



Integrated Pollution Prevention and Control (IPPC) Licensing

Application Form

EPA Reg. No.
(Office use only)

Environmental Protection Agency
P.O. Box 3000, Johnstown Castle Estate, Co. Wexford
Lo Call: 1890 335599 Telephone: 053-9160600 Fax: 053-9160699
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ABOUT THIS APPLICATION FORM

This form is for the purpose of making an application for an Integrated Pollution Prevention and Control (IPPC) Licence under the Environmental Protection Agency Acts, 1992 and 2003. There are separate application forms for licensees who wish to apply for a review of existing licences and for Pig & Poultry sector applicants.

The Application Form **must** be completed in accordance with the instructions provided in the *IPPC Licensing Application Guidance Note*. The Guidance Note gives an overview of IPPC Licensing, outlines the licence application process (including number of copies required) and specifies the information to be submitted in the application. The Guidance Note and application forms are available to download from the IPPC Licensing pages of the EPA's website at www.epa.ie. A valid application for an IPPC licence must contain the information prescribed in the Environmental Protection Agency (Licensing) Regulations, 1994 to 2004. Article 10 of the Regulations sets out the statutory requirements for information to accompany a licence application. The application form is designed in such a way as to set out these questions in a structured manner and not necessarily in the order presented in Article 10. In order to ensure a legally valid application in respect of Article 10 requirements, please complete the Article 10 Checklist provided in Annex 2.

This Application Form does not purport to be and should not be considered a legal interpretation of the provisions and requirements of the Environmental Protection Agency Acts, 1992 and 2003 and the Environmental Protection Agency (Licensing) Regulations 1994 to 2004. While every effort has been made to ensure the accuracy of the material contained in the Application Form, the EPA assumes no responsibility and gives no guarantees, undertakings and warranties concerning the accuracy, completeness or up-to-date nature of the information provided herein and does not accept any liability whatsoever arising from any errors or omissions.

Should there be any contradiction between the information requirements set out in the Application Form and any clarifying explanation contained in the accompanying Guidance Note, then the requirements in this Application Form shall take precedence.

SECTION A: NON-TECHNICAL SUMMARY

A non-technical summary of the application is to be included here. The summary should identify all environmental impacts of significance associated with the carrying on of the activity/activities, and describe mitigation measures proposed or existing to address these impacts. This description should also indicate the normal operating hours and days per week of the activity.

The following information must be included in the non-technical summary:

A description of:

- the installation and its activities,
- the raw and auxiliary materials, other substances and the energy used in or generated by the installation,
- the sources of emissions from the installation,
- the environmental conditions of the site of the installation (e.g. soil and groundwater, air, noise, surface water),
- the nature and quantities of foreseeable emissions from the installation into each medium as well as identification of significant effects of the emissions on the environment,
- the proposed technology and other techniques for preventing or, where this is not possible, reducing emissions from the installation,
- where necessary, measures for the prevention and recovery of waste generated by the installation,
- further measures planned to comply with the general principles of the basic obligations of the operator i.e.
 - (a) all the appropriate preventive measures are taken against pollution, in particular through application of the Best Available Techniques (BAT);
 - (b) no significant pollution is caused;
 - (c) waste production is avoided in accordance with Council Directive 75/442/EEC of 15 July 1975 on waste; where waste is produced, it is recovered or, where that is technically and economically impossible, it is disposed of while avoiding or reducing any impact on the environment;
 - (d) energy and other resources are used efficiently;
 - (e) the necessary measures are taken to prevent accidents and limit their consequences;
 - (f) the necessary measures are taken upon definitive cessation of activities to avoid any pollution risk and return the site of operation to a satisfactory state.
- measures planned to monitor emissions into the environment.

Supporting information should form **Attachment N° A.1**

Please see attachment A.1 for details on Non Technical Summary.

SECTION B: GENERAL**B.1. Owner/Operator**

| | |
|-----------------|--|
| Name*: | TopChem Pharmaceuticals Limited. |
| Address: | Ballymote Business Park, Carrownanty, Ballymote, Co Sligo |
| | |
| | |
| Tel: | (071)-9189685 / (087) – 9162685 |
| Fax: | (071)-9197864 |
| e-mail: | ncannon@topchem.ie |

* This should be the name of the applicant which is current on the date this IPPC Licence Application is lodged with the Agency. It should be the name of the legal entity (which can be a limited company or a sole trader). A trading/business name is not acceptable.

Name and Address for Correspondence

Only application documentation submitted by the applicant and by the nominated person will be deemed to have come from the applicant.

| | |
|-----------------|--|
| Name: | Nigel Cannon |
| Address: | TopChem Pharmaceuticals Limited, |
| | Ballymote Business Park, Carrownanty, Ballymote, Co Sligo |
| | |
| Tel: | (071)-9189685 / (087) – 9162685 |
| Fax: | (071)-9197864 |
| e-mail: | ncannon@topchem.ie |

Address of registered or principal office of Body Corporate (if applicable)

| | |
|-----------------|--|
| Address: | TopChem Pharmaceuticals Limited |
| | Ballymote Business Park, Carrownanty, Ballymote, Co Sligo |
| | |
| | |
| Tel: | (071)-9189685 / 087 – 9162685 |
| Fax: | (071)-9197864 |
| e-mail: | ncannon@topchem.ie |

If the applicant is a body corporate, the following information must be attached as **Attachment B1**:

- a) a Certified Copy of the Certificate of Incorporation.
- b) the Company's Registration Number from the Companies Registry Office.
- c) Particulars of Registered Office of the Company.

Name and address of the proprietor(s) of the Land on which the Activity is situated (if different from applicant named above):

| | |
|---------------------------|---|
| Proprietor's Name: | Ballymote Community Enterprise Limited |
| Address: | Emmett Street, |
| | Ballymote, |
| | Co Sligo |
| Tel: | (071) 9183992 |
| Fax: | (071) 9183965 |
| e-mail: | <u>communityenterprise@eircom.net</u> |

Name and address of the owner(s) of the building and ancillary plant in which the activity is situated (if different from applicant named above):

| | |
|-----------------|---|
| Name: | Ballymote Community Enterprise Limited |
| Address: | Emmett Sreet, |
| | Ballymote, |
| | Co Sligo |
| Tel: | (071) 9183992 |
| Fax: | (071) 9183965 |
| e-mail: | <u>communityenterprise@eircom.net</u> |

B.2. Location of Activity

| | |
|----------------------|---|
| Name: | TopChem Pharmaceuticals Limited |
| Address*: | Ballymote Business Park, Carrownanty |
| | Ballymote |
| | Co Sligo |
| Tel: | (071)-9189685 |
| Fax: | (071) 9197864 |
| Contact Name: | Nigel Cannon |
| Position: | General Manager |
| e-mail: | <u>ncannon@topchem.e</u> |

* Include any townland.

| | |
|---|----------------------------|
| National Grid Reference (12 digit 6E,6N) | 165850N and 315640W |
|---|----------------------------|

Location maps ($\leq A3$), appropriately scaled, with legible grid references should be enclosed in **Attachment B.2**. The site boundary must be outlined on the map in colour.

Geo-referenced digital drawing files (e.g. AutoCAD files) in Irish Grid projection of the site boundary and overall site plan, including labelled emission, monitoring and sampling points, are also required. This data should be provided to the Agency on a separate CD-Rom containing sections B.2, E.6 and F.3.

| | |
|---|--|
| Name of geo-referenced digital drawing files | T-FE-DWG-001, T-FE-DWG-002, T-FE-DWG-003, T-FE-DWG-004, T-FE-DWG-005, T-FE- DWG-006 |
| Name of CD-Rom with digital drawing files | EPA Drawings TopChem Pharmaceuticals. |

B.3. Class of Activity

Identify the relevant activities in the First, Third or Fourth Schedule of the PoE Act 2004 to which the activity relates:

| Schedule | Class | Description ^{Note 1} |
|-----------|-------|---|
| Chemicals | 5.6 | The manufacture of pharmaceutical intermediates |

Note 1: In order to give a precise identification select only those words from the description of the class or classes that best describes the nature of the activity for which the licence is being applied for.

B.4. Employees/ Capital Cost

Give-

(i) In the case of an established activity, the number of employees and other persons working or engaged in connection with the activity on the date after which a licence is required and during normal levels of operation, or

(ii) In any other case, the gross capital cost of the activity to which the application relates.

| | |
|--|---|
| Number of Employees (existing facilities): | Current 6 employees, projections to get to 10 by December 2007. |
| Gross Capital Cost (new proposals) € | €800K |

B.5. Relevant Planning Authority

Give the name of the planning authority in whose functional area the activity is or will be carried out.

| | |
|----------|----------------------|
| Name: | Sligo County Council |
| Address: | County Hall |
| | Riverside |
| | Sligo |
| Tel: | (071) 9111111 |
| Fax: | (071) 9141119 |

Planning Permission relating to this application:

| | | | |
|-------------------------------|-------------------------------------|---------------------------|--------------------------|
| <i>has been obtained</i> | <input checked="" type="checkbox"/> | <i>is being processed</i> | <input type="checkbox"/> |
| <i>is not yet applied for</i> | <input type="checkbox"/> | <i>is not required</i> | <input type="checkbox"/> |

| | |
|---|-----------|
| Local Authority Planning File Reference N°: | PL 06/314 |
|---|-----------|

Attachment B.5 should contain all planning permissions, including a copy of *all* conditions, and the required copies of any EIS should also be enclosed. For existing activities, **Attachment N° B.5** should also contain all licences and permits past and present in force at the time of submission.

B.6. Relevant Sanitary Authority.

In the case of a discharge of any trade effluent or other matter to a sewer of a sanitary authority, give the name of the sanitary authority in which the sewer is vested or by which it is controlled.

| | |
|-----------------|-----------------------------|
| Name: | Sligo County Council |
| Address: | County Hall |
| | Riverside |
| | Sligo |
| Tel: | (071) 9111111 |
| Fax: | (071) 9141119 |

In the case of a discharge of any trade effluent or other matter to a sewer not vested by a sanitary authority, the applicant must supply as **Attachment N° B.6**; (a) the name and address of the owner(s) of the sewer and the waste water treatment plant to which the sewer discharges and who are responsible for the quality of the treated effluent discharging to waters and (b) a copy of the effluent regulations and the agreement between the applicant and the aforementioned.

| | |
|-----------------|-----------------------|
| Name: | Not Applicable |
| Address: | |
| | |
| | |
| Tel: | |
| Fax: | |

B.7. Relevant Health Board Region

The applicant should indicate the Health Board Region where the activity is or will be located.

| | |
|-----------------|----------------------------------|
| Name: | Sligo Local Health Office |
| Address: | Markievicz House |
| | Barrack Street |
| | Sligo |
| Tel: | 071 9155100 |
| Fax: | |

B.8 Site Notice, Newspaper Advertisement and Planning Authority Notice.

Attachment N° B.8 should contain a copy of the text of the site notice, a map (no larger than A3) showing its location on site (in accordance with Article 7 of the Regulations) and a copy of the newspaper advertisement. A copy of the notice given to the Planning Authority should also be included.

B.9 Seveso II Regulations

State whether the activity is an establishment to which the EC (Control of Major Accident Hazards involving Dangerous Substances) Regulations (S.I. No. 74 of 2006) apply.

If yes, outline how the process comes under these regulations.

Supporting information should be included in **Attachment N° B.9**.

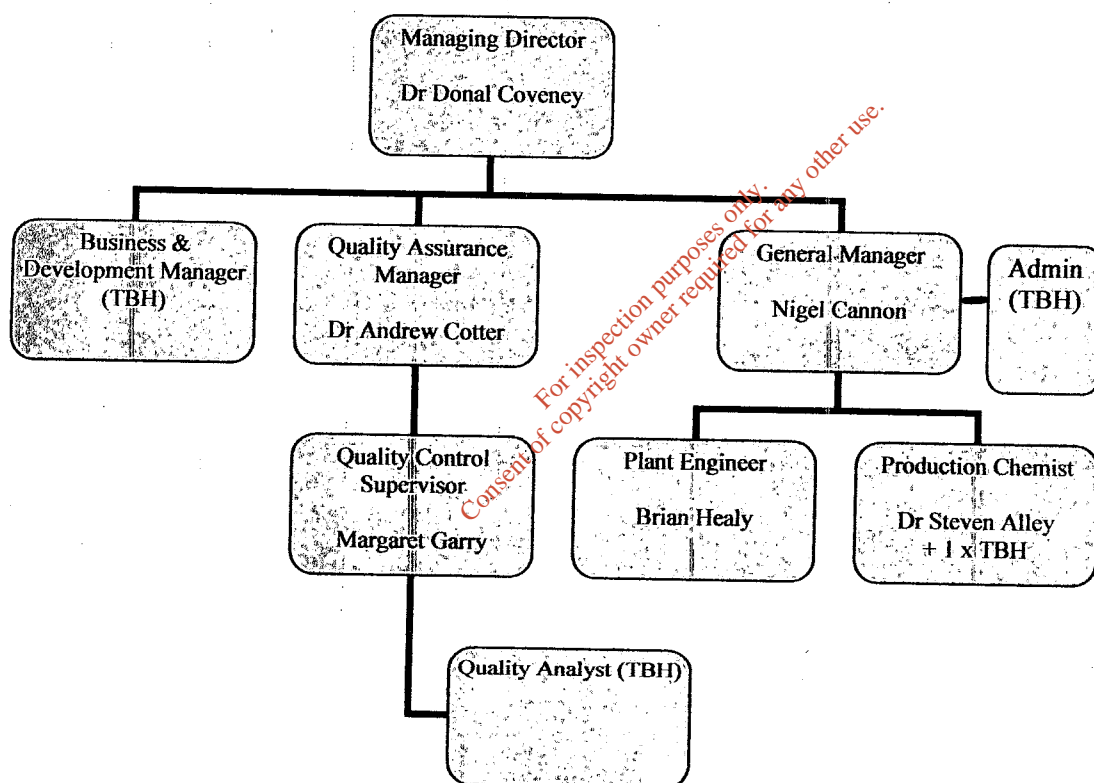
B.10 IPPC Directive

Specify whether the activity is a category of industrial activity referred to in Annex I of the IPPC Directive (96/61/EC) and if yes specify the category.

Supporting information should be included in Attachment N° B.10.

SECTION C: MANAGEMENT OF THE INSTALLATION**C.1 Site Management & Control**

Details should be provided on the management structures for the activity. Organisational charts and all relevant environmental management policy statements, including provisions for on-going assessment of environmental performance, are required.

On-site management structure:

Responsibility for environmental management is part of the General Managers Job Description until such time as a permanent Environmental Health and Safety Officer is appointed in Q1 2008. Specifically, this will involve ensuring compliance with all aspects of the Integrated Pollution Control Licence and the preparation of any relevant reports. The General Manager is responsible for ensuring that all documentation relating to environmental matters and waste disposal are properly recorded and stored. It is the General Managers responsibility to educate relevant staff in matters relating to environmental issues including IPCL compliance and the on-site control of hazardous waste. The General Manager and Plant Engineer will prepare any Standard Operating Procedures relating to environmental issues. It is also the responsibility of the General Manager to audit and inspect production activities and storage conditions to ensure the correct procedures are understood and adhered to.

The Company's Waste Control System is detailed in Standard Operating procedure T-EHS-SOP-004.

Essentially this comprises the drumming of each liquid and solid waste stream into the appropriate UN approved drum – steel for organic waste, plastic for aqueous waste, open top plastic with clamp on lids for solid waste. These containers will be secured in a bunded secure area. Each drum will be labelled prior to use as waste container and each stream that is added to the container is recorded in terms of composition and volume. All drummed waste will then be disposed using an approved Waste Disposal Company. A completed copy of form C.1-Consignment Note for the consignment of Toxic and Dangerous Waste, European Communities (Toxic and Dangerous Waste) Regulations 1982 will be then filed by the General Manager. (See TABLE H.1(ii) Re typical quantities involved).

The Quality system at TopChem Pharmaceuticals is captured under the Quality System Framework. This comprises

Policies – high level documents showing which outlines the strategy or philosophy for a particular subject.

Standard Operating Procedure: Instructions for completing a particular task or activity

Records: e.g., completed batch sheets, QC test sheets, equipment calibrations, etc.

Documentation relating to safety and environmental issues will also be included in this framework to ensure that appropriate control and approval protocols are in place. As yet, the company does not have a formal environmental management program other than the protocols and procedures relating to the storage of process materials already described in this document.

The possibility for a modification to any process (e.g., Malathion for use as an Active Pharmaceutical Ingredient) is limited as these processes are fixed by filings made with various regulatory authorities (e.g., United States FDA) and the requirements of GMP for pharmaceutical compounds. However, TCP will endeavour to ensure that all production processes will be optimised from the standpoint of yield, use of materials, safety and impact on the environment.

Any complaints to TCP in relation to environmental issues will be investigated by the General Manager. Records of the complaint, investigation and any associated corrective action or preventive action will be kept at the site.

C.2 Environmental Management System (EMS)

Indicate whether an Environmental Management System has been developed for the installation. If yes, specify which standard and include a copy of the accreditation certificate.

No Environmental Management System has been developed to date for the installation.

C.3 Hours of Operation

Provide details of the hours of operation for the installation, including:

- (a) Proposed hours of operation.
- (b) Proposed hours of construction and development works and timeframes.
- (c) Any other relevant hours of operation expected.

This information should form Attachment N^o C.

Please refer to attachment No C regarding details of the hours for the installation.

SECTION D: INFRASTRUCTURE & OPERATION

D.1. Operational Information Requirements

Describe the plant, methods, processes, ancillary processes, abatement, recovery and treatment systems, and operating procedures for the activity, to include a copy of such plans, drawings or maps, (site plans and location maps, process flow diagrams), and such other particulars, reports and supporting documentation as are necessary to describe all aspects of the activity. Maps and drawings must be no larger than A3 size.

A development and operational history of the site should be included here.

Attachment N° D should contain a list of all unit operations (processes) to be carried out, including flow diagrams of each with any relevant additional information.

Attachment N° D contains a list of all unit operations (processes) to be carried out, including flow diagram.

SECTION E: EMISSIONS

E.1. Emissions to Atmosphere

E.1.A. Details of all point emissions to atmosphere

Details of all point emissions to atmosphere should be supplied. Complete Table E.1(i) for Boiler Emissions and Table E.1(ii) and E.1(iii) for all other main emission points. Complete Table E.1(iv) for minor emission points.

A summary list of the emission points, together with maps and/or drawings (no larger than A3), and supporting documentation should be included as **Attachment N° E**. Plans of emission elevations, relevant roof heights, etc., should also be included, as should detailed descriptions and schematics of all abatement systems.

The applicant should address in particular any emission point where the substances listed in the Schedule of S.I. 394 of 2004 are emitted.

For emissions outside the BAT guidance limit, a full evaluation of the existing abatement/treatment system must be provided. A planned programme of improvement towards meeting upgraded standards is required. This should highlight specific goals and a time scale, together with options for modification, upgrading or replacement as required to bring the emissions within the limits as set out in the BAT guidance note(s). These notes can be found on the EPA website at www.epa.ie.

Please see attachment E for listing of emission points. Only minor emissions are expected as per table E.1 (iv).

E.1.B. Fugitive and Potential emissions

Give summary details of fugitive and potential emissions in Table E.1(v).

In relation to activities listed in the Schedule of Council Directive 1999/13/EC on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations;

- specify the relevant category of activity in the Schedule
- specify how the requirements in relation to fugitive emissions will be met.

Full details and any supporting information should form **Attachment E.1.B**

There are no fugitive and potential emissions expected from TopChem Pharmaceuticals as outline in attachment E.1.B.

E.2 Emissions to Surface Waters

Tables E.2(i) and E.2(ii) should be completed.

A summary list of the emission points, together with maps/drawings (no larger than A3) and supporting documentation should be included as **Attachment N° E.2**.

The applicant should address in particular any emission point where the substances listed in the Schedule of S.I. No. 394 of 2004 are emitted.

Details of all List I and List II substances listed in the Annex to EU Directive 76/464/EEC (as amended), contained in any emission must be presented. All surface water runoff and storm water drains discharging to surface water bodies must be included. A National Grid References (12 digit, 6E, 6N) must be given for all discharge points. The identity and type of receiving water (river, ditch, estuary, lake, etc.) must be stated.

For emissions outside the BAT guidance limit, a full evaluation of the existing abatement/treatment system must be provided. A planned programme of improvement towards meeting upgraded standards is required. This should highlight specific goals and a time scale, together with options for modification, upgrading or replacement as required to bring the emissions within the limits as set out in the BAT guidance note(s).

There are no emissions to surface waters as per Table E2.(i).

E.3 Emissions to Sewer

Tables E.3(i) and E.3(ii) should be completed.

A summary list of the emission points, together with maps and/or drawings (no larger than A3) and supporting documentation should be included as **Attachment N° E.3**. Details of all List I and List II substances listed in the Annex to EU Directive 76/464/EEC (as amended), contained in any emission must be presented. All relevant information on the receiving sewer, including any effluent treatment/abatement systems, not already described, with schematics as appropriate should also be included in **Attachment N° E.3**.

For emissions outside BAT guidance limit (where given), a full evaluation of the existing abatement/treatment system must be provided. A planned programme of improvement towards meeting upgraded standards is required. This should highlight specific goals and a time scale, together with options for modification, upgrading or replacement as required to bring the emissions within any limits set out in the BAT guidance note(s).

There are no emissions to sewer as per Table E.3(i).

E.4. Emissions to Ground

Describe the existing or proposed arrangements necessary to give effect to Articles 3,4,5,6, and 7 of Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution by certain dangerous substances.

The applicant should supply details of the nature and quality of the substance (agricultural and non-agricultural waste) to be landspread (slurry, effluent, sludges etc) as well as the proposed application rates, periods of application and mode of application (e.g., pipe discharge, tanker).

For emissions outside the BAT guidance limit, a full evaluation of the existing abatement/treatment system must be provided. A planned programme of improvement towards meeting upgraded standards is required. This should highlight specific goals and a time scale, together with options for modification, upgrading or replacement as required to bring the emissions within the limits as set out in the BAT guidance note(s).

There are no emissions to ground as per Table E.4 (i).

E.5 Noise Emissions

Give particulars of the source, location, nature, level, and the period or periods during which the noise emissions are made or are to be made.

Table E.5(i) should be completed, as relevant, for each source.

Supporting information should form **Attachment N° E.5**

Supporting information is attached in Attachment N° E.5

For emissions outside the EPA Guidance Note for Noise in relation to Scheduled Activities 2nd Edition (2006), a full evaluation of the existing abatement/treatment system must be provided. A planned programme of improvement towards meeting upgraded standards is required. This should highlight specific goals and a time scale, together with options for modification, upgrading or replacement as required to bring the emissions within the limits as set out in the Guidance Note.

E.6 Tabular Data on Emission Points

Applicants should submit the following information for each emission point:

| Point Code | Point Type | Easting | Northing | Verified | Emission |
|--|--|--|--|--|--|
| Provide label ID's assigned in section E | A=Atmospheric SW=Surface Water SE = Sewer GW=Groundwater N = Noise SL=Soil/Ground WS=Waste | 6E-digit GPS Irish National Grid Reference | 6N-digit GPS Irish National Grid Reference | Y = GPS used N = GPS not used | e.g. SO ₂ , HCl, NH ₃ |

An individual record (i.e. row) is required for each emission point. Acceptable file formats include Excel, Access or other upon agreement with the Agency. A standard Excel template can be downloaded from the EPA website at www.epa.ie. This data should be submitted to the Agency on a separate CD-Rom containing sections B.2, E.6 and F.3.

Please see emission point details listed in attachment E.6 plus in the enclosed CD ROM.

SECTION F: CONTROL & MONITORING

Describe the proposed technology and other techniques for preventing or, where this is not possible, reducing emissions from the installation/facility.

F.1: Treatment, Abatement and Control Systems

Details of treatment/abatement systems (air and effluent emissions) should be included, together with schematics as appropriate.

For each Emission Point identified complete Table F.1(i) and include detailed descriptions and schematics of all abatement systems.

Attachment N^o F.1 should contain any supporting information.

There are no Treatment, Abatement and Control Systems envisaged.

F.2: Emissions Monitoring and Sampling Points

Identify monitoring and sampling points and outline proposals for monitoring emissions.

Table F.2(i) should be completed (where relevant) for air emissions, for emissions to surface waters, for emissions to sewers, for emissions to ground, and for waste emissions. Where ambient environment monitoring is carried out or proposed, Table F.2(ii) should be completed as relevant for each environmental medium.

Include details of monitoring/sampling locations and methods.

Attachment N^o F.2 should contain any supporting information.

There are no Emissions Monitoring and Sampling Points envisaged.

F.3: Tabular Data on Monitoring and Sampling Points

Applicants should submit the following information for each monitoring and sampling point:

| Point Code | Point Type | Easting | Northing | Verified | Pollutant |
|---|----------------------------|--|--|-------------------------------------|--|
| Provide label ID's assigned in section F3 | M=Monitoring S=Sampling | 6E-digit GPS Irish National Grid Reference | 6N-digit GPS Irish National Grid Reference | Y = GPS used N = GPS not used | e.g. SO ₂ , HCl, NH ₃ |

An individual record (i.e. row) is required for each monitoring and sampling point. Acceptable file formats include Excel, Access or other upon agreement with the Agency. A standard Excel template can be downloaded from the EPA website at www.epa.ie. This data should be submitted to the Agency on a separate CD-Rom containing sections B.2, E.6 and F.3.

Point source monitoring/sampling refers to monitoring from specific emission points (e.g. from a boiler stack or outlet from a wastewater treatment plant). Examples of ambient monitoring includes monitoring of ambient air quality (e.g. boundary or off-site) or monitoring of river quality upstream/downstream of an effluent discharge.

This section is not applicable at TopChem Pharmaceuticals Limited.

SECTION G: RESOURCE USE AND ENERGY EFFICIENCY

G.1 Give a list of the raw and ancillary materials, substances, preparations, fuels and energy which will be produced by or utilised in the activity.

The list(s) given should be very comprehensive, all materials used, fuels, intermediates, laboratory chemicals and product should be included.

Particular attention should be paid to materials and product consisting of, or containing, dangerous substances as described in the EU (Classification, Packaging, Labelling and Notification of Dangerous Substances) Regulations 1994 [SI 77/94]. The list must classify these materials in accordance with Article 2 of these Regulations, and must specify the designated Risk Phrases (R-Phrases) of each substance in accordance with Schedule 2 of the Regulations.

Tables G.1(i) and G.1(ii) must be completed. Copy as required.

Supporting information should be given in Attachment N° G.

Supporting information is listed in Attachment N° G and detailed in Table G.1 (i).

G.2 Energy Efficiency

A description of the energy used in or generated by the activity must be provided. Outline the measures taken to ensure that energy is used efficiently and where appropriate, an energy audit with reference to the EPA Guidance document on Energy Audits should be carried out.

Electricity is the only source of energy used at TopChem Pharmaceuticals Limited. The windows on site are double glazed and the roof is constructed of an insulated clad. Storage heaters are located in areas where it's possible to do so, i.e. Administration areas & QC Laboratory. In addition the exhaust fans on the fume-hoods will only be switched on when the fume-hoods are required.

SECTION H: MATERIALS HANDLING

H.1 Raw Materials, Intermediates and Product Handling

All materials should be listed in Tables G.1(i) and G.1(ii) of Section G.

Details of the storage conditions, location within the site, segregation system used and transport systems within the site should be outlined here. In addition, information relating to the integrity, impermeability and recent testing of pipes, tanks and bund areas should be outlined.

Raw materials, intermediates and Product are detailed in Table G1 (i).

All raw materials will be stored on banded pallets or in safety cabinets with drip trays fitted in the stores area as outlined in the facility drawing attached.

All raw materials will be segregated as follows – acids, bases, flammables, oxidising agents, reducing agents. The transport process utilised at TopChem Pharmaceuticals limited will consist of a trolley with banded trays.

H.2 Describe the arrangements for the recovery or disposal of solid and liquid wastes accepted into or generated by the installation/facility.

For each waste material, give full particulars of:

- (a) Name
- (b) Description & nature of waste
- (c) Source
- (d) Where stored and integrity/impermeability of storage areas
- (e) Amount (m³) and tonnage
- (f) Period or Periods of generation
- (g) Analysis (include test methods and Q.C)
- (h) European Waste Catalogue Code
- (i) Waste Category per EC Reg 1774/2002/EC where relevant

Where any waste would be classified as Hazardous Waste as defined in the Waste Management Acts, 1996 to 2003, this should be made clear in the information provided.

Summary Tables H.1(i) and H.1(ii) should also be completed, as appropriate, for each waste. The licence/permit register number of the waste collection agent or disposal/recovery operator should be supplied as well as the expiry date of the relevant permits.

Supporting information should form Attachment N^o H.2

Supporting information is appended in Attachment N^o H.2

H.3 Waste disposal by on-site landfilling

For wastes to be disposed of by landfilling on-site, full details of the disposal site should be submitted (to include *inter alia*, site selection procedures, location maps, (no larger than A3) geology, hydrogeology, operational plan, containment, gas and leachate management, post-closure care).

Supporting information should form Attachment N^o H.3.

There is no on-site landfilling.

SECTION I: EXISTING ENVIRONMENT & IMPACT OF THE ACTIVITY

Describe the conditions of the site of the installation.

Provide an assessment of the effects of any emissions on the environment, including on an environmental medium other than that into which the emissions are made.

Describe, where appropriate, measures for minimising pollution over long distances or in the territory of other states.

I.1. Assessment of atmospheric emissions

Describe the existing environment in terms of air quality with particular reference to ambient air quality standards.

Provide a statement whether or not emissions of main polluting substances (as defined in the Schedule of S.I. 394 of 2004) to the atmosphere are likely to impair the environment.

Give summary details and an assessment of the impacts of any existing or proposed emissions on the environment, including environmental media other than those into which the emissions are to be made.

Attachment N° I.1 should also contain full details of any dispersion modelling of atmospheric emissions from the activity, where required. When carrying out dispersion modelling, regard should be had to the "Guidelines for the Preparation of Dispersion Modelling Assessments for Compliance with Regulatory Requirements – an Update to Royal Meteorological Society Guidance" or similar guidelines from a recognised authority.

Please see attachment I.1 for details.

I.2. Assessment of Impact on Receiving Surface Water

Describe the existing environment in terms of water quality with particular reference to environmental quality standards or other legislative standards. Table I.2(i) should be completed

Provide a statement whether or not emissions of main polluting substances (as defined in the Schedule of S.I. 394 of 2004) to water are likely to impair the environment.

Give summary details and an assessment of the impacts of any existing or proposed emissions on the environment, including environmental media other than those into which the emissions are to be made.

Full details of the assessment and any other relevant information on the receiving environment should be submitted as **Attachment N° I.2.**

There are no surface water emissions.

I.3. Assessment of Impact of Sewage Discharge.

Give summary details and an assessment of the impacts of any existing or proposed emissions on the environment, including environmental media other than those into which the emissions are to be made.

Full details of the assessment and any other supporting information should form **Attachment N° I.3.**

There are no sewage emissions other than normal domestic sewage from toilet facilities.

I.4 Assessment of Impact of Ground/Groundwater Emissions

Describe the existing groundwater quality. Tables I.4(i) should be completed.

Give summary details and an assessment of the impacts of any existing or proposed emissions on the ground (aquifers, soils, sub-soils and rock environment), including any impact on environmental media other than those into which the emissions are to be made. This includes landspreading, land injection etc.

Land on which material may be landspread shall be identified on a suitable scaled map (1:10,560 and 1:50,000) and submitted as no greater than A3 size. All vulnerable (as a result of ground emissions) surface water bodies must be identified on these maps. Additional information should be included in **Attachment N° I.4**.

Landspreading of Agricultural/Non Agricultural Wastes

Tables I.4(ii) and I.4(iii) should be complete where applicable. Further information is available in the Application Guidance Document.

No such emissions envisaged.

I.5 Ground and/or Groundwater Contamination

Summary details of known ground and/or groundwater contamination, historical or current, on or under the site must be given.

Full details including all relevant investigative studies, assessments, or reports, monitoring results, location and design of monitoring installations, plans, drawings, documentation, including containment engineering, remedial works, and any other supporting information should be included in **Attachment N° I.5**.

No known groundwater contamination.

I.6 Assessment of the Environmental Impact of On-site Waste Recovery and/or Disposal.

Describe the arrangements for the prevention and recovery of waste generated by the activity.

Give details, and an assessment of the impact of any existing or proposed on-site waste recovery/disposal on the environment, including environmental media other than those into which the emissions are to be made.

This information should form **Attachment N° I.6**.

No on-site recovery or waste disposal envisaged.

I.7 Noise Impact

Give details and an assessment of the impacts of any existing or proposed emissions on the environment, including environmental media other than those into which the emissions are to be made.

Ambient noise measurements

Complete Table I.7(i) in relation to the information required below:

- (i) State the maximum Sound Pressure Levels which will be experienced at typical points on the boundary of the operation. (State sampling interval and duration)
- (ii) State the maximum Sound Pressure Levels which will be experienced at typical noise sensitive locations, outside the boundary of the operation.
- (iii) Give details of the background noise levels experienced at the site in the absence of noise from this operation.

Prediction models, maps (no larger than A3), diagrams and supporting documents, including details of noise attenuation and noise proposed control measures to be employed, should form **Attachment N° I.7**.

Noise impact assessment attached in attachment I.7.

I.8 Environmental Considerations and BAT

Describe in outline the main alternatives, if any, to the proposals contained in the application.

Describe any environmental considerations which have been made with respect to the use of cleaner technologies, waste minimisation and raw material substitution.

Describe the measures proposed or in place to ensure that:

- (a) The best available techniques are or will be used to prevent or eliminate or, where that is not practicable, generally reduce an emission from the activity;
- (b) no significant pollution is caused;
- (c) waste production is avoided in accordance with Council Directive 75/442/EEC of 15 July 1975 on waste; where waste is produced, it is recovered or, where that is technically and economically impossible, it is disposed of while avoiding or reducing any impact on the environment;
- (d) energy and other resources are used efficiently;
- (e) the necessary measures are taken to prevent accidents and limit their consequences;
- (f) the necessary measures are taken upon definitive cessation of activities to avoid any pollution risk and return the site of operation to a satisfactory state.

Supporting information should form Attachment N^o I.8.

TopChem Pharmaceuticals will be manufacturing malathion as first product for the facility. The chemistry involved in the manufacture of this product was developed and optimised at TopChem laboratories in Dublin. It is hoped to gain United States Food and drug Administration approval for this compound during 2008. The process for the manufacture of this material has been optimised in terms of the raw material inputs and energy usage. Development work on new compounds is ongoing at TopChem laboratories and environmental considerations will be included at this time.

SECTION J: ACCIDENT PREVENTION & EMERGENCY RESPONSE

Describe the existing or proposed measures, including emergency procedures, to minimise the impact on the environment of an accidental emission or spillage.

Also outline what provisions have been made for response to emergency situations outside of normal working hours, i.e. during night-time, weekends and holiday periods.

Describe the arrangements for abnormal operating conditions including start-up, leaks, malfunctions or momentary stoppages.

Supporting information should form Attachment N^o J.

Operating procedures are designed to minimise the possibility of a spillage. However, should a spillage occur, procedures are in place to ensure that the spill is contained and residue disposed of in a safe manner. All reactions and work-ups are performed in fume-hoods to a maximum volume of 50 Litre vessel contents. Reactor vessels will be housed in containment trays in order that any accidental spillage will be contained in the fume-hood.

Solvent raw materials are purchased in 2.5 Litre bottles and/or 25 Litre containers from approved suppliers. Liquid waste, (organic or aqueous) will be kept in UN approved drums to a maximum volume of 200 Litres per drum. Steel drums will be used for organic wastes and plastic drums for aqueous waste. These drums are kept in a designated area within the Stores on the ground floor of the building. This area will be bunded to contain as spillages. Also, access to the stores area is limited to authorised personnel.

Products will be stored in sealed containers. Liquid products will be stored in plastic coated glass bottle (to contain contents should glass break). Solid raw materials will be stored in storage racks in their original containers.

In the event of a situation arising out of hours, the TopChem Pharmaceuticals facility is monitored by Power Right security firm who have a 24 hour monitoring station. Power Right have the names and telephone numbers of all relevant TopChem Pharmaceutical employees. In the event of an incident, the first person to be contacted will be Nigel Cannon, (General Manager). Second on the list of persons to be contacted is Brian Healy (Plant Engineer) followed by Support staff personnel. The intruder alarm

and fire alarms are linked into the Power Right Security system.

TopChem Pharmaceuticals does not operate a shut-down period so the only time the site will be unoccupied for a prolonged period of time is at Christmas. During this period arrangements will be made to ensure at least one employee is available for cover.

SECTION K: REMEDIATION, DECOMMISSIONING, RESTORATION & AFTERCARE

Describe the existing or proposed measures to minimise the impact on the environment after the activity or part of the activity ceases operation, including provision for post-closure care of any potentially polluting residuals.

Supporting information should be included as **Attachment No. K**.

Supporting information is attached in Attachment No. K.

SECTION L: STATUTORY REQUIREMENTS

Indicate how the requirements of Section 83(5)(a)(i) to (v) and (vii) to (x) of the EPA Acts, 1992 and 2003 shall be met, having regard, where appropriate, to any relevant specification issued by the Agency under section 5 (3) of the Act and the reasons for the selection of the arrangements proposed.

Indicate whether or not the activity is carried out, or may be carried out, or is located such that it is liable to have an adverse effect on -

- (a) a site placed on a list in accordance with Chapter 1 of SI 94 of 1997, or
- (b) a site where consultation has been initiated in accordance with Article 5 of the EU Habitats Directive (92/43/EEC), or

Indicate whether or not the activity is liable to have an adverse effect on water quality in light of S.I. No. 258 of 1998 (Local Government (Water Pollution) Act, 1977 (Water Quality Standards for Phosphorus) Regulations, 1998).

Indicate whether any of the substances specified in the Schedule of the EPA (Licensing)(Amendment) 2004, S.I. 394 of 2004, are discharged by the activity to the relevant medium.

Fit and Proper Person

The PoE Act in Section 83(5)(xi) specifies that the Agency shall not grant a licence unless it is satisfied that the applicant or licensee or transferee as the case may be is a fit and proper person. Section 84(4) of the PoE Act specifies the information required to enable a determination to be made by the Agency.

- Indicate whether the applicant or other relevant person has been convicted under the PoE Act, the Waste Management Act 1996, the Local Government (Water pollution) Acts 1977 and 1990 or the Air Pollution Act 1987.
- Provide details of the applicant's technical knowledge and/or qualifications, along with that of other relevant employees.
- Provide information to show that the person is likely to be in a position to meet any financial commitments or liabilities that may have been or will be entered into or incurred in carrying on the activity to which the application relates or in consequence of ceasing to carry out that activity.

Supporting information should be included as **Attachment N^o L** with reference to where the information can be found in the application.

Supporting information which is included in Attachment N^o L

SECTION M: DECLARATION**Declaration**

I hereby make application for a licence / revised licence, pursuant to the provisions of the Environmental Protection Agency Acts, 1992 and 2003 and Regulations made thereunder.

I certify that the information given in this application is truthful, accurate and complete.

I give consent to the EPA to copy this application for its own use and to make it available for inspection and copying by the public, both in the form of paper files available for inspection at EPA and local authority offices, and via the EPA's website. This consent relates to this application itself and to any further information, submission, objection, or submission to an objection whether provided by me as Applicant, any person acting on the Applicant's behalf, or any other person.

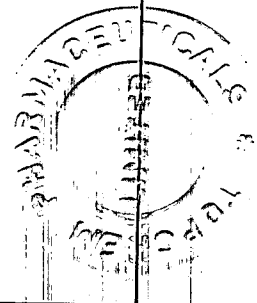
Signed by: [Signature]
(on behalf of the organisation)

Date: 31st MAY 2007

Print signature name: DONAL COVENEY

Position in organisation: MANAGING DIRECTOR

Company stamp or seal:



ANNEX 1: TABLES/ATTACHMENTS

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Table E.1 (i) BOILER EMISSIONS TO ATMOSPHERE (1 Page for each emission point)**Not Applicable – No boiler present.****Emission Point:**

| | | |
|-----------------------------------|-----------|-------------------------|
| Emission Point Ref. N°: | | |
| Location: | | |
| Grid Ref. (12 digit, 6E,6N): | | |
| Vent Details | Diameter: | Height above Ground(m): |
| Date of commencement of emission: | | |

Characteristics of Emission:

| | | |
|--------------------------------------|----------------------|--|
| Boiler rating | | |
| Steam Output: | | |
| Thermal Input: | | kg/hr |
| Boiler fuel | | MW |
| Type: | | |
| Maximum rate at which fuel is burned | | |
| % sulphur content: | | kg/hr |
| NOx | | mg/Nm ³ |
| Maximum volume* of emission | | 0°C, 3% O ₂ (Liquid or Gas), 6% O ₂ (Solid Fuel) |
| | | m ³ /hr |
| Temperature | °C(max) °C(min) | 0°C, 3 % O ₂ (liquid or gas), 6 % O ₂ (solid fuel) |
| | | °C(avg) |

* Volume flow limits for emissions to atmosphere shall be based on Normal conditions of temperature and pressure, (i.e. 0°C, 101.3kPa), dry gas; 3% oxygen for liquid and gas fuels; 6% oxygen for solid fuels.

(i) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up/shutdown to be included*):

| | | | | |
|---------------------------|--|--------|--------|--------|
| Periods of Emission (avg) | | min/hr | hr/day | day/yr |
|---------------------------|--|--------|--------|--------|

TABLE E.1(ii) MAIN EMISSIONS TO ATMOSPHERE (1 Page for each emission point)*Not Applicable – only minor emissions expected (Table E.1 (iv)).*

| | |
|--------------------------------------|--|
| Emission Point Ref. N ^o : | |
| Source of Emission: | |
| Location: | |
| Grid Ref. (12 digit, 6E,6N): | |
| Vent Details Diameter: | |
| Height above Ground(m): | |
| Date of commencement: | |

Characteristics of Emission:

| | | | |
|--|--------------------|---------------------|---------------------|
| (i) Volume to be emitted: | | | |
| Average/day | Nm ³ /d | Maximum/day | Nm ³ /d |
| Maximum rate/hour | Nm ³ /h | Min efflux velocity | m.sec ⁻¹ |
| (ii) Other factors | | | |
| Temperature | °C(max) | °C(min) | °C(avg) |
| For Combustion Sources: Volume terms expressed as : <input type="checkbox"/> wet. <input type="checkbox"/> dry. %O ₂ | | | |

(iii) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up /shutdown to be included*):

| | | | |
|---------------------------|--------|--------|--------|
| Periods of Emission (avg) | min/hr | hr/day | day/yr |
|---------------------------|--------|--------|--------|

TABLE E.1(iii): MAIN EMISSIONS TO ATMOSPHERE - Chemical characteristics of the emission (1 table per emission point)

Emission Point Reference Number: _____

Not Applicable.

| Parameter | Prior to treatment ⁽¹⁾ | | | | Brief description of treatment | As discharged ⁽¹⁾ | | | | | |
|-----------|-----------------------------------|-----|------|-----|--------------------------------|------------------------------|-----|-------|-----|---------|-----|
| | mg/Nm ³ | | kg/h | | | mg/Nm ³ | | kg/h. | | kg/year | |
| | Avg | Max | Avg | Max | | Avg | Max | Avg | Max | Avg | Max |
| | | | | | | | | | | | |

1. Concentrations should be based on Normal conditions of temperature and pressure, (i.e. 0°C, 101.3kPa). Wet/dry should be the same as given in Table E.1(ii) unless clearly stated otherwise.

TABLE E.1(iv): EMISSIONS TO ATMOSPHERE - Minor atmospheric emissions

| Emission point Reference Numbers | Description | Emission details ¹ | | | | Abatement system employed |
|-------------------------------------|--|-------------------------------|-----------------------|-------|---------|---------------------------|
| | | material | mg/Nm ³⁽²⁾ | kg/h. | kg/year | |
| E1 | FumeHood 1, Exhaust fan in Production Laboratory | Organic Vapour | <6.6 | <0.01 | <26 | Not Applicable |
| E2 | FumeHood 2 Exhaust fan in Process Development Laboratory | Organic Vapour | <6.6 | <0.01 | <26 | Not Applicable |
| E3 | Material Handling Unit | Air | N/A | N/A | N/A | Not Applicable |
| E4 | Local Laboratory Exhaust | Air | N/A | N/A | N/A | Not Applicable |

1 The maximum emission should be stated for each material emitted, the concentration should be based on the maximum 30 minute mean.

2 Concentrations should be based on Normal conditions of temperature and pressure, (i.e. 0°C/101.3kPa). Wet/dry should be clearly stated. Include reference oxygen conditions for combustion sources.

One of the Production laboratory fume-hoods has an inbuilt scrubber system which can be optionally used to remove unpleasant odours but the quantities expected are in keeping with the scale of solvents used.

TABLE E.1(v): EMISSIONS TO ATMOSPHERE – Fugitive and Potential atmospheric emissions*Not Applicable – none expected.*

| Emission point ref. no. (as per flow diagram) | Description | Malfunction which could cause an emission | Emission details (Potential max. emissions) ¹ | | |
|---|-------------|---|---|--------------------|---------|
| | | | Material | mg/Nm ³ | kg/hour |
| | | | | | |

¹ Estimate the potential maximum emission for each malfunction identified.

TABLE E.2(i): EMISSIONS TO SURFACE WATERS

(One page for each emission)

*Not Applicable – no emissions to surface waters.***Emission Point:**

| | | | |
|--|--------------|--|--|
| Emission Point Ref. N ^o : | | | |
| Source of Emission: | | | |
| Location : | | | |
| Grid Ref. (12 digit, 6E,6N): | | | |
| Name of receiving waters: | | | |
| Flow rate in receiving waters: | | | _____ m ³ .sec ⁻¹ Dry Weather Flow |
| | | | _____ m ³ .sec ⁻¹ 95%ile flow |
| Available waste assimilative capacity: | _____ kg/day | | |

Emission Details:

| | | | |
|--------------------------|----------------|-------------|----------------|
| (i) Volume to be emitted | | | |
| Normal/day | m ³ | Maximum/day | m ³ |
| Maximum rate/hour | m ³ | | |

(ii) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up /shutdown to be included*):

| | |
|---------------------------|--|
| Periods of Emission (avg) | _____ min/hr _____ hr/day _____ day/yr |
|---------------------------|--|

TABLE E.2(ii): EMISSIONS TO SURFACE WATERS - Characteristics of the emission (1 table per emission point)*Not Applicable – no emissions to surface waters.**Emission point reference number :* _____

| Parameter | Prior to treatment | | | | As discharged | | | | % Efficiency |
|-----------|----------------------------|---------------------------|--------|---------|----------------------------|---------------------------|--------|---------|--------------|
| | Max. hourly average (mg/l) | Max. daily average (mg/l) | kg/day | kg/year | Max. hourly average (mg/l) | Max. daily average (mg/l) | kg/day | kg/year | |
| | | | | | | | | | |

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TABLE E.3(i): EMISSIONS TO SEWER(One page for each emission)*Not Applicable – no emissions to sewer other than domestic waste from toilet facilities.***Emission Point:**

| | |
|----------------------------------|--|
| Emission Point Ref. N°: | |
| Location of connection to sewer: | |
| Grid Ref. (12 digit, 6E,6N): | |
| Name of sewage undertaker: | |

Emission Details:

| | | | |
|--------------------------|----------------|-------------|----------------|
| (i) Volume to be emitted | | | |
| Normal/day | m ³ | Maximum/day | m ³ |
| Maximum rate/hour | m ³ | | |

(ii) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up /shutdown to be included*):

| | |
|---------------------------|-------------------------------------|
| Periods of Emission (avg) | _____min/hr _____hr/day _____day/yr |
|---------------------------|-------------------------------------|

TABLE E.3(ii): EMISSIONS TO SEWER - Characteristics of the emission (1 table per emission point)*Not Applicable.***Emission point reference number :** _____

| Parameter | Prior to treatment | | | | As discharged | | | | % Efficiency |
|-----------|----------------------------|---------------------------|--------|---------|----------------------------|---------------------------|--------|---------|--------------|
| | Max. hourly average (mg/l) | Max. daily average (mg/l) | kg/day | kg/year | Max. hourly average (mg/l) | Max. daily average (mg/l) | kg/day | kg/year | |
| | | | | | | | | | |

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TABLE E.4(i): EMISSIONS TO GROUND (1 Page for each emission point)**Not Applicable – no emissions to Ground.****Emission Point or Area:**

| | |
|--|--|
| Emission Point/Area Ref. N ^o : | |
| Emission Pathway: (borehole, well, percolation area, soakaway, landspreading, etc.) | |
| Location : | |
| Grid Ref. (12 digit, 6E,6N): | |
| Elevation of discharge: (relative to Ordnance Datum) | |
| Aquifer classification for receiving groundwater body: | |
| Groundwater vulnerability assessment (including vulnerability rating): | |
| Identity and proximity of groundwater sources at risk (wells, springs, etc): | |
| Identity and proximity of surface water bodies at risk: | |

Emission Details:

| | | | |
|--------------------------|----------------|-------------|----------------|
| (i) Volume to be emitted | | | |
| Normal/day | m ³ | Maximum/day | m ³ |
| Maximum rate/hour | m ³ | | |

(ii) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up /shutdown to be included*):

| | |
|---------------------------|-------------------------------------|
| Periods of Emission (avg) | _____min/hr _____hr/day _____day/yr |
|---------------------------|-------------------------------------|

TABLE E.4(ii): EMISSIONS TO GROUND - Characteristics of the emission (1 table per emission point)*Not Applicable.**Emission point/area reference number:* _____

| Parameter | Prior to treatment | | | | As discharged | | | | % Efficiency |
|-----------|----------------------------|---------------------------|--------|---------|----------------------------|---------------------------|--------|---------|--------------|
| | Max. hourly average (mg/l) | Max. daily average (mg/l) | kg/day | kg/year | Max. hourly average (mg/l) | Max. daily average (mg/l) | kg/day | kg/year | |
| | | | | | | | | | |

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Table E.5(i): NOISE EMISSIONS - Noise sources summary sheet

| Source | Emission point Ref. No | Equipment Ref. No | Sound Pressure ¹ dBA at reference distance | Octave bands (Hz) Sound Pressure ¹ Levels dB(unweighted) per band | | | | | | | | | Impulsive or tonal qualities | Periods of Emission |
|-------------------------|------------------------|-------------------|---|---|------|------|------|------|------|------|------|------|------------------------------|---------------------|
| | | | | 31.5 | 63 | 125 | 250 | 500 | 1K | 2K | 4K | 8K | | |
| Topchem Pharmaceuticals | NSL 1 Day | Cirrus CR:831A | 51.7 | 50.1 | 56.2 | 46.7 | 48.8 | 43.6 | 38.5 | 35.6 | 26.6 | 30.7 | Yes | 15 min. |
| Topchem Pharmaceuticals | NSL 1 Night | Cirrus CR:831A | 35.8 | 29.5 | 29.0 | 21.9 | 21.0 | 17.7 | 18.2 | 11.7 | 12.2 | 12.2 | No | 15 min. |
| Topchem Pharmaceuticals | NSL 2 Day | Cirrus CR:831A | 52.6 | 54.5 | 47.7 | 46.8 | 47.8 | 59.1 | 49.5 | 42.6 | 39.0 | 20.2 | No | 15 min. |
| Topchem Pharmaceuticals | NSL 2 Night | Cirrus CR:831A | 37.8 | 29.6 | 35.8 | 30.1 | 26.3 | 22.6 | 15.8 | 14.0 | 10.7 | 11.4 | No | 15 min. |
| Topchem Pharmaceuticals | NSL 3 Day | Cirrus CR:831A | 50.2 | 58.4 | 50.2 | 41.4 | 32.3 | 25.1 | 24.8 | 32.9 | 26.3 | 19.2 | No | 15 min. |
| Topchem Pharmaceuticals | NSL 3 Night | Cirrus CR:831A | 40.2 | 42.8 | 24.9 | 22.1 | 20.6 | 23.3 | 15.5 | 13.2 | 10.1 | 10.9 | No | 15 min. |
| Topchem Pharmaceuticals | NSL 4 Day | Cirrus CR:831A | 54.4 | 52.2 | 50.4 | 44.1 | 46.2 | 38.9 | 48.1 | 40.3 | 38.1 | 27.2 | Yes | 15 min. |
| Topchem Pharmaceuticals | NSL 4 Night | Cirrus CR:831A | 41.7 | 43.3 | 36.4 | 38.8 | 23.0 | 17.3 | 12.1 | 14.5 | 16.6 | 14.1 | Yes | 15 min. |
| Topchem Pharmaceuticals | NSL 5 Day | Cirrus CR:831A | 50.6 | 62.0 | 53.7 | 43.0 | 37.3 | 48.1 | 45.1 | 38.6 | 29.5 | 24.9 | Yes | 15 min. |
| Topchem Pharmaceuticals | NSL 5 Night | Cirrus CR:831A | 46.8 | 39.2 | 61.5 | 34.6 | 39.1 | 20.5 | 20.4 | 5.7 | 19.4 | 21.4 | No | 15 min. |
| Topchem Pharmaceuticals | NSL 6 Day | Cirrus CR:831A | 53.3 | 60.1 | 61.1 | 31.7 | 42.7 | 37.5 | 39.8 | 33.8 | 33.3 | 18.6 | No | 15 min. |
| Topchem Pharmaceuticals | NSL 6 Night | Cirrus CR:831A | 46.0 | 38.1 | 46.5 | 36.2 | 19.0 | 12.2 | 18.1 | 25.8 | 5.0 | 10.5 | Yes | 15 min. |

1. For items of plant sound power levels may be used.

TABLE F.1(i): ABATEMENT / TREATMENT CONTROL*Not Applicable – No abatement required as there are no such emissions.**Emission point reference number :* _____

| Control ¹ parameter | Equipment ² | Equipment maintenance | Equipment calibration | Equipment back-up |
|--------------------------------|------------------------|-----------------------|-----------------------|-------------------|
| | | | | |

| Control ¹ parameter | Monitoring to be carried out ³ | Monitoring equipment | Monitoring equipment calibration |
|--------------------------------|---|----------------------|----------------------------------|
| | | | |

¹ List the operating parameters of the treatment / abatement system which control its function.² List the equipment necessary for the proper function of the abatement / treatment system.³ List the monitoring of the control parameter to be carried out.

TABLE F.2(i) : EMISSIONS MONITORING AND SAMPLING POINTS

(1 table per monitoring point)

*Not Applicable - None.**Emission Point Reference No. :* _____

| Parameter | Monitoring frequency | Accessibility of Sampling Points | Sampling method | Analysis method/ technique |
|-----------|----------------------|----------------------------------|-----------------|----------------------------|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

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TABLE F.2(ii): AMBIENT ENVIRONMENT MONITORING AND SAMPLING POINTS (1 table per monitoring point)*Not Applicable - None.***Monitoring Point Reference No :** _____

| Parameter | Monitoring frequency | Accessibility of Sampling point | Sampling method | Analysis method / technique |
|-----------|----------------------|---------------------------------|-----------------|-----------------------------|
| | | | | |

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Table G.1(i) Details of Process related Raw Materials, Intermediates, Products, etc., used or generated on the site

| Ref. N° 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 |
|-----------------|---|------------|--|------------------------|-----------------------|--------------------|---------------------------|---------------------------|
| | Diethyl Maleate | 141-05-9 | Not Applicable | 0.025 | 0.025 | Raw Material | Not applicable | Not applicable |
| | O,O-Dimethylphosphorodithoic acid ammonium salt | 756-80-9 | Not applicable | 0.05 | 0.05 | Raw Material | Not applicable | S 24/25 |
| | NaHCO ₃ | 497-19-8 | Not Applicable | 0.025 | 0.025 | Base | Not applicable | Not applicable |
| | Ethanol | 64-17-5 | Flammable | 0.25 | 0.25 | Solvent | R11 | S16, 33, 7, 9 |
| | Hydroquinone | 123-31-9 | Irritant, dangerous to the environment | <0.001 | <0.001 | Catalyst | R-22,40,41,43,50, 68 | S-326,36,37,39,61 |
| | Triethylamine | 121-44-8 | Flammable, corrosive | <0.001 | <0.001 | Catalyst | R-11,20,21,22,35 | S-3,16,26,29,36,37, 39,45 |
| | Dichloromethane | 75-09-2 | Harmful | 0.25 | 0.25 | Solvent | R-40 | S-2,23,24,25,36,37 |
| | Toluene | 108-88-3 | Flammable , Harmful | 0.25 | 0.25 | Solvent | | |
| | HCL (Gas) | 7647-01-0 | Toxic, corrosive | 0.15 | 0.15 | Acid | R-24,37 | S-26,36,37,39,45 |
| | Ammonium Chloride | 12125-02-9 | Irritant | 0.025 | 0.025 | By-product | R-36, 37, 38 | S-22 |
| | Acetone | 67-64-1 | Highly flammable, Irritant | 0.25 | 0.25 | Solvent (cleaning) | R11, 36, 66, 67 | S2, 9, 16, 23 |
| | Malathion | 121-75-5 | Harmful, dangerous for the environment | 0.025 | 0.025 | Product | R22, 50/53 | S2, 24, 60, 61 |

- Notes:
1. In cases where a material comprises a number of distinct and available dangerous substances, please give details for each component substance.
 2. c.f. Article 2(2) of SI N° 77/94
 3. c.f. Schedules 9 and 10 of SI No 62/2004

The below table is Not Applicable.

Table G.1(ii) Details of Process related Raw Materials, Intermediates, Products, etc., used or generated on the site

| Ref. N° or Code | Material/ Substance ⁽¹⁾ | TA Luft Class 1, 2 or 3 | Odour | | | EU Lists I and II (Tick and specify Group/Family Number) | | | |
|-----------------------|---------------------------------------|-------------------------------|--------------------|-------------|------------------------------------|---|---------------------------|------------------------------------|---------|
| | | | Odourous Yes/No | Description | Threshold µg/m ³ | Dangerous Substances Directive 76/464/EEC | | Groundwater Directive 80/68/EEC | |
| | | | | | | List I | List II +129 ⁴ | List I | List II |
| | | | | | | | | | |

Notes (cont.): 4. The European Commission priority candidate list

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TABLE H.1(i): WASTE - Hazardous Waste Recovery/Disposal

| Waste material | EWC Code | Main source ¹ | Quantity | | On-site Recovery/Disposal (Method & Location) | Off-site Recovery, reuse or recycling (Method, Location & Undertaker) | Off-site Disposal (Method, Location & Undertaker) |
|---|----------------|--------------------------|----------------|------------------------|--|--|--|
| | | | Tonnes / month | m ³ / month | | | |
| Waste Stream #1 Non Chlorinated Organic Solvents | 070504 | Production of Malathion | - | 0.06 | Non Applicable | Non Applicable | as per Licensed contractor |
| Waste Stream # 2 Chlorinated Organic Solvents | 070503 | Production of Malathion | - | 0.02 | Non Applicable | Non Applicable | as per Licensed contractor |
| Waste material | Not applicable | General | 0.02 | | Non Applicable | Non Applicable | as per Licensed contractor |

¹ A reference should be made to the main activity / process for each waste.

TABLE H.1(ii) WASTE - Other Waste Recovery/Disposal

| Waste material | EWC Code | Main source ¹ | Quantity | | On-site recovery/disposal ² (Method & Location) | Off-site Recovery, reuse or recycling (Method, Location & Undertaker) | Off-site Disposal (Method, Location & Undertaker) |
|------------------------|----------|--------------------------|----------------|------------------------|---|--|--|
| | | | Tonnes / month | m ³ / month | | | |
| Aqueous waste Acidic | 070501 | Production of Malathion | - | 0.02 | Non Applicable | Non Applicable | As per Licensed contractor |
| Aqueous waste basic | 070501 | Production of Malathion | - | 0.08 | Non Applicable | Non Applicable | As per Licensed Contractor |
| Solid laboratory Waste | 070514 | Production of Malathion | 0.02 | - | Non Applicable | Non Applicable | As per Licensed Contractor |
| Solid Chemical waste | 070513 | Production of Malathion | 0.01 | - | Non Applicable | Non Applicable | As per Licensed Contractor |

1 A reference should be made to the main activity/ process for each waste.

2 The method of disposal or recovery should be clearly described and referenced to Attachment H.1

No waste Disposal Contractors have been selected as yet as no activities have commenced. However, Approved Licensed Waste Disposal Contractors will be advised to the EPA in due course.

Table I.2(i) SURFACE WATER QUALITY

(Sheet 1 of 2) Monitoring Point/ Grid Reference: _____

| Parameter | Results (mg/l) | | | | Sampling method ² (grab, drift etc.) | Normal Analytical Range ² | Analysis method / technique |
|--|-------------------|------|------|------|--|---|--------------------------------|
| | Date | Date | Date | Date | | | |
| pH | | | | | | | |
| Temperature | | | | | | | |
| Electrical conductivity EC | | | | | | | |
| Ammoniacal nitrogen NH ₄ -N | | | | | | | |
| Chemical oxygen demand | | | | | | | |
| Biochemical oxygen demand | | | | | | | |
| Dissolved oxygen DO | | | | | | | |
| Calcium Ca | | | | | | | |
| Cadmium Cd | | | | | | | |
| Chromium Cr | | | | | | | |
| Chloride Cl | | | | | | | |
| Copper Cu | | | | | | | |
| Iron Fe | | | | | | | |
| Lead Pb | | | | | | | |
| Magnesium Mg | | | | | | | |
| Manganese Mn | | | | | | | |
| Mercury Hg | | | | | | | |

This section is not applicable. See Attachment N° I.2. for details..

Surface Water Quality (Sheet 2 of 2)

| Parameter | Results (mg/l) | | | | Sampling method (grab, drift etc.) | Normal Analytical Range | Analysis method / technique |
|--|----------------|------|------|------|------------------------------------|-------------------------|-----------------------------|
| | Date | Date | Date | Date | | | |
| Nickel Ni | | | | | | | |
| Potassium K | | | | | | | |
| Sodium Na | | | | | | | |
| Sulphate SO ₄ | | | | | | | |
| Zinc Zn | | | | | | | |
| Total alkalinity (as CaCO ₃) | | | | | | | |
| Total organic carbon TOC | | | | | | | |
| Total oxidised nitrogen TON | | | | | | | |
| Nitrite NO ₂ | | | | | | | |
| Nitrate NO ₃ | | | | | | | |
| Faecal coliforms (/100mls) | | | | | | | |
| Total coliforms (/100mls) | | | | | | | |
| Phosphate PO ₄ | | | | | | | |

This section is not applicable. See Attachment N° 1.2. for details..

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Table I.4(i) GROUNDWATER QUALITY
(Sheet 1 of 2) Monitoring Point/ Grid Reference:

| Parameter | Results (mg/l) | | | | Sampling method (composite etc.) | Normal Analytical Range | Analysis method / technique |
|--|----------------|------|------|------|----------------------------------|-------------------------|-----------------------------|
| | Date | Date | Date | Date | | | |
| pH | | | | | | | |
| Temperature | | | | | | | |
| Electrical conductivity EC | | | | | | | |
| Ammoniacal nitrogen NH ₄ -N | | | | | | | |
| Dissolved oxygen DO | | | | | | | |
| Residue on evaporation (180°C) | | | | | | | |
| Calcium Ca | | | | | | | |
| Cadmium Cd | | | | | | | |
| Chromium Cr | | | | | | | |
| Chloride Cl | | | | | | | |
| Copper Cu | | | | | | | |
| Cyanide Cn, total | | | | | | | |
| Iron Fe | | | | | | | |
| Lead Pb | | | | | | | |
| Magnesium Mg | | | | | | | |
| Manganese Mn | | | | | | | |
| Mercury Hg | | | | | | | |
| Nickel Ni | | | | | | | |
| Potassium K | | | | | | | |
| Sodium Na | | | | | | | |

THIS SECTION IS NOT APPLICABLE. SEE ATTACHMENT N^o 1.2. FOR DETAILS..

Groundwater Quality (sheet 2 of 2)

| Parameter | Results (mg/l) | | | | Sampling method (composite, dipper etc.) | Normal Analytical Range | Analysis method / technique |
|--|-------------------|------|------|------|---|----------------------------|--------------------------------|
| | Date | Date | Date | Date | | | |
| Phosphate PO ₄ | | | | | | | |
| Sulphate SO ₄ | | | | | | | |
| Zinc Zn | | | | | | | |
| Total alkalinity (as CaCO ₃) | | | | | | | |
| Total organic carbon TOC | | | | | | | |
| Total oxidised nitrogen TON | | | | | | | |
| Arsenic As | | | | | | | |
| Barium Ba | | | | | | | |
| Boron B | | | | | | | |
| Fluoride F | | | | | | | |
| Phenol | | | | | | | |
| Phosphorus P | | | | | | | |
| Selenium Se | | | | | | | |
| Silver Ag | | | | | | | |
| Nitrite NO ₂ | | | | | | | |
| Nitrate NO ₃ | | | | | | | |
| Faecal coliforms (/100mls) | | | | | | | |
| Total coliforms (/100mls) | | | | | | | |
| Water level (m OD) | | | | | | | |

This section is not applicable. See Attachment N° I.2 for details.

TABLE I.4(ii): LIST OF OWNERS/FARMERS OF LAND*Not Applicable – None.*

| Land Owner | Townlands where landspreading | Map Reference | Fertiliser P requirement for each farm |
|------------|-------------------------------|---------------|--|
| | | | *NMP must take account of on-farm slurry |

Total P requirement of the client List _____

TABLE I.4(ii): LANDSPREADING

Land Owner/Farmer _____

Map Reference _____

| Field ID | Total Area (ha) | (a) Usable Area (ha) | Soil P Test Mg/l | Date of P test | Crop | P Required (kg P/ha) | Volume of On-Farm Slurry Returned (m ³ /ha) | Estimated P in On-Farm Slurry (kg P/ha) | (b) Volume to be Applied (m ³ /ha) | P Applied (kg P/ha) | Total Volume of imported slurry per plot (m ³) |
|----------|-----------------|----------------------|------------------|----------------|------|----------------------|--|---|---|---------------------|--|
| | | | | | | | | | | | |

TOTAL VOLUME THAT CAN BE IMPORTED ON TO THE FARM:

| | |
|---|-----------------------|
| Concentration of P in landspread material | - kg P/m ³ |
| Concentration of N in landspread material | - kg N/m ³ |

Table I.7(i): AMBIENT NOISE ASSESSMENT

Third Octave analysis for noise emissions should be used to determine tonal noises

| | National Grid Reference | Sound Pressure Levels | | |
|-------------------------------------|----------------------------|-----------------------|--------------------|--------------------|
| | (6N, 6E) | L(A) _{eq} | L(A) ₁₀ | L(A) ₉₀ |
| 1. SITE BOUNDARY | | | | |
| Location 1: | 165850N, 315640W | 51.7 | 150.0 | 48.9 |
| Location 2: | 165850N, 315640W | 35.8 | 36.6 | 17.7 |
| Location 3: | 165850N, 315640W | 52.6 | 53.6 | 44.2 |
| Location 4: | 165850N, 315640W | 37.8 | 36.6 | 24.3 |
| 2. NOISE SENSITIVE LOCATIONS | | | | |
| Location 1: | 165850N, 315640W | 50.2 | 43.9 | 34.1 |
| Location 2: | 165850N, 315640W | 40.2 | 150.0 | 29.7 |
| Location 3: | 165850N, 315640W | 54.4 | 57.7 | 43.2 |
| Location 4: | 165850N, 315640W | 41.7 | 32.4 | 24.3 |
| | 165850N, 315640W | 50.6 | 150.0 | 37.4 |
| | 165850N, 315640W | 46.8 | 51.0 | 29.3 |
| | 165850N, 315640W | 53.3 | 50.7 | 38.4 |
| | 165850N, 315640W | 46.0 | 39.7 | 25.0 |

NOTE: All locations should be identified on accompanying drawings.

ANNEX 2: CHECKLIST FOR ARTICLE 10 COMPLIANCE

Article 10 of the Environmental Protection Agency (Licensing) Regulations, 1994 to 2004 sets out the statutory requirements for information to accompany a licence application. The Application Form is designed in such a way as to set out these questions in a structured manner and not necessarily in the order presented in Article 10. In order to ensure a legally valid application in respect of Article 10 requirements, all Applicants should complete the following checklist and submit it with the completed Application Form.

| Article 10(2) | | Section in Application | Checked by Applicant ✓ |
|---------------|--|------------------------|------------------------|
| (a) | give the name, address and telephone number of the applicant and, if different, any address to which correspondence relating to the application should be sent and, if the applicant is a body corporate, the address of its registered or principal office, | B1 | ✓ |
| (b) | give - (i) in the case of an established activity, the number of employees and other persons working or engaged in connection with the activity on the date after which a licence is required and during normal levels of operation, or (ii) in any other case, the gross capital cost of the activity to which the application relates, | B4 | ✓ |
| (c) | give the name of the planning authority in whose functional area the activity is or will be carried on, | B5 | ✓ |
| (d) | in the case of a discharge of any trade effluent or other matter (other than domestic sewage or storm water) to a sewer of a sanitary authority, give the name of the sanitary authority in which the sewer is vested or by which it is controlled, | B6 | ✓ |
| (e) | give the location or postal address (including where appropriate, the name of the relevant townland or townlands) and the National Grid reference of the premises to which the activity relates, | B2 | ✓ |
| (f) | specify the relevant class or classes in the First Schedule to the Act to which the activity relates, | B3 | ✓ |
| (g) | specify the raw and ancillary materials, substances, preparations, fuels and energy which will be produced by or utilised in the activity, | G | ✓ |
| (h) | describe the plant, methods, processes, ancillary processes, abatement, recovery and treatment systems, and operating procedures for the activity, | D | ✓ |

| Article 10(2) continued../ | | Section in Application | Checked by Applicant ✓ |
|----------------------------|---|------------------------|------------------------|
| (i) | indicate how the requirements of section 83(5)(a)(i) to (v) and (vii) to (x) of the Act shall be met, having regard, where appropriate, to any relevant specification issued by the Agency under section 5(3) of the Act and the reasons for the selection of the arrangements proposed, | L | ✓ |
| (j) | give particulars of the source, nature, composition, temperature, volume, level, rate, method of treatment and location of emissions, and the period or periods during which the emissions are made or are to be made, | E.5 | ✓ |
| (k) | describe the arrangements for the prevention or minimisation of waste and, where waste is produced, the on and of site arrangements for the recovery or disposal of solid and liquid wastes, | I.6 | ✓ |
| (l) | specify, by reference to the relevant European Waste Catalogue codes as prescribed by Commission Decision 2000/532/EC of 03 May 2000, the quantity and nature of the waste or wastes produced or to be produced by the activity, | H1(i), H1(ii) | |
| (m) | provide: (i) details, and an assessment, of the impacts of any existing or proposed emissions on the environment, including on an environmental medium other than that or those into which the emissions are or are to be made, and (ii) details of the proposed measures to prevent or eliminate, or where that is not practicable, to limit, reduce or abate emissions, | I.1 | ✓ |
| (n) | identify monitoring and sampling points and outline proposals for monitoring emissions and the environmental consequences of any such emissions, | F.2 | ✓ |
| (o) | describe the condition of the site of the installation, | I | ✓ |
| (p) | describe in outline the main alternatives, if any, to the proposals contained in the application which were studied by the applicant, | I.8 | ✓ |
| (q) | specify the measures to be taken to comply with an environmental quality standard where such a standard requires stricter conditions to be attached to a licence than would otherwise be determined by reference to best available techniques, | C1 | ✓ |
| Article 10(2) continued../ | | Section in Application | Checked by Applicant ✓ |
| (r) | describe the measures to be taken for minimising pollution over long distances or in the territory of other states, | I.6 | ✓ |
| (s) | describe the measures to be taken under abnormal operating conditions, including start-up, shutdown, leaks, malfunctions, breakdowns and momentary stoppages, | J | ✓ |

| | | | |
|-----|---|-----|---|
| (t) | describe the measures to be taken on and following the permanent cessation of the activity or part of the activity to avoid any risk of environmental pollution and to return the site of the activity to a satisfactory state, | K | ✓ |
| (u) | describe, in the case of an activity which gives, or could give rise, to an emission containing a hazardous substance which is discharged to an aquifer and is specified in the Annex to Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances, the arrangements necessary to comply with said Council Directive, | E4 | ✓ |
| (v) | include any other information required under Article 6(1) of Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control, | B10 | ✓ |
| (w) | include a non-technical summary of information provided in relation to the matters specified in paragraphs (f) to (v) above, | A1 | ✓ |
| (x) | state whether the activity consists of, comprises, or is for the purposes an establishment to which the European Communities (Control of Major Accident Hazards involving Dangerous Substances) Regulations, 2000 apply, | B9 | ✓ |

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| Article 10(3) Without prejudice to Article 12(1), an application for a licence shall be accompanied by - | | | Section Application | in | Checked Applicant ✓ | by |
|---|--|--|------------------------|----|------------------------|----|
| (a) | a copy of the relevant page of the newspaper in which the notice in accordance with article 6 has been published, | | B.8 | | ✓ | |
| (b) | a copy of the text of the site notice erected or fixed on the land or structure in accordance with article 7, | | B.8 | | ✓ | |
| (c) | a copy of the notice given to the planning authority under section 85(1)(a) of the Act, | | B.8 | | ✓ | |
| (d) | a copy of such plans, including a site plan and location map (no larger than A3), and such other particulars, reports and supporting documentation as are necessary to identify and describe - | | | | | |
| | (i) the activity | | | | | |
| | (ii) the position of the site notice in accordance with article 7, | | A.1 | | ✓ | |
| | (iii) the point or points from which emissions are made or are to be made, and | | B.8 | | ✓ | |
| | (iv) monitoring and sampling points, and | | E | | ✓ | |
| (e) | a fee specified in accordance with section 94 of the Act. | | F.2 | | ✓ | |
| | | | | | ✓ | |

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| Article 10(4) | | Checked by |
|---------------|---|-----------------------------|
| (b) | <p>A signed original and 2 hardcopies of the application and accompanying documents/particulars in hardcopy format plus 2 copies of all files in electronic searchable PDF format on CD-Rom shall be submitted to the headquarters of the Agency.</p> <p>In cases where an E.I.S. is required to be submitted to the Agency in support of the application, a signed original and 2 hardcopies of the EIS plus 16* copies of all files in electronic searchable PDF format on CD-Rom shall be submitted to the headquarters of the Agency.</p> <p>* Energy sector applicants = 18 copies</p> | <p>Applicant ✓</p> <p>✓</p> |
| | Hardcopies submitted. | ✓ |
| | CD version submitted. | ✓ |

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