE42 Combined Process Vent	IE42-V251	A3-100
		*
IE43 Combined Process Vent (Proposed)	----	A3-125
		*
IE43 (Phase 2) combined process vent (Proposed)	----	A3-150

*Numbering system allows for the addition of new emission points in the event of building expansion

Potential Atmospheric Emission Points (as proposed in IPPC Licence review currently being evaluated)

Potential Emission Point	Current label	Proposed Label*
IE8 Scrubber 31EF	IE08-V1	A4-01
IE8-EF23	IE08-V4	A4-02
IE8-EF5	IE08-V5	A4-03
T13 Rupture Disc-IE8	IE08-V7	A4-04
T1 Rupture Disc-IE8	IE08-V8	A4-05
T19 Rupture Disc-IE8	IE08-V11	A4-06
T7 Rupture Disc-IE8	IE08-V12	A4-07
T8 Rupture Disc-IE8	IE08-V16	A4-09
T7 Hydrogen Vent-IE8	IE08-V24	A4-10
T19 Hydrogen Vent-IE8	IE08-V25	A4-11
T11B Rupture Disc-IE8	IE08-V32	A4-13
T7 Drowning Pot Vent-IE8	IE08-V48	A4-14
T12 Rupture Disc-IE8	IE08-V52	A4-15
T11 Rupture Disc-IE8	IE08-V53	A4-16
T106 Rupture Disc-IE8	IE08-V54	A4-17
T22 Rupture Disc-IE8	IE08-V55	A4-18
T22 Filter Rupture Disc-IE8	IE08-V57	A4-19
BL2 Rupture Line-IE8	IE08-V70	A4-20
T20 Rupture Disc-IE8	IE08-V91	A4-21
T101 Rupture Line-IE8	IE08-V92	A4-22
VP101A/VP101B Rupture Line-IE8	IE08-V93	A4-23
T102/103 Rupture Line-IE8	IE08-V94	A4-24
T2 Rupture Line-IE8	IE08-V135	A4-25
IE8-EF22	IE08-V99	A4-26
DB2B Rupture Disc-IE8	IE08-V103	A4-27
DB2A Rupture Disc-IE8	IE08-V104	A4-28

Potential Emission Point	Current label	Proposed Label*
DB3 Rupture Line-IE8	IE08-V105	A4-29
T37 Rupture Line-IE8	IE08-V106	A4-30
T77 Burst Tank Vent-IE8	IE08-V108	A4-31
T24 Rupture Line-IE8	IE08-V113	A4-32
T25 Rupture Line-IE8	IE08-V115	A4-33
T38 Rupture Line-IE8	IE08-V118	A4-34
T43 Rupture Line-IE8	IE08-V120	A4-35
T46 Rupture Line-IE8	IE08-V122	A4-36
T63 Rupture Line-IE8	IE08-V128	A4-37
T64 Rupture Line-IE8	IE08-V129	A4-38
T65 Rupture Line-IE8	IE08-V130	A4-39
T66 Rupture Line-IE8	IE08-V131	A4-40
DB6 Rupture Line-IE8	IE08-V133	A4-41
T2 Rupture Line-IE8	IE08-V135	A4-42
IE8-EF10	IE08-V138	A4-43
IE8-EF6	IE08-V139	A4-44
Ralox Fume Duct A-IE8	IE08-V171	A4-45
Ralox Fume Duct B-IE8	IE08-V172	A4-46
Ralox Fume Duct C-IE8	IE08-V177	A4-47
IE8-EF27	IE08-V193	A4-48
IE8-EF26	IE08-V194	A4-49
T96 Rupture Disc-IE8	IE08-V208	A4-50
Carbon Absorber Bed1 Rupture Line-IE8	IE08-V213	A4-51
Carbon Absorber Bed2 Rupture Line-IE8	IE08-V214	A4-52
Carbon Absorber Exhaust Vent-IE8	IE08-V215	A4-53
FD5 Rupture Disc-IE8	IE08-V218	A4-54
T56 Rupture Disc-IE8	IE08-V219	A4-55
T57 Rupture Disc-IE8	IE08-V220	A4-56
T3B Rupture Disc-IE8	IE08-V228	A4-57
		*
DB1 Rupture line-IE16LS	IE16-V101	A4-71
C1 Rupture line-IE16LS	IE16-V102	A4-72
T-86 Rupture line-IE16LS	IE16-V103	A4-73
T-91 Rupture line-IE16LS	IE16-V114	A4-74
BL1 Rupture line-IE16LS	IE16-V115	A4-75
BR-BL1 Vent line-IE16LS	IE16-V116	A4-76
Scrubber 99 Exhaust Fan-IE16LS	IE16-V121	A4-77
FR5 Rupture line-IE16LS	IE16-V136	A4-78
H-5 Rupture line-IE16LS	IE16-V137	A4-79
T-69 Rupture line-IE16LS	IE16-V140	A4-80

Potential Emission Point	Current label	Proposed Label*
FD-3 Rupture line-IE16LS	IE16-V143	A4-81
MFLT-1 Rupture line-IE16LS	IE16-V144	A4-82
Exhaust Fan EF7-IE16LS	IE16-V126	A4-83
Exhaust Fan EF6-IE16LS	IE16-V145	A4-84
Scrubber exhaust fan -IE16LS (Proposed)	----	A4-85
Exhaust Fan – IE16LS (Proposed)	----	A4-86
Exhaust Fan – IE16LS (Proposed)	----	A4-87
Exhaust Fan – IE16LS (Proposed)	----	A4-88
Exhaust Fan – IE16LS (Proposed)	----	A4-89
		*
SV-51 rupture Disc-IE16SS	IE16-V1	A4-101
DEF3 Exhaust Fan-IE16SS	IE16-V5	A4-102
DEF4 Exhaust Fan-IE16SS	IE16-V6	A4-103
EF1 Exhaust Fan-IE16SS	IE16-V7	A4-104
Reeco Duct Burst Disc-IE16SS	IE16-V8	A4-105
Jet Mill Exhaust Vent-IE16SS	IE16-V10	A4-106
T-54 Vent Line-IE16SS	IE16-V15	A4-107
T-56 Rupture Disc-IE16SS	IE16-V17	A4-108
Scrubber 51 Exhaust Fan-IE16SS	IE16-V18	A4-109
EF2 Exhaust Fan-IE16SS	IE16-V19	A4-110
		*
EF33 Exhaust Fan-IE2	IE02-V106	A4-121
EF34 Exhaust Fan-IE2	IE02-V107	A4-122
EF35 Exhaust Fan-IE2	IE02-V108	A4-123
EF36 Exhaust Fan-IE2	IE02-V109	A4-124
EF37 Exhaust Fan-IE2	IE02-V110	A4-125
EF38 Exhaust Fan-IE2	IE02-V112	A4-126
EF39 Exhaust Fan-IE2	IE02-V113	A4-127
EF40 Exhaust Fan-IE2	IE02-V114	A4-128
Scrubber 1 Exhaust – IE2	----	A4-129
Scrubber 2 Exhaust – IE2	----	A4-130
Scrubber 3 Exhaust – IE2 (proposed)	----	A4-131
Exhaust Fan-IE2 (proposed)	----	A4-132
Exhaust Fan-IE2 (proposed)	----	A4-133
Exhaust Fan-IE2 (proposed)	----	A4-134
Exhaust Fan-IE2 (proposed)	----	A4-135
		*
Scrubber 31 Exhaust Fan-IE3	IE03-V3	A4-151
EF6 Exhaust Fan-IE3	IE03-V4	A4-152

Potential Emission Point	Current label	Proposed Label*
EF3 Exhaust Fan-IE3	IE03-V7	A4-153
EF5 Exhaust Fan-IE3	IE03-V8	A4-154
EF8 Exhaust Fan-IE3	IE03-V39	A4-155
T24 Rupture Disc-IE3	IE03-V47	A4-156
T12 Rupture Disc-IE3	IE03-V48	A4-157
Scrubber 43 Exhaust Fan-IE3	IE03-V51	A4-158
Scrubber 44 Exhaust Fan-IE3	IE03-V52	A4-159
EF7 Exhaust Fan-IE3	IE03-V53	A4-160
EF4 Exhaust Fan-IE3	IE03-V54	A4-161
T14 Rupture Disc-IE3	IE03-V64	A4-162
RF3 Rupture Disc-IE3	IE03-V74	A4-163
T17 Rupture Disc-IE3	IE03-V78	A4-164
T18 Rupture Disc-IE3	IE03-V84	A4-165
EF10 Exhaust Fan-IE3	IE03-V85	A4-166
FBD Exhaust Fan-IE3	IE03-87	A4-167
ST-1 Rupture Disc-IE3	IE03-V91	A4-168
T98 Rupture Disc-IE3	IE03-V98	A4-169
T92 Rupture Disc-IE3	IE03-V99	A4-170
T93 Rupture Disc-IE3	IE03-V100	A4-171
T94 Rupture Disc-IE3	IE03-V101	A4-172
ST1 Vent-IE3	IE03-V102	A4-173
T25 Rupture Disc-IE3	IE03-V104	A4-174
T18 Rupture Disc-IE3	IE03-V115	A4-175
T30 Rupture Disc-IE3	IE03-V117	A4-176
SC53 Rupture Disc-IE3	IE03-V119	A4-177
T32 Rupture Disc-IE3	IE03-V120	A4-178
EF17 Exhaust Fan-IE3	IE03-V121	A4-179
T33 Vent-IE3	IE03-V122	A4-180
SC53 Vent-IE3	IE03-V123	A4-181
EF18 Exhaust Fan-IE3	IE03-V124	A4-182
EF11 Exhaust Fan-IE3	IE03-V129	A4-183
T38 Rupture Disc-IE3	IE03-V136	A4-184
T6A Rupture Disc-IE3	IE03-V137	A4-185
DT32 Vent Line-IE3	IE03-118	A4-186
		*
T220 Vent-IE7	IE07-V38	A4-201
T221 Vent-IE7	IE07-V40	A4-202
T222 Vent-IE7	IE07-V42	A4-203
T225 Vent-IE7	IE07-V44	A4-204
T226 Vent-IE7	IE07-V46	A4-205

Potential Emission Point	Current label	Proposed Label*
T227 Vent-IE7	IE07-V48	A4-206
T228 Vent-IE7	IE07-V50	A4-207
T210 Vent-IE7	IE07-V53	A4-208
		*
T955 Vent –IE20	IEOY-V8	A4-220
T958 Vent –IE20	IEOY-V11	A4-221
T959 Vent –IE20	IEOY-12	A4-222
T960 Vent –IE20	IEOY-V13	A4-223
T961 Vent –IE20	IEOY-V56	A4-224
T962 Vent –IE20	IEOY-V57	A4-225
T963 Vent –IE20	IEOY-V14	A4-226
T964 Vent –IE20	IEOY-V15	A4-227
T969 Vent –IE20	IEOY-V20	A4-228
T970 Vent –IE20	IEOY-V21	A4-229
T973 Vent –IE20	IEOY-V59	A4-230
T977 Vent –IE20	IEOY-V28	A4-231
T978 Vent –IE20	IEOY-V30	A4-232
T979 Vent –IE20	IEOY-V32	A4-233
T982 Vent –IE20	IEOY-V35	A4-234
T983 Vent –IE20	IEOY-V36	A4-235
T992 Vent –IE20	IEOY-V40	A4-236
T993 Vent –IE20	IEOY-V43	A4-237
T1002 Vent –IE20	IEOY-V45	A4-238
T1003 Vent –IE20	IEOY-V46	A4-239
T1004 Vent –IE20	IEOY-V47	A4-240
T1005 Vent –IE20	IEOY-V49	A4-241
T1006 Vent –IE20	IEOY-V51	A4-242
T1007 Vent –IE20	IEOY-V53	A4-243
T1008 Vent –IE20	IEOY-V43	A4-244
T1009 Vent –IE20	IEOY-V44	A4-245
T1010 Vent –IE20	IEOY-V33	A4-246
T1011 Vent –IE20	IEOY-V34	A4-247
T1012 Vent –IE20	IEOY-V38	A4-248
		*
CH-1 Pressure Relief-IE30	IE30-V7	A4-276
CH-2 Pressure Relief-IE30	IE30-V8	A4-277
		*
EF-VC30A Exhaust Fan-IE30	IE30-V14	A4-278
Reeco Duct Bypass vent-IE30	IE30-V15	A4-279
T-31 vent-IE30	IE30-V17	A4-280

Potential Emission Point	Current label	Proposed Label*
T-30 vent-IE30	IE30-V18	A4-281
T-29 vent-IE30	IE30-V19	A4-282
T47 Rupture Disc-IE30	IE30-V21	A4-283
T-19 vent-IE30	IE30-V22	A4-284
		*
Solid Waste Baler Extract Fan-IE18 (proposed)	----	A4-301

*Numbering system allows for the addition of new emission points in the event of building expansion

Emissions to Surface Water

Surface Water Emission Points

Main Emission Point	Current label	Proposed Label
Treated effluent from the facility	6-1	SW1
Wastewater from incineration	W2	SW2
Site storm water runoff	W3	SW3

Details on all emissions to surface water are provided in Tables E.2(i) and E.2(ii) in Annex 1 of the Application form.

Emissions to Sewers

There are no emissions to sewer from the facility.

Emissions to Ground

There are no direct emissions to ground from the facility.

Noise Emissions

Details of Noise sources

Source	Emission Point		Equipment Ref. No.	Sound Pressure dBA at ref distance	Octave bands (Hz) Sound Pressure1 Levels dB (unweighted) per band								Periods of Emission	
	E	N			31.5	63	125	250	500	1K	2K	4K		8K
IE30 Cooling Tower Motor-1	160207	052836		82	41	54	63	72	75	78	74	73	69	Continuous
IE30 External steam lines	160245	052853		84	31	43	60	70	70	76	78	82	71	Continuous
IE30 Glycol Return Pump-1	160256	052830		82	35	47	65	71	76	75	72	78	68	Continuous
IE30 Glycol Return Pump-2	160259	052832		82	35	47	65	71	76	75	72	78	68	Continuous
IE30 Glycol Supply Pump-1	160262	052835		82	35	47	65	71	76	75	72	78	68	Continuous
IE30 Glycol Supply Pump-2	160264	052836		82	35	47	65	71	76	75	72	78	68	Continuous
IE30 Cooling Tower_1	160190	052833		82	38	51	66	72	76	77	73	71	66	Continuous
IE30 Cooling Tower_1	160183	052843		82	38	51	66	72	76	77	73	71	66	Continuous
IE30 Cooling Tower Motor-1	160200	052846		82	41	54	63	72	75	78	74	73	69	Continuous

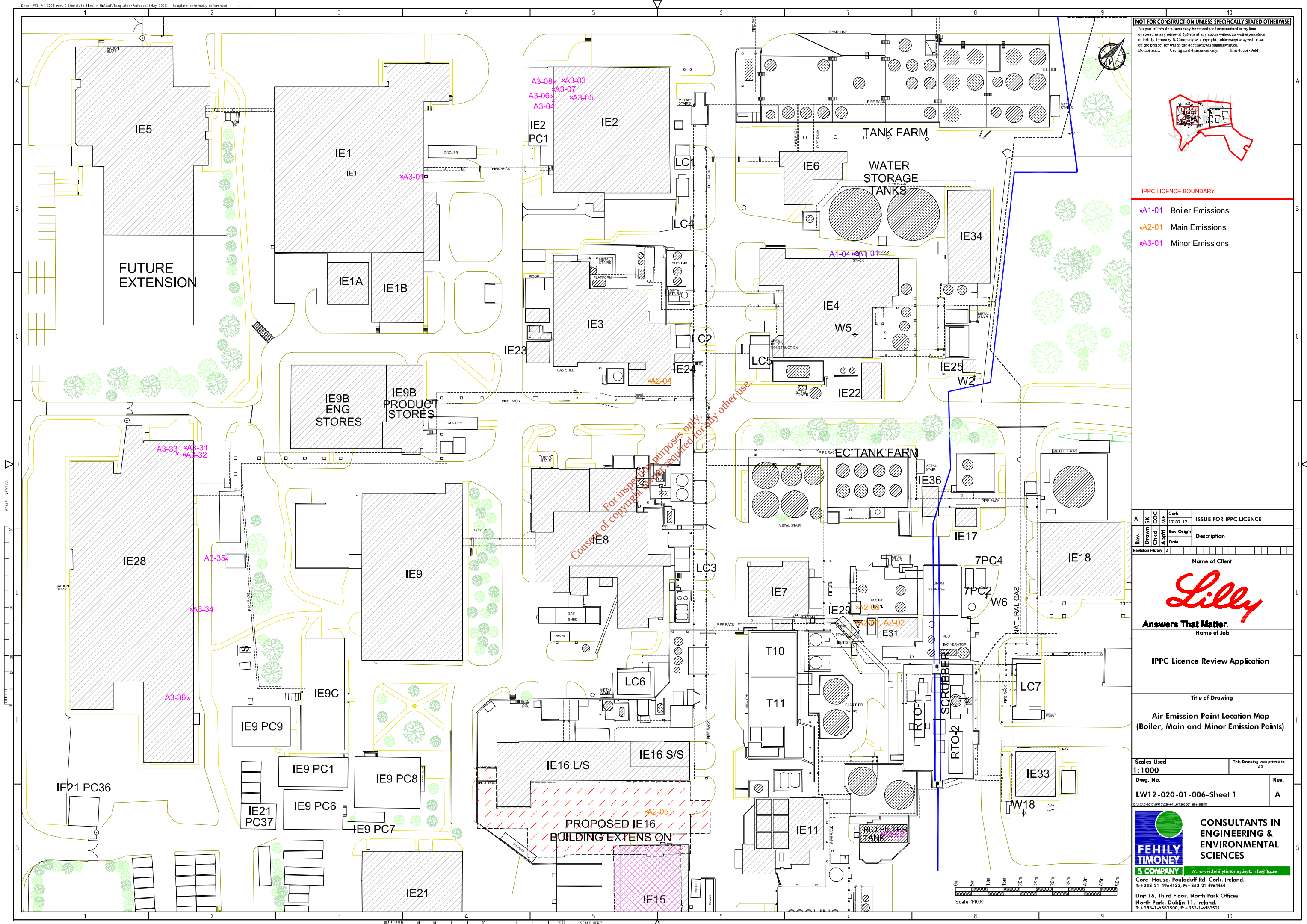
Source	Emission Point		Equipment Ref. No.	Sound Pressure dBA at ref distance	Octave bands (Hz) Sound Pressure Levels dB (unweighted) per band								Periods of Emission	
	E	N			31.5	63	125	250	500	1K	2K	4K		8K
Proposed extractor fan source at 68 dB(A)	159884	052762		68	--	--	--	68	--	--	--	--	--	Continuous
GenSet Generator	159946	052973		92	--	--	--	92	--	--	--	--	--	Continuous
IE42 Cooling Tower	160192	052851		82	38	51	66	72	76	77	73	71	66	Continuous
IE42 Cooling Tower Motor-1	160187	052858		82	41	54	63	72	75	78	74	73	69	Continuous
IE42 Cooling Tower Motor-2	160182	052855		82	41	54	63	72	75	78	74	73	69	Continuous
IE30 Glycol Return Pump-3	160260	052833		82	35	47	65	71	76	75	72	78	68	Continuous
IE30 Glycol Supply Pump-3	160266	052837		82	35	47	65	71	76	75	72	78	68	Continuous
IE42 Glycol Supply Pump-7	160267	052838		82	35	47	65	71	76	75	72	78	68	Continuous
IE30 Glycol Return Pump-8	160268	052839		82	35	47	65	71	76	75	72	78	68	Continuous
EF 1	160265	052941		78	--	78	62	44	43	43	43	43	43	Continuous
EF 2	160268	052943		78	--	78	62	44	43	43	43	43	43	Continuous
AHU17	160302	052974		89	58	71	73	82	83	84	81	78	74	Continuous
AHU18	160265	052949		89	58	71	73	82	83	84	81	78	74	Continuous
AHU12	160287	052965		89	58	71	73	82	83	84	81	78	74	Continuous

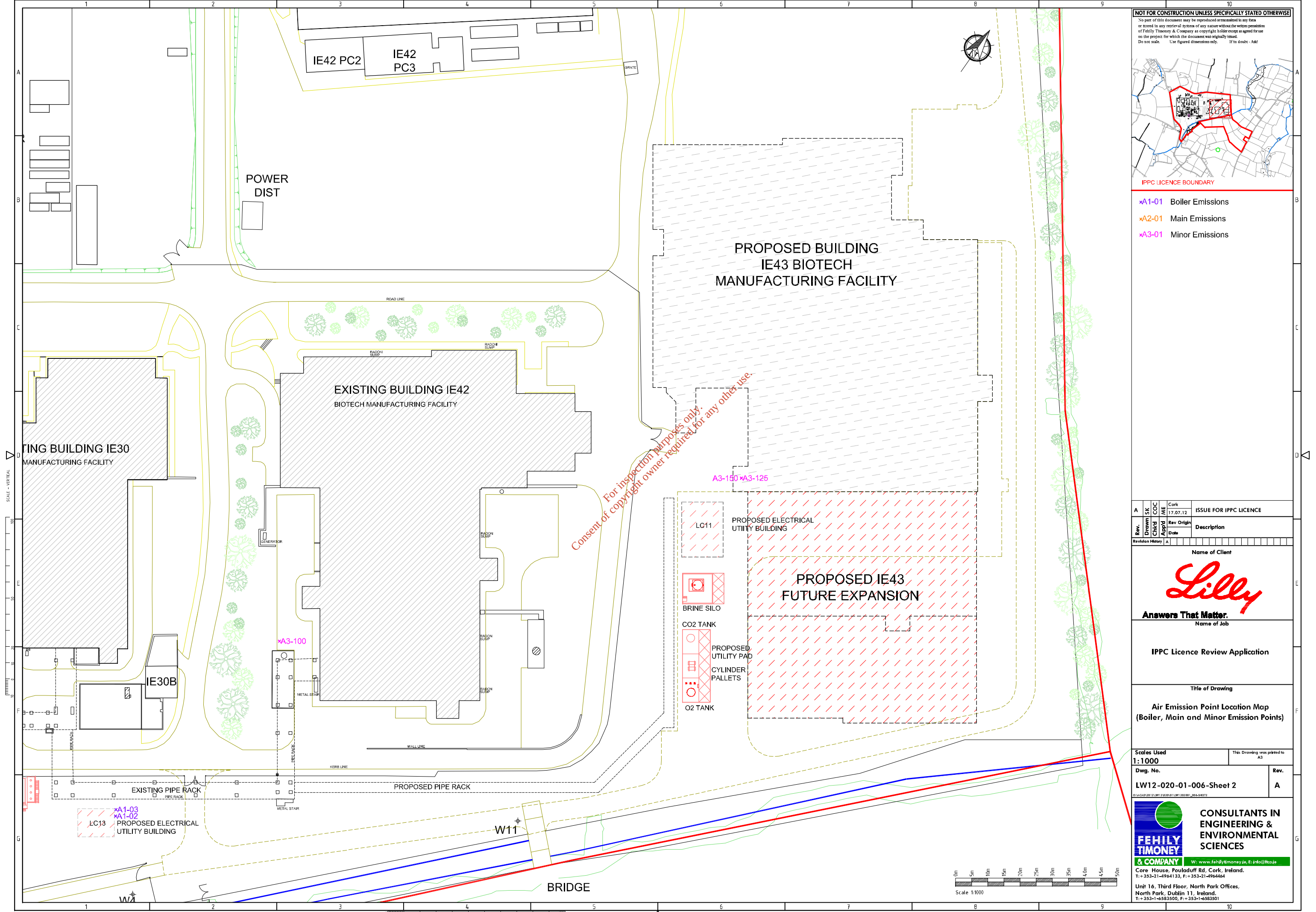
Source	Emission Point		Equipment Ref. No.	Sound Pressure dBA at ref distance	Octave bands (Hz) Sound Pressure Levels dB (unweighted) per band								Periods of Emission	
	E	N			31.5	63	125	250	500	1K	2K	4K		8K
AHU4	160291	052961		89	58	71	73	82	83	84	81	78	74	Continuous
AHU14	160292	052951		89	58	71	73	82	83	84	81	78	74	Continuous
AHU11	160279	052941		89	58	71	73	82	83	84	81	78	74	Continuous
AHU8	160304	052950		89	58	71	73	82	83	84	81	78	74	Continuous
AHU1	160304	052947		89	58	71	73	82	83	84	81	78	74	Continuous
AHU20	160297	052925		89	58	71	73	82	83	84	81	78	74	Continuous
AHU8	160289	052922		89	58	71	73	82	83	84	81	78	74	Continuous
AHU2	160310	052929		89	58	71	73	82	83	84	81	78	74	Continuous
AHU3	160313	052925		89	58	71	73	82	83	84	81	78	74	Continuous
AHU5	160324	052910		89	58	71	73	82	83	84	81	78	74	Continuous
AHU7	160321	052905		89	58	71	73	82	83	84	81	78	74	Continuous
AHU extract fan east side of IE42	160306	052962		88	--	62	71	80	84	83	78	72	61	Continuous
AHU extract fan west side of IE42	160266	052932		88	--	62	71	80	84	83	78	72	61	Continuous
IE43 Condensate return pumps (five)	160377	053003		75	--	47	56	65	68	71	67	66	62	Continuous
	160384	053008												
	160388	053010												
	160392	053013												
	160397	053017												
IE 43 Cooling tower (four)	160247	052795		85	--	54	75	79	80	76	74	74	69	Continuous
	160241	052791												
	160235	052787												
	160229	052783												

Source	Emission Point		Equipment Ref. No.	Sound Pressure dBA at ref distance	Octave bands (Hz) Sound Pressure1 Levels dB (unweighted) per band								Periods of Emission	
	E	N			31.5	63	125	250	500	1K	2K	4K		8K
IE43 Cooling Water pumps (four)	160252	052797		75	--	47	56	65	68	71	67	66	62	Continuous
	160251	052799												
	160250	052800												
	160249	052802												

1. For items of plant sound power levels may be used.
Note: A-weighted sound power levels are provided in this Table

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IPPC LICENCE BOUNDARY

xA1-01 Boiler Emissions
xA2-01 Main Emissions
xA3-01 Minor Emissions

Rev.	Drawn	Chkd	Appd	Rev Orig	Date	Description
A	SK	COC	ME	Cork	17.07.12	ISSUE FOR IPPC LICENCE

Revision History | A

Name of Client
Lilly
Answers That Matter.
Name of Job

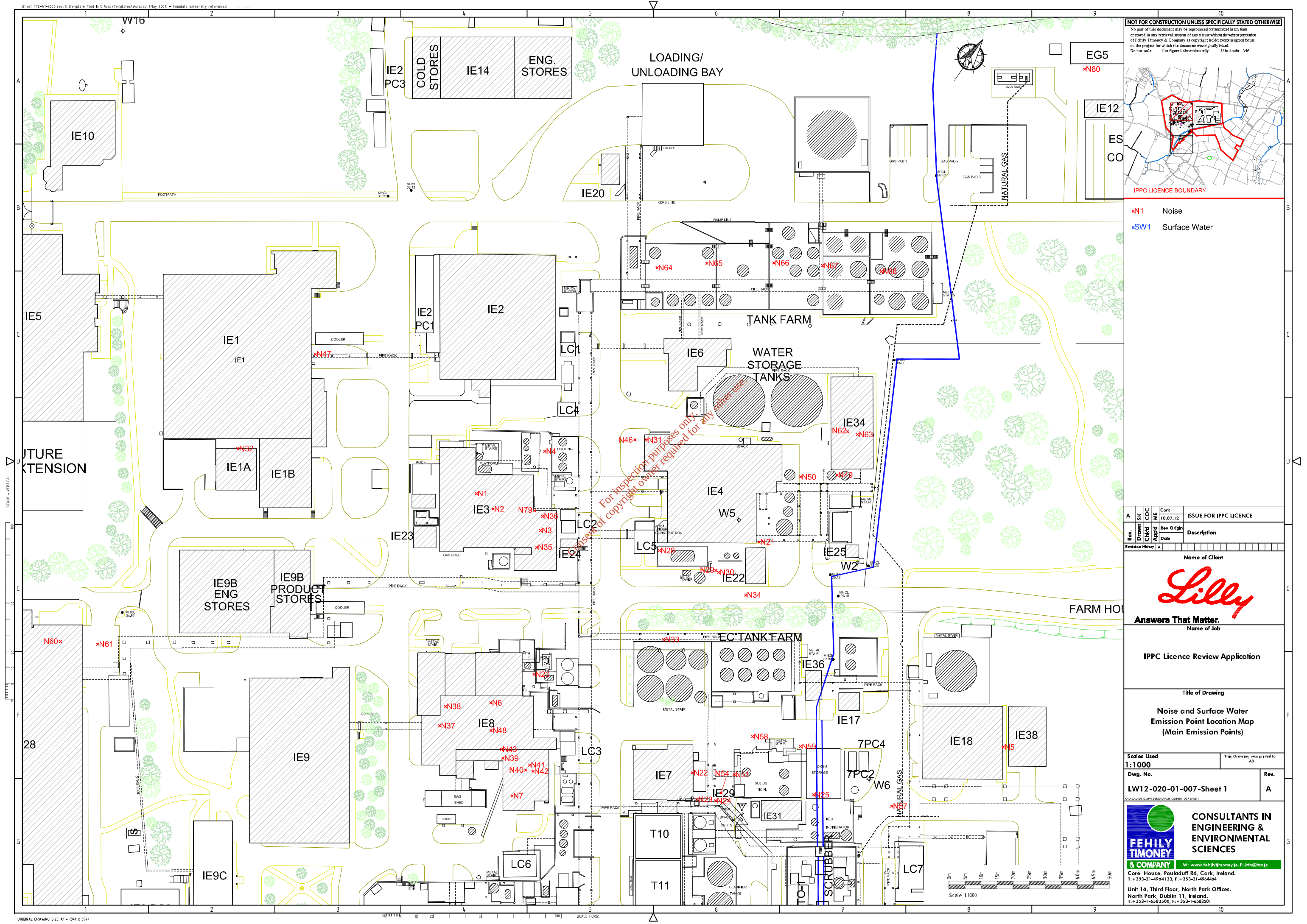
IPPC Licence Review Application

Title of Drawing
**Air Emission Point Location Map
(Boiler, Main and Minor Emission Points)**

Scales Used
1:1000
Dwg. No.
LW12-020-01-006-Sheet 2
Rev.
A

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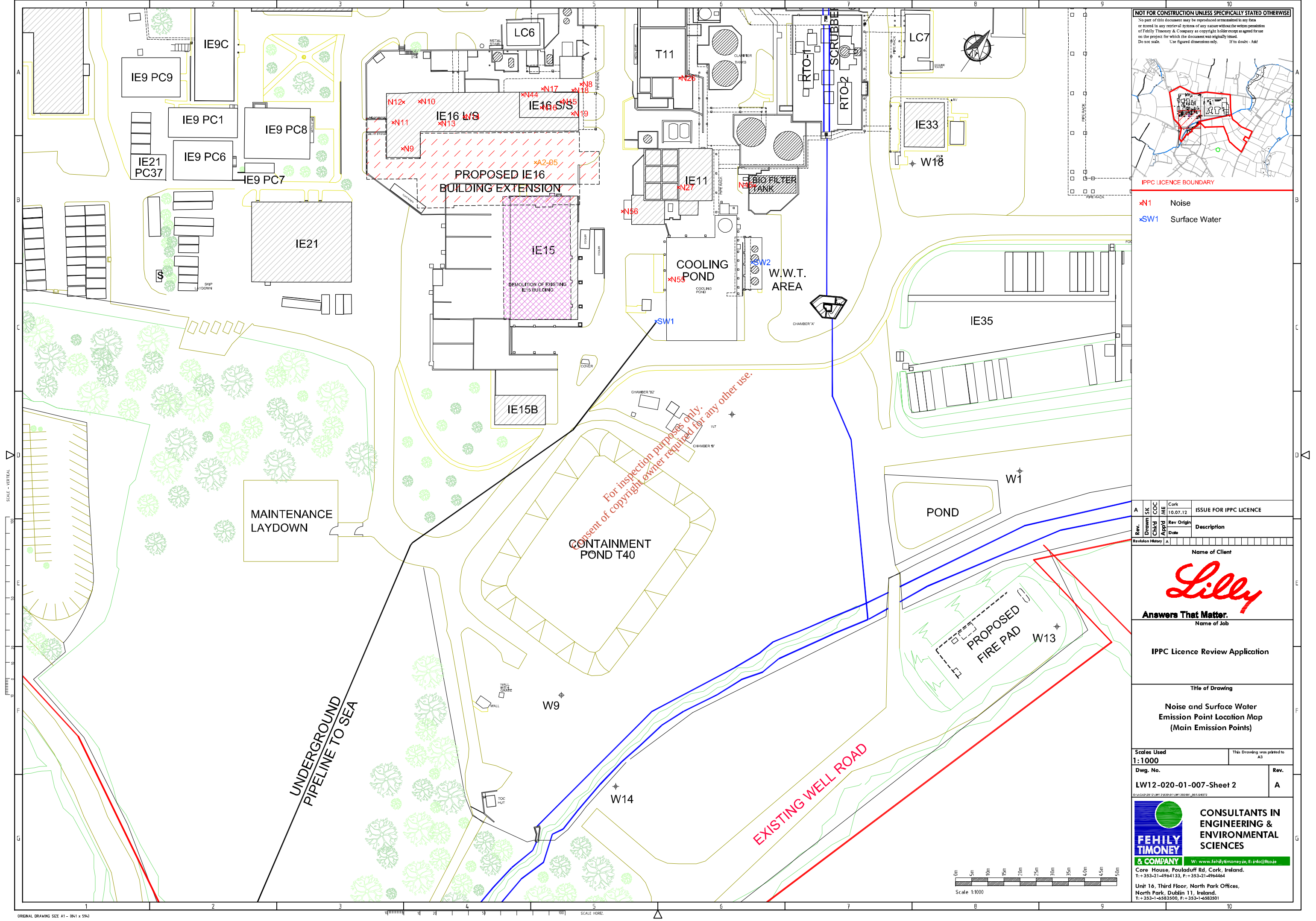
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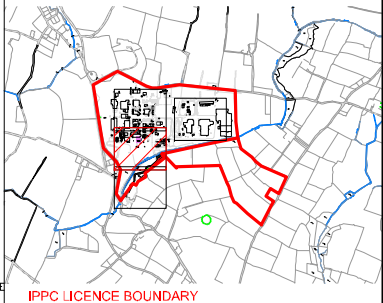
IPPC LICENCE BOUNDARY

- xN1 Noise
- xSW1 Surface Water

Rev.	Drawn	Check	COC	ME	Cork	10.07.12	ISSUE FOR IPPC LICENCE
Rev.	Drawn	Check	COC	ME	Rev Origin	Date	Description
Revision History							
Name of Client							
Answers That Matter. Name of Job							
IPPC Licence Review Application							
Title of Drawing							
Noise and Surface Water Emission Point Location Map (Main Emission Points)							
Scales Used 1:1000							
Dwg. No. LW12-020-01-007-Sheet 1							
Rev. A							
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N1 Noise
SW1 Surface Water

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Rev.	Drawn	SK	COC	ME	Cork	10.07.12	ISSUE FOR IPPC LICENCE
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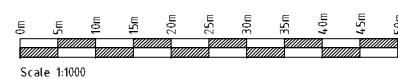
Name of Client
Lilly
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Name of Job

IPPC Licence Review Application

Title of Drawing
Noise and Surface Water
Emission Point Location Map
(Main Emission Points)

Scales Used
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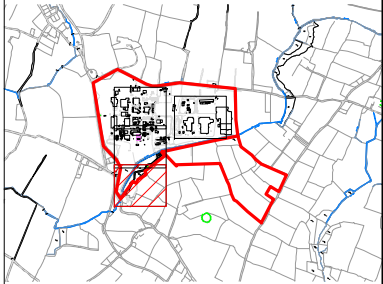
SCALE - VERTICAL

SCALE HORIZ

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- N1 Noise
- SW1 Surface Water

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Rev.	Drawn	Chkd	Appd	Rev Origin	Description
Revision History					

Name of Client
Lilly
Answers That Matter.

Name of Job
IPPC Licence Review Application

Title of Drawing
**Noise and Surface Water
Emission Point Location Map
(Main Emission Points)**

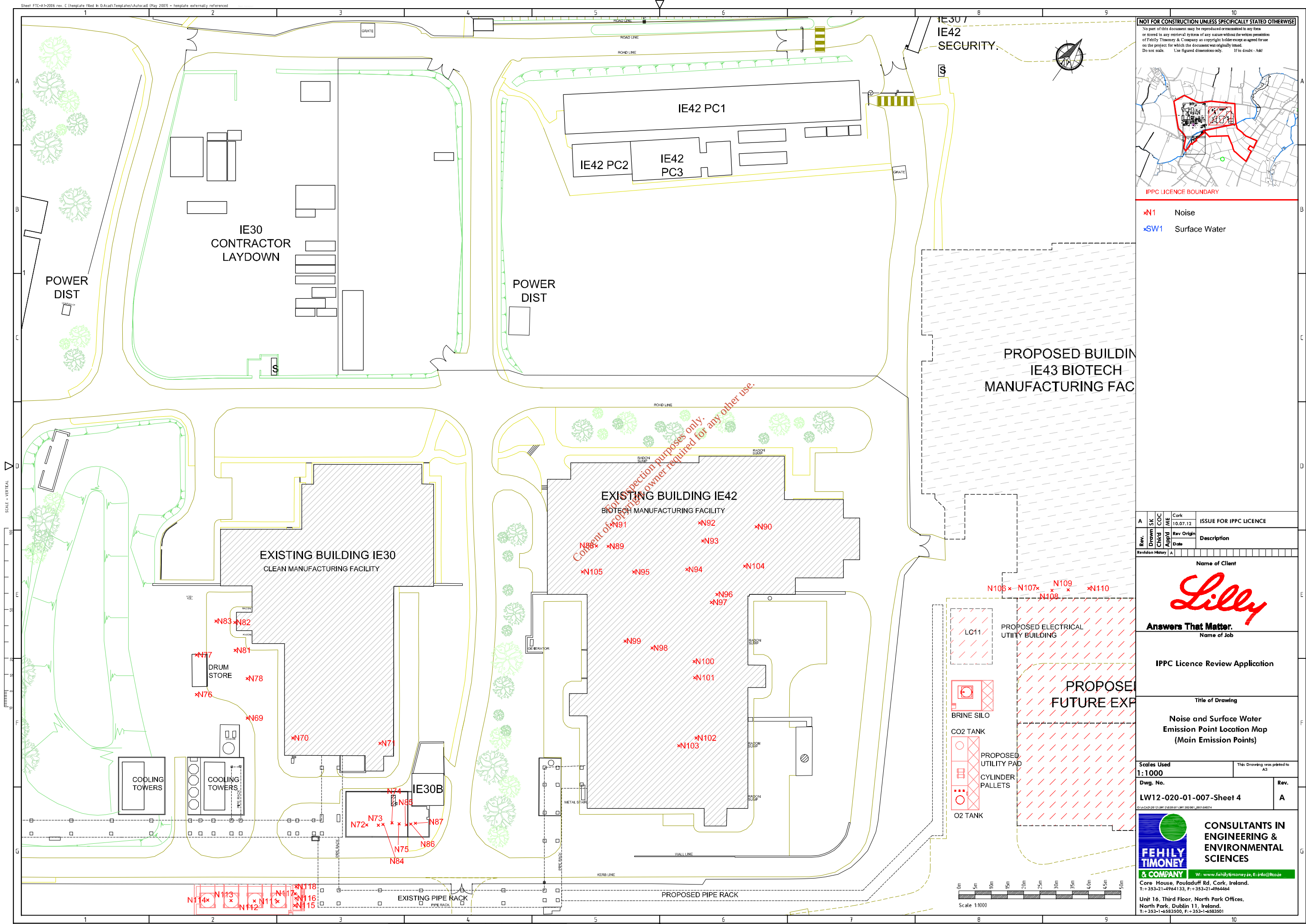
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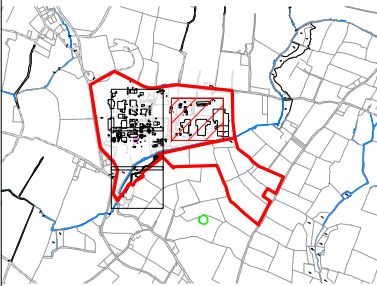
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N1 Noise

SW1 Surface Water

Rev.	Drawn	Check	App'd	Rev. Orig'n	Date	Description
1	SK	COC	ME	Cork	10.07.12	ISSUE FOR IPPC LICENCE

Name of Client

Lilly

Answers That Matter.

Name of Job

IPPC Licence Review Application

Title of Drawing

Noise and Surface Water
Emission Point Location Map
(Main Emission Points)

Scales Used
1:1000

Dwg. No.
LW12-020-01-007-Sheet 4

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Appendix 3

Letter outlining Financial Position

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May 11, 2012

Environmental Licensing Programme Administration
Environmental Protection Agency (EPA) Headquarters
PO Box 3000
Johnston Castle Estate
Co. Wexford
Ireland

To Whom It May Concern:

Request for certificate of insurance or letter of assurance.

We refer to your requirement for a certificate of insurance for environmental pollution insurance covering Eli Lilly and Company's (Lilly) Kinsale facility. Lilly's global property insurance policy does provide coverage for contamination and pollutant clean-up in the amount of US\$2,000,000 for environmental liabilities that result from covered perils such as flooding, fire, explosion, etc. For unknown liabilities not covered by the global property insurance policy, Lilly has determined it is not cost effective to purchase additional insurance but instead rely on the robust loss prevention practices and the strength of Lilly's balance sheet.

At the time of this letter, Kinsale has a near perfect Risk Mark score (99%) as determined by FM Global insurance company. This strong risk rating combined with Lilly's A2 credit rating assigned by Moody's Investor Services enables Lilly to confidently self-insure for any potential environmental liabilities.

Lilly also understands the obligations it has to the known liabilities at the site and will maintain its loss prevention efforts throughout any closure or partial closures of the Kinsale site. In addition, Lilly is committed to maintaining a self-insured program that is sufficient for these obligations.

Regards,



Jeffrey L. Williams
Consultant – Treasury/Risk Management
Corporate Risk Management
Eli Lilly & Company