EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003824-71-06/F Helsinki, 27 February 2014

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

**For Alkenes, C7-9, hydroformylation products, distn. residues, heavy cracked fraction, CAS No 98072-31-2 (EC No 308-482-7), 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 dossier for Alkenes, C7-9, hydroformylation products, distn. residues, heavy cracked fraction, CAS No 98072-31-2 (EC No 308-482-7) submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VII, Sections 7.8. and 8.4., and Annex VIII, Section 8.4. of the REACH Regulation.

This decision is based on the registration dossier as submitted with submission number [redacted] for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 31 October 2013, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

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

The compliance check was initiated on 28 September 2012.

On 17 December 2012 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 23 January 2013 ECHA received comments from the Registrant, in which the Registrant indicated that he would update the registration dossier with further information by 23 March 2013. On 20 May 2013 the Registrant updated his registration dossier.

ECHA considered the Registrant's comments and the updated dossier received.
On basis of the comments and the updated dossier, Section II was amended (one information requirement was removed). The Statement of Reasons (Section III) was also changed.

On 31 October 2013 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annex VII of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

- *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14/OECD 471).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **27 August 2014**.

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 requirement. The scope of the present decision includes the *in vitro* gene mutation study in bacteria (Annex VII, 8.4.1. of the REACH Regulation). In accordance with Articles 10(a)(vii) and 12(1)(e) of the REACH Regulation, any registration for a substance manufactured or imported by a registrant at the tonnage level of 1000 tonnes or more per year shall contain this information.

*In vitro* gene mutation study in bacteria

The technical dossier from the initial submission neither contained an *in vitro* gene mutation study in bacteria nor an adaptation argument to the standard information requirement of Section 8.4.1. of Annex VII. Therefore, the Registrant was requested to submit the information for this endpoint using the abovementioned test method on the registered substance.

Following the draft decision the Registrant commented that the submitted information on mutagenicity was "sufficient to assess the genetic toxicity potential of Alkanes" and that "testing for in vitro gene mutation in bacteria was not scientifically justified". The Registrant also updated the dossier with a weight of evidence justification for this endpoint.

Firstly, ECHA notes that the information submitted for other mutagenicity endpoints such as Sections 8.4.2. and 8.4.3. of Annex VIII does not fulfil the standard information requirement of Section 8.4.1. of Annex VII. As specified in Annex VIII, Column 2, 8.4. "Appropriate *in vivo* mutagenicity studies shall be considered in case of a positive result in any of the genotoxicity studies in Annex VII or VIII". Thus, the Ames test is an important regulatory trigger for further *in vivo* studies that cannot be waived on the basis of other available *in vitro* studies in mammalian cells or of the weight of evidence presented in this dossier.

Secondly, with regard to the weight of evidence analysis, ECHA notes the following. The Registrant's analysis was conducted by assessing hazard potential of individual components of the registered UVCB substance. There are three types of components identified for this substance:

- Isodecanol (predominately dimethyloctanols) accounting for [redacted] of the registered substance
- Dimers of isodecanol (oxygenated hydrocarbons with 17 to 23 carbons, with ethers and ether alcohol functional groups) accounting for [redacted] of the registered substance
- Trimers of isodecanol (oxygenated hydrocarbons with 27 to 33 carbons, with acetal functional groups) accounting for [redacted] of the registered substance.

The weight of evidence is based on several sources of information.

Firstly, the Registrant submitted information corresponding to the information requirements of Annex VII, 8.4.1. and Annex VIII, 8.4.2. and 8.4.3. on the first component, isodecanol. All the tests for this component were negative. ECHA considers that for that individual component, the information is sufficient. The Registrant did not suggest and ECHA does not consider that the information on that component could be read across to the other components of the substance. The component of the registered substance covered by the above studies accounts for only [redacted] of the substance composition and there is no information on the possibility of reconversion of the dimers and trimers to isodecanol.

Secondly, for the remaining [redacted] of the composition of the substance the weight of evidence included three OECD QSAR Toolbox 3.0.0.995 - QSAR Toolbox predictions for bacterial gene mutation assay with negative results for genotoxicity. These predictions, although well documented still show, as stated by the Registrant, "*a moderate degree of uncertainty because there was not absolute consistency in the end result for category members with available data*". In addition, it cannot be ascertained that the three representative structures cover the wide variety of constituents that could be contained in the final registered substance (and especially the constituents grouped under "*oxygenated hydrocarbons (C17-C23), including aliphatic ethers, from the hydroformylation reaction of nonene*" and "*oxygenated hydrocarbons (C27-C33), from the hydroformylation reaction of nonene*").

In conclusion, for the bacterial gene mutation endpoint the available data are prediction-type studies only covering for the dimers and trimers of isodecanol claimed to represent [redacted] of the substance. According to Annex XI 1.2. "There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion". As no experimental data is available to remove the remaining uncertainty from the QSAR predictions for [redacted] of the registered substance the weight of evidence is not considered sufficient to waive the Ames study.

As the Registrant has neither fulfilled the information gap nor submitted a fully justified adaptation, Section II of the decision has not been amended in this respect.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Bacterial reverse mutation test (test method: EU B.13/14. / OECD 471)

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In carrying out the studies required by the present decision it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grade registered to enable the relevance of the studies to be assessed.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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://echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
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