

Introduction:

A process for the synthesis and purification of Manganese Sulfate Monohydrate (CAS Number 10034-96-5) is scheduled to be introduced at TopChem Pharmaceuticals Limited (“TCP”), Ballymote Business Park, Carrownanty, Ballymote, Co Sligo during Q2 2023. Manganese Sulfate Monohydrate is an essential dietary trace element which is used in certain pharmaceutical preparations. TCP plans to manufacture low volumes of pharmaceutical grade Manganese Sulfate Monohydrate for supply to customers who will formulate the substance into various critical-care pharmaceutical products.

Manufacturing Process:

The manufacturing process consists of a single manufacturing step and a product crystallisation. Thus, manganese tetrahydrate is dissolved in water, filtered and then concentrated using a rotary evaporator. Isopropanol (2-propanol) is then added to the solution to precipitate the desired product. The product is filtered and the crystalline product is washed with isopropanol followed by vacuum drying and final packaging. All operations will be performed on a laboratory scale within fume hoods. Approximate batch sizes for this product will be ~ 1.3Kg and use max 20L vessels. The total output per annum is anticipated at 10 kilos.

Material Information:

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

Ref. N° or Code	Material/ Substance	CAS Number	Danger (1) Category	Amount Stored (tonnes)	Annual Usage (tonnes)	Hazard Statements	Precautionary Statements	Nature of Use
	Manganese sulphate tetrahydrate	10101-68-5	Toxic to aquatic life	0.05	0.02	H373, H411	P260, P273, P314, P391, P501	Starting material
	Isopropanol	67-63-0	Highly flammable, Irritant	0.2	0.06	H225, H319, H336	P210 P233 P240 P241 P242 P305+P351+P338	Solvent

Notes: 1. c.f. Article 2(2) of SI N° 77/

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

Ref. N° 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/m ³	Dangerous Substances Directive 76/464/EEC		Groundwater Directive 80/68/EEC	
						List I	List II +129	List I	List II
	Manganese sulphate tetrahydrate	n/a	No	n/a	n/a	Not listed	Not listed	Not listed	Not listed
	Isopropanol	III ⁽¹⁾	Yes	Alcohol	1.1	Not listed	Not listed	Not listed	Not listed

1. https://www.bmu.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	Organic Vapour	<1.3	<0.002	<10	Not Applicable
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 non-chlorinated organic solvents and basic aqueous waste.

WASTE - Hazardous Waste Recovery/Disposal

Waste material	EWC Code	Main source ¹	Quantity		On-site Recovery/Disposal (Method & Location)	Off-site Recovery, reuse or recycling (Method, Location & Undertaker)	Off-site Disposal (Method, Location & Undertaker)
			Tonnes / month ²	m ³ / month ²			
Waste Stream #1 Non-Chlorinated Organic Solvent Waste	070504*	Isopropanol and water washes & mother liquors	0.02	0.02	Not Applicable	Not Applicable	as per Licensed contractor
Waste Stream #2 Basic Aqueous Waste	070501*	Washing Liquids and mother liquors	0.004	0.004	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 (Method & Location)	Off-site Recovery, reuse or recycling (Method, Location & Undertaker)	Off-site Disposal (Method, Location & Undertaker)
			Tonnes / month	m ³ / month			
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