

Helsinki, 15 November 2018

Addressee

Decision number: CCH-D-2114450984-39-01/F  
Substance name: Alkenes, C7-9, hydroformylation products, distn. residues, heavy cracked fraction  
EC number: 308-482-7  
CAS number: 98072-31-2  
Registration number: [REDACTED]  
Submission number: [REDACTED]  
Submission date: 10 April 2018  
Registered tonnage band: Over 1000

### **DECISION TAKEN UNDER ARTICLE 42(1) OF THE REACH REGULATION**

By decision CCH-D-0000001668-65-04/F of 10 November 2011 ECHA requested you to submit information by 10 January 2012 in an update of your registration dossier.

Based on Article 42(1) of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA examined the information you submitted with the registration update specified in the header above, and concludes that further information is required.

#### **Your registration still does not comply with the following information requirement:**

- 1. Name or other identifier of the substance (Annex VI, Section 2.1.);**
  - **Manufacturing process**
- 2. Composition of the substance (Annex VI, Section 2.3.);**
  - **Identity of the constituents**

You have to submit the requested information in an updated registration dossier by **22 February 2019**. You also have to 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 and advice and further observations are provided in Appendix 3.

The scope of this compliance check decision is limited to the standard information requirements of Annex VI, Section 2 to 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, 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<sup>1</sup> by Kevin Pollard, Head of Unit, Evaluation E1

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<sup>1</sup> 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

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

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

According to Annex VI, Section 2.1 of the REACH Regulation, the name and other identifiers reported are required to be sufficient to enable the substance identity to be verified.

According to chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 2.1, May 2017) - referred to as "the SID Guidance" hereinafter, the naming of substances identified following the nomenclature principles for "Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) substances" consists of two parts: (1) the chemical name and (2) a more detailed description of the manufacturing process.

You have reported the identity of the registered substance with the chemical name "*Alkenes, C7-9, hydroformylation products, distn. residues, heavy cracked fraction*". The numerical identifiers reported are EC 308-482-7 and CAS number 98072-31-2.

In IUCLID section 1.2 you have included the description of the manufacturing process, which contains the following statement

[REDACTED]

The composition record in Section 1.2 of the technical IUCLID dossier reports groups of constituents identified with the following chemical names, based on the carbon number ranges and chemical moieties:

- C9-11-iso-alcohols (C10-rich)
- Aliphatic ethers, C16-C22
- Aliphatic ether-alcohols, C17-C23
- Aliphatic acetals, C24-C33
- C8-10-iso-alcohols (C9-rich)

According to the chemical name reported, "C7-9 alkenes" is the starting material that undergoes the hydroformylation process (also called "oxo"process) to obtain a product with an additional carbon unit and an alcoholic function. It is expected that the substance obtained is showing a carbon range of C8-10.

Therefore, the constituents reported in the manufacturing process with a carbon number of C11 are inconsistent with the reported name.

In addition, also considering the [REDACTED] during the manufacturing process, the maximum carbon number expected is a multiple of 10.

Therefore the reported constituents in the composition with carbon numbers of C22 and C33 are also inconsistent with the reported name.

Consequently, you are requested to clarify and revise as appropriate the identity of the starting material reported.

Either the name of the substance needs to be revised to reflect the information given in the manufacturing process description, or constituents with alkyl chain numbers C11 need to be removed from the description of the manufacturing process. This information needs to be added to the manufacturing process description in the "Description" field of the composition record in Section 1.2 of the dossier.

In case other alkenes than C7-9 are used as starting material, information on their identity and ratio shall be given in the manufacturing process description in the "Description" field of the composition record in Section 1.2 of the dossier.

In this case, the current identifiers (name and numerical identifiers) are not appropriate to correctly identify the registered substance and will need to be revised:

- A chemical name representative of the substance needs be reported in the IUPAC name field, in Section 1.1 of the dossier.
- The CAS number 98072-31-2 needs to be removed from the "CAS information" field (but can still be reported in the "other identifiers" field). An appropriate CAS number (if available) for the registered substance need to be reported in the "CAS information" field.
- The EC entry 308-482-7 cannot be removed or modified at this stage, because the registration is linked to this number in REACH-IT. Your update will not be recognised by the IT system as an update to an existing registration if you modify this number. You should instead provide in the 'Remarks' field in IUCLID section 1.1 the following text: *"The currently assigned reported EC entry 308-482-7 is not appropriate for the registered substance. This number cannot be modified or deleted at this stage in the present registration update for technical reasons."* ECHA has established a process, subject to certain conditions, enabling registrants to adapt the EC identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

Pending the resolution of the non-compliances addressed in the present decision, any possible adaptation of the identifier can only become effective once ECHA is in a position to establish unambiguously the identity of the substance intended to be covered by you with this registration. Should the information submitted by you as a result of the present decision enable ECHA to identify the substance unambiguously and result in a need to modify the identifier of the substance, the process of adapting the identifier will be considered relevant. In that case, ECHA will inform you in due time as to when and how the identifier adaptation process shall be initiated. In any case, you should note that the application of the process of adapting the identifier does not affect your obligation to fulfil the requirements specified in this decision.

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

According to Annex VI, Section 2.3 of the REACH Regulation, sufficient compositional information is required to be reported in a registration dossier such that the substance identity can be verified.

According to Chapter 4.3 of the SID Guidance, for UVCB substances the following applies:

- all known constituents and all constituents present at concentrations  $\geq 10\%$  should be specified by at least an English-language IUPAC name and preferably a CAS number;
- the typical concentrations and concentrations ranges of the known constituents should be given as well;
- constituents that are relevant for the classification and/or PBT assessment of the substance shall always be identified by the same identifiers, independently from their concentration;
- unknown constituents should be identified as far as possible by a generic description of their chemical nature.

In the registration dossier you have reported the following groups of constituents:

- C9-11-iso-alcohols (C10-rich), conc. range [REDACTED]
- Aliphatic ethers, C16-C22, conc. range [REDACTED]
- Aliphatic ether-alcohols, C17-C23, conc. range [REDACTED]
- Aliphatic acetals, C24-C33, conc. range [REDACTED]
- C8-10-iso-alcohols (C9-rich), conc. range [REDACTED]

In the Description field in the composition record in Section 1.2 of the dossier you included the following statement: *"A complex mixture of oxygenated hydrocarbons, primarily iso-alcohols and aliphatic ethers, and other heavy oxygenated hydrocarbons. All structure are branched and multi-isomeric."*

In addition, in Section 1.4 of the dossier, the file named [REDACTED], provides the results of the Gas Chromatography –Mass Spectrometry (GC-MS) analysis. The following results are reported:

- Fig 1.1 – Group I: Alcohols (range [REDACTED], typical [REDACTED])  
C10 and C11 iso-alcohols
- Fig 1.2 – Group II: Dimers (range [REDACTED], typical [REDACTED])  
C17 to C22 ethers  
C19 to C22 ether alcohols
- Trimers (group III) [REDACTED]

[REDACTED]. The concentration range of this group of constituent has been reported to be [REDACTED].

Alkyl descriptors like C7-9 without any further specification used to describe oleochemicals refer solely to saturated, linear alkyl chains comprising all chain lengths. This practice is explained in the SID Guidance and also described in the OECD guidance for characterising oleochemical substances for assessment purposes, Series on Testing & Assessment, No. 193 (available on the OECD website). For example "C12–14" corresponds to "C12, C13, C14" including both even and odd numbered but only linear alkyl-chains.

With the exception of C9-11-iso-alcohols (C10-rich) and C8-10-iso-alcohols (C9-rich), which with the pre-fix "iso" indicate the branched nature of the constituents, the names used for the "aliphatic" groups of constituents do not indicate the branched nature of the alkyl chain.

This is not in line with what you reported in the Description field in the composition record. Accordingly there is an inconsistency regarding the branched nature of the reported constituents.

Based on the analytical results included in the report [REDACTED], the only alcohols clearly identified and quantified are C10 and C11 iso-alcohols. This data is not in line with the 2 groups of iso-alcohol reported in the composition record (C9-11-iso-alcohols (C10-rich) and C8-10-iso-alcohols (C9-rich)). The presence of C8 and C9 constituents is not supported by analytical data. Therefore there is an inconsistency between analytical data and reported composition regarding the branched nature of constituents.

In addition, also the concentration values reported in the composition record in Section 1.2 of the dossier for "C9-11-iso-alcohols (C10-rich)" and "C8-10-iso-alcohols (C9-rich)" are not consistent with the analytical data. "Group I: Alcohols" have been reported in the analytical data to be present with a range of [REDACTED] whereas in the composition there are two overlapping groups of alcohols reported each with a range of [REDACTED], leading to a combined range of [REDACTED]. In addition, the typical concentration value reported for "Group I: Alcohols" is [REDACTED] which is not possible as this value is outside of the [REDACTED] range reported in the same document. Therefore there is an inconsistency between analytical data and reported composition regarding existence and concentration of alcohol constituents.

Also, the carbon ranges reported for dimers in the composition record (C16-C22 ethers and C17-C23 ether alcohols) are not consistent with the analytical data. The corresponding groups have been identified in the analytical results as C17-22 ethers and C19-C22 ether alcohols.

Finally, also the carbon ranges of trimers reported in the composition record (Aliphatic acetals, C24-C33) are not in line with the analytical data. The corresponding groups have been described in the analytical results as containing C29-C30 molecules, possibly acetals.

In conclusion, there are inconsistencies in the way the composition has been reported, because

- The identities of some groups of constituents have been reported with names that would refer only the linear structures, whereas the constituents are all branched, as indicated in the "Description of composition" statement.
- The compositional information is not fully supported by the analytical data provided in Section 1.4 of the dossier. According to such data, the carbon numbers would be different from those reported in the names which have been used to identify the groups of constituents in Section 1.2 of the dossier.
- The reported concentration ranges are not fully supported by the analytical data provided as some concentrations found in the analysis are outside the range reported in the composition.

You will need to report the names for the groups of constituents such that the branched nature is given in the name. You will also need to revise the carbon numbers reported for each group of constituents such that they are consistent with the analytical data reported in Section 1.4 of the dossier. In case you have determined the carbon number ranges by alternative methods and the carbon numbers reported are correct, you will need to include a description of how you determined the values reported.

Additionally you need to ensure that the identification of your substance is consistent with both composition and analytical results throughout the dossier.

The information requested above should be provided in Section 1.2 of the IUCLID dossier.

You will need to ensure that the identity information reported in the different sections of the IUCLID dossier is consistent and refers unambiguously to what you have registered.

## **Appendix 2: Procedural history**

The compliance check was initiated on 29 November 2017.

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 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 did not receive any comments by the end of 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 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 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 your Member State.