

Determination of an Application for a PPC Permit under the Pollution Prevention and Control (England and Wales) Regulations 2000 (SI 2000 No.1973)

Decision document recording the decision-making process

Note: all references to the “PPC Regulations” are to the Pollution Prevention and Control (England and Wales) Regulations 2000 (SI 2000 No.1973), as amended.

Administrative details

Duly made application date	3 April 2006
Permit number (the “Permit”)	SP3030LZ
Applicant (the “Applicant”)	Ipsen Biopharm Ltd
Address/location of installation (the “Installation”)	Wrexham Pharmaceutical Works Ash Road Wrexham Industrial Estate Wrexham LL13 9UF
Name of Authorising Officer	M J Peacock

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INTRODUCTION

Purpose of this document

The decision document explains how the applicant's application has been determined and why the specific conditions in the permit have been imposed. It is a record of the decision-making process to show how all relevant factors have been taken into account.

The permit contains many conditions taken from our standard non-landfill PPC permit template (version 3). We developed these conditions in consultation with industry having regard to the legal requirements of the PPC regulations and other relevant legislation. This decision document does not include an explanation for these standard conditions. Where they are imposed we have considered the application and accepted the details are sufficient and satisfactory to control that aspect of the operation. This decision document does however, provide an explanation for the use of alternate conditions where our permit template allows for two or more options. Emission and monitoring compliance levels and any additional conditions that have been imposed in order to take installation-specific factors into account are explained

Summary of the decision

We have decided to grant a permit for the operator, subject to the conditions in the permit. Where the permit includes standard conditions (see above), these have been considered to be appropriate for the installation, in particular in ensuring that all appropriate measures will be taken against pollution and that no significant pollution will be caused. We consider in reaching that decision we have taken into account all relevant considerations and legal requirements and that the permit will ensure that all appropriate measures will be taken against pollution and that no significant pollution will be caused.

Part A – General Issues

A1 Administration

This section includes administrative information relating to the application and information about the applicant and the installation.

The application was duly made on 3 April 2006

The operator has not made a claim for commercial confidentiality. We have not received any information in relation to this application that appears to be confidential in relation to any party.

The application was advertised and consulted in accordance with the regulations. Details of the advertising and consultation are on the public register. Any responses received are summarised in Annex 1. We have taken these into consideration as described in Annex 1 when determining the application.

The requirements of PPD do not apply to this application.

A2 Description of the installation

A brief description of the installation is in the introductory note to the permit.

A3 Operator competence

We are satisfied that the applicant (now the operator) is the person who will have control over the operation of the installation after the grant of the permit. We are satisfied that they will be able to operate the installation so as to comply with the conditions we have included in the permit.

Although the site was not regulated by the EA under IPC the nature of the materials and processes used has dictated a high standard of management competence and regulatory compliance. The site manufactures sterile injectable therapeutic medicines, the principal activity being the production of an API (Active Pharmaceutical Ingredient) from a Class II pathogen using a fermentation process. Production is done under aseptic conditions and all materials entering the production areas are steam sterilised. The high level of containment requires systems in accordance with ACDP (Advisory Committee on Dangerous Pathogens) documents such as: 'The Management, Design and Operation of Microbiological Containment Laboratories'. In addition the site operates to cGMP (current Good Manufacturing Practice) standards and is regulated under the COSHH Regulations by the HSE (Chemical & Biological Divisions).

A4 Requirements for SWMAs

The operator has replied to application question B7.1.1 stating that the installation does not contain an SWMA and we agree with this assessment.

A5 EOPRA profile

We are not fully satisfied that the EOPRA profile submitted with the application remains accurate following the determination of the application and we have amended the EOPRA score to 80 (from 68) for the following reasons :

i) Location Attribute Total Score is increased from 4 to 7 since a Habitats assessment was required (add 3). Hence the Band increases from A to B i.e. 3 points is increased to 10.

ii) The Complexity Band is a C, the revised EOPRA Charging Scheme (2006/07) increased a C from 40 to 45 points

The revised EOPRA score will be used as the basis for subsistence and other charging. In accordance with our EOPRA Scheme however, the operator's EOPRA profile for the installation may change over time.

PART B : THE INSTALLATION AND ITS MANAGEMENT

B1 General Management

[Permit condition 1.1](#)

Based upon the information submitted in the application, we are not fully satisfied that appropriate management systems and management structures are in place for this installation and that sufficient financial, technical and manpower resources are available to the operator to ensure compliance with all the permit conditions.

The maintenance system does not include auditing against environmental requirements (ref Application B2.3.4), this is now required by Improvement Condition IP3

The Operator's Environmental Management System is externally accredited to Green Dragon Level 3.

B2 Accidents that may cause pollution

[Permit Condition 1.2](#)

Based upon the information submitted in the application, we are not fully satisfied that appropriate measures are in place to ensure that accidents that may cause pollution are minimised.

There is no accident response plan in place (ref Application B2.3.6), this is now required by Improvement Condition IP8.

B3 Energy efficiency

[Permit condition 1.3](#)

Based upon the information submitted in the application, we are not fully satisfied that appropriate measures are in place to ensure that energy is used efficiently.

There is no energy reduction plan in place (ref Application B8.2, B2.7.6/7), this is now required by Improvement Condition IP11

The operator is required to report with respect to energy usage under condition 4.2.1/2 and Schedule 5. Annual reporting of a performance indicator is considered sufficient.

B4 Efficient use of raw materials

[Permit condition 1.4](#)

Based upon the information submitted in the application we are not fully satisfied that the appropriate measures are in place to ensure the efficient use of raw materials and water.

A water efficiency audit has not been carried out (Application B2.4.10), this is now required under Improvement Condition IP10. Note water is the main raw material.

The operator is required to report with respect to raw material usage under condition 4.2.1/2 and Schedule 5. Annual reporting of a performance indicator is considered sufficient.

B5 Avoidance, recovery and disposal of wastes produced by the activities

[Permit condition 1.5](#)

Based on the information submitted in the application we are satisfied that the appropriate measures are in place such that waste production will be avoided as far as possible, and where waste is produced it will be recovered unless technically and economically impossible. We are satisfied that the operator's justification for their proposed waste disposal option shows that such waste that does arise from the installation that can not be recovered will be disposed of using a disposal method that avoids or reduces any impact on the environment.

B6 Site Security

[Permit condition 1.6](#)

Based upon the information submitted in the application, we are satisfied that appropriate infrastructure and procedures are in place to ensure that site remains secure.

B7 Multiple operator installations

[Permit condition 1.7](#)

This is not a multi-operator installation

B8 The permitted activities

[Permit condition 2.1](#)

We have determined that the installation comprises the following activities listed in Part 1 of Schedule 1 to the PPC Regulations and the following directly associated activities.

- 4.5 A(1) (a) (Producing pharmaceutical products using a chemical or biological process)
- Steam supply [2x1.706 MW thermal output natural gas boilers - Includes purified steam and water for infusion (WFI)]
- Electrical power supply (3xDiesel powered generators for the provision of emergency energy to assure safe shutdown)
- Waste storage [(Provision of designated storage areas and segregation for generated waste (inert, hazardous and non-hazardous)).
- Waste water treatment (Heat treatment of effluent from manufacturing operations before discharge to sewer).
- Cooling supply (Provision of chilling - Includes climate control during manufacture and chilled storage)

The activities comprise a single installation because the directly associated activities all serve the single listed activity

B9 The site

[Permit condition 2.2](#)

The operator has provided a plan which we consider is satisfactory, showing the site of the installation and its extent A plan is included in the permit at Schedule 2, and the operator is required to carry on the permitted activities within the site boundary.

Part C : Operations and releases

C1 Operating techniques

[Permit condition 2.3/table S1.2](#)

We have specified that the applicant must operate his installation in accordance with the following descriptions in his application

Description	Parts Omitted	Justification
The response to sub-section B2.1.1 and section B2.2.	B2.1.2 – 2.1.6 of B2.1	Relate to multi-purpose plant, WID & SED. None are relevant.
Additional information	Responses 10 – 14	Not related to operating techniques, mainly ASR.

[Permit condition 2.3/Table S3.1](#)

We have specified the following limits and controls on the use of raw materials and fuels

Raw Material or fuel	Specifications	Justification
-	-	-

C2 Off-site conditions

[Permit condition 2.4](#)

Based on the information submitted in the application, we consider that it is not necessary to impose any off-site conditions.

C3 Improvement Conditions

[Permit condition 2.5](#)

Based in the information in the application we consider that we need to set improvement conditions. These are listed in annex 2- justifications for these are provided at the relevant section of the decision document or in the annex.

C4 Pre-operation conditions

[Permit condition 2.6](#)

Based on the information on the application, we consider that we do not need to impose any pre-operational conditions

C5 Closure and decommissioning

[Permit condition 2.7](#)

Based upon the information submitted in the application we are not fully satisfied that the appropriate measures are in place for the closure and decommissioning of the installation.

A site closure plan is not in place (see Application B2.11.1), this is now required by Improvement Condition IP7

C6 Site protection and monitoring programme

[Permit condition 2.8](#)

The applicant has provided a site report the main elements of which are:
The site (area 7.5Acres) is on Wrexham Industrial Estate and surrounded on all sides by other industrial operations. There is a secure perimeter fence and access is controlled 24 hours, 365 days per year by CCTV and permanent security staff.

The geological map indicates the site is underlain by landscaped ground over lying glacial till. The superficial deposits are underlain by Carboniferous solid deposits of Westphalian, Erbistock Formation. The only surface water feature within the site is the culverted stream which forms an open pond on site. On leaving the site the stream feeds into the Redwither Brook then the River Clywedog and finally the River Dee. The site is within the Dee Water Protection Zone. Records indicate that the site is located upon a major aquifer and the soil is of low leaching potential. There are no groundwater abstraction wells within 1km of the site.

A ground investigation (2004) to determine ground conditions to enable foundation and road/hard standing design to be carried out including an assessment of contamination and gas emissions. From laboratory testing on bore hole samples, no contaminants were observed at concentrations above generic values. There have been no recorded pollution incidents on site recently or historically.

The nature of operations on the site mean there is no bulk storage of chemicals in liquid, gaseous or solid form and a high level of containment within buildings, hence the likelihood of a release of any significant quantity of pollutant is low. The CSM summary indicated that the highest risk areas were assessed as –

- a) The 18,000 litre underground (treated) trade effluent tank
- b) The on site surface water pond
- c) Spillages on hard-standing areas or vehicle areas

Assessment of the of the likelihood of Land Pollution was for –

- A) Delivery and storage of cleaning and utility chemicals
- B) Delivery and storage of diesel oil for emergency generators
- C) Site foul water drainage

Items A) and B) were assessed as “little likelihood” and item C) “reasonable possibility” (underground tank)

The applicant has provided adequate information to enable us to determine the application. However we have set an improvement condition (IP1) to obtain additional information, as described below.

Site Protection and Monitoring Programme to include:

- a) zoned areas to include areas used for the transport of substances
- b) reference data for substances associated with the below ground effluent tank area
- c) maintenance work to the effluent drainage
- d) programme of inspection and maintenance of hardstanding areas
- e) programme of inspection, maintenance and reporting of pollution prevention measures identified in the ASR Appendix D2. To include waste storage areas, effluent drainage, transformer oils and diesel oil.

To ensure the continued effectiveness of pollution prevention measures to protect the land we are requiring the operator to implement and operate a Site Protection and Monitoring Programme, the design of which must be reported to the Agency within three months from the date of permit issue.

The application indicates that there is a "reasonable possibility" of future pollution of the land and therefore reference conditions must be established. Collection of reference data is required and the data must be reported to the Agency within eight months from the date of permit issue.

C7 Emissions to water, air or land.

[Permit condition 3.1](#)

Air

We have reviewed the techniques used by the operator and compared these with the relevant guidance notes – the high level of containment requires systems in accordance with ACDP (Advisory Committee on Dangerous Pathogens) document ‘The Management, Design and Operation of Microbiological Containment Laboratories’.

We have reviewed emissions - the only one is formaldehyde during fumigation. Measurement of releases to atmosphere during fumigation is covered by Improvement Condition IP9. On completion of IP9 consideration will be given to the use of H1, however, given the intermittent, minor use of formaldehyde this may well not be of benefit as the environmental impact is considered to be insignificant.

SGN IPPC S4.02 gives an emission to air benchmark for formaldehyde of 2 mg/m³, this is based (ref BREF) on continuous monitoring of resins manufacture – a large – scale, continuous manufacturing operation, completely different from the Operator's very small scale, batch operation (and lies outside the Organic Sector guidance).. Formaldehyde is the industry standard for breaking down protein/DNA. Limits are most likely to be set based on mass release rate.

Water

The only emission to controlled water is storm water, there are no process emissions to controlled water. See above for containment comment. There are no limits set.

Sewer

The main discharge of storm and process (following heat treatment) is to sewer for treatment at the local WWTP, this is accepted as BAT.

Land

There are no emissions to land. See above for containment comment. Reference data and inspection for the underground effluent tank area have been included in the SPMP requirements (see Improvement Condition IP1).

Overall the proposed techniques for control are consistent with the requirements of the ACDP and we consider them to represent BAT for the installation.

C8 Fugitive emissions of substances

[Permit condition 3.3](#)

Based upon the information we are satisfied that the appropriate measures are in place to prevent fugitive emissions.

C9 Conditions relating to Odour

[Permit condition 3.4](#)

Based upon the information in the application we are satisfied that the appropriate measures are in place to prevent annoyance from odour.

C10 Noise and vibration

[Permit condition 3.5](#)

Based upon the information in the application we are satisfied that the appropriate measures are in place to prevent annoyance from noise and vibration.

C11 Monitoring

Permit condition 3.6

We have decided that monitoring should be carried out for the parameter listed in tables S4.1 and S4.4 in schedule 4 using the methods and to the frequencies specified in those tables. These monitoring requirements have to be established (Improvement Condition IP9) from the emission profiles of formaldehyde for emission points A1 to A5 during fumigation and hence set limits (emission and annual).

Based on the information in the application we are not fully satisfied that the operator's techniques, personnel and equipment have either MCERTS certification or MCERTS accreditation as appropriate. However, the operator will use a contractor with MCERT credentials to undertake the required monitoring (Improvement Conditions IP9 & 13)

C13 Reporting

We have specified reporting as specified in Schedule 5 for the following reasons:

Air – “To be established”, this is due the absence of any monitoring data, this will be resolved by Improvement Condition IP9. However, since the only release to air is the periodic release of formaldehyde during fumigation it is possible that the requirement will be annual reporting based on calculation (the quantities of formaldehyde used during fumigation are known).

Performance parameters – annually, this is the norm.

C14 Miscellaneous

None

Part D : Other legal requirements

A Habitats assessment concluded that there is no likely significant effect alone or in combination on the identified European sites in the locale.

ANNEX 1 : CONSULTEE AND PUBLIC RESPONSES

Advertising and statutory consultation

Summary of responses to advertising and statutory consultation and the way in which we have taken these into account in the determination process:

Brief summary of issues raised	Response received from	Summary of actions taken or show how this has been covered
No comments	Wrexham BC	None
Recommended: 1) Regulator considers whether the H1 screening tool should be used to determine whether the releases to air are significant. 2) The applicant should carry out a noise survey in accordance with BS4142	Wrexham LHB	1) Measurement of releases to atmosphere during fumigation is covered by Improvement Condition IP9. On completion of IP9 consideration will be given to the use of H1, however, given the intermittent, minor use of formaldehyde this may well not be of benefit. 2) A noise survey was carried out in Sept. 2004 by Diamond Environmental Ltd – no items were identified which could be seen as a potential cause of negative impact. Given the work to date, the enclosed nature of virtually all site operations, the location on an industrial estate and the absence of complaints, further noise surveying does not appear to be beneficial.
Concurred with the EA's "no likely significant effect alone or in combination on the	CCW	See Improvement programme IP12

identified European sites” provided that the “Assessment of the impact of fire water “ also concludes that the development is unlikely to have a significant effect on the River Dee SAC		
Unlikely that there will be any unacceptable effects on the safety of the human food chain	Food Standards Agency	None
No comments	Welsh Assembly	None

Welsh Water was also consulted but no response received.

ANNEX 2 Improvement conditions

Ref no	Condition	Date	Reason
IP1	The operator shall include, but not be limited to, the following items in the Site Protection and Monitoring Programme: a)zoned areas to include areas used for the transport of substances b)reference data for substances associated with the below ground effluent tank area c)maintenance work to the effluent drainage d)programme of inspection and maintenance of hardstanding areas e)programme of inspection, maintenance and reporting of pollution prevention measures identified in the ASR Appendix D2. To include waste storage areas, effluent drainage, transformer oils and diesel oil	4 months from issue of the permit	See section C6
IP2	The operator shall complete the colour coding of surface water and foul water manhole covers.	31/07/07	Proposed by the applicant – Application section B2.2.44
IP3	The operator shall establish an Environmental Audit system. A written procedure for the system shall be submitted to the Agency for approval. The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the procedure. The procedure shall be implemented by the operator from the date of approval by the Agency.	30/06/07	See section B1
IP4	The operator shall review procedures for control of noise from maintained equipment and submit the review document and any improvement plan to the Agency for approval. The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the review and plan. The plan shall be implemented by the operator from the date of approval by the Agency.	30/06/07	Proposed by the applicant – Application section B2.9.6
IP5	The operator shall establish an easily accessible detailed inventory of raw materials and quantities used.	31/03/07	Proposed by the applicant – Application section B2.4.4
IP6	The operator shall complete drawings of water circuits and indicative flows. The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the drawings to the Agency.	30/06/07	Proposed by the applicant – Application section B2.4.94

IP7	The operator shall complete a Site Closure Plan and submit it to the Agency for approval. The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the plan. The plan shall be considered suitable for implementation, should the need arise, by the operator from the date of approval by the Agency	30/09/07	See section C5
IP8	The operator shall complete an Accident Response Plan and submit it to the Agency for approval. The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the plan. The plan shall be considered suitable for implementation by the operator from the date of approval by the Agency	30/09/07	See section B2
IP9	The operator shall measure formaldehyde emissions (release points A1 – A5) to air resulting from fumigation activities. Emission profiles for the periods of release shall be established for the 5 points. The environmental impact of the releases shall be assessed by the operator and a report on the measurements/profiles, impact assessment and including an improvement programme, if necessary, shall be submitted to the Agency for approval. The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the report. The improvement programme shall be considered suitable for implementation by the operator from the date of approval by the Agency	30/06/07	See sections C11 & C13
IP10	The operator shall review water usage and wastage on site. A report shall be produced, including an improvement programme, and be submitted to the Agency for approval. The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the report. The improvement programme shall be considered suitable for implementation by the operator from the date of approval by the Agency	30/09/07	See section B4
IP11	The operator shall review energy usage and wastage on site. A report shall be produced, including an	30/09/07	See section B3

	improvement programme, and be submitted to the Agency for approval. The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the report. The improvement programme shall be considered suitable for implementation by the operator from the date of approval by the Agency		
IP12	The operator shall provide risk and environmental impact assessments for the release of fire-water during a fire (particular recognition must be given to the fact that the site pond is in hydraulic continuity with the Redwither Brook and hence the River Clywedog and the River Dee). The assessments shall include an improvement programme, if necessary, and be submitted to the Agency for approval. The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the report. The improvement programme shall be considered suitable for implementation by the operator from the date of approval by the Agency	31/03/07	Potential for contaminated fire-water entering the River Dee (Habitats environment and abstracted for potable water).
IP13	A written procedure shall be submitted to the agency detailing the measures to be used so that monitoring equipment, personnel and organisations employed for the emissions monitoring programme shall have either MCERTS certification or accreditation in accordance with condition 3.6.3. The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the procedure. The procedure shall be implemented by the operator from the date of approval in writing by the Agency	31/03/07	See section C11