

Register No.: P0110-03
Company Name: Arran Chemical Co. Ltd.
Report Ref: EPA861
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 SPIR4X. The R&D process is a new intermediate potentially for use in pharmaceutical sector.

SPIR4X Process

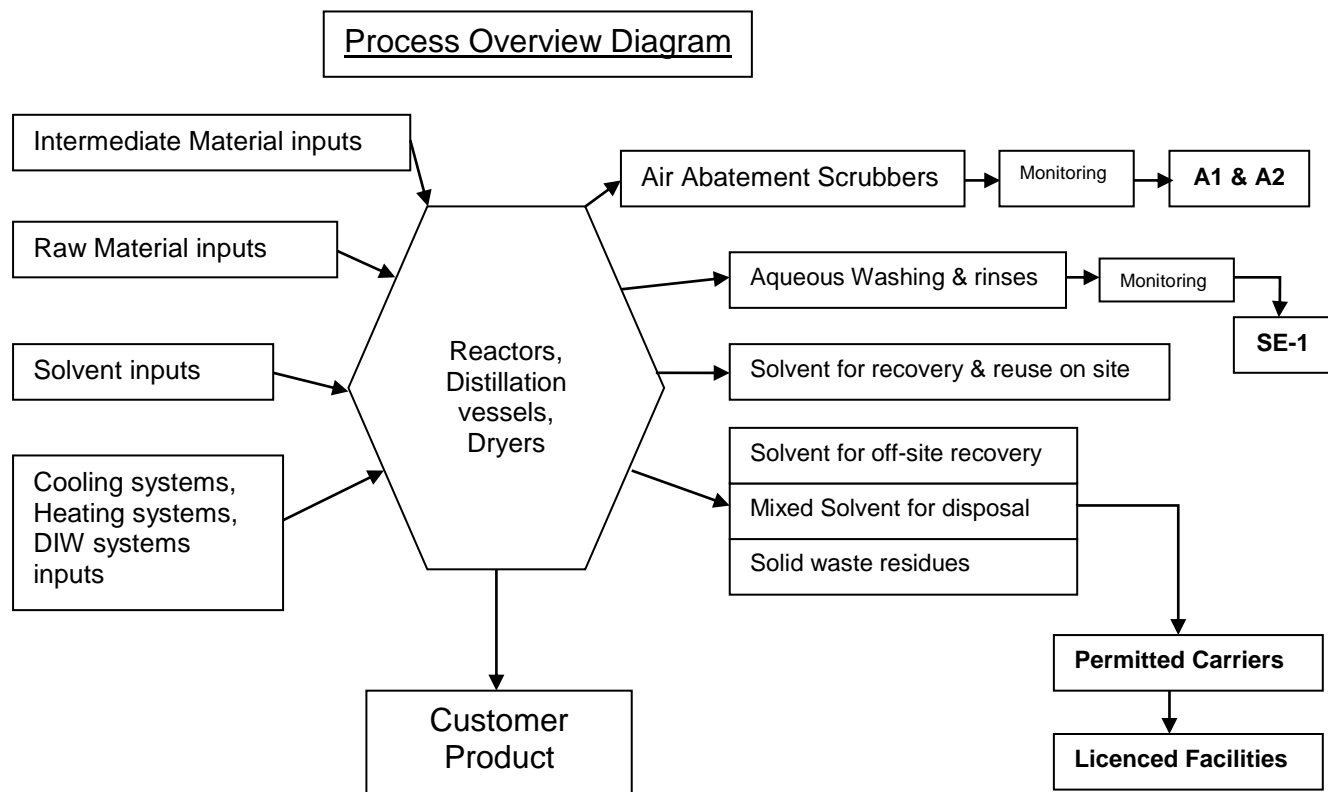
1. Background, Anticipated Scale of Production

This for a material for a new R&D product application making intermediate building blocks. We expect initial production will be on a scale up to combined 70kg.

2. Manufacture

One step process, manufacture of an alcohol using a ketoreductase enzyme CRED followed by extractions, filtration concentration and drying 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
Trans-tert-butyl-2-hydroxy-6-azaspiro[3,4]octane-6-carboxylate	-	Reagents Not tested	-
Tert-butyl-2-oxo-6-azaspiro[3,4]octane-6-carboxylate	-	Reagents Not tested	-
NADP monosodium salt	1184-16-3	Non-Hazardous	-
			-

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
Heptane	98	II
Dimethylsulphoxide (DMSO)	189	III
Methyl Tert-butyl Ether	55	III

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

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.