EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000003067-77-06/F Helsinki, 17 June 2013

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

For reaction products of N,N'-ethane-1,2-diylbis(1,3-propanediamine), cyclohexane, peroxidized 4-butylamino-2,2,6,6-tetramethylpiperidine and 2,4,6-trichloro-1,3,5-triazine, CAS No 191680-81-6 (EC No 425-020-0), 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 proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1) (d) thereof for reaction products of N,N'-ethane-1,2-diylbis(1,3-propanediamine), cyclohexane, peroxidized 4-butylamino-2,2,6,6-tetramethylpiperidine and 2,4,6-trichloro-1,3,5-triazine CAS No 191680-81-6 (EC No 425-020-0), by [redacted] (Registrant).

- Daphnia magna Reproduction Test OECD Guideline 211
- Earthworm Acute Toxicity Test OECD Guideline 207

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 does not take into account any updates after 18 January 2013, the date upon which 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 its registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the present dossier at a later stage.

The examination of the testing proposals was initiated upon the date when receipt of the complete registration dossier was confirmed on 22 May 2012.

On 30 October 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 5 November 2012 ECHA received comments from the Registrant, requesting to prolong the timeline for submission of the requested information from 9 months to mid 2014 for providing the information required by this decision.

ECHA considered the Registrant's comments received and the evidence substantiating the prolongation to the timeline. On the basis of the comments and the evidence substantiating the prolongation to the timeline, only the deadline in Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 18 January 2013 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 21 February 2013 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and amended the draft decision accordingly.

On 4 March 2013 ECHA referred the draft decision to the Member State Committee.

The Registrant did not provide any comments on the proposed amendments.

A unanimous agreement of the Member State Committee on the draft decision was reached on 8 April 2013 in a written procedure launched on 27 March 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

The Registrant shall carry out the following proposed tests pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test method[s] and the registered substance subject to the present decision:

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211);

2. Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222);
   or,
   Short-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1.; test method: Toxicity for earthworms, EU C.8/OECD 207).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **17 June 2014** an update of the registration dossier containing the information required by this decision.

Once results of the proposed test on long-term toxicity to aquatic invertebrates are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to investigate further the effects on aquatic organisms, the Registrant should submit a testing proposal for a long-term toxicity test on fish in order to fulfil the standard

information requirement of Annex IX, 9.1.6. If the Registrant comes to the conclusion that no further investigation of effects on aquatic organisms is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.6.

Once results of the proposed test on toxicity to earthworms are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to investigate further the effects on terrestrial organisms, the Registrant shall submit testing proposals covering additional studies on terrestrial organisms in order to fulfil the standard information requirement of Annex IX, 9.4. If the Registrant comes to the conclusion that no further investigation of effects on terrestrial organisms is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.4.2. and 9.4.3.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other Registrants.

III. Statement of reasons

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

1. Long-term toxicity testing on aquatic invertebrates

According to column 1 of Section 9.1.5. of Annex IX of the REACH Regulation, long-term toxicity testing on invertebrates is required to fulfil the standard information requirements. The information on this endpoint 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.

The Registrant has not provided specific justifications for conducting the proposed test.

There were no indications in the dossier from the short-term toxicity studies on aquatic species that the fish would be substantially more sensitive than Daphnia.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., August 2008), Chapter R7b, Figure R.7.8-4 page 53, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. 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, if a risk is indicated, a testing proposal for a long-term fish study needs to be submitted.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211) using the registered substance.

2. Effects on terrestrial organisms

According to column 1 of Section 9.4. of Annex IX of the REACH Regulation, terrestrial organisms testing, in particular, short-term tests on invertebrates and plants, and effects on soil micro-organims, is required to fulfil the standard information requirements. In addition, column 2 of that Annex specifies that long-term toxicity testing shall be considered by the registrant instead of short-term if the substance has a high potential to adsorb to soil. As the registered substance is highly adsorptive, long-term tests should be preferred as the condition of column 2 is met. The information on this endpoint 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.

The Registrant provided the following justification for conducting the proposed test: *"No data concerning terrestrial toxicity are currently available. The test substance has a water solubility < 40 microg/L and a calculated log Kow > 10. It is expected, that the substance will end up adsorbed to the solid soil phase.*
Therefore, it is expected, that the main route of uptake is by ingestion of solid soil particles. Hence, in order to investigate the terrestrial toxicity potential of the test substance, an earthworm test according to OECD 207 will be conducted in 2013.
A test design involving earthworms was chosen because of the organisms habit to ingest soil particles in order to fulfill its nutritional needs. This capacity is of great advantage when testing adsorptive and insoluble compounds just like this test substance. In contrary to earthworms, the adsorbed test substance is likely to be less bioavailable to other organisms usually used in terrestrial toxicity testing like arthropods, plants or soil microorganisms. This can be traced back to the fact that terrestrial arthropods and microorganisms mainly get in contact with the pore water or the solid soil phase, respectively, but they do not ingest the compound. Terrestrial plants and soil bacteria for example may only be exposed to the fraction of the test substance which is dissolved in the pore water.
Therefore, it is assumed that, if there are any toxic effects of the test substance on terrestrial organisms at all, earthworms will be affected the most. Due to this reason, terrestrial studies on arthropods, plants and soil microorganisms will not be conducted unless toxic effects of the test substance on earthworms are ascertained".

ECHA notes that the proposed test only addresses invertebrates (i.e. the information requirement in Annex IX, section 9.4.1) and does not address the other two trophic levels requested for this tonnage band (i.e. the information requirements in Annex IX, sections 9.4.2 and 9.4.3). ECHA acknowledges the Registrant's assessment regarding the particular characteristics of this substance, justified by the reported physical-chemical and environmental fate properties as well as the low toxicity observed in a wide variety of toxicological and ecotoxicological studies covering diverse taxonomic groups, exposure routes and conditions. The Registrant has indicated that further testing will be considered depending on the outcome of the current testing proposal. ECHA considers that this approach has been adequately justified by the Registrant, as the available information at present does not allow for a decision concerning which further testing may be required.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is given a choice between carrying out the preferred (long-term) earthworm reproduction test (OECD 222) or – if long-term testing is not considered being appropriate – to perform a (short-term) earthworm acute toxicity test (test method EU C.8/OECD 207) instead. Any of the two tests should be performed using the registered substance subject to this decision.

Depending on the outcome of the test, ECHA invites the Registrant to submit any further testing proposals that may be required by Annex IX, sections 9.4.2 and 9.4.3.

3. Deadline for submitting the 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. On 5 November 2012, in his comments, the Registrant requested to prolong the timeline for submission of the requested information from 9 months to mid 2014 from the date of the final decision. The Registrant based its request on issues related to the laboratory capacity. On 14 December 2012 ECHA requested the Registrant to provide evidence substantiating the prolongation to the timeline. On 19 December 2012, to substantiate the request, the Registrant submitted a letter from the test laboratory, where laboratory capacity issues were outlined and 12 months was indicated for finalisation of the studies. The Registrant provided a comment stating that an additional 3 months is required to update the IUCLID Dossier, the CSR and if needed the risk and exposure assessment. Based on this, the Registrant requested to prolong the timeline for submission of the requested information from 9 months to 15 months from the date of the final decision. ECHA considers that the request made by the Registrant, as substantiated by the letter from the test laboratory, is adequately justified. (The Registrant is requested to provide the information 12 months from the date of adoption of the decision). ECHA considers that this timeline is also sufficient for the Registrant to update the IUCLID Dossier, the CSR and if needed the risk and exposure assessment. Therefore, the decision was modified accordingly.

IV. Adequate identification of the composition of the tested material

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new studies meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for evaluation of the testing proposal. The Registrant must note, however, that this information has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

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 registered to enable the relevance of the studies to be assessed.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation

(EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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