EUROPEAN CHEMICALS AGENCY

Helsinki, 7 December 2017

Addressee [redacted]

Decision number: TPE-D-2114381501-55-01/F
Substance name: D-glucopyranose, oligomeric, C10-16 glycosides (even numbered), carboxymethyl ethers, sodium salts
EC number: 609-542-8
CAS number: 383178-66-3
Registration number: [redacted]
Submission number: [redacted]
Submission date: 21/02/2017
Registered tonnage band: 100-1000

## DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation ((EC) No 1907/2006) (the REACH Regulation), ECHA examined your testing proposal(s) and decided as follows.

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

1. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route 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 to the REACH Regulation.

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 have to submit the requested information in an updated registration dossier by **14 December 2018**. You also have to update the chemical safety report, where relevant.

### Deadline to submit the requested Information

In the draft decision communicated to you the time indicated to provide the requested information was 12 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 18 months. You sought to justify this request by "*the substances is not manufactured permanently and has limited stability, there is additional time needed to get a suitable test sample from an upcoming production campaign*" and "*analytical characterization of the new test sample for the pre-natal developmental toxicity study needs to be adapted to the new chemical description, due to the ongoing substance identity change of the registered substance*".

ECHA notes that the 12 months given in the decision already includes preparation time prior to the testing phase. While OECD TG 414 does not explicitly specify the duration of the test it is ECHA's experience that the conduct of a dose range finding study and completion of the following pre-natal developmental toxicity study may take up to 9 months. You would therefore have at least an additional 3 months for the preparation and characterisation of the material to be tested.

Additionally, you did not provide any information in your comments to substantiate the claim of substance instability, neither has ECHA found such information in the dossier. ECHA notes that in the "guidance on safe use" section of the dossier you indicate that "*The product is stable if stored and handled as prescribed/indicated*." Therefore, there is scope to plan the collection and any necessary storage of a sample from the foreseen production campaign in order to conduct the testing you proposed. ECHA considers that the analytical characterization of the test sample is not dependent on the completion of the ongoing administrative change of the substance identifiers.

ECHA considers that 12 months is sufficient for the preparation and completion of the requested test. Therefore, ECHA has not modified the deadline of the decision.

The reasons for this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and 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, has to 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 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.

## Appendix 1: Reasons

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

### 1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

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

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. 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.

You have submitted a testing proposal for a pre-natal developmental toxicity study in rats according to EU B.31./OECD TG 414.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Reproductive toxicity (pre-natal developmental toxicity). ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirements for which testing is proposed. ECHA has taken these considerations into account.

ECHA considers that the proposed study performed with the registered substance is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

You proposed testing with the rat as a first species. According to the test method EU B.31./OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default consideration, ECHA considers testing should be performed with the rat or rabbit as a first species.

You did not specify the route for testing. ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a solid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in a first species (rats or rabbits), oral route (test method: EU B.31./OECD TG 414).

*Notes for your consideration*

For the selection of the appropriate species you are advised to consult ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017), Chapter R.7a, Section R.7.6.2.3.2.

## Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 9 April 2013.

ECHA held a third party consultation for the testing proposals from 30 November 2015 until 14 January 2016. ECHA did not receive information from third parties.

This decision does not take into account any updates after **4 September 2017**, 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 did not amend the deadline.

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

As no amendments were proposed, ECHA took the decision according to Article 51(3) 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 otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests 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 by each registrant.

If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally 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.

4. ECHA notes this registration dossier is undergoing an adaptation of the substance identifiers. This adaptation is not yet complete. Nevertheless, once completed successfully, it is expected to result in a change of the EC number from the current number to the number 701-129-1 and a change of the name from "D-glucopyranose, oligomeric, C10-16 glycosides (even numbered), carboxymethyl ethers, sodium salts" to "C12-14 (even numbered) alkyl glycosides, oligomeric and C12-14 (even numbered) alkyl glycosides, oligomeric, carboxymethyl ethers, sodium salts". As this process is not yet complete, the draft decision refers to the current identifiers. This eventual change in identifiers does not impact the information request in this decision.