~~Confidential~~

Helsinki, 08 September 2023

Addressee
Registrant listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
13/09/2022

Registered substance subject to this decision ("the Substance")
Substance name: Reaction product of 1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde, methylated and C16-18 fatty alcohols
EC/List number: 947-918-6

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***15 December 2023***.

1. **Obligation to register monomer substances and any other substance in a polymer [Article 6(3) of the REACH Regulation]**

2. **Name or other identifier of the substance (Annex VI, Section 2.1.);**

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

The reasons for the request(s) are explained in Appendix 1. The procedural history is described in Appendix 2.

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report**, where relevant, including any changes to classification and labelling, based on the newly generated information.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

[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 related to the requested information

A substance must be identified as specified in Annex VI, section 2 to REACH. Under this provision, the information provided has to be sufficient to enable the identification of the substance.

ECHA concludes that there are inconsistencies between the substance identity information included in IUCLID sections 1.1, 1.2, and 1.4 of the registration dossier. Consequently, ECHA cannot verify the identity of the Substance and whether or not the Substance meets the polymer definition as specified in Article 3(5) of REACH.

1. Obligation to register monomer substances and any other substances in polymer [Article 6(3) of the REACH Regulation]

Under Article 3(5) of the REACH Regulation, a polymer is a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units.

In addition, under Article 6(3), a manufacturer or importer of a polymer must submit a registration for the monomer substances or any other substances, that have not already been registered by an actor up the supply chain, if both the following conditions are met:

(a) the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);
(b) the total quantity of such monomer substance(s) or other substance(s) makes up one tonne or more per year.

You have register the Substance with the name "*Reaction product of C16-18 (even numbered) alcohols with reaction products of 1,3,5-Triazine, 2,4,6,-triamine, polymer with formaldehyde, methylated*". This chemical name, which is included in the 'IUPAC name' field in IUCLID section 1.1, indicates that the Substance is a polymer.

In addition, the starting material named "*1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde, methylated"* indicates that this starting material is a polymer. Consequently, the reaction of this polymer with C16-18 fatty alcohols could result in a polymeric substance.

In contrast, in the field 'Type of information provided' in the IUCLID section 1.4, you state that "*Based on the GPC results the starting material* [redacted] *(CAS:* [redacted]*) is no polymer. For this reason our substance is also not a polymer and had to be registered.*". Therefore, your dossier contains contradictory information.

In your comments to the draft decision, you have also provided feedback from your Supplier: '*Only* [redacted]*% of the material* [redacted] *can be considered as a polymer. So by Reach definition it is not a polymer.*' However, this information is not supported by any analytical data and as such it remains a unsubstantiated statement. In addition, you have provided GPC analysis of the starting material '[redacted]'. However, as explained further in section 2 below, the information submitted does not provide sufficient information to verify the composition of the starting material. Therefore, the starting material must be analysed as required in this decision.

Based on the information provided in the dossier and in your comments, the identity of the starting material still remains ambiguous. The CAS entry you defined in your comments for the starting material is CAS [redacted]: "1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde, methylated". However, this CAS entry cannot characterise '[redacted]' unambiguously. When searching with the name [redacted]' in the CAS registry it leads to another CAS entry [redacted]. This CAS entry defines the following name: '[redacted]'. These two substances seemingly differ from each other in the degree of methylation. This discrepancy must be resolved in the dossier update by providing unambiguous information on the starting material of your registered substance.

Consequently, you are requested to assess whether or not the Substance meets the polymer definition as set out in Article 3(5) of REACH and the conditions of Article 6(3) are fulfilled. If you consider that these conditions are met, you must indicate the ceasing of manufacture of the polymer substance upon receipt of the draft decision, in accordance with article 50(3) of the REACH Regulation. In parallel you must submit a registration for the monomer substance(s) or any other substance(s) that have not already been registered by an actor up the supply chain. In the meantime, national enforcement authorities may consider that you may not be entitled to manufacture or import this polymer.

However, if you consider that the Substance does not meet the definition of a polymer, you must adapt the chemical name of the substance and align the starting materials accordingly.

In any case, you must ensure that the name and the other identifiers of the Substance in section 1.1 of the IUCLID dossier are in line with each others and consistently reported in sections 1.2 and 1.4 of the IUCLID dossier and in any attached document.

The revised IUPAC name must be provided in the IUPAC name field in section 1.1. You shall ensure that the Substance is referenced using the correct name and other identifiers throughout the dossier.

2. Name or other identifier of the Substance (Annex VI, Section 2.1.)

According to Annex VI, Section 2.1 of the REACH Regulation, the registration dossier must contain the name or other identifier of the Substance.

Following the principles given in the "Guidance for identification and naming of substances under REACH and CLP" (May 2017, Version 2.1) available on ECHA website, the naming of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) substances shall consist of two parts, including a detailed description of the manufacturing process.

The description of the manufacturing process must be in line with the substance as manufactured.

In the 'Description' field of IUCLID section 1.2 of your legal entity composition you have specified the following starting materials: [redacted] and [redacted]. However, CAS [redacted] corresponds to [redacted].

The analytical data and compositional information suggest that the starting material used to manufacture the Substance could actually be the well-defined substance

[redacted]. Therefore, ECHA considers that the identification of the starting material is not sufficiently clear and consistently reported throughout the dossier to enable the identification of the Substance.

Therefore, you must clarify the identity of the starting material by specifying whether it is:

(a) [redacted]
or
(b) [redacted]
or
(c) [redacted] or
(d) none of the above - In this case you must identify the proper starting material.

This information shall be included in the "Description" field in IUCLID section 1.2. The information provided on the starting material must be consistent throughout sections 1.1, 1.2 and 1.4 of the IUCLID dossier.

In your comments on the draft decision, you stated your intention to clarify the starting material for the Substance and to update IUCLID section 1.2 of your dossier accordingly.

ECHA takes note of your statement and asks you to ensure the following considerations. Firstly, you must ensure consistency on the identifier by updating all other relevant IUCLID sections of your dossier with this information.
Secondly, you must submit unambiguous information on the starting material in the updated registration dossier by the deadline set in the decision. Thirdly, you must submit the analytical information on the starting material as discussed under point 1, which clearly shows whether the substance is or is not a polymer according to Article 3(5) of the REACH Regulation.

The submitted analytical information must be in line with the information provided in sections 1.1 and 1.4 of your dossier.

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

The description of the analytical methods is an information requirement as laid down in Annex VI, Section 2.3.7. of REACH.

As explained in section 4.1 of the "Guidance for identification and naming of substances under REACH and CLP", a description of the methods used for the identification of the substance and, where appropriate, for the identification of impurities and additives needs to be given. This information should be sufficient to allow the methods to be reproduced. This means that the information included in the analytical report must be sufficient to verify the identity and quantity of the constituents reported in section 1.2 of the IUCLID dossier.

In IUCLID section 1.4 you have attached the analytical report of a GPC analysis. In this report it is stated on page 2 that: "*The sample apparently only consists of a low molecular weight component. Only a small shoulder can be seen. According to REACh criteria, the sample is not a polymer but a substance.*"

In addition, you provided explanation in IUCLID section 1.4 that your substance "*only consists of a low molecular weight component*" and "*according to REACh criteria, the sample is not a polymer but a substance*".

However, the statement above is not scientifically substantiated because GPC is usually used for the determination of molecular weight distribution of polymers. Therefore, it is not the most suitable method for the analysis of a low molecular weight substance and thus the results cannot be verified. The molecular weight of the potential starting material is 390 Da and the peaks identified as peak 'A' and 'B' are not matching with this molecular weight but show the lower values 124 Da and 41 Da, respectively. Additionally, the CAS number [redacted], used to identify the Substance, refers to a polymer substance in the CAS Registry.

Furthermore, your statement that a substance consisting of low molecular weight components is not a polymer is not substantiated by any scientific evidence. In fact, a substance containing low molecular weight constituents could also qualify of being a polymer since the determining factor is the number of monomer(s)/other reactant(s) attached in a continuous string and not the molecular weight. Depending on the manufacturing process used a substance containing constituents of low molecular weight can also fulfil the polymer definition as set out in Article 3(5) of REACH.

Therefore, you are requested to submit a description of the analytical method and its results that is appropriate to analyse the Substance and which provide an unambiguous identification and quantification of the starting material(s) and of the constituents of the Substance. Such analyses must prove whether the starting material and the Substance do not fulfil the polymer definition as set out in Article 3(5) of REACH.

As for the reporting in the registration dossier, the information should be included in IUCLID Section 1.4.

In your comments on the draft decision, you stated your intention to clarify the starting material for the Substance and to update IUCLID section 1.2 of your dossier accordingly.

ECHA takes note of your statement and asks you to ensure that the considerations highlighted in the previous sections are fulfilled.

Appendix 2: Procedure

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

This decision does not prevent ECHA from initiating further compliance checks at a later stage.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 22 November 2021.

ECHA notified you of the draft decision and invited you to provide comments.

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the requests.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix B: Addressee of this decision

Registrant Name	Registration number
[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.