EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114289310-53-01/F Helsinki, 30 January 2015

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

For Alcohols, C7-9-iso-, C8-rich, CAS No 68526-83-0 (EC No 271-231-4), 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 dossier for Alcohols, C7-9-iso-, C8-rich, CAS No 68526-83-0 (EC No 271-231-4), submitted by [redacted] (Registrant). The scope of this compliance check was limited to the following standard information requirements relating to "Aquatic toxicity" and related environmental hazard assessment (Annex IX, 9.1.5. and 9.1.6. and Annex I, Section 3.3. of the REACH Regulation). Following the submission of proposals for amendement from the Dutch and German Competent Authorities within the 30 days of the receipt of the notification of the draft decision to the Competent Authorities of the Member States, the scope of this compliance check has been expanded to the standard information requirement of the REACH Regulation relating to Growth inhibition study aquatic plants and related environmental hazard assessment (Annex VII Section 9.1.2. 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 present dossier at a later stage.

The compliance check was initiated on 28 February 2013.

On 15 May 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 14 June 2013 ECHA received comments from the Registrant on the draft decision.

On 16 July 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 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.

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. In addition, the Registrant provided comments on the draft decision. The Member State Committee took the comments on the proposals for amendment of the Registrant into account. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5).

A unanimous agreement of the Member State Committee on the draft decision 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 regarding effects on aquatic toxicity

Pursuant to Articles 41(1)(a), 41(3), 10(a)(vii), 12(1)(e), 13 as well as Annexes VII and IX of the REACH Regulation the Registrant is required to carry out the following studies using the indicated test methods and the registered substance subject to the present decision:

a. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Algae, growth inhibition test, EU C.3./OECD 201);
b. Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211); and
c. Long-term toxicity testing on fish (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210)
as specified further under Section III.

Pursuant to Articles 41(1)(c), 41(3), 10(b) and 14 as well as Annex I, 3.3. of the REACH Regulation the Registrant shall submit the following information:

d. Revised PNECs for the aquatic compartment on the basis of data from a. and b. above as it becomes available.

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.

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 **8 August 2016**.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

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 covering Annex VII, 9.1.2. and Annex IX, 9.1.5. and 9.1.6. as well as related to environmental hazard assessment. In accordance with Articles 10(a)(vii), (b), 12(1) and 14(1) of the REACH Regulation, the registration is required to contain this information.

a. b. and c. Long-term aquatic toxicity testing on invertebrates and fish and Growth inhibition study aquatic plants

According to column 1 of Section 9.1.2. of Annex VII and Sections 9.1.5. and 9.1.6. of Annex IX of the REACH Regulation, growth inhibition study aquatic plants, long-term toxicity testing on invertebrates and long-term toxicity testing on fish is required to fulfil the standard information requirements.

The Registrant proposed to adapt these information requirements on aquatic long-term toxicity of the substance by providing results obtained from the application of quantitative structure activity relationship models ((Q)SARs). According to Annex XI, Section 1.3. of the REACH Regulation the results of (Q)SARs may be used instead of testing when the following conditions are met:

- results are derived from a (Q)SAR model whose scientific validity has been established,
- the substance falls within the applicability domain of the (Q)SAR model,
- results are adequate for the purpose of classification and labelling and/or risk assessment, and
- adequate and reliable documentation of the applied model is provided.

In the updated dossier with submission number [redacted] received on 16 July 2013 the Registrant provided further documentation on the QSAR models used. The updated dossier and the provided documentation were assessed by ECHA. 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 SAR Neutral Organics for chronic toxicity can be regarded as having sufficient scientific validity.

- The substance falls within the applicability domain of the (Q)SAR model: The chemical falls within the logKow and molecular weight range and the alcohols are part of the applicability domain as the model is applicable to the registered substance and appears to give reliable results based on the performance for close analogues and a publication in which the results of an external validation are described.

- However, there is a contradiction related to the logKow value used as input parameter (logKow=2.73) compared to the logKow value given in section 4.7 of the registration dossier (logKow = 3.2). This may have an impact on a potential classification need (Category Chronic 3). It should be taken into account that the ChV has to be divided by the root square of 2 to derive a value equivalent to NOEC. Therefore, the QSAR estimation does not fulfil Annex XI, 1.3. 3rd criterion on adequate results for the purpose of classification and labelling and/or risk assessment.

- Adequate and reliable documentation of the applied method is provided: A QMRF or equivalent information is not provided, though is publicly available. In the endpoint study records it is explained why the substance would fall within the applicability domain and a reference is made to a publication on the internal and external validation of the long-term QSARs for neutral organics to fish from ECOSAR™ (SAR & QSAR in Environmental Research 22: 545-559, publicly available). This information covers the QPRF requirements.

In summary, ECHA considers that the criteria set in Annex XI section 1.3. has not been met and the QSAR approach proposed cannot be accepted. There is a contradiction related to the logKow value used as input parameter compared to the logKow value given in section 4.7 of the registration dossier. Furthermore the results of the QSAR provided have not been taken into account for classification and labelling and/or risk assessment.

In his comments on the proposals for amendment the Registrant indicated that he would revise the QSAR estimates and update the dossier.

Furthemore as an outcome of the PNEC derivation update, it was found in the CSR that the Registrant has maintained an assessment factor (AF) of 1 which ECHA considers unjustified. ECHA considers at least an AF of 10 as justified when using 3 valid experimental long-term tests values.

The Registrant did not provide the adequate and reliable documentation of the applied models referred to under the fourth bullet point above. Without such documentation ECHA is not in a position to assess whether the other conditions outlined in the first three bullet points are fulfilled. As the Registrant has not demonstrated that the conditions of the adaptation of Annex XI, Section 1.3. of the REACH Regulation are fulfilled, ECHA cannot accept the adaptation.

For the adaptation to be acceptable, the Registrant would have to provide the above mentioned documentation and he would have to demonstrate that the first three conditions for applying the proposed adaptation are fulfilled. The general form of the (Q)SAR Model Reporting Format (QMRF) and (Q)SAR Prediction Reporting Format (QPRF), are described in the ECHA Guidance on information requirements and chemical safety assessment Chapter R.6: (Q)SARs and grouping of chemicals (ECHA, May 2008). Under REACH, reporting formats can be submitted to ECHA as attached files in an IUCLID dossier.

As the conditions for adapting the information requirements in accordance with Annex XI, Section 1.3. of the REACH Regulation have not been fulfilled and no other information is available in the dossier for the endpoints in question, ECHA concludes that there are information gaps and that it is necessary to provide information for the endpoints in order to bring the registration dossier into compliance with relevant information requirements.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b, Figure R.7.8-4 page 56, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. According to the integrated testing strategy, the *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

Therefore, pursuant to Article 41(3) of the REACH Regulation, the Registrant is requested to submit information using the following test methods on the registered substance:

- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Algae, growth inhibition test, EU C.3./OECD 201);
- Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211); and
- Long-term toxicity testing on fish (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210).

If based on the integrated testing strategy (described above) the Registrant comes to the conclusion that no further investigation of effects on fish is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, Section 9.1.6.

c. Revised PNECs for the aquatic compartment

Annex I, Section 3.3. of the REACH Regulation requires the Registrant to establish predicted no effect concentrations (PNEC(s)) for the registered substance, covering each environmental sphere, including the aquatic compartment.

ECHA notes that, the registration submitted by the Registrant contains PNECs for the aquatic compartment. ECHA notes furthermore that the information provided by the Registrant for the endpoints of Annex VII, Section 9.1.2. and Annex IX, Sections 9.1.5. and 9.1.6. derived from (Q)SAR models was used as available data for the derivation of the PNECs. The use of this data is however only acceptable when the conditions of Annex XI, Section 1.3. are fulfilled, which is not the case as demonstrated under subsections III.a., b. and c. above.

Furthermore, in the derivation of the PNECs the Registrant has applied as lowest an assessment factor (AF) of 1.

The footnote to Annex I, Section 3.3.1. provides information on the application of assessment factors to cover the uncertainty associated with the available data, indicating that an assessment factor of 1000 is typically applied to the lowest of three short term L(E)C50 values derived from species representing different trophic levels and a factor of 10 is applied to the lowest of three long-term NOEC values derived from species representing different trophic levels. This is further explained in the ECHA Guidance Chapter R.10.

According to the Guidance on information requirements and chemical safety assessment Chapter R.10, it is further explained that a factor of 10 cannot be decreased on the basis of laboratory studies. Furthermore, the Guidance notes that if a large data set from long-term tests for different taxonomic groups is available, statistical extrapolation methods may be used to derive a PNEC. The methods should be applied on all reliable available NOECs from chronic/long-term studies preferably on full life-cycle or multi-generation studies. ECHA notes that the use of such a low AF has to be fully justified case by case. No such justification is available in the registration dossier subject to the present decision.

ECHA notes that in his comments to the proposals for amendment the Registrant indicated that ECHA had not specifically addressed the justification provided by the Registrant for the AF in his IUCLID file. ECHA notes that the justification has been assessed, but ECHA considered it not to be sufficient for the reasons outlined above.

ECHA concludes that the Registrant's choice of an AF is not in line with the provisions of the footnote to Annex I, Section 3.3.1. and of ECHA Guidance chapter R.10, Section R.10.3.1.2 and therefore not acceptable.

Consequently, the derived aquatic PNECs are invalid. The Registrant shall therefore provide revised aquatic PNEC derivations in line with the provisions of Annex I as indicated above, in particular by applying an appropriate and fully justified AF. They shall be kept updated, along with the whole Chemical Safety Report. In particular, when data becomes available from the studies required under Section II.a., b. and c. it shall be taken into consideration in an updated derivation of the PNECs.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and by 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 studies 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 studies 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 studies 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 studies to be assessed.

V. General requirements for the generation of information

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/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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