

Attachment 4.9.4 – IED Art 59(7) Precautions

While in use, Isopropyl Alcohol (including IPA wipes and IPA in spray bottles) will be stored in the production area and the laboratories within an air-controlled environment. During start-up operations, IPA will be shipped to the site in sealed wipes packaging and sealed bottles and will be stored in the Warehouse. Following cleaning, and in the event of a shut down, spent IPA wipes and cloth wipes will be stored in sealed, flammable waste containers for disposal. Unused 1L bottles of 2-Propanol will be disposed of as flammable waste by a licenced/permitted contractor.

Ethanol will be used for the sanitization step of some of the chromatography operations and for the storage of some of the chromatography columns respectively. Ethanol will arrive onsite as 20% Ethanol and will be delivered through a closed pressurised loop to the columns for column regeneration (cleaning) and storage of the columns.

Benzyl alcohol will be used for the sanitization step of some of the chromatography operations and for the storage of some of the chromatography columns respectively. Benzyl alcohol will arrive onsite as 2% Benzyl and will be delivered through a closed pressurised loop to the columns for column regeneration (cleaning) and storage of the columns.

In the event of a shut down, spent the 20% ethanol and 2% Benzyl alcohol in the chromatography columns will be drained to the onsite Wastewater Neutralisation Plant for treatment and disposal. Unused drums of 20% Ethanol and 2% Benzyl alcohol will be removal offsite by a licenced/permitted contractor.

Glacial acetic acid will be delivered to the site in sealed containers (15L bottles of acetic acid) and will be stored in the Warehouse prior to their use in the production suites and in the laboratory. The acetic acid will be dispensed directly into the buffer solution in the buffer prep production room. During shut down, unused sealed containers stored in the installation will be disposed of offsite by a licenced/permitted contractor. Any spent Acetic Acid in solution during an emergency shut down will be disposed via the onsite Wastewater Neutralisation Plant.

Lab chemicals will also be delivered to the site in sealed containers (0.5L to 2.5L bottles with some 4L bottles) and will be stored in the laboratory storage areas prior to their use in the laboratory. These solvents will be dispensed as required under fume hoods equipped with HEPA filters. During shut down, unused sealed containers stored in the installation will be disposed of offsite by a licenced/permitted contractor.

Other solvents are used in the equipment and as calibration standards will be provided by the supplier during start up and will be changed out as required. During shut down, equipment will be drained by the supplier or a suitably trained contractor using closed pressurised pipelines to ensure that fugitive emissions are minimised.

There are no anticipated emissions during start up and shut down.