Helsinki, 20 April 2016

Addressee: [redacted]

Decision number: CCH-D-2114326044-62-01/F
Substance name: Linseed oil, polymerized
EC number: 614-114-9
CAS number: 67746-08-1
Registration number: [redacted]
Submission number: [redacted]
Submission date: 01.06.2015

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **Composition of each substance (Annex VI, Section 2.3.) of the registered substance;**

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

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 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 and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **27 July 2016**. You shall also update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

The scope of this compliance check decision is limited to the standard information requirement(s) of Annex VI, Section 2.3. of the REACH Regulation.

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, shall 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

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

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.

"Composition of the substance" is an information requirement as laid down in Annex VI, Section 2.3. of the REACH Regulation. 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. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the registered substance and therefore its identity, as required under Annex VI, Section 2.3 of the REACH Regulation.

ECHA notes that the Registrant reported five constituents in section 1.2 of the IUCLID dossier with the following concentration ranges:

[redacted]

An explanatory note is included in IUCLID section 1.4 which provides a justification for the broad ranges indicated. The Registrant states that "*Different viscosities are also identified and these qualities of stand linseed oil share the same main identifiers, the same constituents as seen in section 1.2 and are here defined as qualities of the same UVCB*". To support this statement the Registrant provided a set of analytical data (1H-NMR, IR and GPC) for two different viscosities manufactured. The Registrant explains in the same document that "*the viscosity is only linked to the ratio of constituents identified in earlier sections (chapter 1.2 –* [redacted]*). Between different viscosities, there is no other difference in the chemical composition than a difference in the ratio of identified constituents. As indicated in the description of the substance, those variations in composition are part of the definition of the UVCB. The current substance Linseed oil, polymerized should therefore be regarded as one UVCB regardless of the viscosity.*"

ECHA considers that there is not enough supportive information in the dossier to confirm this statement that the different viscosity grades all derive from the same substance.

Firstly, as the different substance grades are not reported separately in IUCLID section 1.2 it is not possible to carry out a meaningful comparison of the compositions. Each substance grade should be reported as a unique composition in IUCLID section 1.2 with a list of constituents and a concentration range for each constituent.

The IR and 1H-NMR spectra show similarities in functional groups between the two viscosities tested and the GPC chromatograms illustrate a similar pattern in the weight distribution for the two tested viscosities but none of these analyses provide information on breakdown of constituents. Furthermore, in the GPC chromatograms there is a clear difference in the overall weight between the two tested viscosities which indicates a difference in composition. As described above it is not possible to determine the impact of this difference without a decription of the composition for each viscosity grade.

Therefore ECHA concludes that the information provided on the composition has not been provided to the required level of detail.

The Registrant is accordingly requested to specify the identity and typical, upper and lower concentration level of the constituents and groups of constituents required to be reported for each grade of the substance.

Regarding how to report the composition in IUCLID, the following applies:

The Registrant shall indicate the composition of each grade of the registered substance in IUCLID Section 1.2.

For each constituent required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID. For the unknown constituents to be reported under a generic description, a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.

Further technical details on how to report the composition of UVCB substances in IUCLID are available in paragraphs 2.1 and 2.2.2 of the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012).

ECHA highlights that the Registrant shall also ensure that the compositional information is verifiable and therefore supported by qualitative and quantitative analytical data, as required under Annex VI section 2.3.7. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

In the comments on the draft decision the Registrant indicated his intention to address the information requirement in an update of the registration providing further details on the manufacturing process and the composition of the various grades manufactured. ECHA notes that the information outlined would appear to satisfy the requirements of the draft decision.

However, the Registrant is reminded that this decision does not take into account any updates submitted after 23 October 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.

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

"Description of the analytical methods" is an information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has provided GPC chromatograms for two different viscosity grades. However, the report from the GPC analysis does not provide any information on the identity and concentration levels of the constituents in the substance as the peaks in GPC chromatogram are not integrated and constituent identities are not assigned to them.

The Registrant is therefore requested to provide a description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

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

The Registrant shall ensure that the composition reported in the dossier is consistent with the analytical results obtained.

In the comments on the draft decision the Registrant indicated his intention to address the information requirement in an update of the registration dossier by providing GPC analysis for each grade of the substance together with a molecular weight distribution for each grade with peak assignment and mass distribution.

The Registrant is reminded that this decision does not take into account any updates submitted after 23 October 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.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 9 October 2015

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation:

ECHA notified you of the draft decision and invited you to provide comments. ECHA took into account your comments, which were sent within the commenting period, and they are reflected in the Reasons (Appendix 1).

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

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

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the information required by the present decision, the sample of substance used for the new test(s) 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 composition 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 substance tested in the new test(s) 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 test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.