

# Notice of variation with introductory note

Environmental Permitting (England & Wales) Regulations 2010

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Ipsen Biopharm Limited

Wrexham Pharmaceutical Works  
Ash Road  
Wrexham Industrial Estate  
Wrexham  
LL13 9UF

Variation notice number  
EPR/SP3030LZ/V002

Permit number  
EPR/SP3030LZ

# Wrexham Pharmaceutical Works

## Permit number EPR/SP3030LZ

### Introductory note

#### **This introductory note does not form a part of the notice**

The following notice gives notice of the variation of an environmental permit.

The variation is for a new secondary manufacturing facility in Unit 12 with two associated natural gas boiler emission points, a new Biotech Pilot Suite in Unit 9 with associated emission points, introduction of a biofill suite to Unit 9, and acquisition of Unit 8 for storage and office space to be included in the Installation Boundary. A new fire water tank has also been installed in the North West Quadrant of the site.

The schedules specify the changes made to the original permit.

The status log of a permit sets out the permitting history, including any changes to the permit reference number.

<b>Status Log of the permit</b>		
<b>Description</b>	<b>Date</b>	<b>Comments</b>
Application SP3030LZ	Duly made 03/04/06	
Additional Information Received	17/10/06	
Permit SP3030LZ determined	04/12/06	
Variation Application EPR/SP3030LZ/V002	Duly Made 21/10/10	
Additional information requested	30/11/10	
Additional information received	31/01/11	
Additional information received	14/08/12	
Variation EPR/SP3030LZ/V002 determined	19/12/12	Varied permit issued
Permit number EPR/SP3030LZ		

End of Introductory Note

## Notice of variation

Environmental Permitting (England and Wales) Regulations 2010

The Environment Agency in exercise of its powers under regulation 20 of the Environmental Permitting (England and Wales) Regulations 2010 varies

**Permit number**  
**EPR/SP3030LZ**

**issued to:**  
**Ipsen Biopharm Ltd** (“the operator”)

**whose registered office is**

**Ash Road**  
**Wrexham Industrial Estate**  
**Wrexham**  
**LL13 9UF**

company registration number **01653765**

to operate a regulated facility at

**Wrexham Pharmaceutical Works**  
**Ash Road**  
**Wrexham Industrial Estate**  
**Wrexham**  
**LL13 9UF**

to the extent set out in the Schedules.

The notice shall take effect from 19 December 2012

Name	Date
<b>Eirian Macdonald</b>	<b>19 December 2012</b>

Principal Permitting Team Leader, National Permitting Service.

Authorised on behalf of the Environment Agency

## **Schedule 1 – conditions to be deleted**

None.

## Schedule 2 – conditions to be amended

The following conditions are amended as a result of the application made by the operator

1. Table S1.1 shall be amended to:

<b>Table S1.1 activities</b>		
<b>Activity listed in Schedule 1 of the EP Regulations</b>	<b>Description of specified activity</b>	<b>Limits of specified activity</b>
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
<b>Directly Associated Activity</b>		
Steam supply	2x2.205 MW and 2x2.430 MW thermal input natural gas boilers	Includes purified steam and water for infusion (WFI)
Electrical power supply	4xDiesel 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
Product verification	Product tests and checks throughout the manufacturing process	Purpose built laboratories
Material storage	Storage of raw materials, intermediates and products	Provision of designated storage areas

2. Table S1.2 shall be amended to:

<b>Table S1.2 Operating techniques</b>		
<b>Description</b>	<b>Parts</b>	<b>Date Received</b>
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
Application for variation EPR/SP3030LZ/V002	The response to application form Part C2 Question 2 and 5. Excluding Drawings W-001-05-02-0012 Site Drainage Plan and W-001-05-02-0013 Emission points.	21/10/10
Response to Schedule 5 Notice	Responses 1 to 5	31/01/11
Additional information	Includes fumigation comments and revised Drawings W-001-05-02-0012 Site Drainage Plan rev C and W-001-05-02-0013 rev B Emission points.	14/08/12

3. Table S4.1 shall be amended to:

<b>Table S4.1 Point source emissions to air – emission limits and monitoring requirements</b>						
<b>Emission point ref. &amp; location (Note1)</b>	<b>Parameter</b>	<b>Source</b>	<b>Limit (including unit)</b>	<b>Reference period</b>	<b>Monitoring frequency</b>	<b>Monitoring standard or method</b>
A1 & A2	Formaldehyde	Unit 10, Room HVAC Exhausts	No limit set	-	-	Sampling access required following advance notice
A3, A4 & A5	Formaldehyde	Unit 10, MSC (Microbiological Safety Cabinets) Exhaust	No limit set	-	-	Sampling access required following advance notice
A6, A7, A11 & A12	No parameters set	Unit 10 and Unit 12, Natural Gas Boilers Exhaust	No limit set	-	-	Permanent sampling access not required
A8, A9, A10, A15 & A16	No parameters set	Units 8, 9 & 11, Domestic Natural Gas Boilers Exhaust	No limit set	-	-	Permanent sampling access not required
A13	Formaldehyde	Unit 9, BPS Room HVAC Exhaust	No limit set	-	-	Sampling access required following advance notice
A14	Formaldehyde	Unit 9, BPS MSC (Microbiological Safety Cabinet) Exhaust	No limit set	-	-	Sampling access required following advance notice
Diesel generator exhausts	No parameters set	Site Standby Generators (4)	No limit set			Permanent sampling access not required
<b>Note1:</b> Refer to variation Application Appendix 13 Emission Points to Atmosphere (WM-001-05-02-0113 Rev B), for locations						

4. Table S4.2 shall be amended to:

<b>Table S4.2 Point Source emissions to water (other than sewer) – emission limits and monitoring requirements</b>						
<b>Emission point ref. &amp; location</b>	<b>Parameter</b>	<b>Source</b>	<b>Limit (incl. unit)</b>	<b>Reference Period</b>	<b>Monitoring frequency</b>	<b>Monitoring standard or method</b>
W1, W2, W3, and W4 on MSO Wrexham Site Drainage Plan (Drawing WM-001-05-02-0012 Revision C)	No parameters set	Surface water	No limit set	-	-	Permanent sampling access not required

5. Table S4.4 shall be amended to:

<b>Table S4.4 Annual limits</b>		
<b>Substance</b>	<b>Medium</b>	<b>Limit (including unit)</b>
Formaldehyde	Air	As per application, maximum usage per annum: <ul style="list-style-type: none"> <li>Primary Manufacturing 30 litres/yr (20 litres/yr normal operation and 10 litres/yr emergency).</li> <li>Biotech Pilot Suite 20 litres/yr (15 litres/yr normal operation and 5 litres/yr emergency).</li> </ul>

6. Table S5.1 shall be amended to:

<b>Table S5.1 Reporting of Annual limits</b>		
<b>Substance</b>	<b>Medium</b>	<b>Annual Usage (litres/year)</b>
Formaldehyde	Air	<ul style="list-style-type: none"> <li>Primary Manufacturing normal and emergency operation.</li> <li>Biotech Pilot Suite normal and emergency operation.</li> </ul>



**Schedule 3 – conditions to be added**

**None.**

The site plan in Schedule 2 of the Permit shall be amended to:

