

Protherics UK Ltd

2021 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 2021 (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 increased by 11% mainly due to an increase in hazardous waste. This was predominantly driven by an increase in product output in the year 2021 due to a carryover over of in-process material from 2020 that was a result of COVID-19 strategic business planning.

In addition, the comparisons between 2020 and 2021 shows a decrease 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.

Note – An error has been noted on waste data reported within the 2020 submitted report in relation to Total waste produced, Total waste recovered and Recovery %. This was due to an error when calculating the weight of recycled glass. A calculation correction has resulted in a reduction of Total waste produced, total waste recovered and the Recovery % during the 2020 period and is reflected in the table below.

5.1. Waste Data Table - Previous Year

5.1.1. Reported (Error in calculations)

	2020	Percentage change from previous year
Total Waste Produced (kg)	107,292 Kg	3.2% higher than 2019
Total Waste recovered (kg)	74,711 Kg	12.8% higher than 2019
Recovery percentage (kg)	69.63 %	5.9% difference from 2019

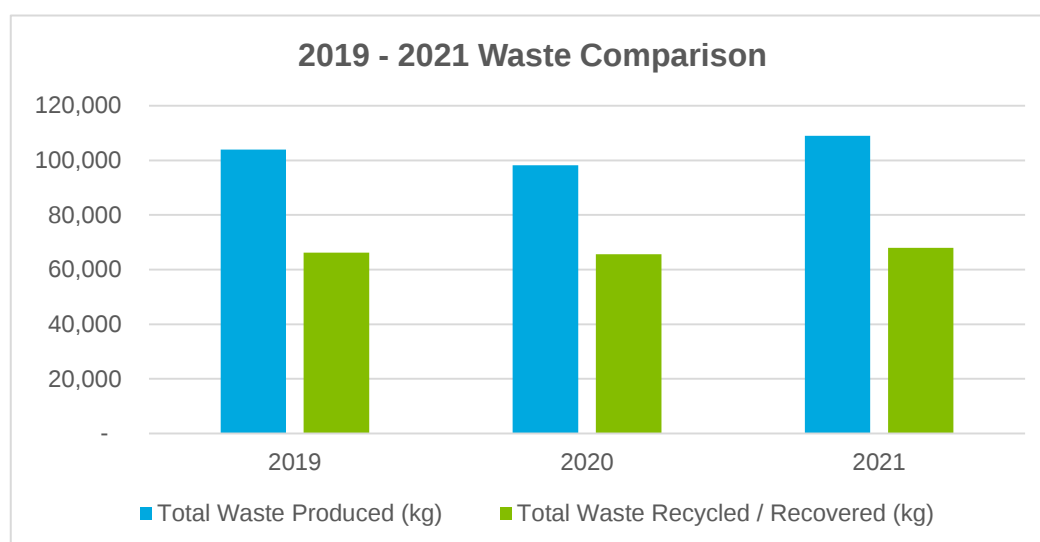
5.1.2. Corrected

Previous Year	2020	Percentage change from previous year
Total Waste Produced (kg)	98,162 Kg	5.5% lower than 2019
Total Waste recovered (kg)	65,581 Kg	1.0% lower than 2019
Recovery percentage (kg)	66.81 %	3.1% difference from 2019
Total Hazardous Waste	33,719 kg	3.54% lower than 2019
Total Liquid Trade Effluent Produced	6,558,732 Kg	12.6% higher than 2019

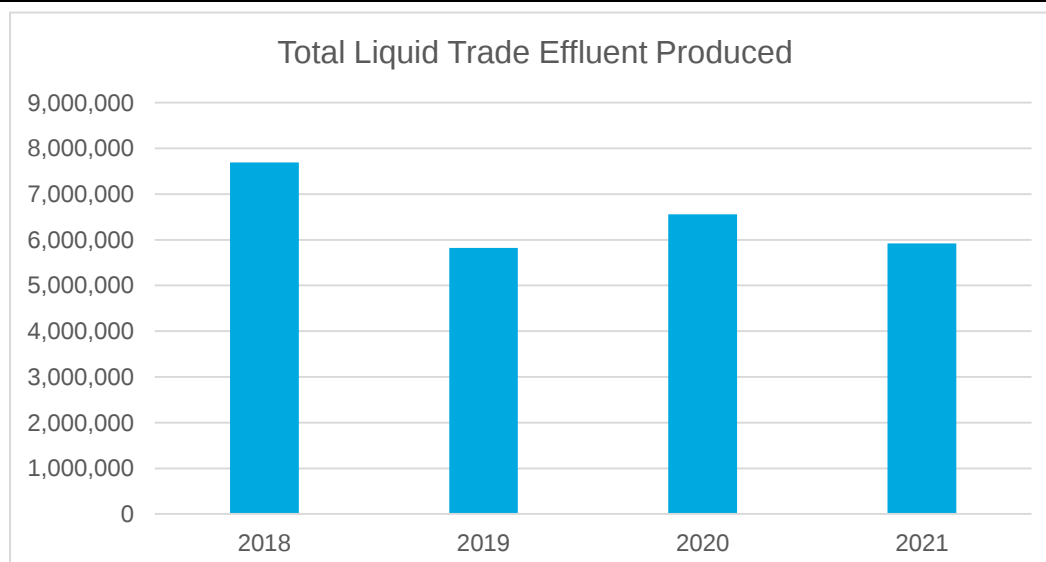
5.2. Waste Data Table – Current Year

Current Year	2021	Percentage change from previous year
Total Waste Produced (kg)	109,004 Kg	11.0% higher than 2020
Total Waste recovered (kg)	67,918 Kg	3.6% higher than 2020
Recovery percentage (%)	62.31 %	4.5% difference from 2020
Total Hazardous Waste	48,074 Kg	42.6% higher than 2020
Total Liquid Trade Effluent Produced	5,919,610 Kg	9.7% lower than 2020

5.3. Graph of Waste Comparison



5.4. Graph of Effluent Chart



6. S4.2 Annual Production / Treatment

Annual production output of drug substance (Kg) for 2020	629.0 Kg
Annual production output of drug substance (Kg) for 2021	920.4 Kg
Percentage change from previous year:	46.3 %
Comments	The production output for the 2021 reporting period increased by 291.4 Kg due to a more normal rate of manufacturing compared to 2020, where we saw a drop due to challenges which included COVID-19.

7. S4.3 & 4.4 Performance Parameters

7.1. Utilities Data Table – Previous Year

	2020	Percentage change from previous year
Water Usage	18,482.4 M ³	7.2% higher than 2019
Specific Water Consumption	29.38 m ³ /kg DS	68.5% higher than 2019
Electricity Usage	2,207,772 kWh	11.0% lower than 2019
Specific Energy Consumption	3,509.97 kWh / Kg DS	39.9% higher than 2019
Gas Oil Usage	375,698 Ltrs	32.2% higher than 2019
Specific Gas Oil consumption	597.29 Ltrs/Kg DS	107.7% higher than 2019
LPG usage	Nil*	Nil*
Specific LPG consumption	N/A*	N/A*

7.2. Utilities Data Table – Current 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*

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

Owner(s): Elaine Davies , Emma Madden

8. Water Usage

Permit Number: EPR/SP3338LF

Operator: Protherics UK Ltd

Installation: Pharmaceutical Plant, Blaenwaun

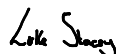
8.1. Reporting of Water Usage for the year 2021

Water Source	Usage (M ³ /Year)	Percentage change over previous year	Specific Usage (m ³ /Kg DS)
Mains Water	18,713.5 M ³	1.3 % Increase	20.33 m ³ /kg DS
Total Water Usage	18,713.5 M ³		

8.2. Water Usage Conclusion

The water usage for 2020 has been retrieved from the two Welsh Water meters servicing the site. In 2021, there was a slight increase in water usage, this can be attributed to enhanced cleaning protocols for the site due to the Covid pandemic i.e., additional site cleaning, hand washing etc.

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Owner(s): Elaine Davies , Emma Madden

9. Energy Usage

Permit Number: EPR/SP3338LF

Operator: Protherics UK Ltd

Installation: Pharmaceutical Plant, Blaenwaun

9.1. Reporting of Energy Usage for the year 2021

Energy Source	Quantity	Specific Usage
LPG	N/A	N/A
Electricity	2,334,133 kWh	2,536 kWh / Kg DS
Gas Oil	276,605 Ltrs	300.53 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 an increase in comparison to 2020 and the gas oil usage shows a decreased in comparison to 2020. The increase in electrical usage may be attributable to the increase of production output by 46.3%, this is reflected in the specific usage, which has decreased by 27.7%.

The Gas Oil figures show a decrease overall in 2021, this can be attributed to a reduced switch over time to generators as adverse weather affected the site less than 2020. Improvement projects have also increased generator efficiencies which has also contributed to the reduction of gas oil usage.

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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 2021

Parameter	Units
Production of Serum (Drug Substance)	920.4Kg

10.2. Other Indicator Performance

During the 2021 production period, there was an increase of 46.3 % in the manufacturing productivity in comparison to 2020. This was due to strategic changes to the manufacturing plan and the Covid pandemic.

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