EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114308118-57-01/F Helsinki, 9 September 2015

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For D-glucopyranose, oligomeric, C10-16 glycosides (even numbered), carboxymethyl ethers, sodium salts, CAS No 383178-66-3 (EC No 609-542-8), 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 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for D-glucopyranose, oligomeric, C10-16 glycosides (even numbered), carboxymethyl ethers, sodium salts, CAS No 383178-66-3 (EC No 609-542-8), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

This decision is based on the registration 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 the date when the draft decision was notified to the Registrant under Article 50(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 25 August 2014.

On 13 March 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.

On 14 April 2015 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 23 July 2015 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. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Name or other identifier of the substance (Annex VI, Section 2.1.)
2. Composition of the substance (Annex VI, Section 2.3.)
3. Description of the analytical methods (Annex VI, Section 2.3.7.)

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **16 December 2015** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Name or other identifier of the substance (Annex VI, Section 2.1.)

ECHA notes that the Registrant has not provided sufficient information to identify the substance, as required by Annex VI, Section 2.1 of the REACH Regulation.

More specifically, the Registrant identified the substance as a of unknown or variable composition, complex reaction products or biological materials (UVCB substance). The Registrant reported the name "*D-glucopyranose, oligomeric, C10-16 glycosides (even numbered), carboxymethyl ethers, sodium salts*" in the IUPAC, EC and CAS name fields section 1.1 of the IUCLID dossier. The name reports in generic terms that the substance is composed of different groups of alkyl glycosides constituents. However no information on the identity of these groups or constituents was included in section 1.1 of the dossier.

The Registrant has included the following in the remarks field "*Due to a high No. of isomers and homologues (Post reacted APG) neither a structural formula nor a SMILES notification can be given. Molecular weights above are estimated due to the well known MW-distribution in APGs*". However, no information has been provided on the isomers, homologues nor has "APG" been defined in section 1.1. The information provided in section 1.1 is thus not sufficient to allow the registered substance to be unambiguously identified.

Moreover, the naming of a UVCB substance consists of two parts: the chemical name and the more detailed description of the manufacturing process as indicated in chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version:

1.2, March 2012) - referred to as "the Guidance" thereinafter. The Registrant did not provide sufficient information on the name, other identifiers and the description of the manufacturing process that would enable the substance identity to be verified.

In addition, the compositional information reported in section 1.2 of the dossier describes the substance as only one constituent present at >[redacted]%. This constituent has the same identity as the substance reported in section 1.1 of the dossier and does not identify any specific constituents of the substance. The following was included in the remarks field in section 1.2. "*Komplex mixture of different isomers of APG carboxylates and unreacted APG*".

Furthermore, the information included in the analytical report "[redacted]" attached in section 1.4, does not provide information that would enable the identity or composition to be verfied. It is thus also not possible to determine the identity of the registered substance from the information in these other sections.

Concerning the manufacturing process, firstly, no description of the manufacturing process was reported in section 1.1 of the dossier and the Registrant has provided a very generic description of the manufacturing process in section 3.1 of the dossier: "[redacted]" More specifically, in the description given in section 3.1, the starting material has been identified by the trade name "[redacted]" described as "[redacted]". As the chemical identity of this specific starting material is one of the factors determining the composition of the registered substance, the compositional information of this starting material is a necessary element for its identification as well as for the identification of the registered substance. In particular, the compositional information of the starting material has to describe the distribution of the content of each specific alkyl chain lengths (C10 to C16) present in the registered substance.

Secondly, the ratio of reactants and any solvent used, the description of the different steps and process parameters (temperature and pressure) determining the degree of completion of the Williamson ether synthesis have not been indicated. Consequently, there is insufficient information included in the dossier to establish the identity of the registered substance.

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration.

The Registrant outlined in the comments to the draft decision the action he planned to take, in an updated dossier, to comply with the requests made.

Specifically regarding the request concerning the description of the manufacturing process, the Registrant indicated his intention to clarify the identity of the starting material "[redacted]" (used as the part of the substance name for the substance) and to include a reference to literature describing the reaction performed (Williamson ether synthesis).

In his comments, the Registrant also indicated that it is possible to identify several groups of constituents present in the substance described as i.e. "[redacted]". ECHA highlights that these constituents and groups of constituents need to be identified, quantified and reported in section 1.2 of the IUCLID dossier. This information would also be relevant for the identification of the substance (i.e. that both alpha and beta linkages are possible).

Irrespective of whether the newly provided information may be sufficient to meet the information requirement addressed in this decision, ECHA can already point out the following:

ECHA notes that the Registrant has indicated his intention to revise the name of the substance and highlights that the name is required to be consistent with the composition reported in section 1.2 of the dossier. The proposed IUPAC name starting with "reaction mass of" refers to well defined multi-constituent substances and cannot be used for the naming of UVCB substances.

For the above reasons, the comments submitted are not sufficient to address the requests made concerning the name and other identifiers.

The Registrant is reminded that this decision does not take into account any updates submitted after 13 March 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Accordingly, in line with Annex VI, Section 2.1, the Registrant is requested to revise the name and other identifiers as appropriate for the substance as manufactured. This includes the provision of a detailed description of the manufacturing process, including the chemical identity of the source and information on the most relevant steps of the manufacturing process. The Registrant shall ensure that the information reported is consistent throughout the dossier. In accordance with the Guidance, the name of a UVCB substance shall adequately reflect the source materials and process.

The description of the manufacturing process shall be sufficiently detailed to allow ECHA to verfiy the starting materials are used, and how any other steps and process parameters may affect the substance composition and therefore its identity. It shall include, as appropriate:

- Identity and ratio of starting materials/reactants,
- Specifications of the process parameters determining the degree of completion of the Williamson ether synthesis such as temperature, pressure and time,
- A description of any other relevant operating parameters or process.

Regarding how to report the requested information in the IUCLID dossier, the following applies as appropriate:

- The substance will be named based on each constituent or group of constituents of defined alkyl chain length, present at concentration ≥10% (based on the maximum concentration of the concentration range). The groups of constituents to be considered for the naming shall compose at least 80% (w/w) of the substance.
- The revised name shall be reported in the IUPAC name field in IUCLID section 1.1. Where the current CAS entry (i.e. 383178-66-3) does not identify the registered substance, it shall be reported under the "related CAS information" field in IUCLID section 1.1.
- The description of the manufacturing process shall be included in the description of the substance field in section 1.1.
- For technical reasons the Registrant is requested at this stage, not to remove or revise the list entry in the updated dossier. As this registration is linked to this EC entry in REACH-IT, the IT system will not accept the updated dossier as an update when the EC entry has changed. The Registrant shall instead include the following in the "Remarks field" of the reference substance: "*This EC entry is not appropriate to*

identify the registered substance. This identifier cannot be modified in the present registration at this stage for technical reasons."

Further information on how to report the description of the manufacturing process is available in "Data Submission Manual Part 18 – How to report the substance identity in IUCLID 5 for registration under REACH" published on the ECHA website at http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

2. Composition of the substance (Annex VI, 2.3)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the cornerstone of all the REACH obligations.

ECHA notes that the Registrant has not included sufficient information on the composition of the substance to enable the identity of the registered substance to be verified, as required under Annex VI, Section 2.3. of the REACH Regulation.

Specifically, the Registrant has reported one composition in section 1.2 and this composition identifies as its main constituent the same reference substance as in section 1.1: "*D-glucopyranose, oligomeric, C10-16 glycosides (even numbered), carboxymethyl ethers, sodium salts*". This constituent is reported to be present at [redacted] % (w/w) indicating that [redacted] % of the composition has not been reported. From this limited information, together with the limted information provided on the name and other identifiers in section 1.1 (see above 1.) , the compsition of the substance registered cannot be verifed.

In accordance with section 4.2 of the Guidance, the composition shall normally be described up to 100%, and each constituent requires a complete chemical specification, including structural information. For UVCB substances, section 4.3 of the Guidance recognizes that they either cannot be fully specified with the IUPAC name of the constituents, as not all the constituents can be identified, or they may be specified with a lack of specificity due to variability of the exact composition. However, the chemical composition and the identity of the constituents shall be reported as far as known for UVCB substances.

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration.

The Registrant outlined in the comments to the draft decision the action he planned to take, in an updated dossier, to comply with the requests made.

In his comments, the Registrant has clarified the composition of the substance as [redacted]% unreacted material CAS#110615-47-9, -Glucopyranose, oligomeric, C10-16(even numbered) alkyl glycosides (UVCB), [redacted]% D-Glucopyranose, oligomeric, C10-16 glycosides (even numbered), carboxymethyl ethers, sodium salts, CAS# 383178-66-3 (UVCB), [redacted]% Sodium chloride, [redacted] % Sodium glycolate and has additionally indicated how the identities of these constituents were determined and quantified.

Irrespective of whether the newly provided information may be sufficient to meet the information requirement addressed in this decision, ECHA can already point out the following:

However, besides from the fact that this information needs to be included in an updated dossier together with the corresponding detailed description of the methods used, the

information provided in the comments is not considered sufficient to verify the composition of the substance.

ECHA notes that the Registrant stated in his comments that "*2 mayor side products were found in the freeze dried sample, both not the target molecules and therefore falling under REACH, Annex V, 5. "By-products, unless they are imported or placed on the market themselves*". However, the registration exemption set out in Annex V, point 5 of the REACH Regulation applies to the registration of by-products as separate substances. But in the present case, in accordance with the definition of substance in Article 3(1) of the REACH Regulation, the purported "*side products*" are two different constituents of the substance subject to this registration. Constituents are however not exempt from being reported in the composition of the substance.

For the above reasons, the information included in the Registrant comments is not sufficient to address the requests made concerning the composition of the substance.

The Registrant is reminded that this decision does not take into account any updates submitted after 13 March 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

The Registrant is accordingly requested to revise the composition reported in section 1.2 to report the chemical compostion of the registered substance including all known constituents.

The Registrant is reminded that for UVCB substances the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
- All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature.
- For each constituent or group of constituents, the typical, minimum and maximum concentration levels shall be specified.

The Registrant is reminded that as the substance is identifed based on alkly chain length distributions, composition information on each alkyl chain length is required to be reported in section 1.2 of the dossier.

Further technical details on how to report details on the constituents of a substance in IUCLID are available in the "Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH."

3. Description of the analytical methods (Annex VI Section 2.3.7)

ECHA notes that the Registrant has not provided sufficient information and appropriate description of the analytical methods used to determine the identity and composition of the substance registered by his legal entity, as required by Annex VI, 2.3.7 of the REACH Regulation.

Specifically, the Registrant has provided a full set of analytical data (IR, UV, NMR, TCL, titration, ICP and GC-FID). However, the information provided is not sufficient to establish the identities of the chemical constituents of the substance and their respective

concentration values. The substance has been identified in section 1.2 as a specific D-glucopyranose with substituents of defined alkylchain lengths (C10-16 glycosides (even numbered)). However, the Registrant has not included any information in section 1.4 that would enable these identifiers to be verified.

The Registrant provided the quantification results of water content, salts (Na, K, Cl) content and by-products or impurities such as glycolic and diglycolic acids, however the detailed description of the analytical methods and calculations were not included in the dossier. These values were not correlated with substance constituents.

The Registrant provided a gas chromatographic analysis with FID detection and a chromatogram which shows at least four major peaks. However the peak table provided with the corresponding concentrations reports only one constituent identified solely by a trade name "*Plantacare 1200*". This is insufficient to enable the composition of the substance to be verified as no constituents are identified. Furthermore the description of the methods with details of calibration and calculation used to identify the peaks and determine the concentration of the constituents were not included in the dossier.

Consequently the registration does not include sufficient description of the analytical methods required for the identification and quantification of the registered substance.

In the comments to the draft decision the Registrant disagreed with the information requirement in the draft decision. Nevertheless, he indicated his intention to address the information requirement in an update of the registration.

The Registrant outlined in the comments to the draft decision how he could address the information requirement by stating that "all analytical methods used in the attached analytics file are described in the attached analytical file sufficiently to be used by an analytical expert having the technical equipment to use them."

Irrespective of whether the newly provided information may be sufficient to meet the information requirement addressed in this decision, ECHA can already point out the following:

ECHA notes that the additional information provided in the comments does not address the request made. As outlined in the decision, the description is not sufficiently detailed to be able to verify the composition of the substance.

In accordance with Annex VI, Section 2.3.7, the Registrant is therefore requested to provide a description of methods used for the quantification of the registered substance including its constituents. This information shall be sufficient to enable the substance identified in section 1.1 of the dossier and all constituents reported in section 1.2 to be verified as revised based on requests in section III.A.1 and 2 above.The information is required to be sufficient for each method to be reproduced and shall include details of the experimental protocol followed, the calculations used and the results obtained.

As for the reporting of the above data in the registration dossier, the information should be attached in IUCLID section 1.4.

IV. 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 an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be

found on 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[1] by Leena Ylä-Mononen, Director of Evaluation

[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.