

Register No.: P0110-03
Company Name: Arran Chemical Co. Ltd.
Report Ref: EPA860
Re: Notification of New Process

Dear Inspector,

I write to you, in line with Section 1.2 of our IPPC Licence, to inform you of our plan to introduce a new product into our manufacturing range, designated SSTR4S1-3. The R&D process is a new intermediate potentially for use in pharmaceutical sector.

SSTR4S1-3 Process

1. Background, Anticipated Scale of Production

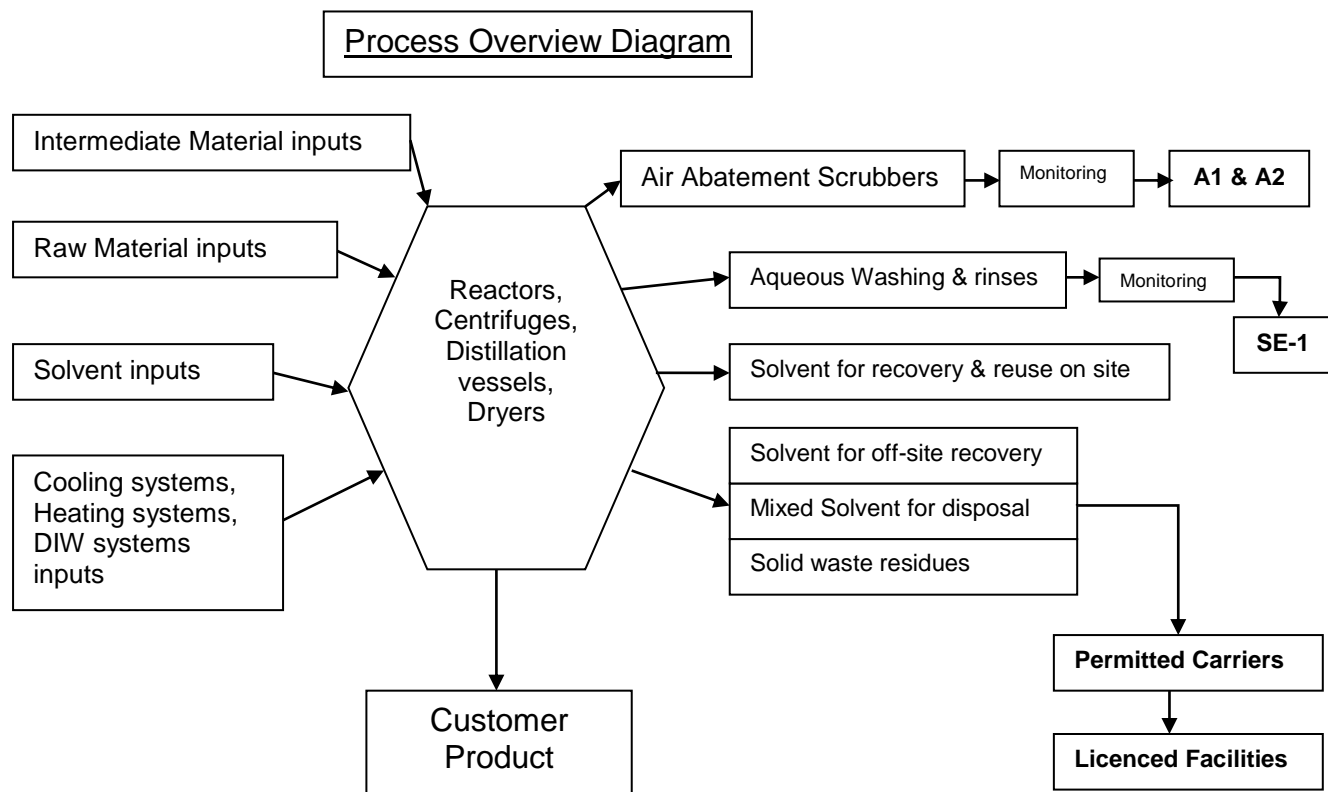
This for a material for a new R&D product application. We expect initial production will be on a scale up to 30kg.

2. Manufacture

The first intermediate is manufactured in two steps via N-alkylation, cyclization, concentration, salt formation and drying phases.

In third step above intermediate is subjected to debenzoylation followed by Boc protection, concentration phases.

Solvents used in the process are listed below. Reaction vessel pressures and temperatures will not exceed normal boiling points or standard atmospheric pressure, and all emissions are vented through the licence point A2-3, using the Regenerative Thermal Oxidiser (RTO). There will be no significant impact on other abatement systems and/or controls.



3. Hazard/Toxicity Characteristics of the New Processes

Reagents/raw materials not previously used are listed below:

Substance name	CAS No.	Hazard Statements	Boiling Point °C
(S)-2-Benzylamino-3-TBDPS-Oxypropanol Oxalic Acid	-	H302: Harmful if swallowed. H315: Causes skin irritation. H319: Causes serious eye irritation.	
Epichlorohydrin	515-94-55-9	H226: Flammable liquid and vapour. H301: Toxic if swallowed. H311: Toxic in contact with skin. H314: Causes serious skin burns and eye damage. H317: May cause an allergic skin reaction. H331: Toxic if inhaled. H350: May cause cancer.	
Hydrogen Chloride (1M) in Ethyl Acetate	7647-01-0	H225: Highly flammable liquid and vapour. H314: Causes serious skin burns and eye damage. H319: Causes serious eye irritation. H331: Toxic if inhaled. H336: May cause drowsiness or dizziness. EUH066: Repeated exposure may cause skin dryness or cracking.	
Lithium Triflate	33454-82-9	H302: Harmful if swallowed. H319: Causes serious eye irritation.	

Sodium Ethoxide (21%) in Ethanol	123-86-4	H225: Highly flammable liquid and vapour. H314: Causes serious skin burns and eye damage. H335: May cause respiratory irritation. H336: May cause drowsiness or dizziness. H340: May cause genetic defects. H360FD: May damage fertility. May damage the unborn child. H372: Causes damage to organs through prolonged or repeated exposure : Liver H373: May cause damage to organs through prolonged or repeated exposure.	
Di-t-butyl Dicarboxylate [PS141]*	24424-99-5	H226: Flammable liquid and vapour. H315: Causes skin irritation. H317 - May cause an allergic skin reaction H319: Causes serious eye irritation. H330 - Fatal if inhaled H335: May cause respiratory irritation.	56

None of these are “listed substances”.

Safety Data Sheets (SDS) are held on file for all of these materials and all others used in the company, as part of the safety management system. All manufacturing processes, including production operations, are defined within an established written system, ISO 9001-2000, and ISO 14001:2004, Batch Sheets and Standard Operating Procedures.

4. Solvent Usage

Solvents employed in the process are listed below:

Solvent	Boiling Point °C	TA Luft Class
Methyl t Butyl Ether	55	III
N Butyl acetate	125	II
Toluene	110	II

Reaction vessel pressures and temperatures will not exceed normal boiling points or standard atmospheric pressure, and all emissions are vented through the licence point A2-3 post RTO abatement system.

Because of the small scale of operation planned initially, all solvent residues will be sent for disposal or incineration through approved licensed contractors. Thereafter, if the production scale should increase, it is proposed to recover the solvents on site to the maximum practical extent, in line with our standard operating procedures.

5. Air Emissions

All emissions will comply with limits set in the licence. A system of two condensers is in use for all reaction vessels used in this manufacture with

glycol/chilled water cooling on the secondary condenser to minimise emissions and all reactions are connected at all times to the plant scrubber system, and directed to the RTO abatement, onto emission point A2-3.

6. Aqueous Discharge Characteristics

The limited aqueous & solvent discharge will be directed to mixed solvent waste for offsite incineration & disposal.

All expected aqueous discharges are similar in character to aqueous streams already being managed onsite. These will be balanced for disposal through our aqueous effluent system to the STW, within the permitted discharge conditions, or sent for disposal through a licensed contractor as appropriate. There will be no increase (with respect to daily volumes discharged) and it is not expected that there will be any significant impact on any of the licence parameters. The intermediate produced by this process is not physiologically active; therefore no active pharmaceutical ingredient will be released to the sewer.

7. Solid Waste

Some small amount of solid waste is expected which will be drummed for off-site disposal (incineration) at a licenced facility.

8. Conclusion

This process does not present any additional environmental risks from plant operations, or chemistry and the process will use all the existing controls and process reaction vessels. The process has been fully reviewed internally for Chemical and Operational Hazard Assessment (COHA) procedures to review & assess & control the process.