ECHA
EUROPEAN CHEMICALS AGENCY

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Background document for 1,2-dichloroethane

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

Information comprising confidential comments submitted during public consultation or relating to content of Registration dossiers, which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

1. Identity of the substance

Chemical name:	1,2-dichloroethane
EC Number:	203-458-1
CAS Number:	107-06-2
IUPAC Name:	1,2-dichloroethane

2. Background information

2.1. Intrinsic properties

1,2-dichloroethane was identified as a Substance of Very High Concern (SVHC) in accordance with Article 57 (a) as it is classified in 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, Carc. 1B[1] (H350: "May cause cancer"), and was therefore included in the Candidate List for authorisation on 19 December 2011, following ECHA's decision ED/77/2011.

2.2. Imports, exports, manufacture and uses

2.2.1. Volume(s), imports/exports

According to registration information, the total amount of 1,2-dichloroethane or ethylene dichloride (EDC) manufactured in the EU is between 1,000,000 – 10,000,000 t/y. Another 10,000 – 50,000 t/y are imported into the EU.

[1] This corresponds to a classification as carcinogen cat. 2 (R45: "May cause cancer") in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) N° 1272/2008

The substance is mainly used in the synthesis of vinyl chloride monomer (VCM). The use as an on site isolated intermediate represents more than 95 %, and use as an (transported) intermediate for VCM synthesis more than 4 %, of the total amount of the substance. The substance is also used as an intermediate in the synthesis of fine chemicals. Therefore, it appears that > 99% of the total tonnage manufactured or supplied in the EU is used as an intermediate.

About 0.2 % of the total tonnage of EDC (Annex XV, 2011) is estimated to be used within the scope of Authorisation. This corresponds to a tonnage between 2,000 – 20,000 t/y. The aggregated use specific volume given in the registration dossiers for uses within the scope of Authorisation is in the range of 1,000 – 10,000 t/y, however several registration dossiers do not provide use specific tonnage information. Information provided during public consultation (RCOM, 2012) by the EDC REACH consortium confirms that the total volume within the scope of authorisation lies very likely within the range of 1,000 t/y to 10,000 t/y.

2.2.2. Manufacture and uses

2.2.2.1. Manufacture and releases from manufacture

EDC is manufactured by chlorination or oxychlorination of ethylene. According to the Annex XV report (2011), the manufacturing process takes place in closed systems with no or only occasional controlled exposure. However, registration information (ECHA, 2012) shows that this is not always the case. Even though most of the use descriptions for EDC manufacture describe closed processes only, there are some descriptions of EDC manufacture in the registrations that report processes with the possibility of exposure, like use in batch processes where opportunity for exposure arises, or transfer at non-dedicated facilities (PROC 4 and 8a respectively, ECHA 2012). Also in closed systems, workers could be exposed during maintenance, sampling, testing or other process steps.

According to the Annex XV report (2011), releases resulting in occupational exposure in the order of magnitude of established national OELs are reported from manufacture of the substance. Moreover, an exposure survey carried out in 2006/2007, covering EDC manufacture and the synthesis of VCM, also indicated significant exposure.

It is noted that the DMEL derived in the registration for long-term inhalative exposure to EDC is 6.6 mg m^{-3} (1.6 ppm) (as disseminated on ECHA's website; ECHA, 2012). This corresponds to a residual risk of $4*10^{-3}$, 400 times higher than the value of 10^{-5}, which is considered as acceptable lifetime cancer risk level for workers in the Guidance on Information Requirements and Chemical Safety Assessment (ECHA, 2008). However, the value of 1.6 ppm is within the range of OELs (1ppm – 10 ppm) set by some European countries (Annex XV, 2011).

2.2.2.2. Uses and releases from uses

The main use of EDC (more than 99 % of the total volume) is as intermediate in the manufacture of VCM. The use as intermediate is not within the scope of authorisation.

The main uses within the scope of Authorisation are in formulation and as a solvent in different applications. Information from registrations (ECHA, 2012), the

Annex XV report (2011) and the RCOM (2011) indicates that EDC is used as a processing aid in the manufacture of fine chemicals, an extraction agent, a solvent in the preparation of mixtures for biochemical applications (e.g. liquid media and cell cultures) and as an inhibitor. The registrations that earlier reported uses of EDC in the production of rubber, formulation of degreasing solvents, adhesives or biocidal formulations have been updated and now are advising against these uses. Nevertheless, other registrations include plant protection products within the product categories of their uses.

During data gathering for the Annex XV report (2011) several Member States informed about imports of EDC to their countries, in small quantities by several distributors, not likely to be used for VCM manufacture. During public consultation (RCOM, 2012), information on sites of use has been provided by the members of the REACH EDC consortium. According to this information, EDC is used for manufacture of pharmaceuticals, at 18 sites within the EU. However, it seems that EDC is also used in a few other specific applications for other fine chemicals, fuels or plant protection products. Nevertheless, the number of sites where the substance is used seems to be rather in the 10s than in the hundreds. On the basis of this information it can be reasonably assumed that EDC is used as a solvent at a medium number of sites.

The information provided in the registration dossiers, does not allow conclusions to be drawn on releases and exposure in all cases. However, for the uses as a solvent, several registration dossiers indicate activities that take place at non-dedicated facilities (PROC 8a) or report activities where opportunity for exposure arises (PROC 4). For the formulation stage, PROC 5 (Mixing or blending …. multistage and/or significant contact) is also listed. Considering the higher potential for releases from such activities, significant exposure can not be excluded.

Both inhalation and dermal contact are relevant exposure routes, with inhalation being the dominant one. Taking into account the relatively high volatility of EDC, it can be assumed that significant releases with a high potential for exposure of workers might result from the uses in the scope of authorisation. The fact that the DMEL derived in the registration and the OELs in place in some Member States may result in a residual risk for workers that is approximately 400 times higher than that considered acceptable in the REACH guidance deserves in this context particular consideration. Additionally, it is known (RCOM, 2012) that EDC can be recycled and reused within the same facility. This increases the possible releases and exposure resulting from a certain volume of solvent (saying that, recycling and reuse is still an overall better approach than using *multiple amounts* of fresh solvent – provided that the distillation and recovery equipment/processes are adequately controlled).

For all these reasons, despite the high level of containment that might for most of the uses be in place, significant exposure of workers is still likely or at least cannot be excluded.

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

According to information in the Annex XV report (2011; confirmed by registration information), EDC is known to be used within the scope of authorisation by companies in several EU countries. However, no further information is available.

Taking into account the nature of the uses, it appears reasonable to assume that EDC is used all over Europe.

2.3. Availability of information on alternatives[2]

The Annex XV report (2011) does not provide detailed information on alternatives to EDC for its use as a solvent. It is stated that industry is making efforts to substitute EDC, where possible. However, it might be difficult to develop alternatives for some specific applications, particularly in the pharmaceutical industry.

2.4. Existing specific Community legislation relevant for possible exemption

There seems to be no specific Community legislation in force that would allow consideration of an exemption(s) of (categories of) uses from the authorisation requirement on the basis of Article 58(2) of the REACH Regulation.

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

Not available.

[2] Please note that this information was not used for prioritisation.

3. Conclusions and justification

3.1. Prioritisation

The substance is used in high volumes in the scope of authorisation. The substance is assumed to be used at a medium number of sites, with significant potential for worker exposure from its uses as a solvent.

Verbal-argumentative approach

On the basis of the prioritisation criteria, 1,2-Dichloroethane gets high priority for inclusion in Annex XIV.

Scoring approach

Score			Total Score
Inherent properties (IP)	Volume (V)	Uses - wide dispersiveness (WDU)	(= IP + V + WDU)
1 Art. 57 (a); Carc 1B	7 High volume used in the scope of authorisation (1,000 - 10,000 t/y)	Overall score: 2 * 3 = 6 Site-#: 2 Substance is used at a medium number (10-100) of sites Release: 3 Significant potential for worker exposure resulting from uses as a solvent	14

Conclusion, taking regulatory effectiveness considerations into account

On the basis of the prioritisation criteria, 1,2-dichloroehtane gets high priority for inclusion in Annex XIV.

Therefore, it is proposed to prioritise 1-,2-dichloroethane for inclusion in Annex XIV.

4. References

Annex XV (2011): 1,2-dichloroethane. Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Submitted by Slovakia, August 2011.

http://echa.europa.eu/documents/10162/57c002b0-db53-4f7c-ac5e-7c8dd46a53bf

ECHA (2008): Guidance on information requirements and chemical safety assessment. Chapter R.8: characterisation of dose [concentration]-response for human health.

ECHA (2012): 1,2-dichloroethane. ECHA's dissemination website on registered substances. http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d8264f2-839d-4628-e044-00144f67d249/DISS-9d8264f2-839d-4628-e044-00144f67d249_DISS-9d8264f2-839d-4628-e044-00144f67d249.html

RCOM (2011): "Responses to comments" document. Document compiled by Slovakian CA from commenting period 29/08/2011 – 13/10/2011 on the identification of 1,2-dichloroethane as Substance of Very High Concern.
http://echa.europa.eu/documents/10162/3874bfa0-c216-43da-b24f-1c6cb7887963

RCOM (2012): Responses to comments document (RCOM) on ECHA's draft 4th for 1,2-dichloroethane (EC number: 203-458-1). Document compiled by ECHA from the commenting period 20/06/2012 – 19/09/2012

http://echa.europa.eu/documents/10162/13640/axiv_4th_recommendation_edc_rcom_en.pdf