

Protherics UK Ltd

2022 Annual Report

EPR/SP3338LF

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2. Introduction

The purpose of this report is to provide submission of the performance of Protherics UK Ltd environmental activities for the year 2022 (Calendar), in line with the obligations outlined in Permit Number EPR/SP3338LF.

3. Facility Information Summary

Permit Number: EPR/SP3338LF.
Name of Site: Protherics UK Ltd
Site Location: Blaenwaun, Ffostrasol, Llandysul, Ceredigion, SA44 5JT
Class of Activity: S4.5 A1(a)
National Grid Reference: SN36673 46375

The Protherics site is responsible for the production of polyclonal antibody products and the manufacture of materials for clinical development. There have been no changes to the physical infrastructure of the site since the last reporting period.

4. S4.2 Reporting of Monitoring Data

4.1. Air Emissions

In accordance with S3.1 there are no parameters set for the monitoring of air emissions and the site does not produce licensed air emissions.

4.2. Waste / Wastewater

In accordance with S3.1, there are no parameters for testing set and permanent sampling access is not required.

4.3. Groundwater / Contaminated Land

In accordance with S3.1 & 3.2 of the permit, there are no parameters set and permanent sampling access is not required.

4.4. Noise / Odour / Vibration

In accordance with S3.3 & 3.4 of the permit, the site is not required to monitor these emissions, and there were no related complaints from offsite received in 2020.

5. Waste

Total waste decreased by 21% mainly due to a reduction in Annual Production Output and hazardous waste.

In addition, the comparisons between 2021 and 2022 shows a similar trend in Trade Effluent production. Continued work has been completed with regards to focus on excess use of water for injection (WFI) and purified water (PFW) in order to reduce the amount that the site uses during the manufacturing process.

5.1. Waste Data Table - Previous Year

	2021
Total Waste Produced (kg)	<u>109,004</u>
Total Waste recovered (kg)	<u>67,918</u>
Recovery percentage (kg)	<u>62.31</u>
Total Hazardous Waste	48,074
Total Liquid Trade Effluent Produced	5,919,610

5.2. Waste Data Table – Current Year

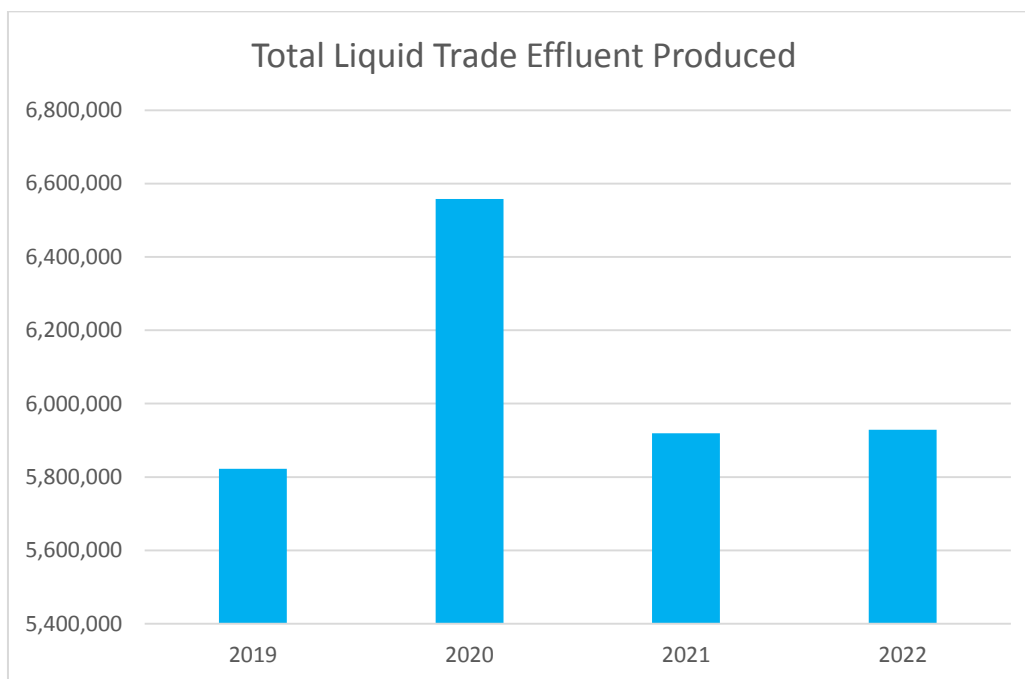
Current Year	2022	Percentage change from previous year
Total Waste Produced (kg)	86,391	-20.7%
Total Waste recovered (kg)	56,675	-16.6%
Recovery percentage (kg)	65.60%	5.3%
Total Hazardous Waste	29,283	-39.1%
Total Liquid Trade Effluent Produced	5,928,501	0.2%

5.3. Graph of Waste Comparison

Current Year	2022	Percentage change from previous year
Total Waste Produced (kg)	86,391	Lower than 2021
Total Waste recovered (kg)	56,675	Lower than 2021
Recovery percentage (%)	65.60%	Higher than 2021
Total Hazardous Waste	29,283	Lower than 2021
Total Liquid Trade Effluent Produced	5,928,501	No change from 2021



5.4. Graph of Effluent Chart



6. S4.2 Annual Production / Treatment

Annual production output of drug substance (Kg) for 2021	920.4 Kg
Annual production output of drug substance (Kg) for 2022	617.6 Kg
Percentage change from previous year:	-32.9 %
Comments	The production output for the 2022 reporting period decreased by 302.8 Kg. This was mainly due to the engineering trials of new products in place of current commercial products and due to the removal of overlaps as a planned business change, in January 2022.

7. S4.3 & 4.4 Performance Parameters

Following review of the previous 12 months, a review of the Gas Oil usage was undertaken as this has increased in 2022. This increase can be attributed to an increased use of generators as adverse weather affected the site more than 2021. Improvement projects have increased generator efficiencies. However, site coverage of generators has expanded to 99% of site compared with 3 buildings previously. Adverse weather (wind) during spring and winter months caused increased use of the generator to mitigate risk of power loss to site to ensure no interruptions to the manufacturing plan.

Following the removal of Red Diesel in April 2022, White Diesel was used until an alternative was sourced. Our new oil is an industrial heating oil which includes a reduction in the sulphur content at 0.1%. White Diesel continues to be used on our generator for the site.

7.1. Utilities Data Table – Previous Year

Previous Year	2021	Percentage change from previous year
Water Usage	18,713.5 M ³	1.3% higher than 2020
Specific Water Consumption	20.33 m ³ /kg DS	30.8% lower than 2020
Electricity Usage	2,334,133 kWh	5.7% higher than 2020
Specific Energy Consumption	2,536 kWh / Kg DS	27.7% lower than 2020
Gas Oil Usage	276,605 Ltrs	26.4% lower than 2020
Specific Gas Oil consumption	300.53 Ltrs/Kg DS	49.7% lower than 2020
LPG usage	Nil*	Nil*
Specific LPG consumption	N/A*	N/A*

7.2. Utilities Data Table – Current Year

	2022	Percentage change from previous year
Water Usage	16,878.3 M ³	Lower than 2021
Specific Water Consumption	27.33 m ³ /kg DS	Higher than 2021
Electricity Usage	2,115,523 kWh	Lower than 2021
Specific Energy Consumption	3425.39 kWh / Kg DS	Higher than 2021
Gas Oil Usage	363,873 Ltrs	Higher than 2021
Specific Gas Oil consumption	589.17 Ltrs/Kg DS	Higher than 2021
LPG usage	Nil*	Nil*
Specific LPG consumption	N/A*	N/A*

* LPG is no longer used on the Protherics / BTG Wales site. This was removed from use in September 2017.

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8. Water Usage

Permit Number: EPR/SP3338LF

Operator: Protherics UK Ltd

Installation: Pharmaceutical Plant, Blaenwaun

8.1. Reporting of Water Usage for the year 2022

Water Source	Usage (M ³ /Year)	Percentage change over previous year	Specific Usage (m ³ /Kg DS)
Mains Water	16,878.29 M ³	2.0 % Decrease	27.33 m ³ /kg DS
Total Water Usage	16,878.29 M ³		

8.2. Water Usage Conclusion

The water usage for 2022 has been retrieved from the two Welsh Water meters servicing the site. In 2022, water usage decreased on site, this can be contributed to reviews performed on our existing infrastructure and remediation plans. The water information is reviewed on a daily basis via the Welsh Water WaterCore system where we have installed 2 dataloggers and can see usage to enable early detection of any high usage and to gain further understanding of the usage.

Additional work is ongoing to review usage and continuation of projects in place to identify and reduce and reuse water for the site.



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9. Energy Usage

Permit Number: EPR/SP3338LF

Operator: Protherics UK Ltd

Installation: Pharmaceutical Plant, Blaenwaun

9.1. Reporting of Energy Usage for the year 2022

Energy Source	Quantity	Specific Usage
LPG	N/A	N/A
Electricity	2,115,23 kWh	3,425.39 kWh / Kg DS
Gas Oil	363,873 Ltrs	589.17 Litres/Kg DS

9.2. Energy Usage Conclusion

LPG is no longer utilised on site and the storage tank has been removed.

The electrical energy usage on site shows a decrease in comparison to 2021 and the gas oil usage shows an increase in comparison to 2021. The decrease in electrical usage may be attributable to the decrease of production output by 32.9 % and introduction of Thorlux lighting in B1.

The Gas Oil figures show an increase overall in 2022, this can be attributed to an increased use of generators as adverse weather affected the site more than 2021. The generators have been replaced with one new generator and site coverage of generator has expanded to 99% of site compared with 3 buildings previously, this would attribute to the increase in the oil figures alongside adverse weather (wind) during spring and winter months which caused increased use of the generator to mitigate risk of power loss to site to ensure no interruptions to the manufacturing plan.

Following the removal of Red Diesel in April 2022, White Diesel was used until an alternative was sourced. Our new oil is an industrial heating oil which includes a reduction in the sulphur content at 0.1%. White Diesel continues to be used on our generator for the site.

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10. Production – Drug Substance

Permit Number: EPR/SP3338LF

Operator: Protherics UK Ltd

Installation: Pharmaceutical Plant, Blaenwaun

10.1. Reporting of other performance indicators for the Period 2022

Parameter	Units
Production of Serum (Drug Substance)	617.6 Kg

10.2. Other Indicator Performance

During the 2022 production period, there was a decrease of 32.9 % in the manufacturing productivity in comparison to 2021. This was mainly due to the trials of new products in place of current commercial products and due to the removal of overlaps as a planned business change, in January 2022.

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