ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114288759-24-01/F Helsinki, 12 December 2014

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

For Alcohols, secondary C11-15, ethoxylated, CAS No 68131-40-8 (EC No 614-295-4), 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 Alcohols, secondary C11-15, ethoxylated, CAS No 68131-40-8 (EC No 614-295-4, submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex IX, Sections 8.6.2 and 8.7.2 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or moreper year. This decision does not take into account any updates submitted after 12 June 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 3 July 2013.

On 30 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. That draft decision was based on submission number [redacted]

On 29 August 2013 ECHA received comments from the Registrant on the draft decision. On 7 October 2013 the Registrant updated his registration dossier with submission number [redacted]

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

On 12 June 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.

Subsequently, proposals for amendment to the draft decision were submitted.

On 18 July 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

The draft decision was split into two draft decision documents: one relating to the request for a two-generation reproductive toxicity study and one relating to the request for a sub-chronic toxicity study (90-day) and a pre-natal developmental toxicity study.

The present decision relates solely to compliance checks for a sub-chronic toxicity study (90-day) and a pre-natal developmental toxicity study. The other compliance check requirement of a two-generation reproductive toxicity study (Annex X, 8.7.3) is addressed in a separate decision although all endpoints were initially addressed together in the same draft decision.

On 28 July 2014 ECHA referred the draft decision to the Member State Committee.

By 18 August 2014, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant on the proposals for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision relating to a sub-chronic toxicity study (90-day) and a pre-natal developmental toxicity study was reached on 1 September 2014 in a written procedure launched on 21 August 2014.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

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

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, 8.6.2.; test method: EU B.26./OECD 408) in rats;

2. Pre-natal developmental toxicity study (Annex IX, 8.7.2.; test method: EU B.31./OECD 414) in rats or rabbits, oral route.

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 **19 December 2016**. The timeline has been set to allow for sequential testing as appropriate.

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 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.

Pursuant to Articles 10(a)(vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes IX and X of the REACH Regulation.

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, 8.6.2.)

A "Sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has not provided any study record of a sub-chronic repeated dose toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.6.2. Instead, the Registrant has sought to adapt the information requirement for a sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.). The Registrant has justified the proposal for adaptation with the following justification: "*The substance is used in accordance with Strictly Controlled Conditions (SCC) as defined in Chapter 2, Article 18(4) of Regulation (EC) No. 1907.2006 i.e.:*
(a) The substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage.
(b) Procedural and control technologies are be used to minimise emission and any resulting exposure.
(c) Only properly trained and authorised personnel handle the substance.
(d) In the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered.
(e) In cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures.
(f) Substance-handling procedures are well documented and strictly supervised."

The Registrant provided comments to the draft decision and an update of the registration. ECHA notes that the Registrant provided in this update sufficient documentation to demonstrate strictly controlled conditions during the use of the substance to manufacture a new substance. However, ECHA notes that the substance is used to produce polymers [redacted].

In the case at hand, ECHA notes that the Registrant does not seem to consider the potential release of either the reacted or unreacted "other substance" in the polymer and the consequences for the further life cycle stages. Therefore, further information needs to be produced to assess the risks of the substance that may be released during the life cycle of the polymer it is part of.

Therefore, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement of a standard registration dossier. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In light of the properties of the substance (liquid with low vapour pressure not classified for skin or eye corrosion or irritation) and the information provided on the uses and human exposure (no uses with spray application), ECHA considers that testing by the oral route is most appropriate.

A Member State Competent Authority submitted a proposal for amendment (this proposal for amendment also applies to the pre-natal developmental toxicity study) underlining that the registered substance is not a monomer but it falls within "other substances" according to Article 6(3) of the REACH Regulation.

ECHA acknowledges the fact that the registered substance is not a monomer but falls within the scope of "other substances" according to Art. 6(3) of REACH.

Article 6(3) sets out that a registration should be submitted for any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met:
(a) the polymer consists of 2% weight by weight (w/w) or more of such other substance in the form of chemically bound substance(s);
(b) the total quantity of such other substance(s) makes up one tonne or more per year.

Moreover, ECHA agrees that Article 6(2) refers only to monomers and, therefore, does not prevent "other substances" to be registered as intermediate. Accordingly, as stated in ECHA Guidance for monomers and polymers (Version 2.0, April 2012), Articles 17 and 18 of REACH do apply to "other substances" provided that the conditions specified in those Articles are met.

Regarding the specific situation of the dossier, ECHA notes that the Registrant has chosen the format of a full registration that would give him the right to use the registered substance for both intermediate and non-intermediate uses. It is not clear in which percentage the [redacted] and which are the uses of the substance (i.e. if intermediate only or not).

According to the test method EU B.26/OECD 408 the rat is the preferred rodent species. ECHA considers this species as being appropriate.

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: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD 408) in rats.

2. Pre-natal developmental toxicity study (Annex IX, 8.7.2.)

A "Pre-natal developmental toxicity study" for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has not provided any study record of a pre-natal developmental toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.6.2. Instead, the Registrant has sought to adapt the information requirement for a prenatal developmental toxicity study (Annex IX, 8.7.2.). The Registrant has justified the proposal for adaptation with the same argumentation as cited in Section III.1. above.

As the Registrant has not demonstrated and documented that strictly controlled conditions indeed apply throughout the whole life cycle (see Section III.1. above), the adaptation is not justified.

The Registrant provided comments to the draft decision and an update of the registration. ECHA notes that the Registrant has provided sufficient documentation in this update to demonstrate strictly controlled conditions during the use of the substance to manufacture a new substance. However, ECHA notes that the substance is used to produce polymers [redacted]. For the same considerations as set out in section III.1 above, further information needs to be produced to assess the risks of the other substance that may be released during the life cycle of the polymer it is part of.

Accordingly, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

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: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rats or rabbits by the oral route.

Notes for consideration by the Registrant

In addition, a pre-natal developmental toxicity study on a second species is part of the standard information requirements as laid down in Annex X, Section 8.7.2. for substances registered for 1000 tonnes or more per year (see sentence 2 of introductory paragraph 2 of Annex X).

The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if weight of evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed. If the Registrant considers that the conditions for these adaptations are not fulfilled, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species. If the Registrant comes to the conclusion that the conditions for these adaptations can be fulfilled, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex X, 8.7.2. of the REACH Regulation.

3. Deadline for submitting the information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 36 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also addressed a two-generation reproductive toxicity study (Annex X, 8.7.3.). As this endpoint is not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated registration is 24 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

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(s) registered to enable the relevance of the studies 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/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

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