



**ENVIRONMENT
AGENCY**

Permit with introductory note

Pollution Prevention and Control (England & Wales) Regulations 2000

Wrexham Pharmaceutical Works

**Ipsen Biopharm Ltd
Ash Road
Wrexham Industrial Estate
Wrexham
LL13 9UF**

**Permit number
SP3030LZ**

Wrexham Pharmaceutical Works

Permit Number SP3030LX

Introductory note

This introductory note does not form a part of the permit

The main features of the installation are as follows. The Ipsen Biopharm installation is located in the Wrexham Industrial Estate, Wrexham on a site that covers an area of 7.5 Acres. 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. The required product is isolated from the fermentation liquor by a number of separation techniques including filtration and centrifugation. The API is formulated and freeze-dried to produce the finished, sterile product. Production is done under aseptic conditions and all materials entering the production areas are steam sterilised.

Operations are supported by two natural gas boilers (< 20MW) which generate heat and steam for fermentation, effluent treatment, autoclaving and the provision of sterile water. Chilling is provided to maintain climate control in the manufacturing areas and for the fermenter and effluent plant. Diesel powered generators provide emergency power back-up.

As a result of the high containment standards required during production of the API the only emissions to atmosphere are during fumigation with formalin and releases from the various site utility units. Effluent from the production areas is discharged to sewer under consent from Welsh Water [there are two discharge consents – for the units 9 (which incorporates the effluent from unit 11) & 10, not for the whole installation]. Most storm water goes to sewer with the exception of the area in the NW corner of the site which drains to a pond within the installation. A culverted stream enters and leaves the pond feeding into the Redwither Brook then the River Clywedog and finally the River Dee. The site Environmental Management System standard is to Green Dragon Level 3.

Status Log of the permit		
Detail	Date	Response Date
Application SP3030LZ	Duly made 03/04/06	
Additional Information Received		17/10/06
Permit determined	04/12/06	

End of Introductory Note

Permit

Pollution Prevention and Control
(England and Wales) Regulations 2000

Permit

Permit number

SP3030LZ

The Environment Agency (the Agency) in exercise of its powers under Regulation 10 of the Pollution Prevention and Control (England and Wales) Regulations 2000 (SI 2000 No 1973) hereby authorises

Ipsen Biopharm Ltd ("the operator"),

whose registered office (or principal office) is

Ash Road, Wrexham Industrial Estate, Wrexham LL13 9UF

company registration number **01653765**

to operate an installation at

Ash Road

Wrexham Industrial Estate

Wrexham

LL13 9UF

to the extent authorised by and subject to the conditions of this permit.

Signed

Date

	04/12/2006
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M J Peacock

Authorised to sign on behalf of the Agency

Conditions

1 Management

1.1 General management

1.1.1 The activities shall be managed and operated:

- (a) in accordance with a management system, which identifies and minimises risks of pollution, including those arising from operations, maintenance, accidents, incidents and non-conformances and those drawn to the attention of the operator as a result of complaints; and
- (b) by sufficient persons who are competent in respect of the responsibilities to be undertaken by them in connection with the operation of the activities.

1.1.2 Records demonstrating compliance with condition 1.1.1 shall be maintained.

1.1.3 Any person having duties that are or may be affected by the matters set out in this permit shall have convenient access to a copy of it kept at or near the place where those duties are carried out.

1.2 Accidents that may cause pollution

1.2.1 The operator shall:

- (a) maintain and implement an accident management plan;
- (b) review and record at least every 4 years or as soon as practicable after an accident, (whichever is the earlier) whether changes to the plan should be made;
- (c) make any appropriate changes to the plan identified by a review.

1.3 Energy efficiency

1.3.1 The operator shall:

- (a) take appropriate measures to ensure that energy is used efficiently in the activities;
- (b) review and record at least every 4 years whether there are suitable opportunities to improve the energy efficiency of the activities; and
- (c) take any further appropriate measures identified by a review.

1.4 Efficient use of raw materials

1.4.1 The operator shall:

- (a) take appropriate measures to ensure that raw materials and water are used efficiently in the activities;
- (b) maintain records of raw materials and water used in the activities;
- (c) review and record at least every 4 years whether there are suitable alternative materials that could reduce environmental impact or opportunities to improve the efficiency of raw material and water use; and

- (d) take any appropriate further measures identified by a review.

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

1.5.1 The operator shall:

- (a) take appropriate measures to ensure that waste produced by the activities is avoided or reduced, or where waste is produced it is recovered wherever practicable or otherwise disposed of in a manner which minimises its impact on the environment;
- (b) review and record at least every 4 years whether changes to those measures should be made; and
- (c) take any further appropriate measures identified by a review.

1.6 Site security

- 1.6.1 Site security measures shall prevent unauthorised access to the site, as far as practicable.

2. Operations

2.1 Permitted activities

- 2.1.1 The operator is authorised to carry out the activities specified in schedule 1 table S1.1 (the "activities").

2.2 The site

- 2.2.1 The activities shall not extend beyond the site, being the land shown edged in red on the site plan at schedule 2 to this permit.

2.3 Operating techniques

- 2.3.1 The activities shall, subject to the conditions of this permit, be operated using the techniques and in the manner described in the documentation specified in schedule 1 table S1.2, unless otherwise agreed in writing by the Agency.
- 2.3.2 No raw materials or fuels listed in schedule 3 table S3.1 shall be used unless they comply with the specifications set out in that table.

2.4 Off-site conditions

There are no off-site conditions under this section.

2.5 Improvement programme

- 2.5.1 The operator shall complete the improvements specified in schedule 1 table S1.3 by the date specified in that table unless otherwise agreed in writing by the Agency.
- 2.5.2 Except in the case of an improvement which consists only of a submission to the Agency, the operator shall notify the Agency within 14 days of completion of each improvement.

2.6 Pre-operational conditions

There are no pre-operational conditions in this permit.

2.7 Closure and decommissioning

- 2.7.1 The operator shall maintain and operate the activities so as to prevent or where that is not practicable, to minimise, any pollution risk on closure and decommissioning.
- 2.7.2 The operator shall maintain a site closure plan which demonstrates how the activities can be decommissioned to avoid any pollution risk and return the site to a satisfactory state.
- 2.7.3 The operator shall carry out and record a review of the site closure plan at least every 4 years.
- 2.7.4 The site closure plan (or relevant part thereof) shall be implemented on final cessation or decommissioning of the activities or part thereof.

2.8 Site protection and monitoring programme

- 2.8.1 The operator shall, within 4 months of the issue of this permit, submit a site protection and monitoring programme.
- 2.8.2 The operator shall implement and maintain the site protection and monitoring programme and shall carry out and record a review of it at least every 4 years.

3. Emissions and monitoring

3.1 Emissions to water, air or land

- 3.1.1 There shall be no point source emissions to water, air or land except from the sources and emission points listed in schedule 4 tables S4.1, S4.2 and S4.3.
- 3.1.2 The limits given in schedule 4 shall not be exceeded.
- 3.1.3 Not applicable
- 3.1.4 Total annual emissions from the emission point(s) set out in schedule 4 tables 4 S4.1, S4.2 and S4.3 of a substance listed in schedule 4 table S4.4 shall not exceed the relevant limit in table S4.4.

3.2 Transfers off-site

- 3.2.1 Records of all the wastes sent off site from the activities, for either disposal or recovery, shall be maintained.

3.3 Fugitive emissions of substances

- 3.3.1 Fugitive emissions of substances (excluding odour, noise and vibration) shall not cause pollution. The operator shall not be taken to have breached this condition if appropriate measures have been taken to prevent or where that is not practicable, to minimise, those emissions.
- 3.3.2 Not applicable.

3.3.3 Not applicable

3.3.4 All liquids, whose emission to water or land could cause pollution, shall be provided with secondary containment, unless the operator has used other appropriate measures to prevent or where that is not practicable, to minimise, leakage and spillage from the primary container.

3.4 Odour

3.4.1 Emissions from the activities shall be free from odour at levels likely to cause annoyance outside the site, as perceived by an authorised officer of the Agency, unless the operator has used appropriate measures to prevent or where that is not practicable to minimise the odour.

3.5 Noise and vibration

3.5.1 Emissions from the activities shall be free from noise and vibration at levels likely to cause annoyance outside the site, as perceived by an authorised officer of the Agency, unless the operator has used appropriate measures to prevent or where that is not practicable to minimise the noise and vibration.

3.6 Monitoring

3.6.1 The operator shall, unless otherwise agreed in writing by the Agency, undertake monitoring specified in the following tables in schedule 4 to this permit:

(a) point source emissions specified in tables S4.1, S4.2 and S4.3;

3.6.2 The operator shall maintain records of all monitoring required by this permit including records of the taking and analysis of samples, instrument measurements (periodic and continual), calibrations, examinations, tests and surveys and any assessment or evaluation made on the basis of such data.

3.6.3 Monitoring equipment, techniques, personnel and organisations employed for the emissions monitoring programme specified in condition 3.6.1 shall have either MCERTS certification or MCERTS accreditation (as appropriate) unless otherwise agreed in writing by the Agency.

3.6.4 Permanent means of access shall be provided to enable sampling/monitoring to be carried out in relation to the emission points specified in schedule 4 tables S4.1, S4.2 and S4.3 unless otherwise specified in that schedule.

3.6.5 Within 8 months of the issue of this permit (unless otherwise agreed in writing by the Agency) the site reference data identified in the site protection and monitoring programme shall be collected and submitted to the Agency.

4. Information

4.1 Records

4.1.1 All records required to be made by this permit shall:

(a) be legible;

(b) be made as soon as reasonably practicable;

- (c) if amended, be amended in such a way that the original and any subsequent amendments remain legible, or are capable of retrieval; and
- (d) be retained, unless otherwise agreed in writing by the Agency, for at least 6 years from the date when the records were made, or in the case of the following records until permit surrender:
 - (i) the site protection and monitoring programme.

4.1.2 Any records required to be made by this permit shall be supplied to the Agency within 14 days where the records have been requested in writing by the Agency.

4.1.3 All records required to be held by this permit shall be held on the site and shall be available for inspection by the Agency at any reasonable time.

4.2 Reporting

4.2.1 A report or reports on the performance of the activities over the previous year shall be submitted to the Agency by 31 January (or other date agreed in writing by the Agency) each year. The report(s) shall include as a minimum:

- (a) a review of the results of the monitoring and assessment carried out in accordance with this permit against the relevant assumptions, parameters and results in the assessment of the impact of the emissions submitted with the application;
- (b) where the operator's management system encompasses annual improvement targets, a summary report of the previous year's progress against such targets;
- (c) the annual production /treatment data set out in schedule 5 table S5.2;
- (d) the performance parameters set out in schedule 5 table S5.3 using the forms specified in table S5.4 of that schedule; and
- (e) details of any contamination or decontamination of the site which has occurred.

4.2.2 Within 28 days of the end of the reporting period the operator shall, unless otherwise agreed in writing by the Agency, submit reports of the monitoring and assessment carried out in accordance with the conditions of this permit, as follows:

- (a) in respect of the parameters and emission points specified in schedule 5 table S5.1;
- (b) for the reporting periods specified in schedule 5 table S5.1 and using the forms specified in schedule 5 table S5.4 ; and
- (c) giving the information from such results and assessments as may be required by the forms specified in those tables.

4.2.3 A summary report of the waste types and quantities accepted and removed from the site shall be made for each quarter. It shall be submitted to the Agency within one month of the end of the quarter and shall be in the format required by the Agency.

4.2.4 The operator shall, unless notice under this condition has been served within the preceding 4 years, submit to the Agency, within 6 months of receipt of a written notice, a report assessing whether there are other appropriate measures that could be taken to prevent, or where that is not practicable, to minimise pollution.

- 4.2.5 All reports and notifications required by the permit shall be sent to the Agency using the contact details supplied in writing by the Agency
- 4.2.6 The results of reviews and any changes made to the site protection and monitoring programme shall be reported to the Agency, within 1 month of the review or change.

4.3 Notifications

- 4.3.1 The Agency shall be notified without delay following the detection of:
- (a) any malfunction, breakdown or failure of equipment or techniques, accident, or fugitive emission which has caused, is causing or may cause significant pollution;
 - (b) the breach of a limit specified in the permit;
 - (c) any significant adverse environmental effects.
- 4.3.2 Any information provided under condition 4.3.1 shall be confirmed by sending the information listed in schedule 6 to this permit within the time period specified in that schedule.
- 4.3.3 Prior written notification shall be given to the Agency of the following events and in the specified timescales:
- (a) as soon as practicable prior to the permanent cessation of any of the activities;
 - (b) cessation of operation of part or all of the activities for a period likely to exceed 1 year; and
 - (c) resumption of the operation of part or all of the activities after a cessation notified under (b) above.
- 4.3.4 The Agency shall be given at least 14 days notice before implementation of any part of the site closure plan.
- 4.3.5 Where the Agency has requested in writing that it shall be notified when the operator is to undertake monitoring and/or spot sampling, the operator shall inform the Agency when the relevant monitoring is to take place. The operator shall provide this information to the Agency at least 14 days before the date the monitoring is to be undertaken.
- 4.3.6 Not applicable
- 4.3.7 Not applicable
- 4.3.8 Not applicable
- 4.3.9 The Agency shall be notified within 14 days of the occurrence of the following matters, except where such disclosure is prohibited by Stock Exchange rules:
- (a) any change in the operator's trading name, registered name or registered office address;
 - (b) any change to particulars of the operator's ultimate holding company (including details of an ultimate holding company where an operator has become a subsidiary); and
 - (c) any steps taken with a view to the operator going into administration, entering into a company voluntary arrangement or being wound up.

Climate Change Agreement

4.3.10 Where the operator has entered into a climate change agreement with the Government, the Agency shall be notified within one month of:

- (a) a decision by the Secretary of State not to re-certify the agreement;
- (b) a decision by either the operator or the Secretary of State to terminate the agreement; and
- (c) any subsequent decision by the Secretary of State to re-certify such an agreement.

4.4 Interpretation

4.4.1 In this permit the expressions listed in schedule 7 shall have the meaning given in that schedule.

Schedule 1 - Operations

Table S1.1 activities

Activity listed in Schedule 1 of the PPC Regulations	Description of specified activity	Limits of specified activity
4.5 A(1) (a) Producing pharmaceutical products using a chemical or biological process	Manufacture of pharmaceutical injectable products	From receipt of raw materials to despatch of product
Directly Associated Activity		
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	Includes oil receipt and storage
Waste storage	Storage of inert, hazardous and non-hazardous waste	Provision of designated storage areas and segregation for generated waste
Waste water treatment	Heat treatment of effluent from manufacturing operations	From generation of effluent to the disposal to sewer
Cooling supply	Provision of chilling	Includes process cooling and climate control during manufacture and chilled storage

Table S1.2 Operating techniques

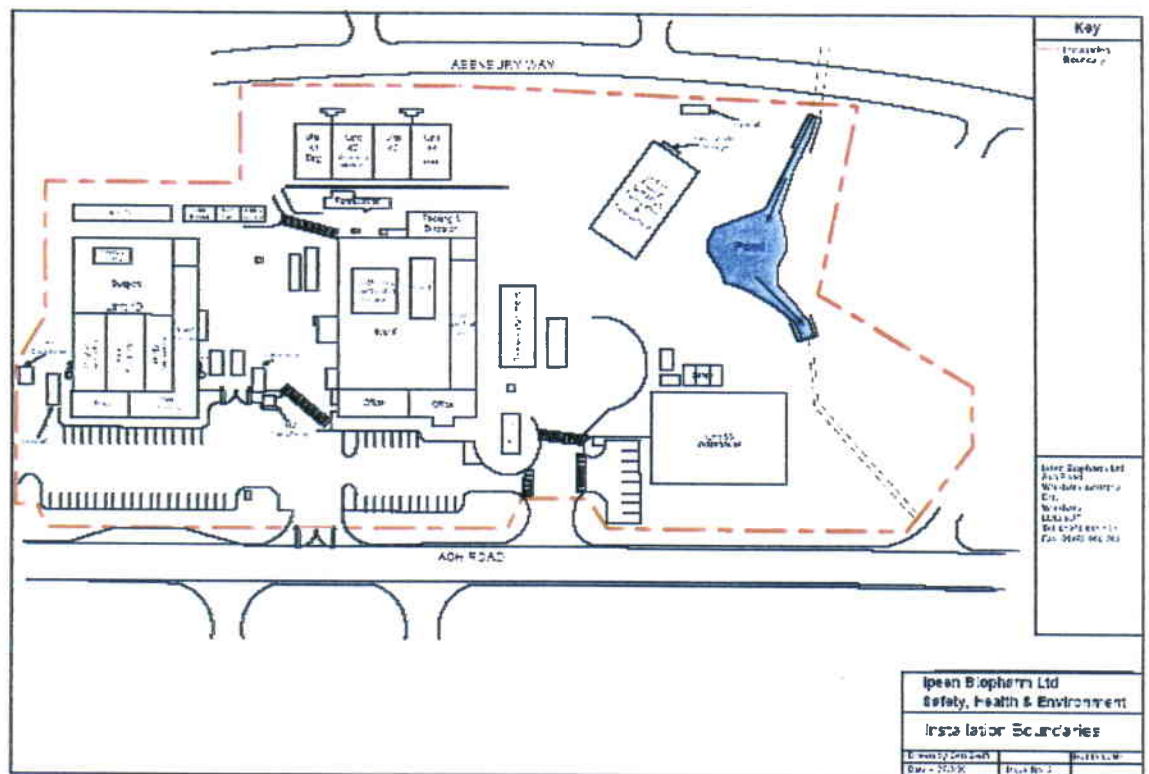
Description	Parts	Date Received
Application	The response to sub- section B2.1.1 and section B2.2 in the Application.	03/04/06
Additional information	Responses 1 to 9	17/10/06

Table S1.3 Improvement programme requirements

Reference	Requirement	Date
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
IP2	The operator shall complete the colour coding of surface water and foul water manhole covers.	31/07/07
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
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
IP5	The operator shall establish an easily accessible detailed inventory of raw materials and quantities used.	31/03/07
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
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
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
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
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
IP11	The operator shall review energy 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.	30/09/07

	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.	31/03/07
	The improvement programme shall be considered suitable for implementation by the operator from the date of approval by the Agency	
IP13	A written procedure shall be submitted to the Agency detailing the measures to be used so that monitoring equipment, techniques, 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.	31/03/07
	The procedure shall be implemented by the operator from the date of approval in writing by the Agency	

Schedule 2 - Site plan



Schedule 3 - Waste types, raw materials and fuels

Table S3.1 Raw materials and fuels

Raw materials and fuel description	Specification
-	-

Schedule 4 – Emissions and monitoring

Table S4.1 Point source emissions to air – emission limits and monitoring requirements

Emission point ref. & location (Note1)	Parameter	Source	Limit (including unit)	Reference period	Monitoring frequency	Monitoring standard or method
A1 & A2	Formaldehyde	Unit 10, Room HVAC Exhausts	To be established	To be established	To be established	To be established
A3, A4 & A5	Formaldehyde	Unit 10, MSC (Microbiological Safety Cabinets) Exhaust	To be established	To be established	To be established	To be established
A6 & A7	No parameters set	Unit 10, Natural Gas Boilers Exhaust	No limit set	–	–	Permanent sampling access not required
A8, A9 & A10	No parameters set	Units 9 & 11 Domestic Natural Gas Boilers Exhaust	No limit set	–	–	Permanent sampling access not required

Note1: Refer to Application (additional information) Figure 3 Emission Points to Atmosphere (Issue No4), for locations

Table S4.2 Point Source emissions to water (other than sewer) – emission limits and monitoring requirements

Emission point ref. & location	Parameter	Source	Limit (Incl. unit)	Reference Period	Monitoring frequency	Monitoring standard or method
W1 on drainage plan ground floor site layout (Drawing WM-001-05-02-0012)	No parameters set	Surface water	No limit set	–	–	Permanent sampling access not required
W2 on drainage plan ground floor site layout (Drawing WM-001-05-02-0012)	No parameters set	Surface water	No limit set	–	–	Permanent sampling access not required

Table S4.3 Point source emissions to sewer, effluent treatment plant or other transfers off-site– emission limits and monitoring requirements

Emission point ref. & location	Parameter	Source	Limit (incl. Unit)	Reference period	Monitoring frequency	Monitoring standard or method
S1 on drainage plan ground floor site layout (Drawing WM-001-05-02-0012)	No parameters set (Note 1)	Process effluent from units 9, 10 & 11, surface water, domestic sewage	No limit set (Note 1)	–	–	Permanent sampling access not required
S2 on drainage plan ground floor site layout (Drawing WM-001-05-02-0012)	No parameters set	Surface water & domestic sewage	No limit set	–	–	Permanent sampling access not required
S3 on drainage plan ground floor site layout drawing (Drawing WM-001-05-02-0012)	No parameters set	Surface water & domestic sewage	No limit set	–	–	Permanent sampling access not required

Note 1 There are two trade effluent discharge consents with Welsh Water – for the units 9 (which incorporates the effluent from unit 11) & 10

Table S4.4 Annual limits

Substance	Medium	Limit (including unit)
Formaldehyde	Air	To be established

Schedule 5 - Reporting

Parameters, for which reports shall be made, in accordance with conditions of this permit, are listed below.

Table S5.1 Reporting of monitoring data

Parameter	Emission or monitoring point/reference	Reporting period	Period begins
Emissions to air	A1, A2, A3, A4, A5	To be established	01/01/07
Parameters as required by condition 3.6.1.			

Table S5.2: Annual production/treatment

Parameter	Units
Standard unit output	number

Table S5.3 Performance parameters

Parameter	Frequency of assessment	Units
Water usage	Annually	m ³
Energy usage	Annually	MWh

Table S5.4 Reporting forms

Media/parameter	Reporting format	Date of form
Air	Form air 1 or other form as agreed in writing by the Agency	25/10/06
Water usage	Form water usage1 or other form as agreed in writing by the Agency	25/10/06
Energy usage	Form energy 1 or other form as agreed in writing by the Agency	25/10/06
Annual production	Form performance 1 or other form as agreed in writing by the Agency	25/10/06

Schedule 6 - Notification

These pages outline the information that the operator must provide.

Units of measurement used in information supplied under Part A and B requirements shall be appropriate to the circumstances of the emission. Where appropriate, a comparison should be made of actual emissions and authorised emission limits.

If any information is considered commercially confidential, it should be separated from non-confidential information, supplied on a separate sheet and accompanied by an application for commercial confidentiality under the provisions of the PPC Regulations.

Part A

Permit Number	
Name of operator	
Location of Installation	
Time and date of the detection	

(a) Notification requirements for any malfunction, breakdown or failure of equipment or techniques, accident, or fugitive emission which has caused, is causing or may cause significant pollution	
To be notified within 24 hours of detection	
Date and time of the event	
Reference or description of the location of the event	
Description of where any release into the environment took place	
Substances(s) potentially released	
Best estimate of the quantity or rate of release of substances	
Measures taken, or intended to be taken, to stop any emission	
Description of the failure or accident.	

(b) Notification requirements for the breach of a limit	
To be notified within 24 hours of detection unless otherwise specified below	
Emission point reference/ source	
Parameter(s)	
Limit	
Measured value and uncertainty	
Date and time of monitoring	
Measures taken, or intended to be taken, to stop the emission	

Time periods for notification following detection of a breach of a limit	
Parameter	Notification period

(c) Notification requirements for the detection of any significant adverse environmental effect	
To be notified within 24 hours of detection	
Description of where the effect on the environment was detected	
Substances(s) detected	
Concentrations of substances detected	
Date of monitoring/sampling	

Part B - to be submitted as soon as practicable

Any more accurate information on the matters for notification under Part A.	
Measures taken, or intended to be taken, to prevent a recurrence of the incident	
Measures taken, or intended to be taken, to rectify, limit or prevent any pollution of the environment which has been or may be caused by the emission	
The dates of any unauthorised emissions from the installation in the preceding 24 months.	

Name*	
Post	
Signature	
Date	

* authorised to sign on behalf of Ipsen Biopharm Ltd.

Schedule 7 - Interpretation

"accident" means an accident that may result in pollution.

"annually" means once every year.

"application" means the application for this permit, together with any additional information supplied by the operator as part of the application and any response to a notice served under Schedule 4 to the PPC Regulations.

"authorised officer" means any person authorised by the Agency under section 108(1) of The Environment Act 1995 to exercise, in accordance with the terms of any such authorisation, any power specified in section 108(4) of that Act.

"emissions to land", includes emissions to groundwater.

"fugitive emission" means an emission to air, water or land from the activities which is not controlled by an emission limit.

"groundwater" means all water, which is below the surface of the ground in the saturation zone and in direct contact with the ground or subsoil.

"land protection guidance", means Agency guidance "H7 - Guidance on the protection of land under the PPC Regime: application site report and site protection monitoring programme".

"MCERTS" means the Environment Agency's Monitoring Certification Scheme.

"notify without delay" and *"notified without delay"* means that a telephone call can be used, whereas all other reports and notifications must be supplied in writing, either electronically or on paper.

"PPC Regulations" means the Pollution, Prevention and Control (England and Wales) Regulations SI 2000 No.1973 and words and expressions used in this permit which are also used in the Regulations have the same meanings as in those Regulations.

"quarter" means a calendar year quarter commencing on 1 January, 1 April, 1 July or 1 October.

"site protection and monitoring programme" means a document which meets the requirements for site protection and monitoring programmes described in the Land Protection Guidance.

"year" means calendar year ending 31 December.

Where a minimum limit is set for any emission parameter, for example pH, reference to exceeding the limit shall mean that the parameter shall not be less than that limit.

Unless otherwise stated, any references in this permit to concentrations of substances in emissions into air means:

- (a) in relation to emissions from combustion processes, the concentration in dry air at a temperature of 273K, at a pressure of 101.3 kPa and with an oxygen content of 3% dry for liquid and gaseous fuels, 6% dry for solid fuels; and/or
- (b) in relation to emissions from non-combustion sources, the concentration at a temperature of 273K and at a pressure of 101.3 kPa, with no correction for water vapour content

END OF PERMIT