

## Compliance Assessment Report CAR\_NRW0051617

**Permit being assessed:** SP3030LZ.

**For:** Wrexham Pharmaceutical Works, **held by:** Ipsen Biopharm Limited

**At:** Unit 9 Ash Road North , Wrexham Industrial Estate, Wrexham, WREXHAM, Clwyd, LL13 9UF.

**Type of assessment:** Report/Data Review,

**Reason:** Routine.

**On:** 24/04/2026.

**Parts of permit assessed:** See below.

**NRW Lead Officer:** Libby Hughes.

**Report sent to:** EHS Manager , EHS Manager , on 19/05/2026.

### 1. Summary of our findings (full details in section 4)

Part of permitted activity assessed (compliance criteria)	Assessment result	Permit condition
IR3B - Installations - Emissions and monitoring - Emissions of substances not controlled by emission limits	C3 Minor	3.3.1
IR3B - Installations - Emissions and monitoring - Emissions of substances not controlled by emission limits	C3 Minor	3.3.1
IR4C - Installations - Information - Notification	C3 Minor	4.3.1
IR4C - Installations - Information - Notification	C3 Minor	4.3.1
IR4C - Installations - Information - Notification	C3 Minor	4.3.1
IR4C - Installations - Information - Notification	C3 Minor	4.3.2
IR1A - Installations - Management - General Management	C3 Minor	1.1.1a

Result types are explained in more detail in the 'Important Information' section below.

Total non-compliances recorded	Total non-compliance score
7	28

How we use the non-compliance score to calculate your annual fee is explained in the 'Important Information' section below.

## 2. What action is required?

Criteria	Action needed	Complete by
IR3B	See Action 1 below	30/06/2026
IR3B	See Action 1 below	30/06/2026
IR4C	See Action 2 below	30/06/2026
IR4C	See Action 2 below	30/06/2026
IR4C	See Action 2 below	30/06/2026
IR4C	See action 3 below	30/06/2026
IR1A	See Action 4 below	30/06/2026

Compliance criteria codes are listed in the 'Important information' section below.

## 3. What will happen next?

Any non-compliance we have identified and recorded on this form is an offence. It can result in criminal prosecution and/or suspension or revocation of your permit.

### **You are non-compliant with your permit.**

**At this time, we are issuing you with a warning for the non-compliance recorded above. Warnings may influence future enforcement response for continued or further non-compliance.**

This statement does not stop us from taking additional enforcement action if further relevant information comes to light or offences continue.

## 4. Details of our assessment

This Compliance Assessment Report (CAR) form has been prepared following the submission in March 2026 of Pollutant Release & Transfer Register (PRTR) data for 2025 via the Government Portal and to Natural Resources Wales (NRW). The PRTR reporting process in March 2026 highlighted that several fugitive emissions of refrigerant F-gases had occurred during 2025 which had not been reported to NRW at the time of release occurrence.

NRW requested further details of these emissions. The operator provided a report; however, an initial review identified discrepancies in the reported figures, and further clarification was requested. A revised report was subsequently produced by Ipsen Biopharm Ltd which appeared to address these discrepancies.

The information provided confirms that fugitive emissions occurred on multiple occasions throughout 2025. None of these emissions were reported to NRW at the time they

occurred.

### **IR3B - Emissions of substances not controlled by emission limits**

Releases of greenhouse gases within the range of 25–250 tonnes CO<sub>2</sub> equivalent occurred during January, February, and December 2025. These releases are classified as minor but reportable.

Category 3C non-compliances have been recorded per quarter for each of these incidents against permit condition 3.3.1 under subheading IR3B Emissions of substances not controlled by emission limits.

### **IR4C - Notification**

Permit condition 4.3.1 states:

The Agency (Natural Resources Wales) 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.

Permit condition 4.3.2 states:

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 within that permit.

Failure to notify NRW at the time that the emissions occurred is considered as a breach of permit condition 4.3.1, and has resulted in the following non-compliances being recorded above:

Failure to report the fugitive gas emissions to NRW which occurred during **Q1 of 2025** in a timely manner has resulted in a category 3C non-compliance being recorded against **IR4C - Notification**

Failure to report the fugitive gas emissions to NRW which occurred during **Q2 of 2025** in a timely manner has resulted in a category 3C non-compliance being recorded against **IR4C - Notification**

Failure to report the fugitive gas emissions to NRW which occurred during **Q4 of 2025** in a

timely manner has resulted in a category 3C non-compliance being recorded against **IR4C - Notification**

Reports detailing the emissions were sent to NRW in March 2026.

The permit holder was advised in 2025 to report fugitive emissions using the appropriate Schedule Reporting form. This form is still referred to as Schedule 6 in older permits, such as the current iteration of Ipsen Biopharmaceutical's permit but as Schedule 5 in more modern permits. Returns for 2024 were submitted on a schedule 5

Failure on this occasion to report the gas emissions using the correct reporting method, permit condition has resulted in a further category C3 non-compliance score being recorded against **IR4C - Notification**

### **IR1A - General Management**

NRW has taken the view that the operator has;

- failed to notify NRW of fugitive emissions at the time that they occurred,
- failed to provide complete and accurate information when first requested, and
- failed to implement improvements to notification procedures despite the advice provided in previous compliance assessment reports.

These observations indicate that the site is not being managed in accordance with a sufficiently robust environmental management system (EMS).

A further Category C3 non-compliance has been recorded against **IR1A - General Management**

### **Actions**

**Action 1:** Review and if necessary update operations to reduce or preferably avoid releases of greenhouse gases through improved maintenance and/or improved operations.

**Action 2:** In future ensure that reports are submitted to NRW without delay following an unpermitted discharge to air, as set out in permit condition 4.3.1. Small releases may be reported collectively at the end of the quarter.

**Action 3:** Submit all notifications using the correct Schedule Reporting form and should be reported to the Industry Regulation Team inbox [north.wales.ppc@cyfoethnaturiolcymru.gov.uk](mailto:north.wales.ppc@cyfoethnaturiolcymru.gov.uk) as well as the relevant NRW regulatory officer.

**Action 4:** By 30th June 2026 review and if necessary update Ipsen's EMS / reporting procedures to ensure that breaches are reported to NRW in accordance with permit requirements. Confirm to NRW in writing when this has been completed.

#### **Actions from previous CAR form**

CAR form CAR\_NRW0051144 sent to the operator on 10th April 2026 included the following:

*Action 1: Provide NRW with details of the specifics of the validation batch production tests by 30th April 2026.*

Details of the batch production tests were submitted to NRW together with a timeline by the required date. NRW is currently reviewing the information provided and will respond in due course.

If you have any queries about this report, or to discuss completion of any actions, please contact the NRW Officer named above.

## Important information

### Legal status of this report

Your permit is issued to you under the Environmental Permitting Regulations. You have a responsibility to comply with the conditions of your permit and prevent pollution/harm of the environment. You must also ensure that you comply with any other relevant legislation that may apply to your site's operations.

This report explains the findings of our assessment and any action you are required to take. We categorise non-compliance using our guidance for assessing non-compliance at regulated sites.

When we find potential non-compliance/s we will normally give you advice on how to maintain compliance.

To correct non-compliance, we may:

- require you to take specific actions
- issue a notice
- review the conditions of your permit.

Any advice and guidance we give will be without prejudice to any other enforcement response that we consider may be required.

### Assessment results and non-compliance categories (used in section 1):

Assessment result	Description
Assessed (A)	Assessed or assessed in part, no evidence of non-compliance found
Action only (X)	Action required for the permit condition assessed to avoid non-compliance. No non-compliance scored at this time
Ongoing (O)	Ongoing non-compliance, not scored

Non-compliance category	Description	Score
C1 Major	Potential to have a major, serious, persistent and/or extensive impact or effect on the environment, people and/or property	60
C2 Significant	Potential to have a significant impact or effect on the environment, people and/or property	31
C3 Minor	Potential to have a minor or minimal impact or effect on the environment, people and/or property	4
C4 No environmental impact	Non-compliance at a regulated site that cannot foreseeably have any impact on the environment, people and/or property	0.1

### **How we use assessment scores**

The number and severity of non-compliances recorded in a year will affect your annual subsistence fee the following year. A non-compliance factor is added to your site's Operator Performance Risk Appraisal (OPRA) score when we calculate your fee to reflect the additional resource we use to assess permit compliance.

### **If your assessment result in Section 1 is suspended, what does this mean?**

In line with our guidance, we may suspend scores for up to six months to allow time for remedial action to be taken. Suspended scores will be re-instated if the action is not completed.

### **Full list of Industry compliance criteria (used in section 1 and 2):**

#### **1. Management**

- IR1A – General management
- IR1B – Finance (only applicable to Landfill)
- IR1C – Energy efficiency
- IR1D - Efficient use of raw materials
- IR1E - Avoidance, recovery and disposal of wastes produced by the activities
- IR1F - Multiple operator installations

#### **2. Operations**

- IR2A – Permitted activities
- IR2B – The site
- IR2C – Operating techniques
- IR2D – Technical requirements
- IR2E – Improvement programme
- IR2F – Pre-operational conditions
- IR2G – Landfill engineering (only applicable to Landfill)
- IR2H – Waste acceptance (only applicable to Landfill)
- IR2I – Leachate levels (only applicable to Landfill)
- IR2J – Closure and aftercare (only applicable to Landfill)
- IR2K – Landfill gas management (only applicable to Landfill)

#### **3. Emission and Monitoring**

- IR3A(1) – Emissions to water
- IR3A(2) – Emissions to air
- IR3A(3) – Emissions to land
- IR3B – Emissions of substances not controlled by emission limits
- IR3C – Odour
- IR3D – Noise and vibration
- IR3E – Monitoring
- IR3F – Pests
- IR3G – Air quality management plans
- IR3H – Monitoring for the purposes of the Industrial Emissions Directive (this heading includes Large Combustion Plants)
- IR3I – Fire

#### **4. Information**

- IR4A – Records
- IR4B – Reporting
- IR4C – Notification

### Enforcement response

Any non-compliance with a permit condition is an offence and we may take legal action against you. Action we take can include prosecution, serving a notice on you and/or suspension or revocation of your permit. See our Enforcement and Sanctions Guidance for further information.

### Data protection notice

You should make sure that anyone named in this report knows that the information it contains will be processed by Natural Resources Wales to fulfil its regulatory and monitoring functions and to maintain the relevant public register(s).

We may also use and/or disclose the report in connection with:

- offering or providing you with our literature or services relating to environmental matters
- consulting with the public, public bodies and other organisations (e.g. Health and Safety Executive, local authorities) on environmental issues
- carrying out statistical analysis, research and development on environmental issues
- providing public register information to enquirers
- investigating possible breaches of environmental law
- assessing customer service satisfaction and improving our service
- Freedom of Information Act or Environmental Information Regulations requests.

We may also pass it on to our agents or representatives to do these things on our behalf.

### Disclosure of information – this report will be available to view on-line

If you think this report contains commercially confidential information that should not be placed on our public register, you must contact your local Natural Resources Wales office within **fifteen working days** of receiving this report, using the contact details in the accompanying email or letter. You must give a full explanation of why it should not be added to our public register, including specifying which information is commercially confidential. We will assess your request and respond to you within twenty working days to let you know if we agree to your request.

### Disputing the Content of this Compliance Assessment Report Form

If you disagree with the content of this Compliance Assessment Report form, you should submit your concerns, in writing, to the regulating officer who issued it within **15 working days** of its issue. This will be treated as a **Stage 1 review**.

If you are not satisfied with the outcome of the stage 1 review, you may request a **Stage 2 appeal**. This request must be submitted **within 21 working days** of receiving the response from the stage 1 review.

Further details on our review and appeal process are available at: [Natural Resources Wales / Appeal a regulatory decision from Natural Resources Wales](#)

### Concerns Not Related to the Content of this Compliance Assessment Report Form

If your concerns do not relate to the content of the Compliance Assessment Report form, you should first attempt to resolve the issue with the regulating officer or their line manager.

If the issue remains unresolved, please contact our **Customer Contact Team**:

- **Telephone:** 0300 065 3000 (Monday to Friday, 09:00–17:00)
- **Email:** [enquiries@naturalresourceswales.gov.uk](mailto:enquiries@naturalresourceswales.gov.uk)

They will provide details on how to escalate your concerns through our **Complaints and Commendations procedure**.

If you are dissatisfied with our response, you may contact the **Public Services Ombudsman for Wales**:

- **Telephone:** 0300 790 0203
- **Email:** [ask@ombudsman.wales](mailto:ask@ombudsman.wales)

### **Welsh Language Standards**

We are committed to establishing Natural Resources Wales as a naturally bilingual organisation. We will provide compliance reports in your preferred language.