

EPA Approval Request for “Benzyl Alcohol Buffer” Project

Introduction

A new product is proposed to be introduced to the Arklow site in 2022, details are provided below.

Class of the Activity

Class 5.16: The use of a chemical or biological process for the production of basic pharmaceutical products.

Class 11.1: The recovery or disposal of waste in a facility, within the meaning of the Act of 1996, which facility is connected or associated with another activity specified in this Schedule in respect of which a license or revised license under Part IV is in force or in respect of which a license under the said part is or will be required.

Description of the Activity

The product will be produced in a combination of the production building areas and the process is similar to the existing chemical processes at Sigma Aldrich Ireland Ltd. Utilities will be the same as in the existing plant. The services required to support production are a combination of existing services. The existing services are listed below:

- Electricity
- Nitrogen
- Process water
- Air and instrument air
- Cooling water
- Chilled water
- Vacuum
- Waste air header
- Wastewater treatment plant
- Steam

There are no new services required for the production of this product.

PROCESS DESCRIPTION

Proposed Process:

An aqueous buffer solution containing Benzyl Alcohol, Acetic Acid, Sodium Acetate and water will be prepared in a stirred batch reactor. The buffer will be packed off in suitable drums for supply, e.g. 200 litre HDPE drums.

The Arklow output will be **the buffer solution**, which will be supplied to a sister site in Irvine Scotland for final processing. Individual batch sizes will be approx 5,000 litres, while the total annual output will be approx. 15,000 litres.

This first production campaign, which is planned for Q3 of 2022, involves processing three batches as process validation batches.

Operational information Requirements

Contents

- 9.1 List of unit operations
- 9.2 List of abatement, Treatment and Recovery options
- 9.3 Emissions to the Environment from unit operations
- 9.4 Process control
- 9.5 Capacities and throughputs, i.e. Equipment No, Material of construction, capacity and output
- 9.6 Bund register

9.1 List of unit operations

No change.

9.2 List of abatement treatment and recovery options

Vent header is connected to the waste air thermal oxidiser system.

9.3 Emissions to the environment from unit operations

The equipment to be used is connected into the vent header.

9.4 Process Control

Instrumentation and Control:

The equipment and associated tank farm equipment are controlled by an extension of the sites Distributed Control System. Both DCS systems are validated in accordance with the requirements of FDA regulations.

9.5 Capacities and Throughput

As in the existing plant, throughput will vary depending on the products and batch sizes required by the customer. Typical vessel capacities are given below.

Item	Equipment	Material	Capacity
B5	Stainless Steel reactor	SS	8,000 litres
B7	Stainless Steel reactor	SS	6,000 litres

Note: GL= Glass Lined.

GMP All items meet GMP standard. Explosion protection: All motors are of E Ex dII A + IIB standard.

9.6 Bund Register

No change.

10.0 Raw Materials and Product.

Details are attached on the following page.

Table 1: Details of Process related Raw Materials, Intermediates, Products, etc., used or generated on the site

Ref. N° or Code	Material/ Substance ⁽¹⁾	CAS Number	Danger ⁽²⁾ Category	Amount Stored (tonnes)	Annual Usage (tonnes)	Nature of Use	H Statement	P Statements
Raw material	Benzyl Alcohol	100-51-6	Warning - Harmful	For this process 0.3T. Also involved in other processes total on site 1.5T.	For this process 0.3T. Also involved in other processes total annual 3T.	Component of the buffer solution	H302 + H332 Harmful if swallowed or if inhaled. H319 Causes serious eye irritation.	P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P301 + P312 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Raw material	Acetic Acid	64-19-7	Danger – Flammable & corrosive	For this process 0.02T. Also involved in other processes total on site 12T.	For this process 0.02T. Also involved in other processes total annual 12 T.	Component of the buffer solution	H226 Flammable liquid and vapor. H314 Causes severe skin burns and eye damage.	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P240 Ground and bond container and receiving equipment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Raw material	Sodium Acetate trihydrate	6131-90-4	None	For this process 0.15T.	For this process 0.15T.	Component of the buffer solution	None	None

Ref. N° or Code	Material/ Substance ⁽¹⁾	CAS Number	Danger ⁽²⁾ Category	Amount Stored (tonnes)	Annual Usage (tonnes)	Nature of Use	H Statement	P Statements
				Also involved in other processes total on site 0.3T.	Also involved in other processes total annual 0.3 T.			
Product	Benzyl Alcohol Sodium Acetate & Acetic acid buffer	Not Applicable to Mixtures	None	15T.	15T.	Buffer Solution	None	None

Notes:

1. In cases where a material comprises a number of distinct and available dangerous substances, please give details for each component substance. 2. c.f. Article 2(2) of SI N° 77/94
3. c.f. Schedules 9 and 10 of SI No 62/2004

Table 2: 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	m ³ / month			
None, other than final portion of batch/part filled drum of aqueous buffer solution	07 01 01 (Aqueous liquids)	Final portion of batch/part filled drum of aqueous buffer solution	0.3 T in 2022.	Production scheduling dependent – some months will be zero, while one month might be the full annual quantity	As a non-hazardous aqueous buffer, via WWTP.	N/a	N/a

¹ All organic solvent waste will be disposed of off site for recovery or incineration

11. Emissions to Atmosphere

- 11.1 Process emissions
- 11.2 Vent listing
- 11.3 Abatement and Treatment and Recovery Systems
- 11.4 Emissions to the Environment from Unit Operations
- 11.5 Emissions monitoring

11.1 Process Emissions

Process emissions will be combined into the main header system and directed to a dual scrubber system and then directed to the Waste Air Treatment Plant (Thermal Oxidiser).

11.2 Vent Listing

Vent No.	Building	Description	Major	Minor	Potential	Connected to Header
A1-7	Thermal Oxidiser vent	Thermal Oxidiser	✓	-	-	Combination of all vents in header system

11.3 Abatement and Treatment and Recovery Systems

All relevant process vents are connected to vent header/abatement system.

11.4 Emissions to the Environment from Unit Operations

Emissions from Reaction Synthesis

During normal operation of a reaction, controlled emissions may result from the following operations

- Inerting a vessel with nitrogen
- Chemical reaction
- Charging liquids to a vessel
- Applying vacuum
- Applying heat
- Transferring contents from one vessel to another
- Filling bulk tanks

The following procedures are applied to control the emissions

- Condensers are cooled using Cooling Water.

Emissions during a Malfunction

- Bursting disc rupture
- Failure of the cooling medium to condenser's
- Failure of cooling medium to reactor.
- Emissions during a vent failure.
- Any potential new malfunctions shall be identified as part of the HAZOP.

11.5 Emissions Monitoring

As all process vents are connected to the dual scrubber system emission monitoring from the proposed new product shall take place at A1-7 (Thermal Oxidiser stack). Any samples shall be taken and analysed as per routine method.

12 Emissions to Surface Water

There are no emissions to surface water as a result of this process.

13 Emissions to Sewer

There are no emissions to sewer as a result of this process.

14 Emissions to Ground

There will be no emissions to ground as a result of this process.

15 Noise

There will be no additional noise sources added as part of this process.

16 Waste Management

Although a new product is being produced, the type of wastes generated will not vary from the waste currently being produced now. There will therefore be no new requirements for the handling, storage, and disposal of waste. There should not therefore, be any significant adverse environmental impact resulting from the disposal of waste from this project. As the proposed new process will be run in existing equipment and replaces existing production while it is running, there will not be an increase in the amount of overall waste being produced.

17 Environmental Considerations

Where appropriate, Sigma-Aldrich Ireland Ltd. has sought to use the most cost-effective methods of reducing its environmental impact.

The following waste minimization technologies as outlined in the relevant Guidance Note for the Chemical Sector will be used.

a) Technologies for load minimization

I Optimisation of Condenser Efficiency

Checks will be carried out before each vacuum distillation on major items of equipment to ensure air leakage is kept to a minimum.

II. Inventory Control

Where possible, only the amount of chemical used in the process will be ordered.

There are regular stock checks done on raw materials inventory

There is a computerised inventory listing

Quantities of raw materials used are specified on batch sheets to avoid overuse of materials.

III. Separation of Cooling Water, Storm Water and Process Effluent

Storm water is kept separate to effluent and cooling water is cooled in cooling towers and recirculated for reuse.

b) Technologies for Containment of Emissions

- I. Reactor operation is via computerised system to reduce the risk of Operator error.
- II. Vent collection from all major items of equipment into the centralised scrubber system prior to further treatment.
- III. Bunding of all stored materials with separate bunding for incompatibles IV. A Sprinkler System on Bulk tank storage

c) Technologies for Recovery and Recycle

- I. Waste solvent sent off site is recycled where possible and reused as fuel where possible.
- II. Re-use in another industry
- III. Solvents, steel paper, glass, pallets, are reused/recycled in other industries.

d) Technologies for Treating Air Emissions

- I. Selective chemical reaction scrubbers are used e. g. caustic scrubbing for acid removal.

e) Technologies for Treating Water Emissions

- I. Primary treatment: pH correction/ neutralization
- II. Secondary treatment: Biological degradation of effluent
- III. Tertiary treatment: Settleability of final effluent

f) Technologies for Treatment and Disposal of Wastes

- I. **Incineration:** Toxic and dangerous waste which is unsuitable for recovery shall be sent offsite for reuse as fuel or will be incinerated.

18 Accidental Emissions

All tanks are bunded so that in the event of a spill arising all material shall be contained. All bunds shall be constructed in accordance with the Agency's guidelines on bund construction.

All control equipment is maintained and calibrated in accordance with manufacturer's instructions and inspected and tested regularly as part of the site's Preventative Maintenance Programme.

The onsite emergency plan shall be reviewed to take into account any new emergency situations arising on site. The firewater retention tank shall enable any contaminated effluent to be contained on site.

Any contaminated surface water will be detected by an online TOC meter and pH analyser. If levels greater than 100 ppm TOC, or <6 >8 pH, are detected, the diversion valve will divert this contaminated water to the firewater retention tank. The effluent can be analysed prior to feeding into the wastewater treatment plant at a pre-controlled rate.

Accidental air emissions shall go to the combined vent header system. Any abnormal/elevated emissions shall be detected by the online FID detector.

19 Training

Operator training for the new product manufacture will be carried out on-site and will be fully documented

20 Cessation of Activity

The site's Residual Management Programme (Closure, Restoration and Aftercare Management plan) will not be affected as a result of this new process.

21 Site Management and Control

A copy of the following is available:

- Sigma Aldrich Ireland Ltd. Environmental, Health and Safety Policy.
- Sigma Aldrich Ireland Ltd. Organisational Charts.
- ISO14001 Manual.