EUROPEAN CHEMICALS AGENCY

Helsinki, 23 July 2019

Addressee: [redacted]

Decision number: CCH-D-2114476330-54-01/F
Substance name: Quaternary ammonium compounds, benzyl-C16-C18 (even numbered)-alkyldimethyl, chlorides
List number: 939-290-7
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 27/04/2016
Registered tonnage band: 100-1000

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: CO2 evolution test, OECD TG 301B) or**

   Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: MITI test (I), OECD TG 301C) or

   Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Closed bottle test, OECD TG 301D) or

   Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Manometric respirometry test, OECD TG 301F) or

   Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Ready biodegradability – CO2 in sealed vessels (headspace test), OECD TG 310) with the registered substance.

You have to submit the requested information in an updated registration dossier by ***30 January 2020***. You shall also update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

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Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to 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[1] by **Claudio Carlon**, Head of Unit, Hazard Assessment

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

Appendix 1: Reasons

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

1. Ready biodegradability (Annex VII, Section 9.2.1.1.)

"Ready biodegradability" is a standard information requirement as laid down in Annex VII, section 9.2.1.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided a study record for a ready biodegradability study entitled [redacted] (2010) conducted according to OECD TG 301D with the registered substance, key study, reliability 1, GLP compliance: yes. However, this study does not provide the information required by Annex VII, Section 9.2.1.1., because it is not valid.

More specifically, ECHA notes that:

a. in the test material description, you specify that the test substance contains "*2-propanol (12.4%)*". ECHA notes that 2-propanol is not a constituent of the registered substance. ECHA considers that the presence of 2-propanol may be responsible for some of the measured O_2 consumption and that the results of this study likely overestimate the biodegradability of the registered substance under the conditions of this test.

b. you state that: "*ammonium chloride was omitted from the medium to prevent oxygen consumption due to nitrification*". However, ECHA notes that some nitrification could occur due to the presence of nitrogen in the test material itself. According to OECD 301D, corrections for uptake of oxygen by nitrification should be made. ECHA notes that you did not report such a correction in your robust study summary.

In your comments on the draft decision, you acknowledge that co-solvents (2-propanol and water) were present in the test material but indicate that the presence of 2-propanol was accounted for in the ThOD (Theoretical Oxygen Demand) calculation. You state that "*the overall percentage biodegradation calculation for the test substance does take into account possible oxygen consumption due to the biodegradation of 2-propanol and does not overestimate the biodegradability of the active*". You further consider that these two carbon sources "*are degraded by different sets of micro-organisms*".

ECHA disagrees that the test does not overestimate the biodegradability of the active substance. Firstly, it is likely that the active ingredient (i.e. the quaternary ammonium compounds) and 2-propanol likely show differing degradation kinetics (2-propanol is known to biodegrade very fast under the conditions of ready biodegradability tests). Accordingly, it may be assumed that 2-propanol was fully degraded by the end of the study period and hence the % biodegradation of the active substance would *de facto* be overestimated. Then the assertion that quaternary ammonium compounds and 2-propanol are degraded by different sets of micro-organisms is insufficient to demonstrate that the addition of a

significant amount of an easily metabolized source of carbon in the test did not influence the degradation kinetics of the active substance. ECHA also emphasizes that the OECD TG 301 and ECHA Guidance on Information Requirement and Chemical Safety Assessment, Chapter R.7b, section R.7.9.1.1 specifies that the substance being tested should be the sole source of organic carbon for energy and growth. Taken together with the other deficiencies discussed below, ECHA does not consider this study as valid and consequently concludes that it does not support the conclusion that the registered substance is readily biodegradable.

You also specify in your comments that you intend to update your technical dossier with biodegradability studies conducted on analogue substances. You refer to a study by [redacted] (1992) on C12-16 ADBAC (EC number 939-253-5) and [redacted] (2005) on C18 TMAC (EC number 203-929-1). You indicate that the category justification has been updated in the context of the registrations for other similar substances in 2018 and that a read-across justification following the RAAF (read across assessment framework)will be submitted in a dossier update. Finally, you state that the "*read across between the ADBACs and the TMACs has also been supported in the biocides dossier evaluation for Coco alkyltrimethylammonium chloride (CAS 61789-18-2)*".

ECHA will evaluate any additional information in your dossier at the follow-up stage of the compliance check. However, ECHA would like to point out that there are ongoing compliance check on similar substances (i.e. EC number 939-350-2 and 939-253-5) and similar deficiencies were identified in the study by [redacted] (1992). ECHA further notes that the registration dossier of C18 TMAC (EC number 203-929-1) does not contain a study referred to as [redacted] (2005).

Regarding point b., you state that "*Ammonium chloride is omitted from the test medium to prevent oxygen consumption by nitrifying bacteria. The reason for this omission is to lower the endogenous oxygen consumption in the BOD bottles*". ECHA understands that you consider that nitrification of ammonium can occur.

You also provide a calculation of the $ThOD_{NH3}$ (Theoretical Oxygen Demand without nitrification) and $ThOD_{NO3}$ (Theoretical Oxygen Demand with nitrification) of the test material and state that "*using the $ThOD_{NO3}$ of 2.66 g/g would result in a biodegradation percentage of 60.1, not allowing classification of the substance as readily biodegradable*". However, you consider that "*the use of $ThOD_{NO3}$ is not obligatory for all nitrogen-containing test substances*". You also state that "*organic nitrogen is always liberated by microorganisms as ammonium when nitrogen is present as primary amine (amino group), secondary amine group, tertiary amine or quaternary ammonium group*".

ECHA agrees that ammonium will likely be released upon the degradation of quaternary ammonium compounds by micro-organisms. It is probable that ammonium may then undergo nitrification. Therefore, the ThOD correction for nitrification need to be applied. As already explained above, ECHA also considers that the reported value does not reflect the biodegradation percentage of the active substance (as it assumes identical degradation kinetics between the solvent and the active substance which is unlikely). ECHA concludes that even under the conditions of this modified OECD TG 301D study the results do not support that the active substance is readily biodegradable.

ECHA further notes that the inoculum density is reported as "2 mg DW/L" and it remains therefore unclear if the cells concentration in the test bottles was within the acceptable range (i.e. 10^4-10^6 cells/L) of OECD TG 301D.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to perform one of the following tests with the registered substance subject to the present decision:

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: CO2 evolution test, OECD TG 301B) or

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: MITI test (I), OECD TG 301C) or

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Closed bottle test, OECD TG 301D) or

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Manometric respirometry test, OECD TG 301F) or

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Ready biodegradability – CO2 in sealed vessels (headspace test), OECD TG 310).

Depending on the substance profile, you may conclude on ready biodegradability, by applying the most appropriate and suitable test guideline among those listed in the ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) and in the paragraph above. The test guidelines include the description of their applicability domain.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 20 November 2017.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the request.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment.

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

Appendix 3: Further information, observations and technical guidance

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

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

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.