



Solvent Management Plan 2022

Re: Reg. No. P0828-01

for

**TopChem Pharmaceuticals Limited,
Ballymote Business Park,
Carrownanty,
Ballymote,
Co. Sligo.**

Approved By:


Name	Title	Signature	Date
Frances King	QA & EHS Manager		31/03/2022

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1.0 Introduction:

The TopChem Pharmaceutical (TCP) installation is located in the town land of Carrownanty, in the Ballymote Business Park of Ballymote town, County Sligo.

This document has been produced to address the following conditions of IPPC license register N° P0828-01.

Condition 6.11.1: *'The licensee shall report on the use of solvents for each calendar year as part of the AER'.*

Condition 6.11.2: *'The license shall prepare a solvent management plan in accordance with any relevant guideline in Annex III of council directive 1999/13/EC or as may be issued by the agency from time to time. The solvent management plan shall be used to demonstrate compliance with fugitive emissions limit value. The SMP shall be submitted as part of the AER.'*

Due to the scale of operations at TCP, only small volumes of solvent are used and there is no requirement for fugitive emissions monitoring or a solvent reduction plan.

The procurement, disposition and disposal of solvents are monitored on an ongoing basis at TCP under the auspices of our internal quality control and environmental health and safety systems.

2.0 Solvent Procurement:

Solvents at TCP are acquired when required, with all purchases recorded for the previous year in a solvent acquisition Table and uploaded to EDEN and the EPA at the end of the year via this report.

3.0 Solvent Storage:

All solvents at TCP are stored on banded pallets or in banded flame proof solvent cabinets within the External Chemical Storage Area. Within the laboratories, solvents are stored in dedicated cabinets and/or dedicated storage areas as per standard operating procedure T-EHS-SOP-006.

4.0 Use of Solvents:

Solvent use within the production laboratory at TCP is tightly regulated, with all usage being accounted for on a manual Cardex System (T-MAT-FORM-004). This is updated usually on a daily basis if solvent is in use in Production. Total Solvent Usage at TCP is determined on an annual basis by reconciling acquisition data with the volume of solvents remaining in-house at the time of the audit.

5.0 Solvent Waste Disposal:

Solvent waste is transferred to the appropriate solvent waste drum in the External Chemical Store at TCP. The volume of solvent waste transferred to each drum is recorded in solvent waste logbooks (T-EHS-FORM-007) located within the stores waste area. These logbooks are updated each time waste is transferred into the waste area and reviewed on a weekly basis as per T-EHS-SOP-004. When the drums are full, arrangements are made for their removal by an approved, licensed waste disposal contractor.

6.0 Reconciliation and Reporting:

Solvent management at TCP involves the documentation of solvent acquisitions and the outcome of this reconciliation will form part of the annual solvent management report.

7.0. Regulatory Requirements:

Under the terms and conditions specified in the TopChem Pharmaceuticals IPPC licence (P0828-01), TCP is required to prepare a solvent management plan that complies with the relevant guideline in Annex III of council directive 1999/13/EC or as may be issued by the agency from time to time. The solvent management plan is to be submitted as part of the annual Environmental Performance Report.

This document fulfils that requirement of the licence application.

Council Directive 1999/13/EC specifies emission limit values, time frames for implementation of a solvent management plan and the procedures to evaluate emissions deriving from an installation, during activities defined in the Annex I of the directive in so far as they are operated above the solvent consumption threshold listed in Annex IIA of the same directive.

The activities carried out at TCP fall within the scope of Annex I of the directive i.e.:

- The chemical synthesis, fermentation, extraction, formulation and finishing of pharmaceutical products and manufacture of intermediate products.

Solvent consumption at TCP does not exceed the threshold defined in item 20 of annex IIA 'thresholds and emissions controls' of the directive i.e.:

- Manufacturing of pharmaceutical products with a solvent consumption threshold > 50 tonnes/ year.

The annual solvent usage at TCP is considerably less than 50 tonnes per annum, therefore a fugitive emissions monitoring programme is not required.

8.0 Terms Glossary and References

TCP	TopChem Laboratories
IPPC	Integrated Pollution Prevention Control
SOP	Standard Operating Procedure
SMP	Solvent Management Plan
T-EHS-SOP-006	Control and Storage of Hazardous Materials
T-MAT-SOP-004	Waste Disposal
T-EHS-FORM-007	Waste Disposal Log
T-MAT-FORM-004	Cardex – Stock Control System

