Decision number: TPE-D-2114343929-35-01/F Helsinki, 22 September 2016

DECISION ON TESTING PROPOSAL(S) SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For isodecyl acrylate, CAS RN 1330-61-6 (EC No 215-542-5), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined the following testing proposal submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for isodecyl acrylate, CAS RN 1330-61-6 (EC No 215-542-5), submitted by [redacted] (Registrant).

- Earthworm Reproduction Test (OECD 222) Eisenia fetida/Eisenia Andrei

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision was adopted without considering any dossier submitted after ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant in his 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.

ECHA received the registration dossier containing the above-mentioned testing proposal for further examination pursuant to Article 40(1) on 28 March 2013.

On 29 January 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

On 5 March 2015 ECHA received comments from the Registrant on the draft decision.

On 25 March 2015 the Registrant updated his registration dossier with submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update.
On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 21 July 2016 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Testing required

A. Tests required pursuant to Article 40(3)

The Registrant shall carry out the following proposed test pursuant to Articles 40(3)(a) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2); test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222

The Registrant shall carry out the following additional test pursuant to Article 40(3)(c) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

2. Long-term toxicity testing on plants (Annex IX, 9.4.3., column 2); test method: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) or test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030);

Pursuant to Articles 41(1), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, once the results of the above terrestrial studies are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including an updated derivation of the terrestrial PNEC.

B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **29 September 2017** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

Note for consideration by the Registrant

The Registrant 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 to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

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.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal submitted by the Registrant for the registered substance.

A. Tests required pursuant to Article 40(3)

Effects on terrestrial organisms (Annex IX, Section 9.4.)

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

The Registrant must address the standard information requirements set out in Annex IX, section 9.4., for different taxonomic groups: effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), and short-term toxicity testing on plants (Annex IX, section 9.4.3.). Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing shall be considered by the Registrant 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 the endpoint 'effects on terrestrial organisms' is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements.

In applying the Integrated Testing Strategy (ITS) for terrestrial toxicity, the Registrant indicated that based on the properties of the substance (high adsorption potential (log Pow>5) and no indication that the substance is very toxic (EC/LC50 <1 mg/L for algae, daphnia or fish), the registered substance would fall into soil hazard category 3. In particular, ECHA notes that the information related to the endpoints underlying the application of the ITS, i.e. aquatic toxicity and ready biodegradability, are covered by means of read-across to the analogue substance 2 -ethylhexyl acrylate (EC No 203-080-7, CAS RN 103-11-7).

In the draft decision sent to the Registrant, ECHA rejected the read-across justification on the basis that the Registrant, did not provide any data in support of his hypothesis that the environmental fate is related to the chain length and the toxicity to the acrylate function and did not demonstrate where a breaking point is for alkyl acrylates. Therefore it was uncertain whether the aquatic toxicity of the registered substance isodecyl acrylate would be above or below the threshold level of 1 mg/l for the assignment of the soil hazard classes. As a consequence, the ITS could not be applied and additional testing, on top of the one proposed by the Registrant, was required.

In his comments to the draft decision and the subsequent update of the registration dossier (submission number [redacted]), the Registrant furthermore provided an updated read-across justification.

ECHA has evaluated the updated read-across justification and has following observations:

The Registrant provided read-across data for all short-term aquatic toxicity endpoints. Key studies were conducted with the analogue substance ethylhexyl acrylate (CAS RN 103-11-7). In addition, a supporting study was submitted for short-term toxicity to aquatic invertebrates for another analogue substance isooctyl acrylate (CAS RN 29590-42-9).

To support the read-across, the Registrant submitted an analogue justification document "*Analogue approach; Justification to fill by read-across the registration dossier of Isodecyl acrylate (CAS N. 1330-61-6) with the data of 2-ethylhexyl acrylate (CAS N. 103-11-7)*". In the document an analogue approach from 2-ethylhexyl acrylate (source substance) to isodecyl acrylate (target substance) is proposed and a data matrix for these two substances has been provided by the Registrant. Furthermore, he provides a data matrix for two groups of other substances which are used to support read-across for some endpoints. The Registrant states that toxicity for acrylates is determined by the acrylate function and not by the chain length. The Registrant only refers to the analogue approach between the source and the target and did not build a category approach.

Therefore, ECHA understands that the Registrant uses an analogue approach between the source and target substances, supported by additional information from the two groups of substances mentioned above to justify its claim of the toxicity being caused by the acrylate function and the fate being determined by the chain lengths.

Concerning the potential similarity of source and target substance, ECHA notes that the differences in physico-chemical properties and the potential impact on fate and ecotoxicity have not been addressed. The Registrant states: "*The n-octanol/water partition coefficient logarithmic values (log Kow) of Isodecyl acrylate experimentally measured according to OECD testing guideline 117 were ranged between 5.55 and 5.7. The log Kow of 2-ethylhexyl acrylate was quite close with a value of 4.64 measured according to OECD testing guideline 107. The difference between these substances was expected, the main carbon chain of 2-ethylhexyl acrylate (6 carbons) being shorter than the one of Isodecyl acrylate (9 carbons). However, the log Kow of 2-ethylhexyl acrylate remains close to the value of Isodecyl acrylate and above the screening criterion of 4.5 for bioaccumulation in the PBT assessment.*" ECHA notes that such statement does not explain the impact of the difference in logKow on ecotoxicity taking into account that logKow as a measure for hydrophobicity is related to the tendency of chemicals to partition between the lipids of the test organisms and the water. The parameter logKow is therefore related with the uptake and potential bioconcentration of a substance. Hence, for homologous substances with the same mode/mechanism of action, there is a relationship between logKow and aquatic toxicity. Moreover, ECHA notes that the source substance is a mono-constituent substance while the target substance is a UVCB with different constituents with different degrees of branching. The impact of these differences on fate and ecotoxicity has not been addressed by the Registrant.
Concerning the Registrant's claim of exotoxicity being only driven by the acrylate function ECHA notes that it is not substantiated.
As explained already in the initial draft decision there is a concern that the ecotoxicity depends on the chain length: "*Generally aquatic toxicity increases with increasing logKow for a series of homologues substances up to the point where the substances are not soluble enough to exert adverse effects. The Registrant however did not demonstrate where this breaking point is for alkyl acrylates. Therefore it is uncertain whether the aquatic toxicity of the registered substance isodecyl acrylate would be above or below the threshold level of 1 mg/l for the assignment of the soil hazard classes.*" (section III. A.2 of the initial draft decision). This concern has not been addressed in the updated dossier.

For daphnids for instance, the data in Table 1 of the Registrant's justification document vary between different group members (e.g. for daphnids a factor of 7-8, both expressed as mg/L or on a molar basis). Also, no reasoning has been provided why a higher potential for uptake of the target substance (assumption based on differences in logKow) and thus potentially higher internal substance concentrations, would not cause higher toxicity compared to the source substance. ECHA observes that the target and source substances and alkyl acrylates as mentioned in Table 1 of the Registrants read-across justification document, may cause both baseline narcotic effect and effects caused by other modes of action. It is possible that as a consequence of different modes of action no clear trends for the alkyl acrylates are observed (e.g. Table 1, Table 2 of the read-across justification document). With lower chain lengths the reactive mechanism can be dominant while for higher chain lengths the baseline narcotic effect can become more important (see e.g. Freidig, Verhaar, Hermens 1999, Environmental Science and Technology, 333, 3038-3043). This is further confirmed by the US New Chemicals Category (from QSAR Toolbox v3.2 helpfiles): "*Environmental Toxicity: The ecotoxicity of acrylates and methacrylates is a function of the octanol-water partition coefficient. They exhibit simple narcosis at log P's >5, but display excess toxicity at lower log P's. The toxicity of acrylates and methacrylates can be predicted by a QSAR (quantitative structure-activity relationship), although there are some members of the class such as allyl methacrylate that are significantly more toxic than predicted by the QSAR. Boundaries. Typically, environmental toxicity concerns are confined to those species with molecular weights <1,000. Acute and chronic toxicity is possible at log P's <5, and chronic toxicity is possible at log P's <8.*" This indicates that excess toxicity may be observed for the source substance, while for the target substance with a logKow above 5, baseline narcotic effect may cause toxicity. The Registrant did not address such a difference in mode/mechanism of action between source and target substance and how aquatic toxicity can be predicted for the target substance in this case.

Therefore, ECHA concludes that even with the updated read-across justification it remains not possible to predict whether the proposed read-across to the source substance is worst-case. ECHA also notes that the possible effects of the different constituents of the target has not been addressed by the Registrant (target = UVCB, source = monoconstituent). It is uncertain whether the aquatic toxicity of the target substance would be above or below the threshold level of 1 mg/l for the assignment of the soil hazard classes.

Consequently, ECHA considers that the adaptation of the information requirements suggested by the Registrant does not fulfil the criteria set in Annex XI section 1.5. and cannot be accepted.

1) Terrestrial Invertebrates (Annex IX, 9.4.1. and Column 2 of Annex IX, 9.4.)

a) Examination of the testing proposal

The Registrant proposed a long-term toxicity test on terrestrial invertebrates (Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222), with the following justification: "In accordance with column 2 of REACH Annex IX in the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms.

As the substance indicate high adsorption potential (log Pow>5) and there is no indication that the substance is very toxic (EC/LC50 <1 mg/L for algae, daphnia or fish), the substance belongs according to REACH Guidance R.7C Table R.7.11-2 to soil hazard category 3. According to the short-term toxicity tests, the most sensitive organism to the test item was aquatic macroinvertebrate. Therefore, a long-term toxicity test (reproduction) with soil macroinvertebrate (earthworm, OECD testing guideline 222) was proposed to be carried out."

According to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (November 2012), 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 has a high potential to adsorb to soil (log Pow>5) and therefore ECHA agrees that long-term testing is indicated (Column 2 of Section 9.4. of Annex IX). The proposed test is suitable to address the information requirement of Annex IX, section 9.4.1.

In his comments the Registrant had agreed with ECHA's draft decision to perform the test proposed: Long-term toxicity to terrestrial invertebrates *(Annex IX, 9.4.1, test method: Earthworm reproduction test (Eisenia fetida/Eisenia Andrei) OECD 222).*

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Long-term toxicity to invertebrates (Annex IX, 9.4.1., column 2); test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (OECD 222), using the registered substance.

2) Terrestrial plants (Annex IX, 9.4.3.)

The proposed test on terrestrial invertebrates, accepted by ECHA under subsection (1) above, is not sufficient by itself to address the standard information requirements of Annex IX, section 9.4.3. ECHA notes that the registration dossier does not contain data for this endpoint.

The Registrant proposed to adapt this standard information requirement by a statement: "According to the short-term toxicity tests, the most sensitive organism to an analogue of test item was aquatic macroinvertebrate. A long-term toxicity test (reproduction) with soil macroinvertebrate (earthworm, OECD 222) was thus proposed. Therefore, no test to assess the toxicity on terrestrial plants was proposed."
As indicated in sections III A. and III. A.1 above, the Registrant assumed that the substance belongs to soil hazard category 3. The assumption is based on data of short term acquatic toxicity, which are all derived from tests on a read-across substance. For the reasons already explained above, the adaptation of the information requirements suggested by the Registrant did not fulfil the criteria set in Annex XI section 1.5. and was not accepted by ECHA.

In his comments to the draft decision and the subsequent update of the registration dossier (submission number [redacted]), the Registrant provided an updated read-across justification. As explained in the section III. A above the updated read-across justification still does not fulfil the criteria set in Annex XI section 1.5.

Therefore the acquatic toxicity data from the analogue substance cannot be used to assign the registered substance to a soil hazard category and it is unfeasible, with the currently available information, to derive a PNEC for aquatic organisms. As explained in the ECHA Guidance on information requirements and chemical safety assessment Chapter R7C, Figure R.7.11-3 in such a case, the Registrant shall conduct soil toxicity testing in accordance to the standard information requirements (Annex IX + X) and derive PNECsoil.

Consequently, it is not possible to waive the standard information requirements for this endpoint, there is an information gap and it is necessary to provide information for terrestrial plants.

Furthermore, ECHA considers based on the substance properties as discussed under subsection (1) above, that there is indication for a high adsorption potential (log Pow>5) of the substance in soil. High adsorption potential of the substance indicates the need for long-term testing to be performed (Column 2 of Section 9.4. of Annex IX). At this tonnage level, according to column 2 the Registrant shall consider long-term testing. No argument has been provided as to why long-term testing is not appropriate. In fact, as evident from the testing proposal on terrestrial invertebrates, the Registrant has considered that due to the indication for a high adsorption potential of the substance the long-term testing is merited. Furthermore, ECHA Guidance on information requirements and chemical safety assessment Chapter R10, section R.10.6.2. (version May 2008) allows the potential application of a lower assessment factor (AF) if information on additional long-term terrestrial toxicity test of two trophic levels were available. In contrast, the Guidance does not allow for a lower AF to be applied if information on a short-term study were to become available in addition to the long-term invertebrate study, which ECHA accepted under subsection (1) above.

Therefore ECHA concludes that considering the properties of the substance only a long-term toxicity test on plants (and not the short-term) will provide the necessary useful information.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. The Registrant should consider if testing on additional species is required to cover the information requirement.

Outcome

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out one of the following additional studies using the registered substance subject to the present decision: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030).

B. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 9 months from the date of adoption of the decision. In his comments on the draft decision of 5 March 2015, the Registrant requested an extension of the timeline to 12 months.

He sought to justify this request by expressing a concern relating to the effect that the complexity of the substance may have on their ability to deliver the requested results on time. ECHA acknowledges the legitimate concerns of the Registrant in relation to testing a complex substance and the effects that this can have on the need for new analytical development.

ECHA has modified the deadline of the decision and set the deadline to 12 months.

IV. Adequate identification of the composition of the tested material

It is important to ensure that the particular sample of substance tested in the new studies 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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised by[1] 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.