EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000005614-74-01/F Helsinki, 1 December 2014

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

For Reaction mass of Amides, rape-oil, N-(hydroxyethyl), ethoxylated and Glycerol, ethoxylated, (EC No 932-164-2), 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 for Reaction mass of Amides, rape-oil, N-(hydroxyethyl), ethoxylated and Glycerol, ethoxylated, (EC No 932-164-2), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VIII, Section 8.4.3. of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration 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 submitted after 24 July 2014, 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 registration at a later stage.

The compliance check was initiated on 4 April 2013.

On 3 July 2013 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 28 July 2013 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 24 July 2014 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 for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposals for amendment were submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

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

- *In vitro* gene mutation study in mammalian cells (Annex VIII, 8.4.3.; test method: EU B.17/OECD 476).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **8 December 2015**.

Note for consideration by the Registrant:

The Registrant 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 sound scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

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 the Member States.

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 requirements. The scope of the present decision is the *in vitro* gene mutation study in mammalian cells (Annex VIII, 8.4.3. of the REACH Regulation).

Mutagenicity, *in vitro* gene mutation study in mammalian cells

In accordance with Articles 10(a)(vii), 12(1)(e) and with Annex VIII, section 8.4.3. of the REACH Regulation, the *in vitro* gene mutation study in mammalian cells is required if there is a negative result in the *in vitro* studies specified under Annex VII, section 8.4.1 and Annex VIII, section 8.4.2. The registration dossier reports negative results for the both *in vitro* studies. Therefore the REACH Regulation requires that information on *in vitro* gene mutation in mammalian cells (Annex VIII, 8.4.3.) is provided in the dossier. ECHA notes furthermore that a cytogenicity study (be it *in vitro* or *in vivo*) cannot be used for *in vitro* or *in vivo* mammalian cell gene mutation information requirements. Cytogenicity studies and gene mutation studies are corresponding to two different endpoints and two distinct mechanisms of genotoxicity: cytogenicity studies detect structural and numerical chromosome aberrations whereas gene mutation studies detect gene or point mutations. ECHA concludes that the Registrant has neither provided this standard information nor adapted the requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA acknowledges that in its comments to the draft decision, the Registrant sought to justify an adaptation of the standard information requirement by presenting arguments for using a read across approach (Annex XI, 1.5). It is the Registrant's responsibility to identify and justify whether the information requirement could be adapted (introductory paragraph 2 of Annex VIII and Annex XI, Section 1.5. of the REACH Regulation). No information on the read across substance was submitted in the technical dossier. Already for this reason the adaptation is not justified. Furthermore, the justification and documentation of the proposed read-across does not fulfil the criteria of Annex XI, Section 1.5. of the REACH Regulation.

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: *In vitro* mammalian cell gene mutation test (test method: EU B.17./OECD 476).

Notes for consideration by the Registrant:

ECHA notes that the Registrant sought to obtain input from ECHA on the plausibility of the submitted read across argument. ECHA cannot take over the responsibility for whether – once the data on the read across substance is available in the technical dossier and the justification of the read-across is completed – this information would fulfil the information requirement. ECHA further notes the following:

The Registrant bases its read across argumentation on 1) structural/compositional similarity, 2) similarity in metabolism and 3) mutagenicity data with similar substances.

The Registrant states in its comments that there is a "[redacted]". While the "[redacted]". If the level of saturation is critical for an effect, the two substances are expected to differ for this effect. It is furthermore stated that [redacted]. Based on the information presented by the Registrant it is difficult to say whether this difference is small or large. Furthermore, it should be explained whether or not such a difference has an effect on the considered endpoint.

The other constituents differ in the sense that for the target it is ethoxylated glycerol, while it is glycerol for the source. This is referred to as "[redacted]". The Registrant further states "Both substances are well known for being a very low hazard profile with no mutagenic concerns." While this can be accepted for glycerol the toxicity of fully ethoxylated glycerol is unknown.

It is stated by the Registrant that "these differences have no structural alerts for mutagenicity and are substances which are closely related to substances of known low toxicity". The Registrant should explain which expert system they used to come to the conclusion that there are no structural alerts. With regard to the second part of the statement concerning low toxicity, no evidence is presented.

The Registrant goes on to state "All other impurities and/or constituents of both substances are [redacted] and are not considered relevant for the classification and labelling of each substance. Besides, none of them have mutagenic properties." The Registrant does not provide a reference to the origin of this information or specify the impurities referred to.

In Section 2.2 it is stated: "The constituents of these substances are based primarily on the alkyl chain length distributions which are similar." When comparing the source and the target similar alkyl chain distributions are not evident.

The Registrant's statement "The differences on the number of unsaturations on the alkyl chain are not considered to affect the negative mutagenic properties of the source substance, as it is demonstrated across all the category approach of the fatty acid alkanolamides referred previously" is not substantiated.

The Registrant refers to a document on alcohol ethoxylates, C6-C18. It is not known whether this document covers the ethoxylated amides such as source and target. Without access to the document ECHA is unable to check whether the statement is valid and relevant.

The remarks about the metabolism and common breakdown products are not substantiated by any data in the dossier. ECHA notes that the Registrant may on its own responsibility update the dossier with the supporting data.

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. The Registrant is reminded of his responsibility to ensure that his registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In carrying out the study 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 study must be suitable to assess these.

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

V. 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]
Leena Ylä-Mononen
Director of Evaluation