

## Compliance Assessment Report CAR\_NRW0050934

**Permit being assessed:** SP3338LF.

**For:** Blaenwaun Pharmaceutical Plant, **held by:** Protherics UK Limited

**At:** Blaenwaun , Ffostrasol, LLANDYSUL, Dyfed, SA44 5JT.

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

**Reason:** Other.

**On:** 09/06/2025 between 10:00 and 14:00.

**Parts of permit assessed:** W2 Surface water drain.

**NRW Lead Officer:** Daren Pike.

**Report sent to:** Elaine Davies , Senior EHS Manager, on 04/03/2026.

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

Part of permitted activity assessed (compliance criteria)	Assessment result	Permit condition
IR3A(1) - Installations - Emissions and monitoring - Emissions to water	C3 Minor (Suspended)	Oil leak from hired temporary generator has emitted to river.

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

Total non-compliances recorded	Total non-compliance score
1	0

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
IR3A(1)	Schedule 5 was submitted retrospectively. Works to mitigate non-compliance have been completed.	Already completed

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.

**At this time, we do not intend to take any further action.**

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**

On 09 July 2025 a Schedule 5 notification was submitted to NRW in relation to an incident on site that resulted in a minor release of Hydrotreated Vegetable Oil (HVO) into a nearby watercourse. The event occurred on 09 June 2025 and was initially reported on the WIRS system. The NRW Regulatory Officer was not notified by the WIRS system, so was unaware of the incident until he attended the site on 09 July 2025. The NRW Officer advised the SERB Pharmaceuticals EHS Manager that alongside the WIRS report, a Schedule 5 notification was required to be submitted. This was completed the same day and was as follows:

## Schedule 5 - 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 EP Regulations.

### Part A

Permit Number	EPR/SP3338LF
Name of operator	Protherics UK Limited
Location of Facility	Blaenwaun, Ffostrasol, Llandysul, Ceredigion, SA44 5JT
Time and date of the detection	09/06/2025

<b>(a) Notification requirements for any activity that gives rise to an incident or accident which significantly affects or may significantly affect the environment</b>	
<b>To be notified Immediately</b>	
Date and time of the event	09/06/2025
Reference or description of the location of the event	W2 Surface Water drain
Description of where any release into the environment took place	W2 section - Surface Water drain into River Cwerchyr (stream)
Substances(s) potentially released	Hydrotreated Vegetable Oil (HVO) Oil
Best estimate of the quantity or rate of release of substances	Minimal release, small sheen seen in the stream and approx. 50m
Measures taken, or intended to be taken, to stop any emission	Area was contained using tertiary system and spill booms.
Description of the failure or accident.	Oil spill which was captured in our tertiary system however, small fracture in the clay pipework which lead to small quantity of HVO oil entering soil around the area and escaping by the stream area


<b>(b) Notification requirements for the breach of a permit condition</b>	
<b>To be notified immediately</b>	
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
N/A	N/A
N/A	N/A
N/A	N/A

(c) In the event of a breach of permit condition which poses an immediate danger to human health or threatens to cause an immediate significant adverse effect on the environment:	
To be notified immediately	
Description of where the effect on the environment was detected	N/A
Substances(s) detected	N/A
Concentrations of substances detected	N/A
Date of monitoring/sampling	N/A

**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	The earth around the drainline has been removed and discarded. New drainline to be installed and tertiary system back in situ.
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	Environmental specialist company called and stream cleaned of all sheen. Laboratory tests show that there is no HVO Oil detected or remnants within the stream.
The dates of any unauthorised emissions from the facility in the preceding 24 months.	N/A

<b>Name*</b>	Elaine Davies
<b>Post</b>	Senior EHS Manager
<b>Signature</b>	
<b>Date</b>	

\* authorised to sign on behalf of the operator

The spill has occurred due to a seal failure on an item of temporarily hired plant. This was captured by the site's tertiary drainage system which would have been directed for treatment prior to discharge. An underground clay pipe had fractured, unknown to the operator prior to this incident, resulting in a small quantity of oil into the nearby River Cwerchyr.

I have reviewed this matter and note that the equipment that failed was hired temporarily and not subject to the operator's maintenance regime. The failed pipe that fractured was buried and was outside of the Operator's site curtilage. The spill was minimal, was not reported by any third party, and immediate remedial action was undertaken to clean the spill. On-site works have now been completed to the drainage system. Whilst the Operator did not initially comply with the permit requirements by submitting a Schedule 5 notification, they did report directly to NRW via the Incident Communication Centre. The site has an exemplary record in relation to permit compliance and engagement with the regulatory process. I am satisfied that this was a one-off incident with a combination of factors that were unforeseen by the operator. My decision is to take no further action in this matter.

For further information please contact:

Daren Pike  
Senior Industry Regulator  
[daren.pike@cyfoethnaturiolcymru.gov.uk](mailto:daren.pike@cyfoethnaturiolcymru.gov.uk)

**END OF REPORT**

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.