EUROPEAN CHEMICALS AGENCY

Helsinki, 23 February 2017

Addressee: [redacted]

Decision number: TPE-D-2114354658-37-01/F
Substance name: 1,10-decanediyl diacrylate
EC number: 235-922-4
CAS number: 13048-34-5
Registration number: [redacted]
Submission number: [redacted]
Submission date: 16.11.2015
Registered tonnage band: 100-1000T

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA has taken the following decision.

Your testing proposal is accepted and you are requested to carry out:

1. **Long-term toxicity on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Earthworm reproduction test, OECD TG 222) using the registered substance.**

You are requested to perform as additional test:

2. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD TG 216) using 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 of the REACH Regulation. In order 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 an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **2 March 2018**. 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. 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, 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[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

The decision of ECHA is based on the examination of the testing proposal(s) submitted by you.

1. **Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2)**

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. This means that you need to address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.). Column 2 of section 9.4 of Annex IX specifies that you shall consider long-term toxicity testing instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The information on "long-term toxicity to invertebrates" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a long-term toxicity test to invertebrates (Earthworm Reproduction Test (*Eisenia fetida/ Eisenia andrei*), OECD TG 222) with the following justification:"*Considering that there is no indication of high persistence or high adsorption and that the test substance is very toxic to aquatic organisms, it has to be assigned in soil hazard category 2 according to Table R.7.11-2, Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 1.1, November 2012). Moreover, according to the section R.7.11.5.3., Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 1.1, November 2012), "the data required should cover not just different taxa but also different pathways of exposure (e.g. feeding, surface contact), and this should be taken into account when deciding on the adequacy and relevance of the data. Thus earthworm testing allows potential uptake via each of surface contact, soil particle ingestion and porewater, while plant exposure will be largely via porewater.". Therefore, the registrant proposes to perform a long-term test on soil earthworm according to the OECD 222 testing guideline*.".

According to Section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance could have a high potential to adsorb to soil. Thus, measured log K_{ow} is very close to being >5 and high adsoprtion probability cannot be excluded (logK_{ow} =5.0). Moreover, in your comments to the draft decision regarding the extension of the timeline, you have stated that the substance has a high adsoprtion potential.

This would indicate the substance has the potential to fall into Soil Hazard Category 4 according to Table R.7.11-2, chapter R.7c of the ECHA Guidance (v2.0, Nov 2014). Therefore ECHA agrees that a long-term testing is indicated and the proposed test is appropriate to fulfil the information requirement of Annex IX, Section 9.4.1., column 2.

A Member State Competent Authority (MSCA) proposed to amend the decision to include a request for a long-term toxicity testing on plants on the basis that they consider the substance falls into a soil Hazard Category 4. The MSCA considers the long-term toxicity testing on plants important, as algae appears to be the most sensitive aquatic species, and therefore, terrestrial plants might belong to the most sensitive soil organisms. The MSCA also indicated that in case the request for three soil toxicity tests would not be supported, their preferred option is to request the long-term toxicity test on plants instead of the long-term toxicity test on terrestrial invertebrates.

In your comments to the proposal for amendment, you indicated the following, "*Considering that there is no indication of high persistence (78.8% at Day 28) or high adsorption (log Kow = 5) and that the test substance is very toxic to aquatic organisms, the substance has to be assigned in soil hazard category 2 according to Table R.7.11-2, Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014). Therefore, the registrant agrees the ECHA's draft decision to perform long-term toxicity tests on soil microorganisms according to OECD testing Guideline 216 and on terrestrial invertebrates according to OECD testing Guideline 222. However, the registrant has no objections to change this last test by a long-term toxicity test on plants as described in OECD testing Guideline 208.*
Based on the results obtained in the long-term test proposed, a $PNEC_{soil}$ will be derived. According to Table R.7.11-2, "If $PEC_{soil}/PNEC_{soil}$ < 1: No additional long-term toxicity testing for soil organisms need to be done. If $PEC_{soil}/PNEC_{soil}$ > 1: Conduct additional or higher Tier test on soil organisms.". If the $PEC/PNEC_{soil}$ is higher than 1, another long-term toxicity tests will be proposed".

As stated above, based on the properties of the substance, this would indicate the substance has the potential to fall into Soil Hazard Category 4. However, ECHA notes that the substance is readily biodegradable, has log Kow equal to 5 and all short term aquatic E/LC50s are below 1 mg/l. Thus, the substance is very toxic to aquatic organisms. However, it is neither persistent (being readily biodegradable) nor formally meets the criterion for high adsorption potential indicated in the integrated testing strategy for soil toxicity testing (ECHA IR&CSA Guidance R.7c., Table R.7.11—2 indicates that highly adsorptive are those with log Kow > 5). Thus, based on available information in the technical dossier, ECHA considers that the substance has a Soil Hazard Category classification of 2.

Regarding the aquatic species sensitivity, ECHA notes that although *Daphnia* (EC50 (48h) = 308.4 µg/L) shows toxic effects at a higher concentration than algae (ErC50 (72h) = 50 µg/L), the difference is below a factor of 10, and therefore sensitivity difference cannot be conclusively concluded (ECHA Guidance R7b, Section R.7.8.5.3). Furthermore, "*care should be taken as the aquatic test does not cover the same species groups as in the terrestrial system.*" (ECHA Guidance R7c, Section R.7.11.4.1.). Also, in addition, in the ECHA Guidance R7c, Section R.7.11.5.3. it states "*in the absence of a clear indication of selective toxicity, an invertebrate (earthworm or collembolan) test is preferred.*"

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study using the registered substance subject to the present decision:

- Earthworm reproduction test (OECD TG 222).

2. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.).

You have sought to adapt the information requirement for "effects on soil micro-organisms". You provided the following justification for the adaptation "*No toxicity on aquatic microorganisms was observed at 100 mg/L in the screening biodegradation test (OECD 301). The test substance is readily biodegradable with high value (78.8%) reached at Day 28. Therefore, the hazard of the test substance for soil-micro-organisms is estimated as low. Indeed, aquatic as well as terrestrial microorganisms are embedded in a biological matrix, also called the biofilm, which is composed of particles, extracellular polymeric substances and microorganisms. This matrix plays a key role in the response of organisms to toxic exposure. Free microorganisms are more sensitive than the same organisms embedded in biofilm. As the test substance was not toxic at 100 mg/L on free microorganisms in the OECD 301 test, it would be also no toxic on microorganisms embedded in biofilm such as terrestrial microorganisms. Based on this information, no test to assess the long-term toxicity on these organisms is proposed".*

ECHA considers that the fact of not observing toxicity on sewage sludge bacteria population does not mean that the pathways of other type of microorganism population would not be affected by that same substance. This being, among others due to the vast bacteria population diversity. Besides, ECHA notices that microorganisms in the sewage sludge are also partially incorporated in biofilms. ECHA notes that no scientifically sound justification has been provided that proves that the soil microorganisms are less sensitive to the registered substance than the activated sludge of a predominantly domestic sewage.

Therefore, your adaptation of the information requirement cannot be accepted. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA notes that the proposed test that ECHA accepted under point 1 above is not sufficient to address this standard information requirement. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test.

To address this endpoint, either a nitrogen transformation test (test method: EU C.21/OECD TG 216) or a carbon transformation test (test method: EU C.22/OECD TG 217) could be performed. According to Section R.7.11.3.1, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), ECHA considers the nitrogen transformation test (EU C.21/OECD TG 216) suitable for non-agrochemicals. For agrochemicals the carbon transformation test (EU: C.22/OECD TG 217) is also required.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the following additional test using the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216.

Notes for your consideration

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4.3. does not apply for the present endpoint.

3. Deadline to submit the requested Information

In the draft decision communicated to you the time indicated to provide the requested information was 9 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 12 months. You sought to justify this request by expressing a concern, among others, that it is a difficult to test substance, has high adsorption potential and preparing the test material will be complex and require technical adaptations in CRO.

ECHA acknowlegdes that due to the difficult to test properties of the substance extension of the timeline is justified. Therefore, ECHA has granted the request and set the deadline to 12 months.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposal(s) for examination pursuant to Article 40(1) on 16 November 2015.

This decision does not take into account any updates after **10 May 2016**, 30 calendar days after the end of the commenting period.

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 one of the requests and the deadline.

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

ECHA received proposal(s) for amendment and did not modify the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

You provided comments on the proposed amendment(s). However, due to an administrative oversight, your comments on the proposed amendment(s) were not submitted to the Member State Committee for their consideration for the MSC 50 timeline.

However, your comments on the proposed amendment(s) were taken into account by the Member State Committee for the MSC 52 timeline.

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-52 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

2. Failure to comply with the requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

3. In carrying out the tests required by the present decision it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new tests must be suitable to assess these. Furthermore, 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.