ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114308070-69-01/F Helsinki, 2 September 2015

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

For 4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid, CAS No 55818-57-0 (EC No 500-130-2), 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 4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid, CAS No 55818-57-0 (EC No 500-130-2), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements of Annex IX, Sections 9.3.2 of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants 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 11 June 2015, 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 7 August 2014.

On 8 October 2014 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 14 November 2014 ECHA received comments from the Registrant on the draft decision. On 17 February 2015 the Registrant updated his registration dossier with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update.

On basis of this information, the deadline in Section II was amended. The Statement of Reasons (Section III) was changed to take into account the Registrant's comments and the information provided in the Registrant's update.

On 11 June 2015 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 proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) 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)(vii), 12(1)(e), 13 and Annex IX 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:

1. Bioaccumulation in fish, aqueous or dietary exposure (Annex IX, Section 9.3.2.; test method: OECD 305).

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 in this decision, or to fulfil otherwise the information requirement with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **9 March 2017** an update of the registration dossier containing the information required by this decision.

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

Pursuant to Articles 10(a)(vi), 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 VII to X of the REACH Regulation. "Bioaccumulation in aquatic species" is a standard information requirement as laid down in Annex IX, Section 9.3.2. 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.

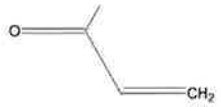
The Registrant has sought to adapt this information requirement. The justification of the adaptation given by the Registrant is that the "Study [is] scientifically unjustified: The logKow of the substance is lower than 4. Therefore, the substance is considered having a low potential for bioaccumulation and further testing is not required under Annex XI, section 1.2.".

While the Registrant himself refers to Annex XI, Section 1.2, the adaptation argument that he seeks to make falls more under the more specific adaptation possibility of the first dash in Annex IX, Section 9.3.2., Column 2, i.e. that the registered substance "has a low potential for bioaccumulation (for instance a log Kow ≤ 3) and/or a low potential to cross biological membranes". The Registrant has not demonstrated that the substance has a low potential for bioaccumulation. He, in fact refers to a log Kow value being lower than 4. No further adaptation arguments were submitted by the Registrant under the relevant heading in the registration dossier. Therefore the adaptation of the information requirement suggested by the Registrant cannot be accepted.

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 the updated dossier with submission number [redacted] received on 17 February 2015 the Registrant provided BCF estimates for the three representative structures of the registered UVCB substance by using two different QSAR models. The updated dossier and the provided documentation were assessed by ECHA Secretariat. The information provided was compared with the requirements set for acceptance of QSAR models in Annex XI section 1.3 as follows:

- Results are derived from a (Q)SAR model whose scientific validity has been established: The QSAR models used by the Registrant (BCF base line model of Catalogic and BCFBAF model from Episuite) are regarded as having sufficient scientific validity.
- The substance falls within the applicability domain of the (Q)SAR model: Two QSAR models were used in predicting the BCF.
  1) Catalogic predictions (3 first IUCLID endpoint study records): As indicated in the Catalogic output results, all 3 representative structures fulfil the parameter and mechanistic applicability domains. However, they fall out of the structural fragment applicability domain. More precisely, they contain too many fragments (64% of unknown fragments for representative structures 1 and 3 and 57% for representative structure 2) that are not recognised by the model. Therefore these predicted values are not reliable.
  2) Episuite predictions (3 last IUCLID endpoint study records): The molecular weights and the logKow of the substances falls within the ranges of the EPISuite training set. However, none of the structures in the BCFBAF model training set are very similar to the representative structures used by the Registrant. In addition none of them contain the following structure at the end of the chain, which is part of the all 3 representative structures:



- Results are adequate for the purpose of classification and labelling and/or risk assessment:
  1) Catalogic predictions: These predictions do not fall in the applicability domain of the model and therefore are not adequate for the purpose of classification and labelling and/or risk assessment.
  2) Episuite predictions: The Registrant used the logKow value of 3.8, which is derived from the partitioning coefficient study performed with the whole UVCB substance. However, for the 3 representative structures used in the model the logKow values predicted by ECHA using the KOWWIN and ADC labs are higher ranging between 6.27 to 7.63 and 7.17 to 8.76, respectively. The predicted BCFs for the 3 representative structures based on the estimated higher logKow's are 5720, 3520 and 3640 in contrast to the BCF of 82 estimated by the Registrant. Therefore the BCFBAF predicted results provided by the Registrant cannot be accepted as adequate for the purpose of classification and labelling and/or risk assessment.
- Adequate and reliable documentation of the applied method is provided: Sufficiently detailed QPRFs have been provided for all of the six QSAR predictions. QMRFs are not considered as necessary for the models used. The documentation provided by the Registrant is therefore considered sufficient.

In summary, ECHA considers that the criteria set in annex XI section 1.3. have not been met and the QSAR approach as it currently stands in the dossier cannot be accepted. The representative structures used in the modelling are not within the applicability domain of the model and the Kow used for the representative structures in the modelling does not correctly describe the octanol-water partitioning of the selected representative structures. Thus, ECHA considers that there is still an information gap for the requested information.

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:

Bioaccumulation in fish: aqueous or dietary exposure (test method: OECD 305).

Notes for consideration by the Registrant:

The Registrant is reminded that the bioaccumulation potential of the relevant constituents, impurities and additives of the registered substance should also be taken into account when designing the bioaccumulation test set-up.

The Registrant is advised to consult the ECHA Guidance on information requirements and chemical safety assessment, chapter R.11: PBT/vPvB assessment (Version 2.0, November 2014).

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

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

Authorised[1] by Guilhem de Seze, Head of Unit, Evaluation

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.