EUROPEAN CHEMICALS AGENCY

Helsinki, 27 September 2017

Addressee: [redacted]

Decision number: CCH-D-2114370491-51-01/F
Substance name: 2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE
EC number: 203-652-6
CAS number: 109-16-0
Registration number: [redacted]
Submission number: [redacted]
Submission date: 16.11.2015
Registered tonnage band: 100-1000T

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;**

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 **4 October 2018**. 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 Ofelia Bercaru, Head of Unit, Evaluation E3

[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.

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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 9.1.6., column 2. You provided the following justification for the adaptation *"Long-term testing in fish is waived for TREGDMA since the substance is rapidly metabolised and readily biodegradable. None of the other ecotoxicological endpoints indicate hazards to the aquatic environment, hence, there is no need for further information or testing. According to REACH regulation Annex IX, 9.1. column 2, long-term toxicity testing shall only be considered when the chemical safety assessment indicates the need for further investigations. Because there is no indication of major differences in sensitivity between trophic levels and in the absence of any significant long-term bioaccumulation potential it is not necessary to perform further chronic fish tests with the substance. The environmental risk assessment can be performed with sufficient reliability with the available long-term ecotoxicity data. Thus, no long-term toxicity testing is required for TREGDMA."*

ECHA notes that contrary to your claim, information present in your dossier indicates the need to investigate further the effects on aquatic organisms, as explained below.
Firstly, although your statement pointing out that *"the substance is rapidly metabolised and readily biodegradable"* may allow conclusion of PBT properties of the substance, it, however, does not allow to conclude on risk assessment and thus the entire CSA. Ready biodegradability and biotransformation properties do not exclude the potential of toxic effects, neither exclude completely exposure of the aquatic environment.

Secondly, your statement that *"None of the other ecotoxicological endpoints indicate hazards to the aquatic environment"* is not supported, or in fact it is contradicted, by the information provided in the technical dossier, where a hazard is reported for a short-term fish: 4-d LC50 value of 16.4 mg/L.

Thirdly, you have argued that *"Because there is no indication of major differences in sensitivity between trophic levels and in the absence of any significant long-term bioaccumulation potential it is not necessary to perform further chronic fish tests with the substance".* ECHA understands that you refer to integrated testing strategy (ITS) described in ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4).

ECHA notes that according to this ECHA Guidance, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially less sensitive than other trophic levels (i.e., fish, invertebrates, algae), long-term studies may be required on both fish and invertebrates. In such case, according to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, ECHA notes that this ITS approach cannot be applied in this case because you have not provided short-term toxicity data for aquatic invertebrates that would allow determination of relative species sensitivity. Therefore the standard information requirement of long-term toxicity to fish cannot be adapted based on ITS for aquatic pelagic toxicity.

Lastly, you have argued that "*According to REACH regulation Annex IX, 9.1. column 2, long-term toxicity testing shall only be considered when the chemical safety assessment indicates the need for further investigations".* ECHA notes, that you have not clearly justified that risk assessment may be concluded using the current data. In particular, ECHA considers that the risk characterisation provided in your CSR relies on an inappropriate justification for the use of an assessment factor of 100. You justify the current PNEC freshwater derivation by "*The PNEC aqua (freshwater) was based on the LC50 of 16.4 mg/L determined in a short term toxicity study with Danio rerio. Two chronic studies were available for this substance, which covered two trophic levels (algal and invertebrates). However, these were not the most sensitive trophic levels in the short-term tests. An assessment factor of 100 was applied to the LC50 to calculate the PNEC aqua (freshwater).*"

ECHA notes that according to ECHA Guidance on information requirements and chemical safety assessment (May 2008), Chapter R10 (Section R.10.3.1.2, including Table R.10-4), an assessment factor of 100 applies to a single long-term result (e.g. EC10 or NOECs) (fish or Daphnia) if this result was generated for the trophic level showing the lowest L(E)C50 in the short-term tests. If the only available long-term result (e.g. EC10 or NOECs) is from a species (standard or non-standard organism) which does not have the lowest L(E)C50 from the short-term tests, it cannot be regarded as protective of other more sensitive species using the assessment factors available. You state that the PNEC was derived based on data that "*were not the most sensitive trophic levels in the short-term tests*". ECHA considers that the PNEC derivation should be based on an assessment factor with an appropriate justification and you have not provided an appropriate justification for using an the assesment factor of 100. ECHA considers based on the available information in the technical dossier, an assessment factor of 1000 is more appropriate. As a result of using an assessment factor of 1000, an increased risk can be clearly demonstrated.

Therefore, the risk assessment in its current form cannot be concluded and your adaptation of the information requirement cannot be accepted.

In your comments to the draft decision, you indicate an intention to update the PNEC assessment factor, update the exposure assessment and risk assessment. As outlined above, ECHA notes that when using a higher assessment factor for PNEC derivation, an increased risk and a need for long-term testing may still be demonstrated. ECHA acknowledges that the risk assessment may be re-iterated by refining the hazard data (deriving PNECs on the basis of long-term data instead of short-term data for example) and/or by refinement of exposure concentrations, if the risk characterisation indicates risks occurring from the manufacture and all identified uses (RCR > 1).

ECHA points out that the exposure assessment should be performed in accordance with the guidance on how to carry out environmental exposure assessment in the context of REACH (ECHA Guidance on information requirements and chemical safety assessment, Chapter R.16, version 3.0, February 2016). The applied refinements in exposure assessment should be accompanied by justification and supporting evidence.

ECHA notes that you have not updated the dossier. Any new information provided in an updated dossier will be evaluated in the Dossier Evaluation Follow-Up Process to come to a conclusion on whether the information provided adequately fulfils the information requirements addressed in the decision.

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.

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) are the preferred tests 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, Figure R.7.8-4).

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).

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: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

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 23 November 2016.

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(s).

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.

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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.

4. 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.

5. 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.