

Decision number: CCH-D-0000004574-71-05/F

Helsinki, 22 August 2014

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006**For 1,2-dichloropropane, CAS No 78-87-5 (EC No 201-152-2), registration number:**
[REDACTED]**Addressee:** [REDACTED]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for 1,2-dichloropropane, CAS No 78-87-5 (EC No 201-152-2), submitted by [REDACTED] (Registrant).

This decision is based on the registration as submitted with submission number [REDACTED], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 6 March 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 22 October 2013.

On 10 December 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 45 days of the receipt of the draft decision.

On 23 January 2014 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

On 6 March 2014 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, proposals for amendment to the draft decision were submitted.

On 10 April 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 22 April 2014 ECHA referred the draft decision to the Member State Committee.

By 12 May 2014 the Registrant did not provide any comments on the proposals for amendment.

After discussion in the Member State Committee meeting on 10 to 13 June 2014, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 12 June 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

1. Revised environmental exposure assessment and risk characterisation as specified in section III.1 below (Annex I, sections 5. and 6. of the REACH Regulation);
2. Missing elements for consumer exposure assessment and a revised consumer exposure assessment and risk characterisation as specified in section III.2 below (Annex I, sections 5. and 6. of the REACH Regulation).
3. Documentation for the recommended personal protective equipment, i.e. gloves to be worn need to be specified clearly when handling the substance or mixture (Article 14(6), Annex I, 5.1.1., in conjunction with Annex II, 0.1.2. and 8.2.2.2.(b)(i)), including:
 - The type of material and its thickness, and
 - The typical or minimum breakthrough times of the glove material.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **2 March 2015**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

Information related to the chemical safety assessment and chemical safety report

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report (CSR) which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

Annex I sets out the general provisions for assessing substances and preparing CSR. ECHA has observed following omissions and inconsistencies in the CSR:

1. Revised environmental exposure assessment and risk characterisation

According to Article 14(4) of the REACH Regulation, if the substance fulfils the criteria for any of the hazard classes of Annex I to Regulation (EC) No 1272/2008 listed in Article 14(4) or is assessed to be a PBT or vPvB, the chemical safety assessment (CSA) shall include an exposure assessment and risk characterisation. ECHA notes that the registered substance is classified as Flam Liquid 2, Acute Tox 4 (oral and inhalation), fulfilling the criteria set out in Article 14(4). The exposure assessment shall be carried out according to section 5 of Annex I and shall include exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards. Annex I, section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario.

ECHA notes that there are 10 exposure scenarios (ES) provided in the CSR:

ES 1 - Manufacturing process;

ES 2 - Formulation process;

ES 3 - Spray application of solvent-based degreasers, cleaners and painting products at industrial sites;

ES 4 - Treatment of articles by dipping with solvent-based degreasers and cleaners at industrial sites;

ES 5 - Spray application of solvent-based degreasers, cleaners and painting products by professional users;

ES 6 - Treatment of articles by dipping with solvent-based degreasers and cleaners by professional users;

ES 7 - Roller application, brushing or by dispensing systems of solvent-based degreasers, cleaners, painting products, paint removers, stain removers and adhesives at industrial sites;

ES 8 - Roller application, brushing or by dispensing systems of solvent-based degreasers, cleaners, painting products, paint removers, stain removers and adhesives by professional workers;

ES 9 - Printing process; and

ES 10 - Roller application, brushing or by dispensing systems of solvent-based degreasers, cleaners, painting products, paint removers, stain removers and adhesives by consumers.

According to the information provided in the technical registration dossier and in the CSR, the following information has not been provided or is not satisfactory:

(i) Operational conditions

Pursuant to the Annex I, section 5.1.1. of the REACH Regulation an exposure scenario includes, where relevant, a description of operational conditions and risk management measures (RMMs). The final exposure scenario shall be presented under the relevant heading of the CSR, and included in an annex to the safety data sheet. Pursuant to the Annex I, section 5.2.2. of the REACH Regulation emission estimation shall be performed under the assumption that the RMMs and operational conditions described in the exposure scenario have been implemented.

ECHA notes that some operational conditions, i.e. information on amount of the substance used per site and the number of emission days of the substance, are not reported in the CSR for exposure scenarios 3-9. Furthermore, the tonnage of use of the substance for exposure scenario 10 is also not reported in the CSR. Information on these operational conditions shall be provided in the CSR to allow ECHA to check the compliance of the exposure estimation performed. Thus, ECHA concludes that this missing information shall be included in respective exposure scenarios.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to provide in the CSR the missing information on operational conditions as detailed above for exposure scenarios 3-10.

(ii) Release factors used in exposure estimation for exposure scenarios 2-10.

Pursuant to the Annex I, section 5.2.1. of the REACH Regulation the exposure estimation entails three elements: (1) emission estimation, (2) assessment of chemical fate and pathways and (3) estimation of exposure levels. Emission estimation shall be performed under the assumption that the RMMs and operational conditions described in the exposure scenario have been implemented.

According to the Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (ECHA, version: 2.1, October 2012) the exposure scenario should contain information (about operational conditions and risk management measures) based on which the assumed release factors and daily use rates can be justified. Furthermore, the Guidance indicates that sector specific environmental release categories (spERCs) developed by industrial sector organisations may be used in place of the more conservative default environmental release categories (ERCs) of ECHA's guidance. As far as possible, spERCs have to be linked to the RMM and the operational conditions driving the release estimation.

ECHA notes that the values of release factors to various environmental compartments used in exposure estimation are not provided for exposure scenarios 2-10. Information on release factors used in exposure estimation shall be provided in the CSR to allow ECHA to check the compliance of the exposure estimation, namely the emission estimation part, performed. Thus, ECHA concludes that values of release factors to various environmental compartments used in exposure estimation shall be included in respective exposure scenarios 2-10.

Furthermore, the Registrant should note that non-default environmental release category release factors (as defined in ECHA Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (ECHA, version: 2.1, October 2012)) should be justified e.g. by operational conditions, RMMs, or physico-chemical properties of the substance. If release factors are based on site(s) specific measurements the summary of results of these measurements (detailed enough to understand whether or not they cover relevant scenarios for possible releases) should be provided in the CSR. Further ECHA notes that the Registrant has applied the same exposure estimation for different industrial uses (described by ERC 4) and uses by professional users (described by ERC 8a) and there is no explanation on the applicability of the same exposure estimation to the different uses provided in the CSR.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to specify in the CSR release factors used in exposure estimation for exposure scenarios 2-10.

(iii) Efficiencies of risk management measures

According to Article 3(37) of the REACH Regulation, exposure scenario is defined as "the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment".

Pursuant to Articles 10(b) and 14(4) as well as Annex I, Section 5.1.1. of the REACH Regulation, generated exposure scenarios shall cover a description of the operational conditions and risk management measures applied to reduce or avoid direct and indirect exposure to humans and the different environmental compartments to the substance.

ECHA notes that efficiencies of RMMs, which were taken into account in environmental exposure estimation, are missing in all exposure scenarios. Information on efficiencies of RMMs shall be provided in the CSR to allow ECHA to check the compliance of the exposure estimation performed and to check adequacy of the proposed RMMs. Thus, ECHA concludes that this missing information on efficiencies of the RMMs shall be included in respective exposure scenarios.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to provide in the CSR the missing efficiencies of risk management measures for all exposure scenarios.

(iv) Exposure estimations and risk characterisation for marine water and sediment

Pursuant to Annex I, section 5.0. of the REACH Regulation an exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the hazards identified.

ECHA notes that according to the information provided in the CSR, information on exposure estimations and risk characterisation for marine water and sediment, for all exposure scenarios, is not reported. It is also noted that there is no justification in the CSR provided on why marine water and marine sediment compartments would not be relevant for any of the specific exposure scenarios reported in the CSR.

The predicted no effect concentrations (PNECs) for marine water and sediment are available and reported by the Registrant in the IUCLID registration dossier. Some of the exposure scenarios provided in the CSR might be assumed to cover the use of the substance by unknown downstream users (e.g. uses by professional users and consumers; information on whether or not location of industrial downstream users sites is known is not provided in the CSR). Therefore, the location of these sites of use of the substance is assumed to be unknown and possible exposure of marine environment shall be considered in the exposure assessment and following risk characterisation shall be provided in the CSR for these relevant exposure scenarios.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to provide quantitative exposure estimations and risk characterisation for marine water and sediment for each exposure scenario. Alternatively, a qualitative argumentation may be provided to explain why these environmental spheres are not relevant or why quantitative exposure estimation/risk characterisation is not relevant for these spheres. The CSR shall be amended accordingly.

(v) Combined environmental risk characterisation

Pursuant to the Annex I, section 6.2. of the REACH Regulation the risk characterisation shall consider the overall environmental risk caused by a substance by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

Chapter R.16: Environmental Exposure Estimation of the Guidance on information requirements and the chemical safety assessment (ECHA, version: 2.1, October 2012) specifies that since all releases to water from each identified wide disperse use will by default enter into the same sewage system, combined risk should be considered. It further notes that releases from uses in industrial settings are assessed as independent point source releases; it means that each identified use of the substance is assumed to occur at a different site. However, in some cases, it is needed to combine those assessments in the "combined risk" section of the CSR, e.g. when manufacture and formulation take place at the same site.

The CSR does not contain a combined risk assessment for the environment for the number of wide dispersive uses by consumers and professional users or, if relevant, for all industrial uses of the substance which might take place on the same site.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to provide a combined risk assessment for the environment in the CSR.

2. Missing elements for consumer exposure assessment and a revised consumer exposure assessment, including risk characterisation

Pursuant to Article 14(4) and Annex I of the REACH Regulation, a CSR shall be provided, including exposure assessment and risk characterisation addressing all identified uses of the substance if the substance fulfils the criteria for any of the hazard classes of Annex I to Regulation (EC) No 1272/2008 listed in Article 14(4) or is assessed to be a PBT or vPvB. The chemical safety assessment (CSA) shall include an exposure assessment and risk characterisation. ECHA notes that the registered substance is classified as Flam Liquid 2, Acute Tox 4 (oral and inhalation), fulfilling the criteria set out in Article 14(4). The exposure assessment shall be carried out according to section 5 of Annex I and shall include exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards. Annex I, section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario.

Article 14(6) as well as Annex I, 5.2.4. and 6.2. to 6.4. of the REACH Regulation, require registrants to identify and apply appropriate measures to adequately control the risks identified in the CSR. The exposure shall be estimated and risks shall be characterised in the CSR under the assumption that relevant risk management measures have been implemented.

ECHA notes that according to the information provided in the technical dossier and in the CSR, there is insufficient information to address consumer exposure assessment and the Registrant needs to provide more detailed descriptions of the exposure scenarios which should include the different tasks and associated duration of exposure. The Registrant shall provide details of the inputs used for the exposure modeling, which are currently not provided. More specifically the inputs used in modeling the exposure estimations for each of the tasks/uses should be provided separately i.e. the substance used in painting products, degreasers and cleaning products, paint removers, stain removers and adhesives. It needs to be clear how the exposure modeling inputs are used to establish the exposure estimations provided in the CSR. The concentration of registered substance in the mixture and the amount applied for each activity covered needs to be stated in the CSR. Only with this information it will be possible to verify whether the risk to humans can be considered adequately controlled throughout the lifecycle of the substance.

It should be noted that frequency of use should not be used to average out exposure over a longer period of time. Exposure should be calculated for the actual duration of the event, and then expressed as that concentration per day (Guidance on information requirements and chemical safety assessment Chapter R.15: Consumer exposure estimation, version:2.1, October 2012).

Therefore, the Registrant is requested to provide the missing information and revise the consumer exposure assessment and assess the related risks accordingly. The CSR shall be amended accordingly.

3. Documentation that risks to workers are adequately controlled

Article 14(6) as well as Annex I, 0.1., 5.1.1., 5.2.4. and 6.2. of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in a CSR. The exposure shall be estimated and risks shall be characterised in the CSR under the assumption that relevant risk management measures have been implemented.

Pursuant to Annex VI, section 5 and Annex II, section 0.1.2. of the REACH Regulation the information provided in the registration dossier shall be consistent with that in the Safety Data Sheet (SDS). The requirements of Safety Data Sheets are specified in Annex II of the REACH Regulation (amended by Commission Regulation (EU) No 453/2010).

According to Annex I, 0.3., 0.5. and 5.1.1. the applied Risk Management Measures (RMM) have to be indicated in the CSR. Annex II, section 8.2.2.2. (b)(i), requires the Registrant to describe the relevant RMM in detail (e.g. the type of gloves to be worn shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of dermal exposure) in order to minimise the exposure for workers handling the registered substance. In particular, the following requirements for hand protection in order to avoid dermal exposure need to be provided consistently in the SDS and CSR:

- The type of material and its thickness,
- The typical or minimum breakthrough times of the glove material.

In the CSR, the Registrant indicated the following for hand protection: "protective gloves, tested to EN374, are recommended."

In section 11 of the technical registration dossier in the part for Exposure controls/personal protection, the following is stated: "Protective gloves."

To ensure the safe use of a substance it is essential to have detailed guidance on risk management measures, e.g. personal protective equipment. Although the gloves are reported in the CSR as required personal protective equipment to prevent dermal exposure to the substance, the material type of gloves to be worn, its thickness and typical or minimum breakthrough time when handling the substance is not specified.

Therefore, pursuant to Article 41(1)(c) and 41(3) of the REACH Regulation the Registrant is requested to provide documentation for the recommended material type, its thickness and the typical or minimum breakthrough time for the glove type recommended., with regard to the amount and duration of dermal exposure.

Notes for consideration by the Registrant:

Regarding how to report the gloves specifications, the information should be included both in section 11 of the technical IUCLID dossier (Guidance on Safe Use) which is the disseminated part of the dossier and in the CSR where the appropriate measures to adequately control the risk are to be reported.

It is the responsibility of the Registrant to ensure consistency of the information within the CSR, and between the CSR, IUCLID section 11 and the safety data sheet.

IV. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at <http://echa.europa.eu/regulations/appeals>. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.



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