ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 10 December 2018

Addressee: [redacted]

Decision number: CCH-D-2114453448-42-01/F
Substance name: Dihexadecyl peroxodicarbonate
EC number: 247-611-0
CAS number: 26322-14-5
Registration number: [redacted]
Submission number: [redacted]
Submission date: 15/02/2018
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. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance or with analogue substance ditetradecyl peroxydicarbonate (EC number: 258-436-4, CAS number: 53220-22-7);**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **17 December 2020**. You also have to 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.

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 **Kevin Pollard**, Head of Unit, Evaluation, **E1**

[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

1. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

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.

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9 ., column 2 of the REACH Regulation. You provided the following justification for the adaptation:

> "*According to column II of REACH Annex IX the study can be waived since the substance does not show short-term toxicity and is readily biodegradable. No long-term exposure to the substance is expected*".

ECHA notes that the water solubility of the registered substance is very low: < 1 µg/L. Poorly soluble substances require longer time to be significantly taken up by the test organisms and so steady state conditions are likely not to be reached within the duration of a short-term toxicity test. Therefore, short-term tests may not give a true measure of toxicity for poorly soluble substances and toxicity may actually not even occur at the water solubility limit of the substance if the test duration is too short. ECHA notes that no effects were observed in the short-term tests reported in your dossier. Still, long-term toxicity cannot be excluded and should be investigated. In particular, Annex VIII 9.1.3. of the REACH Regulation explicitly recommends that a long-term toxicity test on fish should be considered if the substance is poorly water soluble.

ECHA acknowledges that the registered substance is rapidly biodegradable. ECHA further acknowledges that, according to the uses reported in the registration dossier, releases of the registered substance to the water compartment will probably be low, but also notes that you have not performed any quantitative exposure assessment for the environment.

ECHA further notes that appropriate information on toxicity to fish is necessary for the derivation of predicted no effect concentrations (PNEC) and should be considered for the classification and labelling of the substance. Annex I, Section 3 of the REACH Regulation requires an environmental hazard assessment to be conducted and Step 3 of that section requires PNECs to be established. According to the guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R7b, Section R.7.8.5.3, the chemical safety assessment is to be based on all available toxicity information, and the information used for the derivation of the PNEC for water should at least cover species of three trophic levels: algae/aquatic plants, invertebrates (*Daphnia* preferred), and fish. However, ECHA notes that you have reported only short-term data for fish, whereas, as explained above, short-term data are not suitable for poorly soluble substances. Adequate information on the toxicity to fish is thus missing and no sufficient information is available for deriving the PNEC.

Therefore, ECHA considers that your CSA does not rule out the need to further investigate long-term effects on aquatic organisms and therefore that your adaption does not meet the specific rules for adaptation of Annex IX, Section 9., column 2 of the REACH Regulation and cannot be accepted. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) fish early-life stage (FELS) toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) can be performed to cover the standard information requirement of Annex IX, Section 9.1.6.

However, the FELS toxicity test according to OECD TG 210 is more sensitive than the fish, short-term toxicity test on embryo and sac-fry stages (test method EU C.15 / OECD TG 212), or the fish, juvenile growth test (test method EU C.14. / OECD TG 215), as it covers several life stages of the fish from the newly fertilized egg, through hatch to early stages of growth (see ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), *Chapter R7b, Section R.7.8.4.1*).

Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of substances which are expected to cause effects over a longer exposure period, or which require a longer exposure period of time to reach steady state (ECHA *Guidance Chapter R7b,* version 4.0, June 2017).

In your comments following the procedure set out in Article 50(1) of the REACH Regulation you have indicated your agreement to provide this information.

You also explained your strategy for choosing the test substance. Analogue substance ditetradecyl peroxydicarbonate (EC number: 258-436-4, CAS number: 53220-22-7) is considered to be more toxic than the registered substance. Consequently, you contacted the lead registrant of ditetradecyl peroxydicarbonate to discuss the commissioning of a fish, early-life stage (FELS) toxicity test according to OECD TG 210 with that analogue substance. The result of that study could be applicable to both ditetradecyl peroxydicarbonate and, as a worst case, to the registered substance. The results for a long-term study on *Daphnia* with ditetradecyl peroxydicarbonate will also become available. If no effects are observed up to the water solubility limit in this *Daphnia* study, then you proposed to use the results of the long-term fish study with ditetradecyl peroxydicarbonate as a read-across adaptation for the long-term toxicity study on fish requested in the present decision. If, on the contrary, effects are noted below the water solubility limit in the *Daphnia* study, then you indicated that you would perform the long-term fish study with the registered substance. ECHA agrees with this strategy.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision or with analogue substance ditetradecyl peroxydicarbonate (EC number: 258-436-4, CAS number: 53220-22-7): Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Notes for your consideration

ECHA informs you that it has recently notified a draft decision on compliance check to the lead registrant of analogue substance ditetradecyl peroxydicarbonate (EC number: 258-

436-4, CAS number: 53220-22-7). This registrant has been requested to conduct long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with ditetradecyl peroxydicarbonate. You may consider contacting this registrant to use the results from his study as a possible read-across adaptation for the long-term toxicity study on fish requested in the present decision. Further advice can be found in the ECHA Guidance on data sharing (version 3.1, January 2017).

Due to the low solubility of the substance in water you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 REV1 (6 July 2018) and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

If based on the results of the required study fish is observed to be the most sensitive species, then the PNECs will have to be revised accordingly.

The registered substance is currently not classified for environmental endpoints. As explained above, new information on long-term toxicity to fish might warrant the need for classifying the substance for aquatic toxicity.

Deadline to submit the requested information in this decision

ECHA notes that timeline in the present decision has been set in order to allow you to take into account the results of the tests for analogue substance ditetradecyl peroxydicarbonate (EC number: 258-436-4, CAS number: 53220-22-7). However ECHA reminds you that it is your responsibility to bring the dossier to compliance within the set deadline.

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 19 January 2018.

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 amended the request(s).

ECHA notified the draft decision to the competent authorities of the Member States for proposals 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.

4. If the required tests are conducted with an analogue substance in the context of a read-across approach, the identity of the test material used to perform the test should be specified in line with ECHA's Practical Guide on "How to use alternatives to animal testing to fulfil your information requirements" (chapter 4.4). This is required to show that the test material is representative of the analogue substance identified in the read-across approach and used to predict the properties of the registered substance.