Helsinki, 16 June 2017

Substance name: Quaternary ammonium compounds, di-C16-18-alkyldimethyl, chlorides
EC number: 295-835-2
CAS number: 92129-33-4
Date of Latest submission(s) considered[1]: 5 February 2015
Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F)
Addressees: Registrant(s)[2] of Quaternary ammonium compounds, di-C16-18-alkyldimethyl, chlorides (Registrant(s))

DECISION ON SUBSTANCE EVALUATION

1. Requested information

Based on Article 46(1) of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), you are requested to submit the following information on the registered substance:

Environmental exposure-related request: justification for non-default assumption regarding release factors.

You shall provide an update of the registration dossier(s) containing the requested information and, where relevant, an update of the Chemical Safety Report by **23 March 2018.**

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Further information, observations and technical guidance as appropriate are provided in Appendix 3. Appendix 4 contains a list of registration numbers for the addressees of this decision. This Appendix is confidential and not included in the public version of this decision.

2. Appeal

You can appeal this decision to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals

Authorised[3] by Leena Ylä-Mononen, Director of Evaluation

[1] This decision is based on the registration dossier(s) at the end of the 12 month evaluation period.

[2] The terms Registrant(s), dossier(s) or registration(s) are used throughout the decision, irrespective of the number of registrants addressed by the decision.

[3] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

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Appendix 1: Reasons

Based on the evaluation of all relevant information submitted on Quaternary ammonium compounds, di-C16-18-alkyldimethyl, chlorides and other relevant available information, ECHA concludes that further information is required in order to enable the evaluating Member State Competent Authority (MSCA) to complete the evaluation of whether the substance constitutes a risk to the environment.

The evaluating MSCA will subsequently review the information submitted by you and evaluate if further information should be requested in order to clarify the concern for the environment.

Environmental exposure-related request: justification for non-default assumption regarding release factors

The requested information is needed in order to verify the concern related to the environmental risk characterization ratios (RCR) for aquatic compartment.

For the exposure scenario (ES) "Formulation of pastilles" you provided the RCR values for the aquatic compartment (freshwater and marine water) of 0.576. You declared that the predicted environmental concentrations (PECs) were calculated in a tiered assessment using release factors from the Technical Guidance Document (TGD, 2003). However, the evaluating MSCA noted that the adopted release factors are one order of magnitude lower than the corresponding TGD values related to the industrial and use category you declared (IC3 - *chemical industry: chemicals used in synthesis* and UC9 - *absorbents and adsorbents)*.

You justified the used release factors on the basis of tightly controlled processes. This is a generic, qualitative statement and it is not sufficient to justify the use of lower release factors. According to the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation, the use of non-default release factors shall be clearly explained and justified. The Guidance reports that "Exposure scenarios making reference to the A and B tables of the TGD (2003) without providing more specific information on the conditions of use are considered insufficient to meet the REACH requirements". You did not provide a clear and detailed justification, based on both adopted Risk Management Measures/Operational Conditions and substance properties.

The evaluating MSCA noted that the assumed release factors underestimate RCR values for the aquatic compartment (freshwater and marine water) for the abovementioned ES: the use of default ERC release factors determines RCR values higher than 1.

Therefore, based on the substance evaluation and pursuant to Article 46(1) of the REACH Regulation, ECHA concludes that you are requested to provide detailed information on operational conditions and risk management measures, which are clear and well documented in order to justify the adoption of release factors different from the default ERC ones. Otherwise, you are requested to provide the quantitative exposure assessment using the default ERC release factors and to update accordingly the risk characterization.

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Appendix 2: Procedural history

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to wide dispersive use, exposure of environment, high (aggregated) tonnage, Quaternary ammonium compounds, di-C16-18-alkyldimethyl, chlorides, CAS No 92129-33-4 (EC No 295-835-2) was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2015. The updated CoRAP was published on the ECHA website on 17 March 2015. The Competent Authority of Italy (hereafter called the evaluating MSCA) was appointed to carry out the evaluation.

Pursuant to Article 45(4) of the REACH Regulation the evaluating MSCA carried out the evaluation of the above substance based on the information in your registration(s) and other relevant and available information.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 17 March 2016.

On 26 April 2016, ECHA sent the draft decision to you and invited you pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision. This deadline includes an extra seven-day period as addressed in the last update point 9(d) of the Terms of Conditions of REACH-IT.

On 2 June 2016 you submitted your comments to ECHA. ECHA forwarded them to the evaluating MSCA without delay.

The evaluating MSCA took the comments, which were sent within the commenting period, into account and they are reflected in the reasons (Appendix 1). The request and the deadline were not amended.

The evaluating MSCA notified the draft decision to the competent authorities of the other Member States and ECHA for proposal(s) for amendment.

As no amendments were proposed, ECHA took the decision according to Articles 52(2) and 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided by you in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on your dossier(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.