Introduction:

A process for the synthesis and purification of Zinc Sulphate Heptahydrate (CAS Number 7446-20-0) is scheduled to be introduced at TopChem Pharmaceuticals Limited ("TCP"), Ballymote Business Park, Carrownanty, Ballymote, Co Sligo during Q2 2023. Zinc Sulphate Heptahydrate is an essential dietary trace element which is used in certain pharmaceutical preparations. TCP plans to manufacture low volumes of pharmaceutical grade Zinc Sulphate Heptahydrate for supply to customers who will formulate the substance into various critical-care pharmaceutical products.

Manufacturing Process:

The manufacturing process consists of a single synthetic step and a product crystallisation. Thus, sulphuric acid solution (5M/10N) is added to a mixture of zinc oxide in water and the product is crystallised. The product is filtered and the crystalline product is vacuum dried and final packaging. All operations will be performed on a laboratory scale within fume hoods. Approximate batch sizes for this product will be ~ 6Kg and use max 20L vessels. The total output per annum is anticipated at 60 kilos.

Material Information:

Details of Process related Raw Materials, Intermediates, Products, etc., used or generated on the site

Ref. Nº or Code	Material/ Substance	CAS Number	Danger (1) Category	Amount Stored (tonnes)	Annual Usage (tonnes)	Hazard Statements	Precautionary Statements	Nature of Use
	Zinc oxide	1314-13-2	Very toxic to aquatic life	0.1	0.02	H410	P273, P391, P501	Starting material
	Sulphuric acid (5M/10N)	7664-93-9	Corrosive	0.1	0.05	H290, H314, H318	P234, P280, P301+P330+P331, P303+P361+P353, P304+P340+P310, P305+P351+P338	Starting material

Notes: 1. c.f. Article 2(2) of SI Nº 77/

Table G.1(ii) Details of Process related Raw Materials, Intermediates, Products, etc., used or generated on the site

Ref. Nº or Code	Material/ Substance	TA Luft Class 1, 2 or 3	Odour			EU Lists I and II (Tick and specify Group/Family Number)			
			Odourous Yes/No	Description	Threshold[(2)] mg/m³	Dangerous Substances Directive 76/464/EEC		Groundwater Directive 80/68/EEC	
						List I	List II +129	List I	List II
	Zinc oxide	n/a	No	n/a	n/a	Not listed	Not listed	Not listed	Not listed
	Sulphuric acid (5M/10N)	n/a	No	Acid	n/a	Not listed	Not listed	Not listed	Not listed

1. https://www.bmuv.de/fileadmin/Daten_BMU/Download_PDF/Luft/taluft_engl.pdf
2. 3M 2010 Respirator Selection Guide

Emissions

EMISSIONS TO ATMOSPHERE - Minor atmospheric emissions

Emission point Reference Numbers	Description	Emission details[1]				Abatement system employed
		material	mg/Nm$^{3(2)}$	kg/h.	kg/year	
E1	Fume Hood 1 Exhaust fan in Production Laboratory	NONE	N/A	N/A	N/A	No solvents used in this process
E2	Fume Hood 2 Exhaust fan in Production Laboratory	N/A	N/A	N/A	N/A	Not used in this process
E3	Fume Hood 3 Exhaust fan in Production Laboratory	N/A	N/A	N/A	N/A	Not used in this process
E4	Fume Hood 4 Exhaust fan in Development Laboratory	N/A	N/A	N/A	N/A	Not used in this process
E5	Local Laboratory Exhaust	N/A	N/A	N/A	N/A	Not used in this process

1. Fume Hood 1 is used for illustration purposes only, however, any one of the Fume hoods 1-5 in the Production Laboratory maybe used in this process, but only one at a time.

EMISSIONS TO ATMOSPHERE – Fugitive and Potential atmospheric emissions

Not Applicable – none expected.

Waste Streams:

No gaseous waste will be generated during this process. No solid waste will be generated during this process. All waste will be in liquid form. Liquid waste will be aqueous acidic.

WASTE - Hazardous Waste Recovery/Disposal

Waste material	EWC Code	Main source[1]	Quantity		On-site Recovery/Disposal	Off-site Recovery, reuse or recycling	Off-site Disposal
			Tonnes / month[2]	m^3 / month[2]	(Method & Location)	(Method, Location & Undertaker)	(Method, Location & Undertaker)
Waste Stream #1 Aqueous acidic waste	070501*	mother liquors	0.01	0.01	Not Applicable	Not Applicable	as per Licensed contractor

1 A reference should be made to the main activity / process for each waste.
2 Total output per annum averaged over 12-month period. Actual monthly figures may vary up or down.

WASTE - Other Waste Recovery/Disposal

Waste material	**EWC Code**	**Main source[1]**	**Quantity**		**On-site recovery/disposal[2]**	**Off-site Recovery, reuse or recycling**	**Off-site Disposal**
			Tonnes / month	m^3 / month	(Method & Location)	(Method, Location & Undertaker)	(Method, Location & Undertaker)
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

1 A reference should be made to the main activity/ process for each waste.
2 The method of disposal or recovery should be clearly described and referenced to Attachment H.1