Decision number: TPE-D-2114330445-56-01/F Helsinki, 24 May 2016

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

For D-glucopyranose, oligomers, xylityl glycosides and 1,4 anhydro D-xylitol and D-xylitol, EC No 446-990-1, 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 "D-glucopyranose, oligomers, xylityl glycosides and 1,4 anhydro D-xylitol and D-xylitol", EC No 446-990-1, submitted by [redacted] (Registrant).

- Repeated dose 90-day oral toxicity in rodents (OECD 408).
- Prenatal developmental toxicity study (OECD 414).
- Earthworm, Acute toxicity tests (OECD 207).
- Soil microorganisms, Nitrogen transformation test (OECD 216).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of [redacted] per year. This decision does not take into account any updates submitted after the deadline for updating (25 September 2015) communicated to the Registrant by ECHA on 26 June 2015.

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 proposals was initiated upon the date when receipt of the complete registration dossier was confirmed on 21 October 2014.

ECHA held a third party consultation for the testing proposals from 23 January 2015 until 09 March 2015. ECHA received information from third parties with regard to the testing proposal of a repeated dose 90-day oral toxicity study.

ECHA notified the Registrant of the draft decision on 16 April 2015 and invited him to provide comments. That draft decision was based on submission number [redacted]. On 22 May 2015 ECHA received comments from the Registrant on the draft decision.

On 23 September 2015 the Registrant updated his registration (submission number MK577387-14). In the updated dossier, the testing proposal for a repeated dose 90-day oral toxicity in rodents (OECD 408) and a prenatal developmental toxicity study (OECD 414) were no longer present. Therefore they were no longer subject to decision-making and hence removed from this decision.

The ECHA Secretariat considered the Registrant's comments and update. As a result, ECHA amended Section II (the information required and the deadline) of the draft decision. Section III (statement of reasons) was changed accordingly.

On 3 March 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 Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

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

The Registrant shall carry out the following additional test pursuant to Article 40(3)(c) and 13(4) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

2. Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4., column 2); test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222, or Enchytraeid reproduction test, OECD 220, or Collembolan reproduction test in soil, OECD 232.

while the originally proposed test for an Earthworm, Acute toxicity tests (OECD 207) is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

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.

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 **03 March 2017** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

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 and scientific information submitted by third parties. The Registrant does not specify in his dossier the type of glycosidic linkages that are present in the substance. Therefore, based on the information provided in the dossier, ECHA considers that the registration covers a substance where both alpha and beta linkages are present, and not either independently.

A. Tests required pursuant to Article 40(3)

1.– 2. 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) Effects on soil microorganisms (Annex IX, Section 9.4.2.)

The Registrant proposed a toxicity test on soil microorganisms (OECD 216). This test is suitable to address the standard information requirement of Annex IX, section 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 test that ECHA requested under subsection (2) below 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).

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. ECHA notes that, according to the information within the registration dossier, the substance is to be considered very persistent, which is default setting for not readily biodegradable substances when a value of the half-life in soil is not available. Furthermore, based upon the available aquatic toxicity information (EC/LC > 1 mg/L for algae, daphnia and fish) and the physico-chemical properties of the substance (high water solubility and logKow < 5), and in relation to section R.7.11.6., of the above mentioned Guidance, ECHA considers that the substance would fall into soil hazard category 3.

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. does not apply for the present endpoint.

ECHA further notes that the Registrant has not provided any alternative testing strategy to deviate from the screening assessment described in the Table R.7.11-2 of section R.7.11.6.

Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the following additional study using the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216).

2) Terrestrial Invertebrates (Annex IX, Section 9.4.1.)

The Registrant proposed a short-term toxicity test on terrestrial invertebrates (OECD 207).

However, 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. ECHA notes that, according to the evidence presented within the registration dossier, the substance is to be considered very persistent which is default setting for not readily biodegradable substances, when a value of the half-life in soil is not available and therefore the substance meets the column 2 adaptation criteria of Annex IX, section 9.4. concerning the use of long-term testing instead of short-term. Furthermore, based upon the available aquatic toxicity information (EC/LC50 > 1 mg/L) and the physico-chemical properties of the substance (high water solubility, log Kow < 5), and in relation to section R.7.11.6., of the above mentioned Guidance, ECHA considers that the substance would fall into soil hazard category 3. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test. ECHA further notes that the Registrant has not provided any alternative testing strategy to deviate from the screening assessment described in the Table R.7.11-2 of the section R.7.11.6 of the above mentioned Guidance.

The earthworm reproduction test (OECD 222), Enchytraeid reproduction test (OECD 220), and Collembolan reproduction test (OECD 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

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: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222, or Enchytraeid reproduction test OECD 220, or Collembolan reproduction test in soil OECD 232), while the short-term toxicity test on terrestrial invertebrates (OECD 207) is rejected pursuant to Article 40(3)(d) of the REACH Regulation,

Notes for consideration by the Registrant

As the Guidance advocates performing an initial screening assessment based upon the EPM, together with a confirmatory long-term soil toxicity test (the toxicity to terrestrial invertebrates test, specified above), which the Registrant is given the option to carry out by the present decision, ECHA considers that at this stage it is not possible to determine whether a test will be required to fulfil the standard information requirement in section 9.4.3. of Annex IX of the REACH Regulation.

Therefore, 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, and if necessary, submit testing proposals for additional terrestrial toxicity tests. 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.

ECHA notes that, if the Registrant proposes alternative testing strategy to the sceening assessment described in the Table R.7.11-2 of the section R.7.11.6, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014) or Weight of Evidence argument to modify/waive data requirements of Annex IX and X, e.g. based on low toxicity of the substance as described in the section R.7.11.5.3. of the above mention Guidance, it should be indicated in the technical dossier[1].

[1] A dossier update can only be taken into consideration in the decision-making if it is submitted by the date specified in section I of this draft decision.

B. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 24 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested a Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.) and a Pre-natal developmental toxicity study (Annex IX, Section 8.7.2). As the testing proposals for these studies are no longer addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated registration is 9 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

The process of examination 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 examination 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.

In addition, 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.

Finally, 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.

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