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Helsinki, 04 September 2023

Addressee
Registrant name: [redacted]
Registration number: [redacted]

Date of submission of the dossier subject to this decision
13/02/2014

Registered substance subject to this decision ("the Substance")
Substance name: Resin acids and rosin acids, calcium salts
EC/List number: 232-694-8

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 ***11 December 2023***.

Requested information must be generated using the Substance.

1. **Name or other identifier of the substance (Annex VI, Section 2.1.);**
   - **EC/list and/or CAS entry**
2. **Composition of the substance (Annex VI, Section 2.3.);**
   - **Identification and quantification of the constituents**
3. **Description of the analytical methods or the appropriate bibliographical references that are necessary for the identification of the substance (Annex VI, Section 2.3.7.);**
   - **Identification and quantification of the counter-ion**

The reasons for the requests 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.

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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 information under Annex VI to REACH

The 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.

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

Name and any other identifier of each substance is an information requirement under Annex VI Section 2.1 of REACH. The name and any other identifiers are used to identify a substance in an unambiguous manner and are, therefore, fundamental for substance identification. Adequate information needs to be present in the registration dossier to meet this information requirement.

The information requirements listed in Annex VI, Section 2.1. include: "'*Name(s) in the IUPAC nomenclature. If unavailable, other international chemical name(s)*'" (Section 2.1.1.); "*EC number, i.e. Einecs, Elincs or NLP number, or the number assigned by the Agency (if available and appropriate)*" (Section 2.1.3); and "*CAS name and CAS number (if available)*" (Section 2.1.4).

You have identified the Substance as a UVCB substance using the following identifiers:

- EINECS/EC number 232-694-8, (EC name "Resin and rosin acids, calcium salts") and
- CAS number 9007-13-0 (CAS name "Resin acids, calcium salts").

However, in the "IUPAC name" field of IUCLID section 1.1 you report the following IUPAC name: "*calcium (1R,4aR,4bR,10aR)-1,4a-dimethyl-7-propan-2-yl-2,3,4,4b,5,6,10,10a-octahydrophenanthrene-1-carboxylate*".

This name corresponds only to one specific constituent of the UVCB substance "Resin and rosin acids, calcium salts". However, this UVCB substance consists of many constituents.

Therefore, there is an inconsistency between the identifiers (EC/EINECS number 232-694-8, CAS entry 9007-13-0) and the chemical name (Resin and rosin acids, calcium salts") on one hand and the IUPAC name ("calcium (1R,4aR,4bR,10aR)-1,4a-dimethyl-7-propan-2-yl-2,3,4,4b,5,6,10,10a-octahydrophenanthrene-1-carboxylate") which refers only to a specific constituent of the Substance, on the other hand.

Consequently, the information provided is not compliant and you must resolve the inconsistency described above by updating the registration and providing the numerical identifiers and chemical name that will correctly identify the Substance.

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.

Technical instructions on how to report substance identity information in IUCLID format is available in the IUCLID manuals (http://echa.europa.eu/manuals).

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

Annex VI, section 2 to REACH lists information requirements that shall be sufficient to identify a registered substance, including the composition of the registered substance (Annex VI, 2.3.). More in detail, the information requirements listed in Annex VI, section 2.3.2. include for UVCB substances: the names of the constituents (section 2.3.2.) present at ≥10%, names of known constituents present <10%, for constituents that cannot be identified individually, description of groups of constituents based on chemical nature, and description of the origin or source and the manufacturing process. Furthermore, the information requirements listed in Annex VI, section 2.3.3. include the typical concentration and concentration range (in percentage) of constituents, groups of constituents that cannot be identified individually as specified in section 2.3.2 (section 2.3.3).

In IUCLID section 1.2 the following constituents have been reported:

- **sodium** abietate / **sodium** abieta-7,13-dien-18-oate
- **sodium** [1R-(1α,4aβ,10aα)]-1,2,3,4,4a,9,10,10a-octahydro-7-isopropyl-1,4a-dimethylphenanthren-1-carboxylate / **sodium** abieta-8,11,13-trien-18-oate
- [redacted] / **sodium** 1,4a-dimethyl-7-propan-2-yl-2,3,4,5,6,9,10,10a-octahydrophenanthrene-1-carboxylate
- [redacted] / **sodium** (1R,4aR,4bS,10aR)-1,4a-dimethyl-7-propan-2-ylidene-3,4,4b,5,6,9,10,10a-octahydro-2H-phenanthrene-1-carboxylate

Based on the EC name (”Resin and rosin acids, **calcium** salts”) and on the description of the manufacturing process included in IUCLID section 1.2 (“[…] This is reprecipitated by the addition of calcium chloride to form **calcium** resinate”), it is expected that the composition of the Substance contains constituents/groups of constituents that are **calcium** salts, but the listed constituents are reported as Sodium salts.

Therefore, it is unclear whether the registration is indeed for the substance ”Resin and rosin acids, calcium salts” or if the identity of each of the listed constituents and its typical concentration and concentration ranges are incorrect.

Provided that the registration is indeed for the substance ”Resin and rosin acids, calcium salts” each constituent should be reported with its appropriate IUPAC name of the respective calcium salt of individual resin and rosin acids together with their typical concentrations and concentration ranges. In any case, you must ensure that the name and the other identifiers of each constituent of the Substance in section 1.2 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 correctly identified composition must be provided in IUCLID section 1.2. You shall ensure that the constituents names of the Substance are referenced using the correct names and other identifiers throughout the dossier.

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

The description of the analytical methods or the appropriate bibliographical references that are necessary for the identification of a substance (including the identification and quantification of its constituents and, where appropriate, its impurities and additives) is an information requirement of Annex VI, Section 2.3.7 to REACH. The description shall consist of the experimental protocols followed and the relevant interpretation of the results reported

under points 2.3.1 to 2.3.6 of Annex VI. This information shall be sufficient to allow the methods to be reproduced.

In this respect, provision of all necessary quantitative analytical data specific for the identification of a substance, such as chromatographic, titrimetric, elemental analysis or diffraction data, is an information requirement of Annex VI, Section 2.3.6 to REACH.

You registered your substance with EC/EINECS number 232-694-8, CAS entry 9007-13-0 and EC name "Resin and rosin acids, calcium salts" and you provided analytical data relevant to identify the composition of the organic part of your substance. However you have only provided an excel table in pdf format " [redacted].pdf" containing a reference to calcium and sodium standards but with no description of a suitable analytical method, with no spectral data and with no described calculation of the determination of the counter-ion calcium and obtained result, is present.

Therefore, as the analytical method and the relevant analytical report with the obtained results are missing, it is not possible to confirm the identification of the substance including the identification and quantification of its constituents.

Therefore, you are requested to submit a description of the analytical method and its results for the identification and quantification of counter-ion calcium. Such analyses must prove whether the substance and its composition are indeed "Resin and rosin acids, calcium salts".

The quantitative analytical data and the description of the analytical methods must be provided in IUCLID section 1.4.

Appendix 2: Procedure

The scope of this compliance check decision is limited to the standard information requirements of Annex VI, Section 2 to 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 29 March 2022.

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

ECHA did not receive any comments within the commenting period.

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.