Risk Management Option Analysis Conclusion Document

Substance Name: 4-Chloro-α,α,α-trifluorotoluene
EC Number: 202-681-1
CAS Number: 98-56-6

Authority: the Netherlands
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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

The subject of this RMOA is to document the concerns regarding the carcinogenic potential of p-chloro-α,α,α-trifluorotoluene. p-Chloro-α,α,α-trifluorotoluene is a solvent used in paints and coatings and is used as an industrial intermediate in the production of other chemicals.

CLH

p-Chloro-α,α,α-trifluorotoluene is neither listed in Annex VI nor an Annex VI proposal has been submitted. The substance is self-classified by the registrant as Flam. Liquid 3 (H226), Skin Sens. 1B (H317), and Aquatic Chronic 2 (H411). Available data suggests that 4-chloro-α,α,α-trifluorotoluene could be harmonized under CLP as Carc. 2, Repro 2 and Skin Sen. 1B.

OEL

An occupational exposure limit (OEL) value has not been derived however could be considered to compare the reported exposure levels of workers in the CSR to the reported US limit values.

RCR

In the CSR, the derived risk characterization ratios for several exposure scenarios are above the trigger of 1. Based on the initial exposure scenario, risks are not controlled (RCRs > 1), further refinement of the CSA would be needed. Control of risk and safe use of the substance for several exposure scenarios has not been sufficiently demonstrated.

Restriction

The substance will be included in the restriction proposal for PFAS, which is under construction for the next coming three years. However, the national authorities of Germany, the Netherlands, Norway, Sweden and Denmark did agree on preparing a restriction proposal suggesting to restrict all fluorinated substances that contain *1 or more C atoms on which all the H substituents have been replaced by F atoms, in such a manner that they contain at least one aliphatic perfluorocarbon moiety such as -CnF2n-*". 4-Chloro-α,α,α-trifluorotoluene is included by this definition.

The main concern for the group of these fluorinated substances is their persistence and the consequences of their use, e.g. their practically not reversible presence in the environment.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	x
Identification as SVHC (authorisation)	
Restriction under REACH	x
Other EU-wide regulatory measures	x
Need for action other than EU regulatory action	x
No action needed at this time	

The following risk management measures could be considered appropriate to address the (potential) concerns for 4-chloro-α,α,α-trifluorotoluene.

- Draft an annex VI proposal to harmonise the classification of 4-chloro-α,α,α-trifluorotoluene as Carc. 2 and consider also Repro. Cat. 2 and Skin Sens. 1B.

- Setting of an OEL could be an RMO to consider. However, given the fact that the exposure levels of workers are without exception lower than the US limit values, there seems hardly any need for doing so. As a first step an OEL could be derived to compare this with exposure levels derived in the CSR.

- The national authorities of Germany, the Netherlands, Norway, Sweden and Denmark did agree on preparing a restriction proposal suggesting to restrict all fluorinated substances that contain 1 or more C atoms on which all the H substituents have been replaced by F atoms, in such a manner that they contain at least one aliphatic perfluorocarbon moiety such as -CnF2n-". 4-Chloro-α,α,α-trifluorotoluene is included by this definition. The main concern for the group of these fluorinated substances is their persistence and the consequences of their use, e.g. their practically not reversible presence in the environment.

Given the marginal and potential human health concerns, the proposal by the NL-CA is to ask ECHA to perform a compliance check. After the CSR is updated accordingly, the NL-CA would like to check once again if the concern is still considered marginal or not. For the time being we would like to suggest no further action on this substance, since the original concern with respect to carcinogenicity is addressed and resolved sufficiently. In addition, we know that the substance will be included in the restriction proposal for PFAS, which is under construction for the next coming three years.

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

There are some uncertainties in the risk assessment which should be sorted in order to get a better understanding of the risks to the worker population and consumers. The CSR reports risk characterization ratios above 1 for several worker scenarios (manufacture synthesis of PCTB, formulation process and general industrial use of diluent for paints). In addition, exposure assessment and risk characterization for consumers is not provided in the registration dossier.
The main aim of this RMO is to document the concerns regarding the carcinogenic potential for 4-chloro-α,α,α-trifluorotoluene. The assessment suggests that 4-chloro-α,α,α-trifluorotoluene meets the criteria of Carc. 2, Repro. 2 and Skin Sens. 1B. The preparation of Annex VI proposal for harmonised classification for carcinogenicity of 4-chloro-α,α,α-trifluorotoluene can be considered. Harmonized classification will ensure that the (potential) hazards posed by the substance are clearly communicated to workers, but will hardly contribute to the safe use of the substance, since the substance is already classified as hazardous. PPE are already to be included in the SDS and are actively communicated throughout the supply chain.

3.1 Harmonised classification and labelling

p-Chloro-α,α,α-trifluorotoluene is neither listed in Annex VI nor an Annex VI proposal has been submitted. The substance is self-classified by the registrant as Flam. Liquid 3 (H226), Skin Sens. 1B (H317), and Aquatic Chronic 2 (H411). We note that two intermediate registrants self-classify p-Chloro-α,α,α-trifluorotoluene as Flam. Liquid 3 (H226), Skin Irrit. 2 (H315), Eye Irrit. 2 (H319), STOT SE 3 (H335) and Aquatic Chronic 2 (H411).

Available data from a reliable NTP study suggests that 4-chloro-α,α,α-trifluorotoluene could be harmonized under CLP as Carc. 2. Reproductive effects found at doses levels of

1000 ppm and higher can as well lead to Repro. 2 classification. Also, according to the ECHA website[2], a majority of data submitters agree that the substance is skin sensitising, Skin Sen. 1B.

Harmonized classification will ensure that the hazards presented by the substance are clearly communicated to workers and consumers and bring about the implementation of proper risk management measures.

In relation to workers a Carc. 2 classification would not lead to further risk management measures as set out for substances classified as 1A or 1B Carcinogen under the Carcinogens and Mutagens Directive (Directive 2004/37/EC). The directive states that the use of a carcinogen or mutagen at the workplace, shall be avoided or minimize exposure as far as technically possible.

The preparation of an proposal for harmonized classification and labelling for Annex VI entry is therefore considered a potential risk management option for p-Chloro-α,α,α-trifluorotoluene.

3.2 Restriction under REACH

Restriction applies if there is an unacceptable risk to human health or the environment arising from the manufacture, use or placing on the market of substances which needs to be addressed on a community-wide basis. 4-chloro-α,α,α-trifluorotoluene is used as a solvent in paints and as an industrial intermediate of other chemicals. The volume of 4-chloro-α,α,α-trifluorotoluene affected by this risk management option will be small (90 t/a) in comparison to the total volume of manufactured and used (4000 t/a). It is noted, that the use of 4-chloro-α,α,α-trifluorotoluene has increased the United States since it was exempted from the EPA as a volatile organic with non-ozone depleting status, resulting in higher end-user applications than other solvents. It is unclear if this trend will also ensue in Europe.

Based on the information from the CSR, there is concern for workers involved in the use of 4-chloro-α,α,α-trifluorotoluene during the formulations, uses by professional workers and consumers. A total ban on the manufacture and use of the substance would prevent all (potential) health risks. Restriction of specific uses could be considered however based on the information from the CSR and to the knowledge of the eMSCA, there is no data or information suggesting an urgent human health risk for society. Consequently, based on the currently available information, restricting the use or application to 4-chloro-α,α,α-trifluorotoluene via a ban on the substance or a targeted restriction of use or application in certain uses of the substance does not seem proportional for human health risks.
However, we would like to point out that the national authorities of Germany, the Netherlands, Norway, Sweden and Denmark did agree on preparing a restriction proposal suggesting to restrict all fluorinated substances that contain 1 or more C atoms on which all the H substituents have been replaced by F atoms, in such a manner that they contain at least one aliphatic perfluorocarbon moiety such as -CnF2n-". 4-Chloro-α,α,α-trifluorotoluene is included by this definition. The main concern for the group of these fluorinated substances is their persistence and the consequences of their use, e.g. their practically not reversible presence in the environment.

3.3 Substance evaluation

In the CSR, the derived risk characterization ratios for several exposure scenarios are above the trigger of 1. The registrant states that the RCRs would be below 1 (depending on the scenario) if the respiratory protection would be raised in to 95% reduction efficiency, dermal protection would be raised to 90% - 95% reduction efficiency or

[2] https://echa.europa.eu/nl/substance-information/-/substanceinfo/100.002.438

maintenance and cleaning is carried out only periodically.

If the final risk characterization, shows that, based on the initial exposure scenario, risks are not controlled (RCRs > 1), further refinement of the CSA would be needed. We note that the registrant did not apply any refinements to reduce the RCRs. As a result, control of risk and safe use of the substance for several exposure scenarios has not been sufficiently demonstrated.

In addition to the above, the exposure assessment and risk characterization for the consumer is missing. The registrant states that exposure assessment for consumers is not applicable as there are no consumer-relate uses for the substance. According to the dissemination site the substance is used in the following products: Coatings and paints, thinners, paint removes (PC 9a), and ink and toners (PC 18). Consumer exposure is possible. REACH requires, according to Article 14(4), exposure assessment and subsequent risk characterization to be carried out for substances subject to registration, which are manufactured or imported in quantities equal to or greater than 10 tonnes/year, and where the substance fulfils the criteria for any of the hazard classes or categories listed in that provision or is assessed to be a PBT or vPvB. We note that the registrant classified as Flam. Liquid 3 (H226), Skin Sens. 1B (H317), Aquatic Chronic 2 (H411); therefore, it fulfills the criteria set out in Article 14(4) of the REACH regulation to require and exposure assessment and a risk characterization in the chemical safety report.

Based on this information, a compliance check of the registration dossier may be warranted. In order to address the lack of compliance in the registration dossier, this risk management option should be considered by ECHA.

Listing the substance on CoRAP followed by substance evaluation is not considered a suitable regulatory management option given the additional studies from the US on reproduction and carcinogenicity. There are no remaining issues on (eco)toxicological properties that need to be sorted out.

3.4 Other Union-wide regulatory measures

Worker legislation (setting an OEL):

OELs are not established for 4-chloro-α,α,α-trifluorotoluene. For substances for which exposure in the workplace is expected, risks can be controlled by setting an OEL. Establishing an OEL for 4-chloro-α,α,α-trifluorotoluene would minimize worker exposure in the workplace. Such a limit should take into account the available toxicity data, particularly with respect to carcinogenicity and potential toxicity to reproduction. If 4-chloro-α,α,α-trifluorotoluene is to be classified according to the CLP regulation, then indicative or binding OELs could be established. We believe that 4-chloro-α,α,α-trifluorotoluene would be covered by the Chemical Agents Directive (98/24/EC). The Chemical Agents Directive lays down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents. This risk management option could be considered as a possibility.

An United States importer of 4-chloro-α,α,α-trifluorotoluene has issued a permissible exposure limit of 20 ppm for an 8-hour shift (NTP, 2009). The Occidental Chemical Corporation, which used to manufacture 4-chloro-α,α,α-trifluorotoluene in the United States established a corporate exposure limit (CEL) which was a TWA limit of 25 ppm (185 mg/m^3) for an 8-hour shift. The toxicological bases for setting this limit is unknown (Lee et al. 2015).

Occupational exposure has been assessed by the National Institute for Occupational Safety and Health (NIOSH) in vehicle and paint manufacturing plants using industrial hygiene sampling methods across a number of job tasks in each industry (Lee et al., 2015). The geometric mean of personal exposures was 2.1 ppm and 0.7 ppm at the vehicle and painting manufacturing plants, respectively. Most personal exposures were lower than 10 ppm, with the exception of a single interior refurbishment worker in one of the vehicle manufacturing plants (12.2 ppm). This study did not assess exposures in other occupational settings (e.g., autobody repair), which may be higher than was observed by Lee et al. (2015).

4. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

Voluntary measures at the workplace:

Risk management measures to control the risk of exposure such as respiratory protective equipment (RPE) and general good occupational hygiene practices are reported in the CSR. Industry is already obliged to strictly control the production process.

At present, the CSR reports risk characterization ratios above 1 for several worker scenarios (manufacture synthesis of PCTB, formulation process and general industrial use of diluent for paints). In order to ensure that the registration dossier is compliant with REACH requirements, the registrant should refine the scenarios to ensure that risks are adequately controlled taking into account i.e. the use of additional or modified ventilation arrangements and respiratory or dermal protective equipment (PPE). This measure is considered to be sufficient in controlling the risk of exposure to suspected carcinogenic substances. However, this is not considered to be an RMO, registrants are obligated to refine the CSR and to lower the RCR's below 1. ECHA can ask the registrants in the dossier evaluation process for making these refinements in the dossier and the CSR.

5. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Follow-up action	Date for intention	Actor
Draft an annex VI proposal		