EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114294818-30-01/F Helsinki, 23 March 2015

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

For "A mixture of: 2-ethylhexyl mono-D-glucopyranoside; 2-ethylhexyl di-D-glucopyranoside", EC No 414-420-0, 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 proposal submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof "A mixture of: 2-ethylhexyl mono-D-glucopyranoside; 2-ethylhexyl di-D-glucopyranoside", EC No 414-420-0, submitted by [redacted] (Registrant).

- Testing proposal: Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei) (OECD Guideline 222)

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 12 June 2014, 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 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.

The examination of the testing proposal was initiated upon the date when receipt of the complete registration dossier was confirmed on 4 July 2013.

The Registrant submitted a spontaneous update on 01 October 2013, and subsequently a second spontaneous update on 17 October 2013.

On 5 December 2013 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 15 January 2014 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 12 June 2014 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.

Subsequently, a proposal for amendment from a Competent Authority to the draft decision was submitted.

On 18 July 2014 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal for amendment received and amended the draft decision.

On 28 July 2014 ECHA referred the draft decision to the Member State Committee.

By 18 August 2014, in accordance to Article 51(5), the Registrant provided comments on the proposal for amendment. The Member State Committee took the comments of the Registrant on the proposal for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 1 September 2014 in a written procedure launched on 21 August 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

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

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

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

2. Long-term toxicity testing on plants (Annex IX, 9.4.3., column II); 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);

3. Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216).

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.

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

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **30 March 2016** an update of the registration dossier containing the information required by this decision.

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 proposal submitted by the Registrant for the registered substance.

1 - 3 Effects on Terrestrial Organisms

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.

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

The Registrant proposed a long-term toxicity test on terrestrial invertebrates (OECD 222). According to 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), 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 evidences presented within the Registration dossier, the substance has a high potential to adsorb to soil ($logK_{oc}$ ca. 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.

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. and Column 2 of Annex IX, 9.3.)

A Member State Competent Authority submitted a proposal for amendment (PfA) suggesting that an additional request for a long-term toxicity test on plants be included within section II of the present Decision. This proposal was based upon section R.7.11.6., Chapter R.7c of the *ECHA Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012), which indicates that the substance would fall into soil hazard category 3.

Following a re-evaluation of the registration dossier, as a consequence of the PfA submitted, ECHA noted that within their CSR the Registrant has considered that it is unfeasible, with the currently available information, to derive a PNEC for aquatic organisms. Consequently, it is not possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), mentioned in Column 2 of Annex IX, section 9.4. Therefore, there is an information gap and it is necessary to provide information for the standard information requirement of Annex IX, Section 9.4.3.

ECHA agrees with the aspect of the PfA that considers it necessary to provide information for the standard information requirement of Annex IX, Section 9.4.3. The proposed test that ECHA has accepted above can only address the information requirement of Annex IX, section 9.4.1. It is not sufficient by itself to address the standard information requirement of Annex IX, section 9.4.3. ECHA notes that the registration dossier does not contain data for this endpoint.

In the Registrant's comments on the PfA submitted, the Registrant stated the following:

"Toxicity to terrestrial plants:
Based on the available aquatic toxicity data and the physico-chemical properties of the substance, and in relation to section R.7.11.6., chapter R.7c of the ECHA guidance, the substance would fall into soil hazard category 3. In the context of an integrated testing strategy (ITS) for soil toxicity, the guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term toxicity test on invertebrates (OECD 222).
Then, according to the table R.7.11-2, chapter R7c of the ECHA guidance:
- If PEC/PNECscreen < 1 and no indication of risk from confirmatory long-term soil toxicity testing (invertebrates – OECD 222): No further toxicity testing for soil organisms need to be done.
- If PEC/PNECscreen > 1 or indication of risk from confirmatory long-term soil toxicity test (invertebrates – OECD 222): Conduct long-term toxicity tests according to the standard information requirements Annex X (plants), choose lowest value for derivation of PNEC soil.

So at this stage it is not possible to determine whether a test will be required to fulfill the standard information requirement in section 9.4.3 (test on plants) of annex IX of the REACH regulation.
[redacted] *does agree to do the following tests: OECD 222 and OECD 216 and then see if further testing is needed (plants)."*

Furthermore, [redacted] requests to ECHA to have more time than 9 months from the date of the final decision to submit an update of the registration dossier. Based on quotations received from CROs, these tests can be reasonably performed with an update of the dossier within a period of 1 year.

Regarding the Registrant's comments on the proposal for amendment, ECHA considers that the Registrant can only apply the screening assessment for soil risks via the use of the EPM approach (based on the table R.7.11-2 in section R.7.11.6., Chapter R.7c of the *ECHA Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012), when adequate data is available to sufficiently derive a PNEC for aquatic organisms. The Registrant has considered that it is unfeasible, with the current available information, to derive a PNEC for aquatic organisms, and hence this approach cannot be applied.

By proposing a long-term toxicity test (accepted by ECHA under subsection (1) above), ECHA considers that the Registrant has concluded on the need for long-term toxicity testing to be performed instead of short-term, as the substance meets the column 2 adaptation criteria of Annex IX, section 9.4. On this basis, ECHA considers that long-term testing is indicated (Column 2 of Section 9.4. of Annex IX). Moreover, section R.10.6.2., Chapter R10 of the above mentioned Guidance allows the potential application of a lower Assesment Factors (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.

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.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out one of the following additional studies: 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), using the Registered substance.

Note for consideration of the Registrant:
The Registrant may consider adapting the information requirement of Annex IX, section 9.4.3. of the REACH Regulation using a weight of evidence approach as defined within section R.7.11.5.3 of ECHA's *Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012), Chapter R.7C. Alternatively, if the Registrant considers that it is possible to derive a PNECwater, the Registrant may consider the ITS as recommended in section R.7.11.6., Chapter R.7c of the above mentioned guidance, and perform an initial screening assessment based upon the EPM, together with a confirmatory long-term soil toxicity test (the long-term toxicity to terrestrial invertebrates test, specified above). Once results of the requested toxicity test on terrestrial invertebrates are available, the Registrant should consider whether there is a need to investigate further the effects on terrestrial organisms in order to fulfil the information requirements of section 9.4 of Annex IX.

If the Registrant concludes 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 information requirement of Annex IX, section 9.4.3. of the REACH Regulation.

3. Effects on soil microorganisms (Annex IX, 9.4.2. and Column 2 of Annex IX, 9.4.2.)

The hazard to soil microbial communities is a standard information requirement under Annex IX, section 9.4.2. of the REACH Regulation. ECHA notes that the registration dossier does not contain data for this endpoint and that the proposed test that ECHA accepted under subsection (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 (test method: EU C.21 or OECD 216).

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following additional study: Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216), using the registered substance.

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.

In their comments on the draft Decision, the registrant stated the following:

'Toxicity to soil microorganisms: The justification was based on the "Guidance on information requirements and chemical safety assessment - Chapter R.7c: Endpoint specific guidance".

In considering all the data available, expert judgment can be used in deciding whether the Weight of Evidence will allow specific testing to be omitted: The absence of acute effects within the solubility range above 10 mg/l can be used as part of a Weight of Evidence argument to waive the data requirements of Annex IX and X: EC50 72h – algae > 98 mg/l, EC50 48h – daphnia > 100 mg/l, LC50 96h – fish > 310 mg/l. Furthermore, the substance is readily degradable (90% in 28 days) and has a log Kow < 5 (Log Kow = 1.1).

No aquatic species was detected more sensitive according to acute aquatic tests available since no significant effect was observed. The terrestrial species tested should cover three taxonomic groups (plants, invertebrates and micro-organisms) as defined in Annex IX, but also different pathways of exposure (e.g. feeding, surface contact). Where there is no toxicity L(E)C50 in the standard acute toxicity tests at >10 mg/l and the substance is potentially highly adsorptive (log Koc = 5), and/or the substance is very persistent in soil (probably not the case: 90% degraded in water in 28 days), a single long-term soil test on a suitable species would be adequate to meet the requirements of Annex IX.
The choice of test (invertebrate / plant / micro-organism) would be based on all the information available, but in the absence of a clear indication of selective toxicity (that is the case), an invertebrate (earthworm or collembolan) test is preferred. Earthworm testing allows potential uptake via each of surface contact, soil particle ingestion and porewater, while plant exposure will be largely via porewater. Furthermore, the substance is readily degradable. So a long-term test on earthworms was proposed and accepted by ECHA. The other test requested by ECHA (OECD 216) was not judged necessary according to the Weight of Evidence strategy defined above. We look forward to hearing from you and receiving your final decision.'

ECHA's *Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012), Chapter R.7C states that all available data including those available on aquatic organisms should first be examined as part of a stepwise approach.

According to Figure R.7.11-3 of the abovementioned guidance the registrant should evaluate the existing data on the aquatic toxicity, persistence and adsorption of the substance in order to determine whether the existing information is adequate for hazard assessment. If the existing data is adequate for hazard assessment, the substance can be assigned to a soil hazard category and a screening assessment performed. ECHA notes that it is only in situations where a substance is both readily biodegradable and does not have a high potential to adsorb to soil as well as not very toxic to aquatic organisms (i.e. Soil Hazard category 1) that this screening assessment (based on EPM) showing no risk using aquatic toxicity data is sufficient to obviate the need for further information under Annex IX.

Furthermore, the PNEC screen is calculated through EPM on the basis of aquatic toxicity data only. Intrinsic properties of soil microbial communities however are not addressed through the EPM extrapolation method. Thus, the hazard to soil microbial communities must be evaluated as a standard information requirement under Annex IX. 9.4.2. Therefore, ECHA concludes that the application of an integrated testing strategy could only be applied to the need to perform either a long term toxicity test for soil invertebrates or plants, or to perform both of them, and that the effects on soil micro-organisms need to be ascertained by performing a relevant test.

For the reasons specified above, ECHA considers that the Registrant's weight of evidence approach is not a valid adaptation according to column 2 of Annex IX, 9.4., or according to Annex XI and therefore does not sufficiently justify amendment of the Decision to remove the request for an effects on microorganisms test.

4. 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. The Registrant requested an extension to 12 months following the registarants commenting period on the proposal for amendment. To consider the deadline extension request as valid, ECHA contacted the Registrant and requested written evidence of at least one legitimate inquiry made to a laboratory facility indicating that due to scheduling timelines an extension to the stated deadline is necessary. On 21 August 2014, the Registrant provided the written evidence to substantiate his request and therefore ECHA considers that a reasonable time period for providing the required information in the form of an updated registration is 12 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

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/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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