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Background document for trichloroethylene

Document developed in the context of ECHA's third Recommendation for the inclusion of substances in Annex XIV

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1. Identity of the substance

Chemical name: Trichloroethylene

EC Number: 201-167-4 CAS Number: 79-01-6

IUPAC Name: 1,1,2-trichloroethene

2. Background information

2.1. Intrinsic properties

Trichloroethylene was identified as a Substance of Very High Concern (SVHC) pursuant to Article 57(a) as it is classified according to Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as carcinogen 1B, H350 (May cause cancer), and was therefore included in the Candidate List for authorisation on 18 June 2010, following ECHA's decision ED/30/2010.

2.2. <u>Imports, exports, manufacture and uses</u>

2.2.1. Volume(s), imports/exports

According to registration information about 50000 – 100000 t/y of trichloroethylene are manufactured or imported. No information on exports is available.

The larger part of the manufactured/imported volume is used as intermediate in the manufacturing of other substances such as fluorinated compounds. The volume allocated to uses within the scope of authorisation is above 10000 t/y.

2.2.2. Manufacture and uses

2.2.2.1. Manufacture and releases from manufacture

Trichloroethylene is produced by the catalytic hydrogenation of tetrachloroethene (BUA, 1994). A specially activated copper-palladium catalyst on a carrier material is used in the gas phase at temperatures up to 250°C (EC 2004).

Manufacture of trichloroethylene takes place in closed systems, and only occasional controlled releases are assumed to take place (ECHA 2011).

It is estimated that 400-700 workers (including maintenance personnel and contractors) are exposed during manufacture and packing of trichloroethylene (Annex XV 2010).

2.2.2.2. Uses and releases from uses

According to disseminated registration information (ECHA 2011), the substance is still used in industrial settings in the following applications where opportunity of exposure arises:

- Formulation:
- Surface cleaning (closed and enclosed systems),
- Heat transfer fluid (mainly in closed systems),
- Process chemical (e.g. in purification)
- Textile scouring
- Adhesives
- Laboratory chemical

According to Annex XV (2010), the major non intermediate use of trichloroethylene is for hot vapour degreasing of metal parts (surface cleaning). It is used for the removal of substances such as oils, greases, waxes and buffering compounds, or soils. The substance has high solvent power while not being flammable under working conditions. Closed systems, including closed supply and take-back systems in safety containers are today standard in some countries like Germany and Austria. Also in the rest of Europe surface cleaning applications have been converted to closed systems, either to comply with the European Solvent Emission Directive (covers sites where the volume used is > 1 t/y) or with a self commitment by industry to carry out this use only in closed systems (covers as well sites where < 1 t/y is used, Annex XV 2010). The trichloroethylene from this use is often recovered by independent solvent recyclers, which seem to place the substance again on the market for surface cleaning (RCOM 2011).

Trichloroethylene is used as heat transfer medium in the closed secondary heat transfer in industrial climate controlled installations such as wind tunnels in the automotive and aeronautic industry (Annex XV 2010). It is supposed that from such closed systems releases occur only occasionally.

As a process solvent the substance is mainly used in the purification and crystallisation of pharmaceuticals. These uses are reported to be fully-closed processes with recovery of trichloroethylene as solvent for re-use (Annex XV 2010).

In textile scouring the use of chlorinated solvents such as trichloroethylene is reported to be the best available technique, with significant advantages in comparison to water based scouring techniques (Annex XV 2010).

Trichloroethylene use in adhesives is only remaining for specific applications (repair of conveyor belts in mines or rubber coating) (Annex XV 2010).

Trichloroethylene is widely used in laboratories for analysis of medicinal products, foodstuffs or feedingstuffs, as well as for asphalt testing (RCOM 2011). These analyses seem to take place under controlled conditions and may be covered by the exemption of scientific research and development (SRD) from authorisation in accordance with Art. 56(3) of the REACH Regulation. However, in particular for asphalt testing the use per site might exceed 1 t/y and then would not fall under the exemption of SRD set out in Art. 56(3) (see also definition of scientific research and development in REACH Art. 3(23)).

According to disseminated registration information, trichloroethylene is still used in the following professional uses from which exposure might occur:

- Process chemical (e.g. in purification).
- Adhesives

Trichloroethylene is also a component of a wide range of products for professional use, such as adhesives, coatings, inks, dyes (e.g. for leather, paper, textiles) and cleaning products (ECHA 2011). The ERCs given for the professional uses indicate that all the uses are wide dispersive and both, in- and outdoor uses occur (ECHA 2011). In the case of trichloroethylene, the dermal and inhalation exposure routes are relevant (EC 2004, ECHA 2011).

At least some activities carried out in the context of the described uses could result in exposure of the substance to workers and professionals. For instance, operations such as material transfers, maintenance, cleaning and sampling could lead to significant exposure. Particularly, certain processes reported for professionals, such as roller application, brushing, non industrial spraying or dipping and pouring (ECHA 2011) can be expected to lead to exposure. Operators in industrial settings would be expected to wear proper protection, while this can not always be expected for professionals (EC 2004). In particular, uses of the substance in adhesives by professionals could result in widespread use and uncontrolled exposure (\approx wide-dispersive use).

Even though trichloroethylene has low bioaccumulation potential, it is suggested that the substance is not ready biodegradable in the environment (disseminated registration information), which might lead to exposure via environment. However, the RAR (EC 2004) concluded that there is no risk from secondary poisoning, and total volumes have declined since then.

2.2.2.3. Geographical distribution and conclusions in terms of (organisation and communication in) supply chains

The use of trichloroethylene is deemed to take place throughout Europe. In particular, the industrial use for metal degreasing and the professional uses may constitute a high number of point sources.

2.3. <u>Availability of information on alternatives</u>¹

Alternatives for trichloroethylene in its main use as cleaning agent or degreaser

As possible alternative substances to trichloroethylene, alkaline mixtures, halogenated (e.g. perchloroethylene, methylene chloride) and non halogenated solvents (oxygen solvents, aliphatic and cycloaliphatic hydrocarbons, as well as nmethyl 2-pyrrolidone are reported (Annex XV 2010).

For metal degreasing alternative methods, like organic/biological degreasing (using non-pathogenic microorganisms for the dirt removal), supercritical carbon dioxide or plasma cleaning (with an electrically charged gas), high pressure water and others are described (Annex XV 2010, EC 2004).

However, the substitution of trichloroethylene in specific applications, particularly for low temperature cleaning or small/inaccessible parts, might be difficult. Some industry sectors claim that for some applications no alternatives are available (RCOM 2011).

Alternatives for trichloroethylene in other uses

It is difficult to profile the availability of alternatives for trichloroethylene in adhesives, but it is likely that for most applications alternatives are available, also where low flammability is required (EC 2004). In most of these cases substitution has already taken place and for the only remaining uses (repair of conveyer belts in mines and rubber coating) alternatives might be more difficult to find (Annex XV 2010, EC 2004 and RCOM 2011).

No further information on alternatives could be found for the other uses of trichloroethylene.

2.4. <u>Existing specific Community legislation relevant for possible exemption</u>

There seems to be no specific Community legislation in force that would allow to consider exemption of (categories of) uses from the authorisation requirement on the basis of Article 58(2) of the REACH Regulation (see section III and Annex I of RCOM, 2011).

- existing EU legislation aimed at protection of workers against risks to their health (including Directives 98/24/EC and 2004/37/EC) currently do not impose binding minimum requirements for controlling risks to workers health during the use phase or throughout the life cycle of trichloroethylene. However, in case the ongoing discussions under the Carcinogens Directive 2004/37/EC will result in setting of a binding Occupational Exposure Limit for trichloroethylene for protection of workers, this conclusion may be revisited.
- The Solvents Emissions Directive 1999/13/EC and IED Directive 2010/75/EU appear to impose binding minimum requirements for emissions of trichloroethylene to the environment for certain activities,

¹ Please note that this information was not used for the prioritisation.

including surface cleaning when the solvent consumption is above a specified threshold. While these directives and requirements aim primarily at control of emissions of organic compounds which contribute to the local and transboundary formation of photochemical oxidants, the measures taken to fulfil the requirements may also be relevant for the control of exposure of humans to trichloroethylene. Therefore, these additional requirements may be taken into account in further assessment. However, the activities with solvent consumption below the threshold are not covered by these minimum requirements.

2.5. Any other relevant information (e.g. for priority setting)

Not available.

3. Conclusions and justification

3.1. Prioritisation

Verbal-argumentative approach

The volumes of trichlororethylene allocated to uses in the scope of authorisation are very high and at least some of the described uses bear potential to result in significant exposure of industrial workers and professionals and can be considered wide dispersive.

Therefore, based on the criteria, trichloroethylene has very high priority.

Scoring approach

Score			Total Score
Inherent properties (IP)	Volume (V)	Uses - wide dispersiveness (WDU)	(= IP + V + WDU)
Score: 0/1 (carcinogen 1B)	9 (Very high volume used for applications in the scope of authorisation)	Overall score: 3 * 3 = 9 Site-#: 3 (Used at a high number of sites) Release: 3 (At least in some applications significant exposure of workers/professionals and wide dispersive use)	18/19

Conclusion, taking regulatory effectiveness considerations into account

On the basis of the prioritisation criteria, trichloroethylene gets very high priority for inclusion in Annex XIV.

Therefore, it is proposed to prioritise trichloroethylene for inclusion in Annex XIV.

4. References

- Annex XV (2010): Annex XV dossier for identification of a substance as SVHC. Submitted by France, February 2010. http://echa.europa.eu/documents/10162/b6311c04-ef7b-40ef-969c-a2bc7f14090
- ECHA (2011): Substance information, disseminated on ECHA's webpage for trichloroethylene.

 http://apps.echa.europa.eu/registered/data/dossiers/DISS-9c8133b7-2fc3-3484-e044-00144f67d249/DISS-9c8133b7-2fc3-3484-e044-00144f67d249/DISS-9c8133b7-2fc3-3484-e044-00144f67d249.html.
- EC (2004): European Union Risk Assessment Report: trichloroethylene. 1st Priority List, Volume 31. European Commission, Joint Research Centre.
- RCOM (2010): "Responses to comments" documents. Document compiled by the French MSCA from the commenting on SVHC identification 08.03.-22.04. 2010. http://echa.europa.eu/documents/10162/fcd56d88-77c5-4e33-93c5-9ac5075640f0
- RCOM (2011): "Responses to comments" documents. Document compiled by ECHA from the commenting on Annex XIV recommendation 15.06.-14.09. 2011.
 - http://echa.europa.eu/documents/10162/17232/rcom_trichloroethylene_en.rtf