



Summary of Changes to Environmental Management System (EMS) in line with Variation to Permit

Introduction

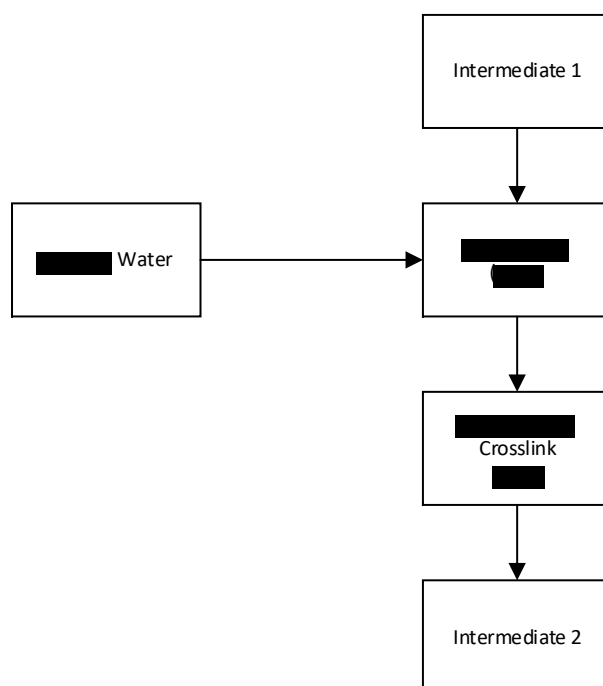
The proposed permit variation is to include a [REDACTED] process (the addition of [REDACTED] to an alkene) and an associated emission point to air. The [REDACTED] gas is passed through a sodium formate scrubber prior to discharge via a stack. The permit variation submitted will allow Purolite to manufacture the agarose based intermediate for the Protein A coupled chromatography resin on commercial scale.

Additionally it is proposed to add another steam generator adjacent to the existing steam generator. There are no changes to the EMS pertinent to the addition of a second steam generator as this will be covered under existing Daily Checks and the service contract for inspection and maintenance in line with manufacturers recommendations.

Process Overview

The manufacture of Intermediate 1 is covered under the existing permit (EPR/AB3894ZF). The intermediate is stirred at ambient temperature and [REDACTED] water is added. Bromine water is made up fresh on site in a separate plant room area. [REDACTED] is brought to site in a UN approved drum and a quantity dispensed into a known volume of water. The water & [REDACTED] are recirculated to fully dissolve then transferred to the process. [REDACTED] agarose is left to react for a period before being neutralised with sodium formate.

The condense crosslink process mixes [REDACTED] agarose with [REDACTED] using equipment already covered in the original permit. Following this process the final intermediate (Intermediate 2) is produced.





Management Systems

Puro-lite operates a BSI certified management system under ISO14001 (Environmental), ISO45001 (Health & Safety) and ISO9001 (Quality). For activities associated with handling of [REDACTED] the Quality Management System (QMS) is used to store relevant documents and forms as they are directly related to product quality.

Examples of documentation have been provided below that directly relate to the operation of the equipment associated with the bromination process. The document examples demonstrate a high level of controls to ensure safe and robust manufacturing.

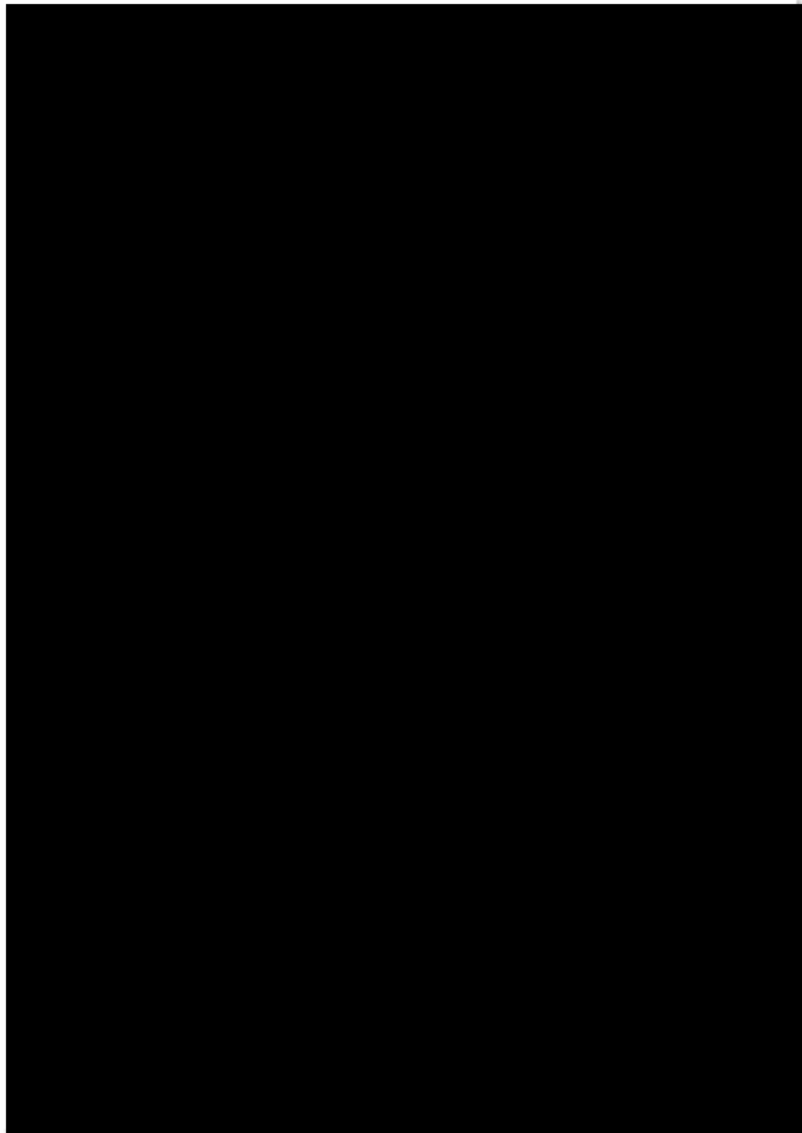
WIM-30 Manufacturing Instruction - AP+ INT2, AC INT3, & Jetted A50 INT2

The document WIM-30 is a Work Instruction that takes the operators through each manufacturing step for the [REDACTED] & condense crosslink process.



**FM-66 [REDACTED] Marshall Checklist**

[REDACTED] Marshall Checklist (FM-66) is completed by a designated operator daily to verify the plant is in a safe state and left in a safe state following a process.



**FM-59 [REDACTED] Drum Connection**

Each time a [REDACTED] drum is connected & disconnected the form below is used to ensure each step is made correctly to eliminate risks of bromine loss of containment.

A large rectangular area that has been completely redacted with a solid black fill, obscuring all content that would otherwise be present in the form.

**WIM-33 [REDACTED] Scrubber Maintenance**

Scrubber maintenance is a key activity to be able to remove any [REDACTED] vapour from the process vent lines. This document describes the measures to be taken and the frequencies of maintenance.

