



Solvent Mass Balance Fugitive Emission Assessments for 2021

Re: Reg. No. P0828-01

for

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

Approved By:

Name	Title	Signature	Date
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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 bunded pallets or in bunded 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 returns. 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 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 Solvent Management Plan (SMP):

The SMP is in essence a solvent mass balance which aims to account for all inputs and outputs of solvents for a given activity.

The main elements of an SMP are outlined in Chapter V and Annex VII of the Industrial Emissions Directive (IED). The IED sets limits on solvent emission levels from certain activities including:

- Emission limit values in gases (mgC/m³);
- Fugitive emission limit values (as a % of total solvent input);
- Total emission limit values (various units applied for these limits, such as mass of solvent released per unit of goods produced or as a % of solvent input).

The IED also allows the application of a 'reduction scheme'. The reduction scheme allows the operator to achieve, by other means, a reduction in solvent emissions equivalent to the reduction achieved by meeting the emission limit values (e.g. by applying techniques to allow use of water-based products). Assessment of compliance according to the reduction scheme is not addressed in this guidance as it is infrequently used at EPA licensed sites.

Completion of an SMP is a specific requirement in some EPA licences and provides for the following, where relevant to the licence:

- Assessment of compliance with a specified total emission limit value
- Assessment of compliance with a specified fugitive emission limit value Identification of areas where reductions in solvent emissions may be achieved
- Provision of information on solvent consumption, emissions and overall compliance
- Assessment of compliance with the requirements of the reduction scheme

Solvent mass balances must be completed using an appropriate methodology to ensure that precise and reliable information is provided to the EPA. The methodology used to determine the various components of the mass balance equation must be clear and robust and must be auditible by the Agency.

Rough estimates or approximations of the components of the mass balance are not acceptable to the EPA.

Generating a solvent management plan to account for solvent use and to quantify fugitive emissions is described in Annex VII, Part 7 of the IED. The licensee should refer to the specific condition within the licence and clarification should be sought from the EPA if there is uncertainty in relation to specific requirements.

The EPA require licensees to record solvent flow through their operation from purchase to usage, re-usage and emission. No more than 20% of solvent input may go unaccounted for in the example condition provided above. The 'unaccounted for' figure in the solvent tracking process is the fugitive emission.

A solvent management plan will track the movement of solvent through an installation and will identify the environmental media where the solvent eventually ends up. The following will be tabulated:

- Inputs of organic solvents (I) & Requirements:
- Outputs of organic solvents (O) & Requirements:

Inputs of organic solvents (I): - Requirements:

Mass Balance Terms	Explanation	Source of Data and Additional Requirements	TopChem Source of Data
I1 The quantity of organic solvents or their quantity in mixtures purchased which are used as inputs into the process in the timeframe over which the mass balance is being calculated	The amount of solvent purchased and used in a year.	Purchase records or data provided directly by the supplier. Also include stock level change: stocks at start of year minus stocks at end of year. The units used should be consistent and take account of variations in the density of different solvents within a given raw material. In some cases, analysis of input materials may be required, for example where technical data sheets or Material Data Safety Sheets (MSDS) do not provide sufficiently accurate data on the solvent content of materials as delivered. Generally, analysis would only be necessary where the solvent quantity is such that the potential errors introduced by using generic data (e.g. MSDS compositional data) would materially impact on the findings of the solvent mass balance, e.g. by resulting in a calculated fugitive emission exceeding the limit as specified in the licence. All potential sources of error and uncertainty should be clearly stated in the report and quantified where possible.	POs and Production Stocks of Solvent. The Quantities purchased and consumed were evaluated. The Carry-over from 2020 was included in the Calculation and the residual stock was also incorporated into the final tally. See Appendix 1 & 2.
I2 The quantity of organic solvents or their quantity in mixtures recovered and reused as solvent input into the process. (The recycled solvent is counted every time it is used to carry out the activity)	This includes solvent that is reused directly or solvent that is recovered and used again on the premises.	For example, calculate reuse based on process solvent capacity and number of batches processed. Analysis of recovered materials may be necessary to determine the solvent composition and overall solvent content of reused materials.	No Solvents reused.

Outputs of organic solvents (O): - Requirements:

Mass Balance Terms	Explanation	Where to get information	TopChem Source of Data
O1 Emissions in waste gases	The amount of solvent emitted from stacks.	<p>Stack emissions monitoring data (concentration and volumetric flow). The calculation must take account of process variations and the relevant parameters should be recorded (e.g. hours of operation of equipment, emission rates at different stages of the process, changes in the nature of production (e.g. different product types). Depending on the consistency of the process, additional monitoring may be required to fully characterise the emissions during different operational conditions. Errors in calculation of this parameter can lead to significant errors in other mass balance outputs.</p> <p>N.B. Total VOC measurements in emissions are typically reported as a carbon equivalent value (e.g. mgC/m³) and must normally be converted to a solvent/total VOC equivalent value based on the VOC composition of the emissions.</p>	In Production the manufacturing process consists of sealed glassware. Transfer of material is normally carried out via transfer lines prior to drying. Solvents themselves are transferred via vacuum through lines, from one vessel to another. The solvent is contained in a narrow neck vessel prior to transfer, emissions are highly unlikely or negligible.
O2 Organic solvents lost in water, if appropriate Taking-into-account waste-water treatment when calculating O5	The amount of solvent emitted in waste-water.	<p>May not be relevant to most processes, but where necessary sufficient data must be captured to fully characterise and quantify waste water emissions in terms of solvent composition. Where solvent losses in water are expected on a batch/ periodic basis (e.g. as a result of periodic cleaning activities), waste water from such activities should be specifically sampled and the overall emissions determined based on the volumes of water used and the frequency of the activity. Again, attention must be paid to ensuring consistency of units.</p>	Solvent and water/waste water is removed via Basic Waste stream. Water volumes of rinse are decided by the size of glassware used in the relevant manufacturing process. Waste levels are monitored and reported.
O3 The quantity of organic solvents which remains as contamination or residue in products output from the process	The solvent which leaves your installation on/in products	<p>Product analysis. Sufficient analytical data must be available to demonstrate that the solvent content of the product has been accurately characterised. This figure does not cover solvent content of products such as paints, where the solvent is intended to be a part of the final product (see O7).</p>	All final products manufactured are evaluated for Solvent residues as appropriate. Worse case scenario is 0.5% (5000ppm) levels of solvent in final product. Max final product QTY is 30 Kg.

Mass Balance Terms		Explanation	Where to get information	TopChem Source of Data
O4	Uncaptured emissions of organic solvents to air. This includes the general ventilation of rooms, where air is released to the outside environment via windows, doors, vents and similar openings.	Solvent emissions from areas which are not covered by extraction systems, e.g. cleaning material handling & storage area, waste storage area (containers, rags), spills, waste water treatment, etc.	Data on these emissions is generally derived via the mass balance calculation rather than being specifically calculated/measured. However, in some cases it is possible to carry out measurements and calculations to determine fugitive losses from specific equipment, processes or production areas, and this may be an appropriate step to validate or cross-check the results of the mass balance calculations. Measurement/assessment of fugitive emissions should be carried out using a robust and comprehensive methodology to provide accurate data. Generally, the assessment need not be done annually unless alterations have been made which may impact on the calculated emissions (e.g. change of equipment or raw materials).	Mass Balance calculation. See Appendix 2.
O5	Organic solvents and/or organic compounds lost due to chemical or physical reactions (including for example those which are destroyed, e.g. by incineration or other waste gas or wastewater treatments, or captured, e.g. by adsorption, as long as they are not counted under O6, O7 or O8)	Solvent destruction by abatement techniques.	There is significant potential for errors in this term if robust methods are not employed. Simply using factors such as the manufacturers quoted destruction efficiency for a thermal oxidiser is not sufficient, and generally in-situ measurement should be considered. As with other parameters in the solvent mass balance, the need to carry out detailed monitoring/assessment of individual sources will depend on the significance of the source and how it influences the overall mass balance. Worst-case assumptions maybe considered where they will not lead to non-compliant mass balance results. Where this approach is taken the basis for the assumptions taken must be clearly outlined in the report. Solvent adsorbed onto activated carbon should only be included under O5 if the solvents are subsequently destroyed.	Not relevant, no solvent destruction by abatement techniques.

Mass Balance Terms		Explanation	Where to get information	TopChem Source of Data
O6	Organic solvents contained in collected waste	Includes waste solvent itself (e.g. spent cleaning solution) plus materials contaminated with solvent (rags, wipes, empty containers, etc.).	Accurate records of solvent containing waste must be kept, e.g. records (not estimates or assumptions) on number and contained liquid volume of drums sent off-site for disposal; and proven solvent content of the waste. Account should be taken of the potential for solvent/ water mixes to separate out when sampling liquids for solvent content. Fugitive losses from solvent waste storage should be included under O4. Waste must be stored in such a way as to minimise fugitive losses.	Full list of waste placed in drums from the Manufacturing Processes, QC and Development Lab is retained. In addition, a full list of Waste removed from the site and its subsequent destruction is also retained.
O7	Organic solvents, or organic solvents contained in preparations, which are sold or are intended to be sold as a commercially valuable product	Only relevant if you sell solvent products.	Sales figures. In activities such as paint manufacture the majority of solvent used in the process remains in the final product and small errors in determination of the solvent content of the product can lead to significant errors in the solvent mass balance. Where final viscosity adjustments are made to a product before packaging (i.e. through addition of solvents), details of the quantities used should be recorded in order to generate accurate figures on solvent content of the products, as small errors in solvent content can be significant where batch sizes are large.	Not Relevant, no Solvent Products sold by TopChem.
O8	Organic solvents contained in preparations recovered for reuse but not as input into the process, as long as not counted under O7	Any waste solvent collected and sent away for recovery/recycling rather than disposal.	Records on number and volume of drums sent off-site for recovery & reuse elsewhere; and the known (not assumed) solvent content of these materials. Also refer to comments in relation to O.6 above.	Not relevant, no recovery/ recycling of Solvents at TopChem.
O9	Organic solvents released in other ways	The 'other' option. Should only be used when supported by full details, not for general use.	Situation dependent.	No other ways for Solvent Release.

9.0 Terms Glossary and References:

TCP	TopChem Pharmaceuticals
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

10.0 Conclusion:

Solvent mass balances were completed using the Stock Quantities and Calculation as outlined in Appendix 1 and 2 as attached to this report.

In Appendix 1 the Quantity of Solvent was evaluated by totalling the Solvent Purchased and then adjusting this Total by the Carry-Over from 2020 purchases. In addition, the Quantity of Solvent remaining in Stock by the end of 2021 was also considered. The final value incorporated the Total Solvent value was for all Labs within TopChem.

In Appendix 2

The value from Appendix was used and from this the Total Quantity of Liquid Waste, again adjusted for the waste generated in 2021 only, was taken away from the Total Solvent Value. There are no solvents emitted from the stacks, no solvent destroyed by abatement, no solvent sent for recovery and there are negligible amounts of solvents in Final Product sold by TopChem.

The Fugitive Emissions was calculated for 2021 for TopChem Pharmaceuticals as 2%. This variation is most likely due to Solvent incorporated as part of the Solid Hazardous Waste removed from the site. This can incorporate Solvent and other chemicals post cleaning. Wipes are used in conjunction with Solvent for Cleaning of Lab areas and Kit. In addition, there may be residues of Solvent remaining in containers after use. These Containers are re-used for Liquid Waste disposal or are disposed of themselves through the appropriate waste stream.

The EPA require licensees to record solvent flow through their operation from purchase to usage, re-usage and emission.

No more than 20% of solvent input may go unaccounted for in the example condition provided in the Reference Document: Air Advice Not No. 1: Good Practice for Solvent Mass Balance and Fugitive Emissions Assessments for EPA Licensed Sites (Printed 2021) The ‘unaccounted for’ figure in the solvent tracking process is the fugitive emission.

Appendix 1

Some solvents have carried over from 2020, with residual stocks remaining coming into 2021. There are three labs consuming, the Production Lab where the manufacturing of product for sale occurs and the Development and Quality Controls Labs.

Solvent	Purchased Quantity (L)	QC/ DEV Carried over from 2020	QC/ Dev Consumed in 2021	Remaining in QC/ DEV from 2021	PL Carried over from 2020	PL Consumed in 2021	Remaining in PL	Total Remaining
Acetone	243	45	206	82	0	0	0	82
Acetonitrile	195	61	136	120	0	0	0	120
MTBE	675	32	0	32	450	580	545	577
Acetone GPR	3950	0	0	20	500	3095	1355	1375
Dichloromethane	5	0	0	0	0	0	5	5
Dichloromethane for GC	20	88	102	6	0	0	0	6
Toluene	455	32	12	20	132	88	499	519
Methanol	400	0	0	0	775	624	551	551
Methanol >99.9%	315	81	276	120	0	0	0	120
IPA	5600	0	0	10	1170	920	5840	5850
IPA	8	27	31	4	0	0	0	4
Ethanol	250	74	22	52	100	0	100	152
Acetic Anhydride	57	0	57	0	0	0	0	0
Tetrahydrofuran	0	10	0	10	0	0	0	10
Ethyl Acetate	287	204	488	3	283	283	0	3
	12460	654	1330	479	3410	5590	8895	9374

Note: Some Solvents may be purchased for Production use but can be transferred to QC/ Development for use as required. This transfer is tracked on the Inventory System and waste is monitored.

Total Solvent Purchased is PL and DEV/QC Combined: 12460L

Total Solvent Carried Over from 2020 for all Areas: 4064L

Total Solvent remaining in Stock for all Labs: 9374L

Total Consumed in 2021: 6920L

Stock Quantity Adjusted for Emissions: $12460 + 4064 - (9374 + 6920) = 230 \text{ L}$

This is all Solvents used at Site, this value will be taken as a % of Waste (13506L).

Appendix 2

Calculation 1:

Fugitive Emissions = Solvent Purchased, minus Solvent emissions in waste gases via stacks, minus solvent destroyed by abatement, minus solvent leaving in waste consignments, minus solvent sold in products (which are intended to be in the product), minus solvent sent for recovery.

Total Liquid Waste in 2021: 13506L

No Solvent emissions in waste gases via stacks.

No solvent destroyed by abatement.

Negligible solvent sold in products (which are intended to be in the product).

No solvent sent for recovery.

Fugitive Emissions from Appendix 1: 230 L

As a percentage: 2%

Fugitive Emissions was calculated for 2021 for TopChem Pharmaceuticals as 2%.