

This form will report compliance with your permit as determined by an NRW officer

Site	Blaenwaun Pharmaceutical Plant	Permit Ref	SP3338LF		
Operator/Permit holder	Protherics UK Limited				
Regime	Installations				
Date of assessment	23/10/2018	Time in	09:30	Out	14:30
Assessment type	Audit				
Parts of the permit assessed	See Agenda				
Lead officer's name	Jenkins, Nicholas				
Accompanied by					
Recipient's name/position	Elaine Davies/ EHS Lead	Date issued	05/02/2019		

Section 1 – Compliance Assessment Summary

This is based on the requirements of the permit under the Environmental Permitting Regulations or the licence under the Water Resources Act 1991 as amended by the Water Act 2003. A detailed explanation is captured in "Compliance Assessment Report Detail" (Section 2) and any actions you may need to take are given in the "Action(s)" (section 4). This summary details where we believe any non-compliance with the permit has occurred, the relevant condition and how the non-compliance has been categorised using our Compliance Classification Scheme (CCS). CCS Scores can be consolidated or suspended where appropriate, to reflect the impact of some non-compliances more accurately. For more details of our CCS scheme, contact your local office.

Permit conditions and compliance summary	CCS Category	Condition(s) breached
<p>KEY: See Section 5 for breach categories, suspended scores will be indicated as such. A = Assessed or assessed in part (no evidence of non-compliance), X = Action only, O = Ongoing non-compliance, not scored.</p>		

Number of breaches recorded	0	Total compliance score (see section 5 for scoring scheme)	0
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If the Number of breaches recorded is greater than zero, please see Section 3 for our proposed enforcement response

Section 2 – Compliance Assessment Report Detail

This section contains a report of our findings and will usually include information on:

- The part(s) of the permit that were assessed (eg. Maintenance, training, combustion plant, etc)
- Where the type of assessment was 'Data Review' details of the report/results triggering the assessment
- Any non-compliances identified
- Any non-compliances with directly applicable legislation
- Details of any multiple non-compliances
- Information on the compliance score accrued inc.
- Details of advice given
- Any other areas of concern
- Any actions requested
- Any examples of good practice
- A reference to photos taken

Attendees

Gethin Phillips - Site director (Protherics UK Ltd) Not present for the whole meeting

Elaine Davies - EHS lead (Protherics UK Ltd)

Dylan Reynolds - Senior site services technician (Protherics UK Ltd)

Nick Jenkins – PPC Officer (Natural Resources Wales)

Agenda

1. Actions from last audit (19/01/18) Ref CAR_NRW0032754
2. Hazardous Waste
 - a. Classification
 - b. Reduction
 - c. How is it handled
3. Site tour
4. Any other business

Summary

Protherics generates hazardous waste in its manufacture of critical care products but it is only a very small proportion of the total amount of waste it creates. It is committed to adopting a sustainable approach to waste management and the responsibilities are clear within relevant documentation. The production, internal transport and storage is well managed under key work instructions and proficient infrastructure. However, there are concerns regarding the onward management of waste once it has been designated for removal from the installation. We recommend that Protherics considers developing its capability for dealing with hazardous waste by attending relevant courses.

Introduction

Protherics generate most of its hazardous waste in the form of clinical liquid and solid waste and is captured under EWC chapter 18 – Healthcare waste. Other hazardous waste types include chapter 20 (Commercial and Industrial Waste) and 16 (Other wastes from industrial processes). The hazardous waste is stored in a designated area for

bulking before being removed off site by its waste contractor. There are two disposal/recovery sites that accept the hazardous waste and each consignee provides producer returns.

Protherics has a requirement to take appropriate measurements to ensure that the waste hierarchy referred to in Article 4 of the Waste Framework Directive, is applied to the generation, treatment and disposal of waste. In addition, it must review and record at least every 4 years whether changes to those measures should be made and take further measures identified by a review.

1. Actions from last audit (19/01/18) Ref CAR_NRW0032754

The focus of the last audit was Protherics' response to a spill that had occurred 18 December 2017. In addition, an ongoing action was reviewed regarding the completion of a of feasibility study to consider the rerouting of any below ground pipework. Two actions were produced following the audit.

Action	By when	Comments
Protherics to consider relocating the mothering tank into a bunded area	At the next opportunity	Protherics had always stated that the mothering tank was a contingency operation and the installation of a new 30m ³ SG Vertical Enduratank in a concrete bunded area to the east of the installation continues that contingency of excess effluent being stored onsite. The tank is constructed of polyethylene capable of storing effluent between 10-25 ^o C. The Operator advised that the bund is fit for purpose and has recently been integrity tested (no reports were reviewed) and the inner surface sealed. During the inspection, the system was not complete, and the expectation was that it would be completed by mid-November 2018. Once operational, instructions will be developed, and training will be provided. Photographs were taken during the site tour and are presented at the end of the report.
Protherics to undertake a feasibility study to present to NRW that considers the re-routing of any below ground fuel pipework.	02/04/18	Protherics has not only completed the feasibility study but also raised all pipework identified within the feasibility study, above ground. This was completed during the August 2018 shutdown.

1. Hazardous Waste – Classification, Reduction, how is it handled

Directive 2008/98/EC on waste and the associated guidance interpreting the Directive are key to understanding how waste is defined and how it must be handled.

An essential part of the Directive is the waste hierarchy. Its primary purpose is to minimise adverse environmental effects from waste and to increase and optimise resource efficiency in waste management and policy.

The hierarchy sets out five possible ways of dealing with waste and prioritises these measures as follows:

- Prevention;
- Preparing for re-use;
- Recycling;
- Other recovery, e.g. energy recovery; and
- Disposal.

This prioritisation lays down a priority order of what constitutes the best overall environmental option in waste legislation and policy. An amendment was made to the Directive in 2018 (Ref Directive (EU) 2018/851) but no changes were made to the hierarchy

Condition 1.4 of Protherics' permit outlines that:

1.4.1 The operator shall take appropriate measures to ensure that:

- a. The waste hierarchy referred to in Article 4 of the Waste Framework Directive is applied to the generation of waste by the activities; and*
- b. Any waste generated by the activities is treated in accordance with the waste hierarchy referred to in Article 4 of the Waste Framework Directive; and*
- c. Where disposal is necessary, this is undertaken in a manner which minimises its impact on the environment.*

1.4.2 The operator shall review and record at least every four years whether changes to those measures should be made and take any further appropriate measures identified by a review.

Protherics outline in WAL-SP-19.010 that it is committed to adopting a sustainable approach to waste management, complying with all applicable legal requirements and is committed to continual improvement and the pursuit of best practice whilst using the waste hierarchy in determining the disposal route of all waste.

Comments provided in Protherics' application for the permit outlined that the raw materials used in the manufacture of its products are tightly controlled and therefore "difficult to change to alternative materials for the process". This is also reflected in the Operator's waste recovery statement which outlines that "due to materials and process being highly regulated by the FDA [United States Food and Drug Administration] to change any of the process or materials would prove technically and economically impractical to do so". However, Protherics' EHS team are now reviewing whether substitutes can be made and has set up a continuous management improvement team to explore alternative hazardous chemicals that can be used in their process.

Protherics produced around 7900 tonnes of waste in 2018 of which the majority (99%) is generated by the production of effluent from its processes (non-hazardous). Around 0.3% of the total figure relates to the production of hazardous waste. This is an incredibly small proportion of the total waste removed from the installation but nevertheless does equate to around 25 tonnes.

What was not clear in the work instructions provided, is whether Protherics undertake an assessment of the waste prior to it being transferred off site. It is essential that for most wastes, an identification of the hazardous properties is undertaken before it can be classified or described. How to do this is outlined in **Technical Guidance WM3 - Guidance on the classification and assessment of waste (1st Edition v1.1)** [Link to WM3](#) This lack of assessment could account for the omission of information in Part B(3) in the reviewed consignment notes

It may well be the case that due to the strict control of raw materials used and the resultant wastes that an assessment of each waste type has been completed but this was not clarified on the day of the audit and although reference is made in section 8.5 of WAL-SP-19.010 (Waste Management) to the technical guidance (mentioned above) it is out of date and will need updating.

Recommendation – Protherics to undertake an assessment of its waste types in accordance with WM3, unless a previous assessment can be provided.

A selection of hazardous waste consignment notes was reviewed:

Consignment Note No.	Date	Time (hrs)	Component	Consignee Name	Comments
CAC633/00050	22/05/2018	12-30	Cuno Filters	Clinipower Ltd	The first concern with these two consignment notes is the replicated note number. Protherics stated that it would not be possible to remove multiple loads of Cuno filters on the same day as outlined by the two different times. The second concern is that the information requested in the LAS consignment notes is not consistent with the data required with the information required by the standard template - Haz waste note There is information missing/incorrect including: <ul style="list-style-type: none"> Part A(6) Consignee is Clinipower Avonmouth Llp Part B(1) Process giving rise to the waste is absent Part B(3) Requires quantity in Kgs not units Part B(3) Chemical/Biological Component Part B(3) Concentration % or mg/kg Part B(3) The Hazard code(s) Part B(3) Transportation/packageing requirements – see http://www.hse.gov.uk/cdg/pdf/infect-subs.pdf Part C(6) & D(4) times in that they are expected to be produced in hours and not am/pm
CAC633/00050	22/05/2018	3-05	Cuno Filters	Clinipower Ltd	
CAC633/00144	08/10/2018	1-15	Cuno Filters	Clinipower Ltd	There is information missing/incorrect including: <ul style="list-style-type: none"> Part A(6) Consignee is Clinipower Avonmouth Llp Part B(1) Process giving rise to the

					<p>waste</p> <ul style="list-style-type: none"> • Part B(3) Requires quantity in Kgs not units • Part B(3) Concentration % or mg/kg • Part B(3) The Hazard code(s) • Part C(6) & D(4) times in that they are expected to be produced in hours and not am/pm
CAC633/00146	08/10/2018	1-15	Clinical Waste	Clinipower Ltd	<p>There is information missing/incorrect including:</p> <ul style="list-style-type: none"> • Part A(6) Consignee is Clinipower Avonmouth Llp • Part B(1) Process giving rise to the waste • Part B(3) Requires quantity in Kgs not units • Part B(3) Chemical/Biological Component • Part B(3) Concentration % or mg/kg • Part B(3) The Hazard code(s) • Part C(6) & D(4) times in that they are expected to be produced in hours and not am/pm
CAC633/00105	10/09/2018	09:00	Multiple Chemicals	Augean Treatment Ltd	<p>There is information missing/incorrect including:</p> <ul style="list-style-type: none"> • Part A(2) Date is different to the date in C(6) and D(4) • Part B(1) Process giving rise to the waste • Part B(3) Container type, number and size

Multiple consignment notes were issued with the same reference (CAC633/00050) but for different times and signed by different Protherics staff. A query was raised with the Environment Agency as the site is regulated under its regime as a waste transfer and treatment operation. Records gathered from the site i.e. Clinipower Avonmouth Llp (not Clinipower Ltd as outlined in the notes) suggest that the site received the waste 05/06/18, 14 days after it was removed from the Protherics (see table below). This is likely to be an administration error as Clinipower did receive a consignment from Protherics 22/05/18 but under reference CAC633/00052. As the standard consignment notes provided by LAS omit the quantity in Kgs from part B(3) it is difficult to match up the movement with the possible note. A query has been raised with the NRW regulating officer of LAS to investigate.

Consignment Details



Consignment Note Number	Single or Multiple Consignment	Round Number	Collection Number	Date Received (dd/mm/yyyy)	Postcode Of Place of Production	EWC Code	Hazard	Physical Form	Quantity (kilograms)	Mode of disposal / recovery
CAC633/00000	Single			26/01/2018	SA44 5JT	180103	HP5	Mixed	796	D10
CAC633/00006	Single			06/02/2018	SA44 5JT	180103	HP5	Mixed	255	D10
CAC633/00009	Single			19/02/2018	SA44 5JT	180103	HP5	Mixed	590	D10
CAC633/00017	Single			07/03/2018	SA44 5JT	180103	HP5	Mixed	274	D10
CAC633/00022	Single			20/03/2018	SA44 5JT	180103	HP5	Mixed	467	D10
CAC633/00028	Single			28/03/2018	SA44 5JT	180103	HP5	Mixed	571	D10
CAC633/00029	Single			10/04/2018	SA44 5JT	180103	HP5	Mixed	570	D10
CAC633/00033	Single			24/04/2018	SA44 5JT	180103	HP5	Mixed	598	D10
CAC633/00045	Single			11/05/2018	SA44 5JT	180103	HP5	Mixed	661	D10
CAC633/00052	Single			22/05/2018	SA44 5JT	180103	HP5	Mixed	1185	D10
CAC633/00050	Single			05/06/2018	SA44 5JT	180103	HP5	Mixed	259	D10
CAC633/00056	Single			19/06/2018	SA44 5JT	180103	HP5	Mixed	595	D10
CAC633/00058	Single			04/07/2018	SA44 5JT	180103	HP5	Mixed	853	D10
CAC633/00063	Single			17/07/2018	SA44 5JT	180103	HP5	Mixed	569	D10
CAC633/00069	Single			25/07/2018	SA44 5JT	180103	HP5	Mixed	248	D10
CAC633/00070	Single			15/08/2018	SA44 5JT	180103	HP5	Mixed	485	D10
CAC633/00084	Single			18/09/2018	SA44 5JT	180103	HP5	Mixed	212	D10
CAC633/00085	Single			01/10/2018	SA44 5JT	180103	HP5	Mixed	575	D10
CAC633/00089	Single			08/10/2018	SA44 5JT	180103	HP5	Mixed	658	D10
CAC633/00093	Single			15/10/2018	SA44 5JT	180103	HP5	Mixed	631	D10

Consignee Returns – Protherics to Clinipower January – October 2018

Consignment notes CAC633/00144 and 00146 were for hazardous waste removed from site on the same date at the same time. It is unclear why the two wastes were not included on the same consignment note.

Consignment note CAC633/00105 relates to the movement of chemical liquid waste from the installation to Augean Treatment Ltd. This note contains far greater detail than the notes reviewed above. There are still small issues with the content including the date in Part A(2) is not consistent with the date outlined in Part C(6) and D(4). The quantity is in units not Kgs are required as well as the container type, number and size.

It is worth highlighting that Part D of the hazardous waste consignment note requires a signature from the consignee i.e. Protherics. It is specific that by signing this form, Protherics has agreed that the information is complete, correct and has advised the carrier of any special requirements, precautionary measures.

The auditing of the waste management procedure will be completed by the EHS lead and senior site services technician, however, it is not clear within the work instructions/documentation provided by Protherics, who is the responsible officer/department for the interaction with the waste contractor during the handover of waste.

The consignee forms reviewed suggest that Simon Preece is single point of contact (since Nicola Winterfeld left the company). There is reference in WAL-SP-19.010 section 8.7.3 which points the reader to instructions on completing a consignment note. This is no longer available on NRW/EA's website but can be found on the internet and can still be useful although some aspects are out of date.



It is essential that greater emphasis is placed on this process particularly the hazardous waste movements. In addition, a greater understanding of the hazardous waste procedures, WM3 and other technical guidance is required, and this can be gained by attending training courses through appropriate companies.

Recommendation – Protherics to consider attending training regarding hazardous waste and how it is consigned using WM3 and other associated guidance.

A warning letter will be sent outlining that Protherics has failed to comply with Regulation 35 of the Hazardous Waste (Wales) Regulations 2005 in that it did not complete all relevant information required in a hazardous waste consignment note.

Hazardous Waste Storage

All hazardous waste generated on site is collected in the associated process area before being bulked in a dedicated storage area i.e. B6. This is a well-managed and maintained area of which access is restricted. The work instruction for this area is WAL-WI-19.013.

All waste except for electrical, clinical, Cuno filters and confidential waste, entering the B6 processing area is entered into the hazardous waste log. It is unclear how the information gathered from the log influences the information entered onto the hazardous waste consignment notes.

No issues were identified during the inspection of this area.

Site Tour

Previous audits at the installation had raised concerns around the containment of hazardous substances namely the large 20,000 litre and 10,000 litre oil tanks. Protherics has:

- replaced the 10,000-litre tank with a new tank. This is now on the PPM and will be inspected on each annual shut down.
- Regraded the land around the 10,000-litre tank to ensure that any escape of fluid is diverted to the new effluent drain rather than the adjacent surface water drain.
- Bring the Fuel lines above ground and these were observed.
- Undertaken hydrostatic testing of its three below ground effluent tanks, tested by GPR Environment Management Services between 20-22/08/18. Results provided suggested a negligible decrease across the three tanks. Annual hydrostatic testing to be completed.
- Installed a bunded drain point at the 20,000-litre tank
- Installed a new 30,000 litre contingency effluent tank within a newly surfaced bunded area.

It is evident that Protherics has invested significant capital to address the environmental concerns raised in previous NRW audits. What is also apparent is the speed at which the operator has not only considered the action but sought quotes and installed/implemented the chosen option. This is very encouraging and provides confidence that Protherics takes its environmental credentials and its commitment to continual improvement very highly.

Any Other Business

Abstraction - From 1 January 2018, most previously exempt abstractions (if over 20m³/day exemption threshold) will require a licence to continue legally abstracting water. Protherics has the ability to abstract water but historically this has been used for infrequent external washing and previously we were advised that it was beneath the 20m³/day threshold. An email was sent to the Operator 02/11/18 outlining the NRW web pages for further guidance. It is attached again : [NRW abstraction pages](#).

What does this mean for Protherics?

You must apply for a transitional water resources licence if:

- At any time since 1 January 2011 you have abstracted under an exemption which will be removed from 1 January 2018 and
- You wish to continue abstracting after 31 December 2017

Special transitional arrangements are in place which require:

- You to submit a transitional water resources licence application between 1 January 2018 and 31 December 2019 (two-year application window)
- Us to determine your licence application between 1 January 2020 and 31 December 2022 (three-year licence determination window)

You can continue to abstract water at the same quantities you abstracted between 1 January 2011 and 31 December 2017 until we have reached a decision on your application.

Water Savings – Protherics use and dispose of ~7900m³ of water (2018). Whereas previously the waste water was spread on adjacent fields this has now stopped and the effluent is tankered from the installation. Inevitably, the greater the amount of water used in the process the greater amount of water than is disposed. The EHS and Site

Services have worked to reduce the amount of water sent for reuse/disposal by reduction at source. Whereas previously we were advised that the reuse of water back into the processing stage was almost impossible due to the constraints by the FDA, the current team have developed a team dedicated to water efficiency and questioned this statement. A list of projects and savings were discussed including:

- Rig cleaning - ~1500L/day
- CDI Diversion to PFW – ~5280L/day
- Hotwell Overflow - ~ 6000L/day
- WFI Passing Valve - ~2500L/day

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Based on the projects discussed above the saving per day equates to around 15,280 litres/15m³ which equates to around 1 day of normal operation (based on August 2018 data) or 100 days of a normal persons consumption (based on UK figures of 150litres day for drinking, washing, flushing the toilet, showering, dishwashers and washing machines).

This work contributes to Protherics continual improvement and links well with its permit condition to improve water efficiency i.e. permit condition 1.3.1.

[END]

EPR Compliance Assessment Report

**Report ID:
CAR_NRW0034529**

This form will report compliance with your permit as determined by an NRW officer

Site	Blaenwaun Pharmaceutical Plant	Permit Ref	SP3338LF
Operator/Permit holder	Protherics UK Limited	Date	23/10/2018

Section 3 – Enforcement Response

You must take immediate action to rectify any non-compliance and prevent repetition. Non-compliance with your permit conditions constitutes an offence and can result in criminal prosecutions and/or suspension or revocation of a permit. Please read the detailed assessment in Section 2 and the steps you need to take in Section 4 below.

Section 4 – Action(s)

This section summarises the actions identified during the assessment along with the timescales for when they will need to be completed.

Criteria Ref.	CCS Category	Action required/advised	Due Date
See Section 1 above			

Section 5 – Compliance notes for the Operator

To ensure you correct actual or potential non-compliance we may

- Advise on corrective actions verbally or in writing
- Require you to take specific actions verbally or in writing
- Issue a notice
- Require you to review your procedures or management system
- Change some of the conditions of your permit
- Decide to undertake a full review of your permit

Any breach of a permit condition is an offence and we may take legal action against you

- We will normally provide advice and guidance to assist you to come back into compliance either after an offence is committed or where we consider that an offence is likely to be committed. This is without prejudice to any other enforcement response that we consider may be required.
- Enforcement action can include the issue of a formal caution, prosecution, the service of a notice and/or suspension or revocation of the permit.

See our Enforcement and Civil Sanctions guidance for further information

This report does not relieve the site operator of the responsibility to

- Ensure you comply with the conditions of the permit at all times and prevent pollution of the environment
- Ensure you comply with other legislative provisions which may apply

Non-compliance scores and categories

CCS category	Description	Score
C1	A non-compliance that could have a major environmental effect	60
C2	A non-compliance which could have a significant environmental effect	31
C3	A non-compliance which could have a minor environmental effect	4
C4	A non-compliance which has no potential environmental effect	0.1

Operational Risk Appraisal (Opra) - Compliance assessment findings may affect your Opra score and/or your charges. This score influences the resource we use to assess permit compliance.

Section 6 – General information

Data protection notice

The information on this form will be processed by the Natural Resources Wales (NRW) to fulfil its regulatory and monitoring functions and to maintain the relevant public register(s). The NRW may also use and/or disclose it in connection with:

- Offering/providing you with its literature/services relating to environmental matters
- Consulting with the public, public bodies and other organisations (eg. 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 its service
- Freedom of Information Act/Environmental Regulations request

The NRW may pass it on to its agents/representatives to do these things on its behalf. You should ensure that any persons named on this form are informed of the contents of this data protection notice.

Disclosure of information

The NRW will provide a copy of this report to the public register(s). However, if you consider that any information contained in this report should not be released to the public register(s) on the grounds of commercial confidentiality, you must write to your local area office within fifteen working days of receipt of this form indicating which information it concerns and why it should not be released, giving your reasons in full.

Customer charter

What can I do if I disagree with this compliance assessment report?

If you are unable to resolve the issue with your site officer, you should firstly discuss the matter with officer's line managers using the informal appeals procedure. If you wish to raise your dispute further through our official Complaints and Commendations procedure, phone our general enquiry number 0300 065 3000 (Mon to Fri 08.00 – 18.00) and ask for the Customer Contact team or send an email to enquiries@naturalresourceswales.gov.uk. If you are still dissatisfied you can make a complaint to the Public Services Ombudsman for Wales. For advice on how to complain to the Ombudsman phone their helpline on 0845 607 0987.

Welsh Language

If you would like this form in Welsh please contact your Regulatory Officer.