Attachment K Remediation, Decommissioning, Restoration and Aftercare

Schwarz Pharma Revised IPCL Application

For inspection purposes only.
Consent of copyright owner is required for any other use.

Issue No 53836-003

EPA Export 25-07-2013:15:06:04

CONTENTS

For inspection purposes only.
Consent of copyright owner required for any other use.

EPA Export 25-07-2013:15:06:04

For inspection purposes only.
Consent of copyright owner required for any other use.

Appendix K1-

Residuals Management Plan for Bay 130

File Reference

EPA Export 25-07-2013:15:06:04

RESIDUAL MANAGEMENT PLAN FOR BAY 130

DRAFT

53836 / 002

SCHWARZ PHARMA LIMITED

APRIL 2004

For inspection purposes only.
Consent of copyright owner required for any other use.

URS Ireland Limited
Iveagh Court
6-8 Harcourt Road
Dublin 2
Tel: + 353 (0) 1 415 5100
Fax: + 353 (0) 1 415 5101
www.urseurope.com

File Reference

EPA Export 25-07-2013:15:06:04

URS IRELAND LIMITED

DUBLIN OFFICE

Site Name: Schwarz Pharma Limited

Client Name: Sinead Mc Aleer

Document Title: Residual Management Plan for Bay 130

URS Job Number: 53836-002

Document Production / Approval Record

ISSUE No.: 1	NAME	SIGNATURE	DATE	POSITION
Prepared by	Ms. Anne Marie Flynn/ Mr. Kevin Forde			
Checked by	Mr. Gerard Kelly			
Approved by	Mr. Gerard Kelly			

Consent of copyright owner required for any other use. For inspection purposes only.

Document Revision Record

Issue No.	Date	Details of Revisions
1		Draft

EPA Export 25-07-2013:15:06:05

CONTENTS

Appendix & Figures

Consent of copyright owner required for any other use.
For inspection purposes only.

EPA Export 25-07-2013:15:06:05

For inspection purposes only.
Consent of copyright owner required for any other use.

EPA Export 25-07-2013:15:06:05

1.1 REQUIREMENT FOR A RESIDUALS MANAGEMENT PLAN

Schwarz Pharma Limited, formerly known as SIFA was granted an Integrated Pollution Licence (IPCL) (Reg. No. 20) by the Environmental Protection Agency for '*The manufacture of pesticides, pharmaceutical or veterinary products and their intermediates*' at a pharmaceutical facility located in the Shannon Free Zone, Shannon, Co Clare. The IPC licence was granted to the company on 26th April 1996.

The facility at Schwarz Pharma is currently undergoing a consolidation of its operation at Shannon. This will involve a number of changes to its operation including the closure and decommissioning of Bay 130, which is expected to occur by the last quarter of 2004.

- A scope statement for the plan
- A programme to achieve the stated criteria

Where relevant, a test programme to demonstrate the successful implementation of the decommissioning plan

This report describes the Schwarz Pharma Limited Bay 130 RMP, which has been prepared as Schwarz plans to close Bay 130 .

For the purposes of this report Bay 130 will hereafter be referred to as "the site".

Consent of copyright owner required for any other use.
For inspection purposes only.

1.2 SITE CLOSE-DOWN SCENARIO: COMMENTS AND ASSUMPTIONS

In order to develop a fully costed RMP for the site, a number of assumptions have been made with regard to the mode and management of a hypothetical site shut down.

Schwarz Pharma Limited operates a strict environmental policy. Therefore any shutdown of the site will be a well-planned and well resourced event. This implies that the shutdown date will be known well in advance and that both production schedules and raw materials purchasing have been planned with the shutdown already factored in. It also implies that Schwarz will have the financial resources to implement the RMP through completion – with no requirement for external financing.

A general assumption is that the site will be returned to Shannon Development the owners of the site, once the RMP has been implemented. The plan will result in a decommissioned and decontaminated site.

The second general assumption is that the RMP includes Bay 130 only. The RMP does not include the main Schwarz Pharma manufacturing site in the Shannon Free Zone. The main Schwarz Pharma facility will still operate under its IPC licence No: 20. The RMP and associated costs have been developed for a number of discrete programme stages arranged

EPA Export 25-07-2013:15:06:05

in a logical sequence to facilitate complete site closure. The actual steps to be carried out and their associated costs for any partial shut downs may be derived from the RMP by simply reviewing that part of the RMP which covers that specific activity or land-parcel.

The third general assumption is that the RMP will be reviewed and updated as necessary.

For inspection purposes only.
Consent of copyright owner required for any other use.

EPA Export 25-07-2013:15:06:05

1.3 RMP REPORT STRUCTURE

Section 1 provides an overview of the need for an RMP and any comments and assumptions made.

Section 2 provides an overview of the scope of the RMP in terms of those buildings, activities and issues that are covered in the plan.

Section 3 describes the proposed criteria to be used to demonstrate successful decommissioning and decontamination.

Section 4 describes the RMP in a Project Management style with discrete stages and associated tasks. Two programmes are considered:

Programme I (PI) Decommissioning and Decontamination of all above and belowground structures – including management of residues arising.

Programme II (PII) Management of long-term residual soil and ground water contamination.

Section 5 provides a summary of the costs associated with implementation of the RMP.

For inspection purposes only.
Consent of copyright owner required for any other use.

EPA Export 25-07-2013:15:06:05

2.0 STATEMENT OF SCOPE

2.1 SITE DESCRIPTION AND HISTORY

SIFA Ltd was established at Shannon in 1976 and began operations at Bay 130 in 1977. Schwarz Pharma Limited purchased SIFA in 1990.

Bay 130, is situated in the Shannon Free Zone, Shannon, Co Clare (grid reference E1389, N1619) see Figure 1 for site location within the industrial estate. Shannon Development developed the site from green field. Bay 130 is a standard 1,700m^2 factory unit. Figure 2 is a site plan of Bay 130. The site plan identifies the main process areas. The areas of the buildings and facilities are listed in the legend of the site plan.

Initially Bay 130 was utilised for the production of Sugar Nitrate but this expanded over time to include the manufacture of approximately 30 different fine chemicals the vast majority of which are pharmaceutical intermediates with cardiovascular applications. A list of processes is contained in appendix 1. The production facilities have however largely been transferred to the newer facilities in the main production site and only limited API production is currently undertaken in the Pharma section of Bay 130. Production is scheduled to cease at Bay 130 by last quarter 2004.

The site is a large single -story building, which has been sub-divided into

- Administration, offices and canteen
- Laboratory
- Production, the Pharma plant and the nitrate production area
- Associated production areas, stores, oven and mill rooms, drying room, blending and ice room
- A small outdoor yard area, which contains the boiler house, neutralisation plant, drum storage and liquid nitrogen tank

Production facilities occupy approximately 900 m^2 of the site.The following utilities are listed and are mainly located in the yard,

- Two Boilers, which provide steam for space heating and process requirements. The boiler blow-down is piped to the foul sewer
- Electricity from the ESB
- Mains water from Shannon Development
- Effluent Neutralisation Tanks, which discharges to the sewer system and is Treated at Tradaree Waste Water Treatment Plant operated by Shannon development
- Liquid Nitrogen
- Chilling systems, which operate on a glycol-water system
- De-ionised water

For inspection purposes only.
Consent of copyright owner required for any other use.

EPA Export 25-07-2013:15:06:05

2.2 SCOPE OF RMP

The proposed RMP addresses both short/medium-term actions and a longer-term programme.

The short/medium term actions, programme **PI**, will involve decommissioning and decontamination of all process related structures currently used for production activities.

This will involve decommissioning and decontamination of all:

- Production buildings
- Service areas
- Storage areas
- Residuals arising as a direct result of decommissioning

The RMP will also address the long-term issues (programme PII) associated with residual soil and groundwater contamination resulting from the Schwarz Pharma Limited activities across the site.

For inspection purposes only.
Consent of copyright owner required for any other use.

2.3 EXCLUSIONS FROM THE RMP

This report is based on the layout drawing Figure 2, site layout and also on the status of the site layout as observed during the residuals management audit. Required annual reviews of this residuals management plan should include for any variations that may occur.

Costs for Building Demolition and Uncontaminated Equipment Removal:

The RMP will be completed when all potential sources of environmental harm have been either removed from the site or rendered harmless. The costs of removing all above and below ground structures, effectively returning the site to "green field" status, have not be included, as it is understood that the site will be returned to the owner, Shannon Development, once decommissioning has been completed.

The only exception is where structures have to be removed to either assess residual soil and groundwater (S&GW) contamination or for the implementation of the S&GW remediation programme – see Section 4.2

EPA Export 25-07-2013:15:06:05

3.0 CRITERIA FOR SUCCESSFUL DECOMMISSIONING

The criteria for successful decommissioning to ensure minimum impact to the environment with respect to residuals management are as follows:

- The decontamination of all process equipment according to site SOP standards and good manufacturing practice (GMP).
- Documented and fully costed reports to ensure that all raw materials and finished product have been dispatched from the site.
- Documented and fully costed reports on the disposal of hazardous waste including full certification required under law (Trans-frontier Shipment of Hazardous Waste Regulations, Waste Management Act, 1996 and IPC Licence).
- Documented and fully costed reports on the disposal of non hazardous wastes including all certification required under the Waste Management Act and IPC licence.
- Documentation to determine that Schwarz Pharma have not installed asbestos containing material on the site.
- Documentation to determine that there are no PCBs/PCTs on site.
- Removal of radioactive sources (if present) and disposal by contractors licensed by the Radiological Protection Board.
- Remediation of site soil and groundwater to pre-determined, risk based, remedial goals, agreed with the EPA and verified by a programme of groundwater monitoring post corrective action.

For inspection purposes only.
Consent of copyright owner required for any other use.

Note that, with respect to the above criteria, the costs and time to complete decommissioning should not exceed that estimated in the most up-to-date revision of the Residuals Management Plan in place at the time of decommissioning.

EPA Export 25-07-2013:15:06:06

4.0 PROGRAMME TO ACHIEVE STATED CRITERIA

4.1 PI PROGRAMME

4.1.1 Introduction

Programme PI involves the decommissioning and decontamination of all above and belowground structures – including management of residues arising.

The structure of PI of the RMP is based on a logical sequence of events (project milestones) that would occur in the event of a shutdown, similar in logic to an annual maintenance shutdown. However, the end point would be the removal of all materials from the site that could pose a residual threat to the environment.

Below ground structures, in-ground sumps, drains and transfer lines, are dealt with in PI only in relation to decontamination of internal surface areas i.e. emptying and flush/rinse etc. Issues associated with removal of structures and assessments of soil/groundwater contamination are dealt with in PII.

For inspection purposes only.
Consent of copyright owner required for any other use.

The programme is constructed in a Project Management style format with a number of Stages, each with a set of specific tasks that involve the management of residual waste. The individual stages are in a logical sequence however, some overlap in terms of time-lines is expected.

The individual stages are:

Stage 1:	Production decommissioning, including transfer of residuals to the main plant facility
Stage 2:	Removal of excess raw materials, bulk solvent and final product from the site.
Stage 3:	Removal of production related hazardous and non-hazardous wastes from the site.
Stage 4:	Cleaning of the production and storage facilities.
Stage 5:	Drain cleaning and surveying of process drains
Stage 6:	Decommissioning of site services
Stage 7:	Removal of remaining hazardous materials
Stage 8:	Documentation and Certification of Decommissioning and decontamination

EPA Export 25-07-2013:15:06:06

Each stage is considered under the following headings:

- Tasks to Complete Stage
- Cost to complete
- Time to complete
- Plant Status at Completion of Stage

Please refer to Figure 3 Gantt chart with stages/tasks and time-lines

4.1.2 Stage 1: Production Decommissioning.

This stage may be applied to:

- Laboratory
- Production, the Pharma plant (which is the only area where production is currently taking place) and the main nitrate production area
- Associated production areas, stores, oven and mill rooms, drying room, blending and ice room

The process equipment that remains in Bay 130 is listed in Appendix 2. There are 25 process vessels. Only the equipment associated with the Pharma section of the building is currently operational.This includes, pelleting pan No.1 and No.2, brabender No.1 and 2, pressure vessels, compressor, two ovens, sieve, heaters, hoist, stirrer and electronic scale. Product runs may vary in duration, depending on product demand. Raw materials are charged to reactors in solid and liquid form. Solids are generally charged from containers. Liquid, such as solvents, are charged from drums via solvent headers and manifolds.

Consent of copyright owner required for any other use.
For inspection purposes only.

EPA Export 25-07-2013:15:06:06

Schwarz Pharma Limited
Residual Management Plan for Bay 130

Task 1. Transfer all raw material & products to warehouse and drum storage

Assume production process steps are completed. Therefore allow for discharge of product from filtration centrifuging, drying and discharging to product containers. Then, in respect of residuals in production area,

- Label product drums and transfer to the warehouse.
- Isolate solvent manifolds, drain solvent back to bulk drum storage, and purge manifolds.
- Remove drums of solvent to drum storage in the main plant.
- Transfer any containers of raw materials to the warehouse in the main plant.
- Create an inventory of obsolete, contaminated chemicals and transfer to waste storage in accordance with appropriate standard operating procedure (SOP).

For inspection purposes only.
Consent of copyright owner required for any other use.

Task 2. Transfer all production wastes, hazardous and non-hazardous, to storage.

This task will specifically include:

Transfer of solid hazard waste, according to appropriate standard operating procedures (SOP's), to UN approved and labelled 25kg fibreboard drums and remove to the solid waste storage area in the main plant.

Transfer of liquid hazard waste, according to appropriate standard operating procedures (SOP's), to UN approved 200l steel drum and labelled.

Transfer of drums, primarily fibre kegs and plastic drums, from production buildings to the waste storage area in the main plant.

- Transfer of pallets to solid waste storage area.
- Removal of general skip waste (e.g., office paper, packaging not product contaminated) to the solid waste storage area.
- Create an inventory of obsolete solid chemicals, product samples and raw material samples in the building and transfer to waste storage in accordance with appropriate standard operating procedures (SOP's).

EPA Export 25-07-2013:15:06:06

Task 3. Clean down of production areas

There are SOPs specific for the clean down of equipment, example, Cleaning of Brabender Powder Doser, SOP 210.027. Equipment should be cleaned according to their specific procedure the cleaning process is divided into major and minor clean. The basic steps of the major clean that will be followed are as follows:

- Ancillary attachment, (ex. trays from oven) are removed from the equipment.
- The empty vessel is then washed out with hot water and dried in an oven if possible or with a lint free cloth. The interior surfaces are then washed with IMS-99 and dried as above
- Ancillary equipment is washed with hot water, dried in an oven and then washed with IMS-99 and dried.
- A second trained person checks and approves the cleaning
- An equipment status label is attached and a clear polyethylene bag is used to cover the equipment item
- The appropriate cleaning sheet for the equipment as per SOP 210.25 is then completed
- All transfer lines and reactor trains should then be purged with nitrogen and then air.
- Washings, which will be produced during the cleaning process, will be routed to effluent neutralisation pit via dedicated pipelines and floor drains.

Plant equipment can be transferred to the main site if there is a use for it, sold for reuse or for scrap metal.

Consent of copyright owner required for any other use.
For inspection purposes only.

Task 5 Isolate from steam, compressed air, liquid nitrogen & other utilities available

No specific residuals.

Task 6 Isolate from low temperature coolant loop, ventilation, and Nederman abatement units

- The isolation of secondary vent condensers and reactor jackets from the closed loop low temperature coolant supply and the draining of the glycol/water coolant back to the supply tanks. Purge all the vent lines
- Implement the procedure for the Cleaning of 3 Nederman Units SOP 210.033

EPA Export 25-07-2013:15:06:06

- Removal of all filters from ventilation to specially labelled drums and transfer to solid waste storage.
- The washings, assuming relatively saturated, shall be sent to the effluent neutralisation pit for pH adjustment before discharge to Tradaree waste water treatment plant

The following waste material will be generated from the cleaning process,

- Waste powder, disposed of in a fibreboard 25kg drum labelled waste for disposal
- IMS used for cleaning, is loaded into 200l steel drum and labelled "Coating Solution Waste Ex Isoket"
- Contaminated disposable protective clothing, gloves etc, is disposed of in large polythene bag

Plant Status at Completion of Stage 1

- All site production equipment decontaminated and in a "safe to work" (and environmentally secure) state.
- All production related residuals transferred to bulk storage or warehouse.
- All auxiliary systems decommissioned and working mediums – glycol/water, nitrogen, etc., isolated.

For inspection purposes only.
Consent of copyright owner required for any other use.

Time to complete

Production occurs 7 days per week. It will take approximately two to three days to complete a clean down of each area. Allowing for contingency time, it is estimated that Stage 1 would take approximately two-three working weeks to complete utilising the full compliment of production and maintenance staff at the Schwarz Pharma site.

Cost

The costs of completing Stage I have not been calculated in monetary terms. As described in Section 2.2 it is assumed that the shutdown is a well planned and resourced event and all costs in terms of manpower will be allocated to normal plant running costs for the period in question.

EPA Export 25-07-2013:15:06:06

4.1.3 Stage 2: Removal of Excess Raw Materials and Final Product

Task 1: Dispatch of intermediates and finished product from final production runs.

Schwarz Pharma Limited does not produce pharmaceuticals in their final dosage form. Minimal product is stored on site; rather it is transported off site for final formulation and packaging. Therefore, in line with normal production scheduling, all product will be dispatched, almost immediately as it is produced.

Task 2: Raw material and solvents

Raw material purchase is planned on a schedule directly related to the planned production schedule. The date for plant shutdown will be known in advance, it is assumed that stocks of raw materials will be reduced accordingly and that the remainder will be transferred from Bay 130 to the main plant as a raw material. The main plant must ensure that it has storage capacity for the extra material. The above route would result in considerable cost savings when compared to the "hazardous waste" route.

Appendix 3 contains a list of raw materials and solvents for Bay 130

In the case of the gas, (liquid nitrogen, ammonia) it is assumed that any gas remaining following production may be returned to the supplier or transferred to the main facility if storage capacity is available at a minimum cost.

Any material that is past its use by date, contaminated or no longer required will be treated as a hazardous waste but this is a "worst case" scenario.

Consent of copyright owner required for any other use. For inspection purposes only.

Plant Status at end of Stage 2

Storage and drum storage pads clear of raw materials.

Time to Complete

A period of 2 week to document (including inventory lists) and arrange transport to the main site is estimated.

Cost

EPA Export 25-07-2013:15:06:06

1. The cost associated with Task 1 is not considered as it is assumed that costs for shipping will be absorbed as part of the net value of intermediates and products.

2. The cost associated with Task 2 above is considered to be minimal

4.1.4 Stage 3: Removal of Production-related Hazardous and Non-hazardous wastes

All substances that can be considered waste, either hazardous or non-hazardous, will have been placed in designated areas in accordance with Schwarz Pharma procedures, Disposal of Hazardous Waste from Bay 130 SOP 206.300 and Disposal of Non-Hazardous Waste from Bay 130 SOP206.301. The waste may include raw materials (detailed in stage 2) that cannot be returned to suppliers, used in the main plant or sold on to interested third parties.

In the case of hazardous waste disposal, all requirements of the current IPC Licence will be considered, especially in relation to hazardous waste that is not scheduled on the IPC Licence. Therefore, this waste will require the prior written approval of the EPA before the waste can be removed from the site.

For inspection purposes only.
Consent of copyright owner required for any other use.

Stage 3 will include the following tasks:

- Administrative organisation of shipments.
- Removal of the waste in accordance with appropriate National and EU Legislation.
- Administrative organisation of relevant paper work. All waste shipments during this period will be documented according to EPA Guidelines. This will facilitate the requirement to have stated criteria for proper decommissioning (see Section 3.0).

Tables 4.1 summarises the expected quantities of hazardous waste and non-hazardous waste respectively that are expected to be shipped from the site during decommissioning.

The cost is based on a flat rate of €500 per metric tonne for transport and disposal of liquid hazardous waste and €1,500 per metric tonne for disposal of solid hazardous waste. This time frame is chosen to correspond with the expected timeframe to complete PI.

EPA Export 25-07-2013:15:06:06

Table 4.1. Hazardous Waste Inventory.

Waste Type	EWC Code	Amount (tonnes)	Disposed/Recovered	Method of Storage	Estimated Cost (€)
Raw Materials (See Section 4.1.3, Task 2 for detail)	-		***Reuse in main plant production***	**Various**	-
Contaminated mop heads	150202*	0.5	***Disposed***	**Drums**	***750***
Contaminated PPE	150202*	0.8	Disposed	**Drums**	1200
Contaminated Cleaning Cloths	150202*	0.5	Disposed	**Drums**	750
Used filter elements from in-line filters	150202*	0.8	Disposed	**Drums**	1200
Used cartridges from respirators	150202*	0.2	Disposed	**IBC**	300
Powder liners	070513*	1.0	Disposed	**Bulk**	1500
Glycol	070504*	-	Disposed	**Drums**	1500
Filter beds	070609*	0.5	Disposed	**Drums**	750
Filter cloths	070609*	0.5	Disposed	**Drums**	750
Fuel oil tank	170409*	4	Disposed or recovered	**Bulk**	6000

For inspection purposes only.
Consent of copyright owner required for any other use.

EPA Export 25-07-2013:15:06:06

Fluorescent tubing	200121*	0.2	Recovered	**Coffin**	500
Oily sludge, oil contaminated material	130208*	1.5	Disposed	**Drum**	2250
Waste oils from Valopric pump	130208*	0.2	***Recovered***	**Drums**	**300**
Miscellaneous costs, Admin, packaging,					**1500**
TOTAL					**€19250**

For inspection purposes only.
Consent of copyright owner required for any other use.

EPA Export 25-07-2013:15:06:06

Table 4.2. Non Hazardous Waste Inventory

Waste Type	EWC Code	Amount (tonnes)	Disposal Method	Estimated Cost (€)
Non-reusable fibre board drums	20139	1.0	Landfill	500
Non contaminated rubbish from Office areas	20101	0.5	***Landfill***	**250**
TOTAL		**1.5**		€750

For inspection purposes only.
Consent of copyright owner required for any other use.

EPA Export 25-07-2013:15:06:06

Time to Complete

This stage will be carried out, in parallel to the decommissioning stages. As the drum store and warehousing areas receive waste to be disposed, licensed waste disposal contractors shall remove waste for landfill, incineration or recovery.

Cost

The predicted costs associated with this stage are summarised in Tables 4.1 and 4.2.

Plant Status at the end of Stage 3

All production related hazardous and non-hazardous wastes removed from the Storage area of the Bay and from the drum storage in the yard area.

For inspection purposes only.
Consent of copyright owner required for any other use.

4.1.5 Stage 4: Cleaning of the production and storage facilities

This stage is started when storage is being emptied of all product, raw materials, waste and recovered solvents removed for return to the main plant or for disposal.

Plant cleaning will occur when all equipment has been decommissioned and cleaned. The Cleaning of Pharma Production Area, SOP 210.025, describes the procedure for cleaning the Pharmaceutical Production Area in Bay 130, this or a similar procedure could be applied to all the internal areas the site

A major clean of Bay 130 is carried out every six weeks or following a campaign of a maximum of 16 batches, whichever is sooner according to equipment SOP. It is documented on the Pharmaceutical Production Area Major Clean Checklist.

Pharmaceutical contract cleaners currently provide a cleaning service for Bay 130 Pharmaceutical Production Area and provide a cleaning certificate verifying cleanliness.

The following waste material will be generated from the cleaning process,

- Waste powder, disposed of in a fibreboard 25kg drum labelled waste for disposal
- IMS, is loaded into 200l steel drum and labelled "Coating Solution Waste Ex Isoket"
- Contaminated disposable protective clothing, gloves etc, is disposed of in large polythene bag

EPA Export 25-07-2013:15:06:06

Time to complete

Assuming that it will take 1-2 days to clean an area, it will take approximately 2-3 weeks to complete this stage, the stage can run in parallel with Stage 3 – Removal of Hazardous and Non-hazardous wastes.

Cost

The approximate average cost per day to clean is estimated to be on average €1,500. Therefore the total approximate cost would be

€1,500 x 10 = €15,000

Plant Status at the end of Stage 4

The internal areas of Bay 130 have been cleaned and are in safe state in respect of the environment, health and safety.

For inspection purposes only.
Consent of copyright owner required for any other use.

4.1.6 Stage 5: Drain Cleaning and Surveying of process drains

In order to return the site to the owners Shannon Development in an environmentally inert condition, there will be a requirement to clean all the drains process drains on the site. This will involve the use of a specialist contractor. It is recommended that cleaning and surveying run in parallel, so that any blockages detected by the camera can be cleared promptly. The survey will identify any repairs that will be required.

Any residual material removed from the drains will be treated in the effluent neutralisation pit and any sludge disposed of as a hazardous waste in stage 6.

Time to complete

It is estimated that the drain surveying and cleaning will take approximately 1 week with reporting taking an additional week.

Cost

EPA Export 25-07-2013:15:06:06

The approximate average cost per day to clean and survey is estimated to be on average €1,400. Therefore the total approximate cost would be

€1,400 x 5 = €7,000

Plant Status at the end of Stage 5

The process drains of Bay 130 have been cleaned, surveyed and any defects identified.

4.1.7 Stage 6: Decommissioning of site services

This stage may be applied to:

- Chilling Systems
- Boiler House
- De-ionised Water Plant
- Effluent Neutralisation Plant

Chilling Systems

For inspection purposes only.
Consent of copyright owner required for any other use.

There is one, closed loop, refrigeration systems in Bay 130. A glycol -water solution is refrigerated using ammonia. The glycol -water solution is circulated as chilled, cold and hot glycol. /The purpose is to provide coolant for temperature control purposes at process vessels and heat exchangers Table 4.3 presents a summary of the quantities of glycol –water, ammonia contained the system at any one time.

It is expected that the company who service the refrigeration systems may retrieve the ammonia. The service company would use a decommissioning vessel that would be used to draw the ammonia refrigerant from the systems. The refrigerant would then be transported and fed into the refrigeration system at the main site. There maybe a small charge to transport the residual liquid nitrogen to the main site. The liquid nitrogen tank can then be removed by the supply company, the owners of the tank

If storage capacity does not exist at the main site then the ammonia will be tested by the service company to determine suitability for re-use. Should the ammonia be unsuitable for re-use, and then it is likely that the ammonia would be disposed of as hazardous waste. The glycol -water solution will be removed from the re-circulation tanks into drums for disposal.

The approximate costs for ammonia removal and methanol/water solution disposal cost estimates are provided in Table 4.3.

EPA Export 25-07-2013:15:06:06

Table 4.3 – Residuals from Refrigeration Decommissioning

RESIDUAL	ESTIMATED QUANTITY (kg)	COST TO DISPOSE (€)
Ammonia	*960*	*Approx. €1,550*
Glycol/Water	*3,000*	*Approx. €1,550*

Boiler House& De-ionised Water Plant

The only anticipated residuals from the decommissioning of the boiler rooms and the de-ionised water plant are Sodium hypochloride, Sulphuric Acid, Nalfloc Transport plus 71, Amberlite Resin 120A+, silica gel and lube oils.

All the above residuals are likely to be small in quantity and can be transported to the main site for use in the two boilers and wastewater treatment plant

For inspection purposes only.
Consent of copyright owner required for any other use.

Fuel Oil tank, Nitric Acid Tank

The fuel oil tank (volume 13,800ltrs) and the nitric acid tank (22712ltrs) will be required to be disposed of. A specialist-licensed contractor will remove any fuel remaining in the fuel oil tank and clean the tank. The tank can then be disposed of, reused at the main site, or sold in tact or for scrap. The nitric acid tank will be required to be drained of its contents, cleaned and disposed of for scrap.

Bunded areas

The bunds associated with the nitric acid (29970ltrs), yard bund (18500ltrs) and fuel oil tank (17270lts) will be required to be inspected and drained of their contents as per SOP 606.025, Bund Management.

Any material drained from bunds must where possible be discharged directly into the drainage network to the effluent neutralisation pit. If it is determined following identification of the bund contents that they are unsuitable for discharge to the effluent neutralisation pit the material will be transferred into suitable, clearly labelled drums and disposed of as a hazardous waste

Integrity testing of the bunds will also be required as per 2.14 of SOP 606.025

EPA Export 25-07-2013:15:06:07

Assuming that only the fuel oil bund is unsuitable for discharge into the effluent neutralisation pit and is one third full, this will leave a volume of 5757ltrs to be disposed of at €1,500 per tonne, resulting in a cost of approximately €8700

Surface Water Sump and Effluent Neutralisation Plant

The contents of the surface water sump located in the yard area can be pumped to the effluent neutralisation plant for treatment. The sump can then be cleaned according to site SOP's.

Once all effluent generated upstream of the treatment plant has been treated, the primary tasks in decommissioning the Effluent Neutralisation Plant will be to:

1. Flush all process lines to the Effluent Neutralisation Plant with fresh water (no surfactants)
2. Drain supernatant and remove any sludge that has accumulated in the two tanks
3. Wash the tanks.
4. Treat washings through the WWTP at Tradaree Waste Water treatment plant with the agreement of Shannon Development.
5. Dispose of the sludge, the sludge will have to be characterised using the hazardous waste identification tool and as a worst case transported off site for incineration.

For inspection purposes only.
Consent of copyright owner required for any other use.

Plant status at the end of Stage 6

All site utilities, with the exception of limited electrical supply, effectively decommissioned.

Time to Complete

Utility decommissioning should not start until contract cleaning of the site and drains (Stage 5) has been completed. The effluent neutralisation tanks would be the final facility to be decommissioned. This is because the effluent neutralisation tanks will treat any liquid wastes arising during the decommissioning process elsewhere. The time required to decommission the utilities will be controlled by the length of time it will take to decommission the effluent neutralisation tanks.

EPA Export 25-07-2013:15:06:07

Costs to Complete

The costs to remove residual glycol from the chilling system are contained in Table 4.3

The principle costs in decommissioning of the effluent neutralisation tanks are:

1. Cleaning and flushing of Effluent Neutralisation Tanks. Estimate: €1500
2. Sludge Disposal: Sludge characterisation 10 (at €500 per sample) samples of sludge analysed by an external laboratory and characterised using the hazardous waste tool is estimated at €5000.

   Assuming in a worst case that the effluent neutralisation pit one third full and has a volume of 15m^3. This will give a volume of sludge to be disposed of, of 6 tonnes assuming that sludge has a density of 1.2.

   The approximate cost to dispose the sludge in an incinerator (at €450 per tonne) is estimated at €5000 including transportation and paperwork

This gives a total budget cost estimate for the effluent neutralisation tanks decommissioning of €11,500.

Consent of copyright owner required for any other use.
For inspection purposes only.

4.1.8 Stage 7: Removal of Residual Hazardous Materials

This stage applies to the situation where there may be specific residuals associated with the building structure and plant equipment that may not be removed. This includes PCBs, Radioactive wastes and fluorescent tubes but does not include for actual concrete that may be contaminated.

Task 1 Remove identified hazardous materials.

There are no PCBs/PCTs and radioactive sources on the site

Task 2. Remove and dispose of radioactive material and fluorescent tubing.

All fluorescent tubes will be removed and stored in coffin containers. A licensed company will then remove the waste for disposal.

It is difficult to estimate the number of fluorescent tubes that exist on the site, however €500 is allowed for lamp disposal.

EPA Export 25-07-2013:15:06:07

4.1.9 Stage 8: Documentation and Certification of Residuals Management Plan

Throughout implementation of the RMP documentation will be generated to track progress. All residues removed from site will be recorded and final clearance certificates will be prepared. A full report will be prepared and submitted to the appropriate agencies.

For inspection purposes only.
Consent of copyright owner required for any other use.

EPA Export 25-07-2013:15:06:07

4.2 PII PROGRAMME – SOIL AND GROUNDWATER.

4.2.1 Introduction

Bay 130 is located off the main Schwarz Pharma site and was built by Shannon Development in the early seventies. It has been occupied by Schwartz Pharma (formerly SIFA) since 1977 and used for the manufacture of pharmaceutical intermediates, including nitrogen-based compounds. It is a free standing building surrounded by grassed or paved areas on all sides. A brief summary of the status of the soil and groundwater condition at the site follows.

The building is constructed with walls supported on ground beams, with cast on grade concrete slab floors between the beams.

Differential subsidence of the floor slabs relative to the structural frame has occurred throughout the building, most likely due to the soft underlying soils (Gibson O'Connor report 1278 dated 23 October 1997). This settlement appears to be oriented parallel to the long axis of the building (i.e. in a NE-SW direction) and is most marked in the production and stores areas, where the floor slab has locally settled by over 0.1 metres in places (Gibson O'Connor report 1278 dated 13 October 1997) and drains and manholes now stand proud of the surrounding floor.

For inspection purposes only.
Consent of copyright owner required for any other use.

Subsidence of the floor slab is reported by Schwarz personnel to have been ongoing since SIFA began occupation in 1978.

Acid resistant effluent drains and storm water drains run the length of the building below the floor slab. Effluent drains run towards the northwest to an effluent treatment pit and sewer connection in the yard area, whereas the storm water drains run southwest to a storm main in the roadway past the office area.

Soil and groundwater investigation work has been completed on behalf of Schwarz Pharma by Bord Na Mona in 1996 (Report ELS K031 dated June 1996 and report K207/R2 dated April 1997) which detected nitrogen compound contamination of shallow groundwater in the soft, clayey, silty, peaty soils, principally by ammonia and nitrate. Three pre-existing wells were sampled and a further four shallow wells were drilled and sampled in late 1996 to obtain higher quality groundwater samples, due to deficiencies in the construction of the earlier wells.

Bay 130 is underlain by very soft, clayey, silty, peaty soils between 5 and 6 metres thick, which are considered to be either natural estuarine muds or dredging used as in-fill material. These soils overly the limestone bedrock, which was not penetrated either by the 1996 study or by the previous monitoring wells.

The bedrock is composed of the Ballysteen Limestone Formation, a fossiliferous dark grey muddy limestone, which underlies virtually the entire Shannon Airport area (Geological Survey of Ireland, Geology of the Shannon Estuary, GSI, 1999). This limestone is ranked as a 'Locally Important' (GSI terminology) aquifer by the GSI, though the well yields are extremely dependant on wells intersecting major fractures or not. High yields have been

EPA Export 25-07-2013:15:06:07

reported from this formation where major fracture zones have been intersected, though water quality is often poor, with high iron and manganese problems common (elevated iron and manganese are detected in the shallow groundwater samples from around Bay 130). A single high yielding well in known to exist (within a bedrock fracture zone) in the Smithstown Industrial Estate, some 2 km to the east. Often the main zone of groundwater movement occurs in a more fractured, weathered zone a few metres thick at the top of bedrock in such situations.

The bedding planes in the Ballysteen Formation 'dip' to the north west at 10° to 35° and the 'strike' is orientated NNE-SSW, parallel to the long axis of Bay 130.

It is possible that a fracture zone or other weak zone in the underlying bedrock could have contributed to the subsidence issue (very soft rock was reported in the base of the borehole in the drilling log for well GS10).

In theory, acid dissolution of the limestone bedrock due to spills of acid or leaking acid effluent drains is a possible cause of subsidence beneath the building, however low pH has never been detected in any of the wells around the perimeter of the building, therefore this appears to be extremely unlikely.

The groundwater in the soil zone is saline (elevated sodium and chloride concentrations) and not suitable for potable use. Saline water would have a high pH buffering effect and argues against acid release as a potential cause of subsidence.

Groundwater in the bedrock aquifer is also suspected to be saline, though this is unproven.

Bord na Mona (report K207/R2) considered that the subsidence of the floors within the building may have led to damage to the subsurface drains and pipework resulting in the observed nitrogen or ammonia inputs to the subsurface. This is considered highly likely. No surveys of drain integrity are known to have taken place at Bay 130.

No evidence of releases to ground of volatile organics, metals or acids (monitoring well pH near neutral) was detected by Bord na Mona. However, acetone (the main volatile organic compound stored and used at bay 130) was not included on the Bord na Mona volatile organic compound list.

Bord na Mona did not investigate the possibility of leakages/ spills of light fuel oil from the site's boiler or aboveground storage tank (no petroleum hydrocarbon analysis).

The groundwater flow direction is not known, as the wells have not been levelled to a common datum to allow comparison of water levels.

Based on current data ammonia and nitrate are considered the two main compounds of concern, based on their concentrations in the shallow aquifer. It is not known if this contamination has migrated into the deeper bedrock aquifer, which in any case is suspected to be a low permeability, poor quality limestone (Ballysteen Limestone Formation) containing saline groundwater.

Consent of copyright owner required for any other use.
For inspection purposes only.

EPA Export 25-07-2013:15:06:07

4.2.2 Characterisation of Potential Source areas of Chemical Release

Following site closure, so as to avoid interference with the decommissioning and plant decontamination phase, investigations of potential source areas of chemical release would be carried out by undertaking an intrusive investigation close to areas of potential concern. Undertaking a post site closure investigation also guarantees that data is collected at a point in time that marks the end of chemical use/transfer/storage on-site. The intrusive investigation would focus primarily on the bedrock zone to establish if there is potential for significant groundwater movement within the as-yet uncharacterised bedrock aquifer.

The existing groundwater database from the existing site wells is comprehensive. Therefore only a relatively limited groundwater investigation will be needed from these, principally to investigate the presence of acetone and other organics. A level survey of the existing wells would be required to allow determination of the direction of groundwater flow and thus aid optimum placement of additional wells.

It is predicted that three groundwater-monitoring wells into the bedrock aquifer close to the production and stores areas and the rear yard, which are considered the main potential source areas will be needed. These wells would be analysed for inorganics (including ammonia), VOCs (including acetone), petroleum hydrocarbons and pH.

Comparison of water levels between the existing shallow wells in the soil zone and the proposed bedrock wells will allow the potential for downward groundwater flow to the bedrock aquifer to be assessed.

It is also recommended that the CCTV survey of the drains beneath the floor slab, as detailed in PI Stage 5, carried out to inspect their condition and assess the likelihood of effluent releases to ground.

For inspection purposes only.
Consent of copyright owner required for any other use.

The budget required to complete a comprehensive investigation of potential source areas, including drilling, laboratory analysis, risk assessment and risk communication is estimated to be of the order of €11,000, (the drain survey has been priced separately) .

4.2.3 Design/Implementation source area soil remediation programme (as appropriate)

If the post-closure investigation encounters significant shallow soil contamination, it could continue to leach to groundwater (acting as an ongoing source of groundwater contamination) or have implications with respect to the potential future use of the site. Therefore the results of the post-closure investigation study will be used to establish whether specific corrective action will be required. This is considered unlikely to be required based on currently available data. Risk based decision making will be used to quantitatively evaluate the appropriate levels of residual contamination that can be left in place.

Since there is no evidence to date that would suggest that there is a significant mass of residual contamination beneath the building, for the purposes of this RMP it has been assumed that no residual contamination beneath the building will be required and no groundwater interception and treatment will be required.

However, previous investigations have been limited in the sense that all potential migration pathways (i.e. via groundwater flow in bedrock) have not been assessed. Annual

EPA Export 25-07-2013:15:06:07

modifications to the Residuals Management Plan may alter this assumption if, in the meantime, further investigations of potential soil contamination are completed

4.2.4 Management of corrective action programme with post remediation monitoring

Following site closure a groundwater monitoring programme will be required.

In a site closure and decommissioning situation, the scope of the groundwater-monitoring programme would be a variation on the current monitoring programme underway at Schwartz Pharma and would be based on the most up-to-date data available on the quality of groundwater at that time.

Assuming a total of two years monitoring until final closure and surrender of the IPC licence, groundwater monitoring and data assessment/reporting costs for Bay 130 are predicted to be of the order of €7,000 per year, totalling €14,000.

For inspection purposes only.
Consent of copyright owner required for any other use.

EPA Export 25-07-2013:15:06:07

5.0 SUMMARY OF COSTS ASSOCIATED WITH THE RMP AND CONCLUSION

This section briefly summarises the costs presented in Sections 4.1 and 4.2 of this report. The summary is presented in Table 5.1 and includes all costs identified during the analysis of Programmes PI and PII.

ITEM	DESCRIPTION	COST (€)
PI.1	**Production Decommissioning**	-
PI.2	**Removal of excess raw material**	-
PI.3	**Hazardous and non –Hazardous waste disposal**	20000
PI.4	**Cleaning of production and storage facilities**	15000
PI.5	**Cleaning and Survey of process drains**	7000
PI.6	**Decommissioning of Site services**	20,500
PI.7	**Disposal of residual hazardous materials**	500
	SUB TOTAL PI (approximate)	63,000
PII.2	**Further investigation of contamination (3 bedrock wells and drains survey)**	11,000
PII.3	**Source area *in situ* soil corrective action**	-
PII.4	**Biannual monitoring of soil & groundwater**	14,000
	SUB TOTAL PII	25,000
	RMP TOTAL (approximate)	88,000

Consent of copyright owner required for any other use. For inspection purposes only.

In conclusion it has been estimated that, in the event of site closure involving complete cessation of all production activities at Bay 130, an allowance of approximately 88,000 Euro should be required to bring the site to an environmentally safe (inert) condition. This excludes any remedial work necessary in the event that this is required.

EPA Export 25-07-2013:15:06:07

ooOOoo

URS would like to thank Schwarz Pharma Limited for the opportunity to participate in this project and hope it fulfils your requirements. Should you have any queries regarding this project please do not hesitate to contact the undersigned.

Yours sincerely,

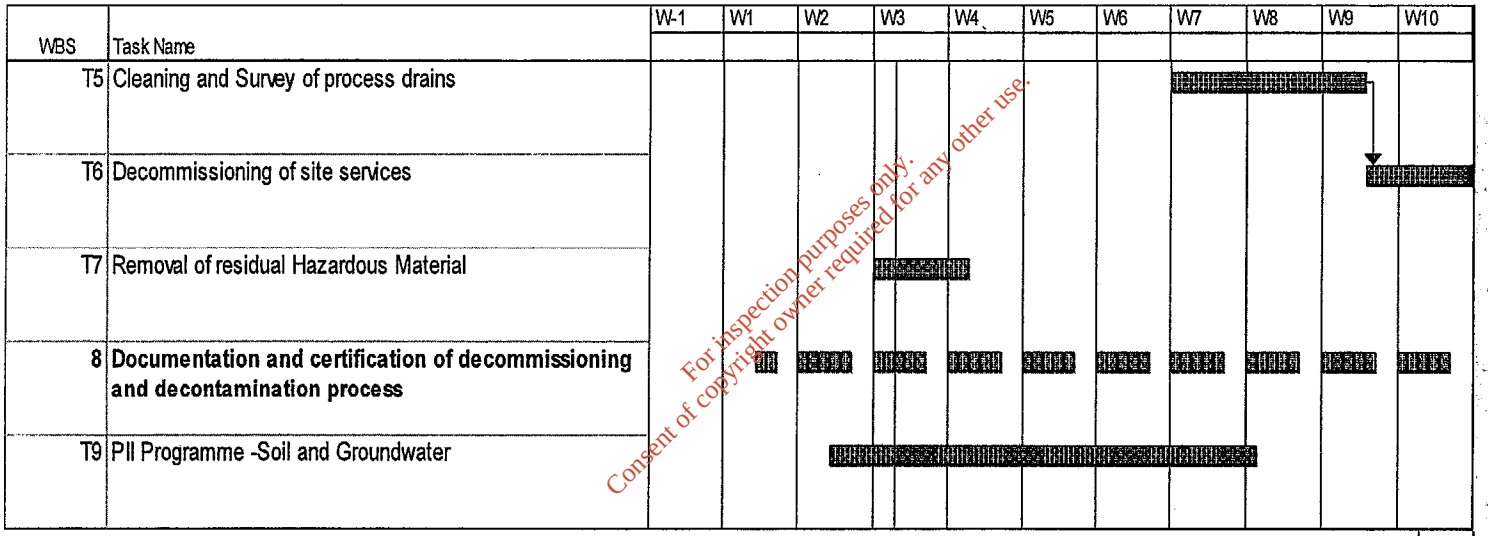
For URS

Anne Marie Flynn	Gerard Kelly
Project Manager	Project Director

For inspection purposes only.
Consent of copyright owner required for any other use.

EPA Export 25-07-2013:15:06:07

Figure 3 – Gantt chart of the Residuals Management Plan for Schwarz Pharma Limited



For inspection purposes only.
Consent of copyright owner required for any other use.

EPA Export 25-07-2013:15:06:07