ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114288399-28-01/F Helsinki, 27 November 2014

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

For 2-acetone, condensation product with phenol, List number 931-252-8, 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 2-acetone, condensation product with phenol, List number 931-252-8 submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VII, Section 7.8. and Annex IX, Sections 8.6.2. and 8.7.2. 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 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 registration at a later stage.

The compliance check was initiated on 2 April 2013.

On 25 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 22 August 2013 ECHA received comments from the Registrant on the draft decision

On 11 September 2013 the Registrant updated his registration dossier with the 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 did not amend 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 partition coefficient n-octanol/water, sub-chronic toxicity study (90-day) and a pre-natal developmental toxicity study.

The present decision relates solely to a compliance check examination for the information requirements listed above. The other compliance check requirement of the 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 the Registrant did not provide any comments on the proposals for amendment.

A unanimous agreement of the Member State Committee on the draft decision relating to the sub-chronic toxicity and a pre-natal developmental toxicity studies 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

A. Information in the technical dossier derived from the application of Annexes VII to XI

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

1. Partition coefficient n-octanol/water (Annex VII, 7.8.);

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

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

B. Deadline for submitting the required information

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 **5 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 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 Authorities of the Member States for possible enforcement.

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.

A. **Information in the technical dossier derived from the application of Annexes VII to XI**

1. Partition coefficient n-octanol/water (Annex VII, 7.8.)

Instead of a value for the partition coefficient n-octanol/water an unbound range of ">=3.24" has been reported in the technical dossier under the appropriate heading in the technical dossier. As no upper limit was indicated, the information provided does not determine the partition coefficient n-octanol/water. The Registrant is therefore requested to submit information on the value of the partition coefficient n-octanol/water using an appropriate test method on the registered substance.

Guidance for determining appropriate test methods for the partition coefficient n-octanol/water is available in ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.7(a), section R.7.1.8.3. (pages 54 to 56, Version 2.0 of November 2012).

ECHA stresses that if the information on the partition coefficient n-octanol/water is provided as a defined range, the range has to be justified and remain within the applicability range of the applied test method. If HPLC test method (OECD Guideline 117, EU A.8) is used, then in accordance with the test method average retention data and interpolated Log Kow value(s) shall be provided, if possible.

In their comments Registrant referred to strictly controlled conditions (1), difficult to measure UVCB substance (2) and no effect on risk assessment (3).

ECHA considers that:

(1) Adaptations based on strictly controlled conditions (SCC), as described in Annex XI 3.1 of the REACH Regulation, are not applicable to Annex VII standard information requirements. Therefore SCC based adaptation cannot be used for n-octanol/water partition coefficient.

(2) According to ECHA Guidance Chapter R.7a: Endpoint specific guidance, p. 59-60 (version 2.4 February 2014):
- If experimental testing including estimation from the individual solubilities is not possible, log Kow must normally be calculated by an appropriate numeric method based on the molecule's structure. Computational tools could be used to provide this information in case experimental testing is not a practical solution.

(3) REACH Regulation; Annex VI preamble, note 1 states that if it does not appear scientifically necessary to give information, the reasons shall be clearly stated, in accordance with the relevant provisions. The technical dossier does not include any information on the endpoint n-octanol/water partition coefficient on SCC and how these conditions would make it unnecessary to report n-octanol/water partition coefficient. Neither has the Registrant – in his comments – referred to an adaptation possibility and explained how its criteria are fulfilled.

2. 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 arguments: "*In accordance with section 3 of REACH Annex XI, a study does not need to be conducted as, based on the Exposure Scenarios developed in the Chemical Safety Report, it is demonstrated and documented that throughout the life cycle Strictly Controlled Conditions as set out in Article 18(4)(a) to (f) of REACH do apply.*"

In this respect, pursuant to Annex XI, Section 3.2. of the REACH Regulation, in order to apply this adaptation, the Registrant has to provide adequate justification and documentation. Moreover, pursuant to Section 3.2.(b) of Annex XI, the Registrant *inter alia* has to demonstrate and document for all relevant scenarios that throughout the life cycle of the substance strictly controlled conditions as set out in Article 18 (4) (a) to (f) are fulfilled.

The Registrant has provided comments to the draft decision and an update of the registration dossier.

The registered substance is used to produce plastic articles which then introduce further lifecycle stages. In the updated registration the Registrant did not address any residual unreacted substance in the plastic articles and consequences for the further life cycle stages. According to the Registrant "*the substance is used for manufacturing phenol resins (prepolymerisation product). During this manufacturing step the original substance is consumed. Consequently, later processing steps are not relevant for this CSR and provide no more possibility of exposure to the substance*". However no evidence for their statement of no further relevant exposure is provided in the technical dossier. According to Annex XI, 3.2 (c)(i) and (ii) a rigorous exposure assessment is required to demonstrate and document that where the substance is incorporated in an article that the substance is not released during its life cycle and that the likelihood that workers or the general public or the environment are exposed to the substance under normal or reasonably foreseeable conditions of use is negligible. ECHA notes that the Registrant has provided in this update sufficient documentation to describe strictly controlled conditions during the use of the substance to manufacture a new substance. In the case at hand ECHA notes that the Registrant did not consider the potential release of substance from plastic articles and consequences of it for the further life cycle stages. Therefore, further information would have had to be produced to assess the risks of the substance that may be released during the life cycle of plastic articles.

Therefore, as explained above, 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.

In light of the properties of the substance (solid marketed or used in granular form classified), its classification (irritating to the skin and damaging to the eyes) and the information provided on the uses and human exposure (no uses with aerosol generation), ECHA considers that testing by the oral route is most appropriate.

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)(b) 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.

3. 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 8.7.2.

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 following arguments: "*In accordance with section 3 of REACH Annex XI, a study does not need to be conducted as, based on the Exposure Scenarios developed in the Chemical Safety Report, it is demonstrated and documented that throughout the life cycle Strictly Controlled Conditions as set out in Article 18(4)(a) to (f) of REACH do apply.*"

As the Registrant has not demonstrated and documented that strictly controlled conditions indeed apply throughout the whole life cycle (see Section III.2. above), the adaptation is not justified.

The Registrant has 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 plastic articles. For the same considerations as set out in section III.2. above, further information needs to be produced to assess the risks of the substance that may be released during the life cycle of a plastic article.

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)(b) 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.

B. Deadline for submitting the required 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 requested (two-generation reproductive toxicity study (Annex X, 8.7.3)). As this study 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 IUCLID5 dossier 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 by the Registrant and other joint registrants 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 relation to the information required by the present decision, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given 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 study 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study 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 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/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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