EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114320276-57-01/F Helsinki, 31 March 2016

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, EC No 271-231-4 (CAS No 68526-83-0), 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, C7-9-iso-, C8-rich, EC No 271-231-4 (CAS No 68526-83-0), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements of Annex I, Sections 5.2.4 and 6.3, Annex VI, Sections 2 and 4, Annex VII, Section 8.2 and Annex IX Section 9.3.2 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 more per year. This decision does not take into account any updates after 25 August 2015, i.e. the date when the draft decision was notified to the Registrant under Article 50(1) of the REACH Regulation.

The substance subject to the present decision is listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2016.

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 05 March 2015.

On 25 August 2015 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 29 September 2015 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 29 October 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 to the draft decision within 30 days of the receipt of the notification.

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

On 04 December 2015 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 14 December 2015 ECHA referred the draft decision to the Member State Committee.

By 4 January 2016, 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 18 January 2016 in a written procedure launched on 8 January 2016.

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

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Name or other identifier of the substance (Annex VI, Section 2.1) as specified under Section III.1 below;
2. Spectral data (ultra-violet and infra-red) (Annex VI, Section 2.3.5) as specified under Section III.2 below.

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

Pursuant to Articles 41(1), 41(3), 3(28), 10(a) (vii), 12(1)(e), 13, 14 and Annexes VII and IX 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:

3. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD 305, [aqueous exposure/dietary exposure]). The bioaccumulation or bioconcentration of each relevant group of homologous constituents shall be assessed.
4. Robust study summary for in vivo eye irritation study equivalent or similar to OECD Guideline 405 "[redacted]", as specified under Section III.4 below.

C. Information in the technical dossier related to the classification and labelling of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(iv) and Annex VI, Section 4 of the REACH Regulation in conjunction with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) the Registrant shall submit the following information for the registered substance subject to the present decision:

5. A hazard classification for skin irritation, consistent with the data available in the registration dossier and the CLP criteria codified in Annex I, 3.2. of Regulation (EC) No 1272/2008. Alternatively, the Registrant shall submit a justification why the hazard classification for skin effects (category 2) is not applied in view of the data presented in the registration dossier.

D. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

6. Environmental exposure assessment and risk characterisation (Annex I, Sections 5.2.4. and 6.3.) representative for each relevant group of homologous constituents of the registered substance.

E. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA an update of the registration dossier containing the information specified in **Sections II.A, II.B.4, II.C and II.D** of the decision by **7 July 2016** including, where relevant, an update of the Chemical Safety Report.

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA an update of the registration dossier containing the information specified in **Section II.B 3** of the decision by **7 April 2017** including, where relevant, an update of the Chemical Safety Report.

Note for information to the Registrant:

The substance Alcohols, C7-9-iso-, C8-rich, EC No 271-231-4 (CAS No 68526-83-0), is included on the Community rolling action plan (CoRAP) update for years 2015–2017 (published on 17 March 2015) to be addressed under substance evaluation in 2016, in accordance with the procedure set out in Articles 44 to 48 and in Article 52 of the REACH Regulation. Following a Member State Competent Authority proposal for amendment, two different deadlines are set in the decision, to allow sufficient time for conducting a new test while still ensuring that the information requested under Sections II.A, II.B.4, II.C and II.D are available in an early phase of the substance evaluation process.

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 requests in this decision, or to fulfil otherwise the information requirements 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.

A. Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Name or other identifier of the substance (Annex VI, Section 2.1)

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2.1 of the REACH Regulation.

ECHA notes that the Registrant has specified that the registered substance is a multi-constituent substance. According to the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" thereinafter, multi-constituent substance is a substance defined by its quantitative composition, in which more than one main constituent is present at concentration ≥ 10 % (w/w) and < 80 % (w/w).

However, ECHA considers the registered substance as of unknown or variable composition, complex reaction products or biological materials (UVCB) and not well-defined substance. This conclusion is based on the information included in IUCLID Section 1.1 (numerical identifiers, description, molecular and structural information), the compositional information included in IUCLID Section 1.2, the results of analyses included in Section 1.4 and technological process information included in Section 3.1.

In particular, the analytical results included in IUCLID Section 1.4 (especially gas chromatogram) clearly demonstrate that the registered substance consists of numerous isomers and these individual isomers cannot be identified. It is also confirmed by the statement included in IUCLID Section 1.2 for each of the reported groups of constituents: "*The product is a mixture of different branched isomers*". The reported groups of constituents ([redacted]), despite structures being provided as examples, do not refer to individual constituents with defined chemical structures, but to the groups of constituents with defined alkyl chain length but with not defined branching. Therefore, the registered substance is not a well-defined multi-constituent substance since identification of the individual constituents (isomers) is not possible and the number of constituents is relatively large.

Additionally, the description of the technological process included in IUCLID Section 3.1 indicates that the starting material ([redacted]) is of UVCB origin due to variable alkyl chain length, not defined branching and double bond position. Therefore the identity of the resulting registered substance cannot be of well-defined character.

The naming of UVCB substances shall consist of two parts: the chemical name and the more detailed description of the manufacturing process, as indicated in Chapter 4.3 of the Guidance. ECHA observes that the Registrant did not provide the chemical name of the substance and did not provide complete information on the description of the manufacturing process for its proper identification, as required under Annex VI Section 2.1 of the REACH Regulation.

More specifically, the information on the manufacturing process currently provided by the Registrant in Section 3.1 of the dossier indicates that "[redacted]." This information is not sufficiently detailed, as the distillation parameters (like distillation temperature and pressure) are missing from this description. These parameters are important for identification of the registered substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested, as specifically explained above, to:

- Submit the complete information on manufacturing process as, based on the information included in the dossier and as explained above, the registered substance is a UVCB substance, and
- Specify a representative chemical name that follows the general naming conventions for this type of substances, as exemplified in the Guidance in Chapters 4.3.1.2 and 4.3.2.1.

The Registrant shall ensure that the information is consistent throughout the dossier.

Regarding how to report the chemical name, the information shall be included in the IUPAC name field in IUCLID Section 1.1. The complete description of the manufacturing process of the UVCB substance shall be included in IUCLID Section 1.1.

Further information on how to report the chemical name and the description of the manufacturing process is available in "Data submission manual Part 18 – How to report the substance identity in IUCLID 5 for registration under REACH" (Version: 2.0, July 2012), available on the ECHA website.

In its comments to the draft decision, the Registrant expressed its intention to update the registration dossier by selecting "UVCB" as substance type and report "Alcohols, C7-9-iso-, C8-rich" as chemical name for the registered substance. The Registrant also committed to provide a more detailed description of the manufacturing process.

The information proposed to be submitted by the Registrant may be sufficient to bring the Registration into compliance for this requirement. However, as indicated in the notification letter of the draft decision from 25 August 2015, ECHA does not take into account any dossier updates after the notification of this draft decision. Any such update will be examined by ECHA after the deadline set in the adopted decision has passed.

Notes for consideration by the Registrant

Under the Registrant's interpretation of the scope of a Member State Competent Authority proposal for amendment, the Registrant indicated its intention to re-define the constituents by revising the identifiers assigned in IUCLID Section 1.2. The EC and CAS identifiers provided by the Registrant in IUCLID Section 1.2 can be considered sufficiently generic to describe the reported groups of constituents (the [redacted] terminology used for these entries does not refer to a specific branching when the alkyl group has at least 7 carbons). ECHA recognises that some of the other identifiers used to describe the groups (e.g. IUPAC names [redacted]) refer to specific structures (as explained by the Registrant in the Remarks fields in IUCLID Section 1.2) and do therefore not take into account the unspecific branched structure of the constituents. ECHA acknowledges the Registrant's commitment to redefine the constituents, which could further reflect the UVCB nature of the substance at the level of composition in IUCLID Section 1.2.

2. Spectral data (ultra-violet and infra-red) (Annex VI, Section 2.3.5)

"Spectral data" is an information requirement as laid down in Annex VI, Section 2.3.5 of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this infromation requirement.

ECHA notes that the registration dossier does not contain full set of analytical data for the registered substance. No ultra-violet (UV) and infra-red (IR) spectral data, as required under Annex VI Section 2.3.5 of the REACH Regulation has been submitted. Moreover, a scientifically based justification for not including this information has not been included.

ECHA regards particularly IR data as scientifically relevant for the identification of the registered substance, as the IR spectrum displays characteristic vibration bands of covalent bonds in molecules present in the substance, including characteristic vibration bands from the chemical functionalities expected to be present in the composition.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: UV and IR spectra. The Registrant shall ensure that the information is consistent throughout the dossier.

Regarding how to report the spectral data, the information shall be attached in IUCLID Section 1.4. The Registrant shall ensure that the description of the analytical methods used for recording the spectra is specified in the dossier in such detail to allow the methods to be reproduced, in line with the requirements under Annex VI Section 2.3.7 of the REACH Regulation.

In its comments to the draft decision, the Registrant expressed its intention to update the registration dossier. However, as indicated in the notification letter of the draft decision from 25 August 2015, ECHA does not take into account any dossier updates after the notification of this draft decision. Any such update will be examined by ECHA after the deadline set in the adopted decision has passed.

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

Pursuant to Articles 10(a)(vi) and/or (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 VII to X of the REACH Regulation.

3. Bioaccumulation in aquatic species (Annex IX, 9.3.2.)

"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.

Article 13(1) and 13(3) of the REACH Regulation allows that information on intrinsic properties of substances may be generated by means other than tests, including information from structurally related substances (grouping or read-across), "provided that the conditions set out in Annex XI are met". Annex IX, third introductory paragraph, requires the Registrant to clearly state reasons for adapting the standard information according to the rules in Annex XI.

The technical dossier contains a statement for the use of a read-across approach from supporting substances (structural or analogue surrogate). Two key studies with the read-across substance alcohols, C9-11-iso, C10-rich are provided: (1) a study according to OECD 305 E with aqueous exposure of rainbow trout and (2) a study with dietary exposure of rainbow trout.

ECHA notes that the Registrant did not provide any rationale or justification for the read-across approach. No information detailing the similarities between the registered substance and the read-across substances according to the following REACH Annex XI, 1.5 criteria has been provided: (i) common functional group, (ii) common breakdown products or (iii) constant pattern in changing of the potency of the properties.

As no sufficient justification was provided for read-across, the requirements of Annex XI, Section 1.5 in conjunction with Annex IX, third introductory paragraph, of the REACH Regulation were not met. Moreover there is no other adaptation in terms of Annex XI or column 2 of Section 9.3.2 of Annex IX presented in the registration dossier. Therefore, ECHA considers that the standard information requirement for the endpoint Bioaccumulation in aquatic species specified in Annex IX, 9.3.2 is not met.

In its comments to the draft decision, the Registrant expressed its intention to update the registration dossier with adequate information on this endpoint, specifically, rationale for read-across based on structural similarity of the registered substance to the tested substance will be provided. Additionally, more detailed information on the studies will be included in the dossier. The information proposed to be submitted by the Registrant may be sufficient to bring the Registration into compliance for this requirement. However, as indicated in the notification letter of the draft decision from 25 August 2015, ECHA does not take into account any dossier updates after the notification of this draft decision. Any such update will be examined by ECHA after the deadline set in the adopted decision has passed.

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.

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 and dietary exposure (test method: OECD 305). The bioaccumulation or bioconcentration of each relevant group of homologous constituents shall be assessed.

Notes for consideration by the Registrant

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes IX and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the 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.

4. Robust study summary for eye irritation study

Article 14 (1) in conjunction with Annex I and Article 10 (a)(vii) require the provision of robust study summaries for information derived from the application of Annexes VII to XI for substances above 10 tonnes per year.

Article 3(28) of the REACH Regulation defines a robust study summary as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the relevance of the study minimising the need to consult the full study report.

Eye irritation study is a standard information requirement as laid down in Annex VII, Section 8.2. of the REACH Regulation: "The assessment of this endpoint shall comprise the following consecutive steps:

(1) an assessment of the available human and animal alternative data,
(2) an assessment of the acid or alkaline reserve,
(3) *in vitro* study for eye irritation".

Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the Registrant has not provided a complete assessment of eye irritation in the dossier that would meet the information requirement of Annex VII, Section 8.2. The dossier contains a concise summary that is inadequate and does not fulfil the requirements of a robust study summary, e.g. the result table contains the mean score per group of animals (6 animals in the group) rather than the mean score per animal. The group mean eye irritation scores between time points 24 and 72 hours were: cornea score 0.5, iris score 0.9, and conjunctival redness 1.5. The classification threshold for cornea, iris, and conjunctival redness per individual animal are greater than or equal to 1, 1, and 2, respectively. Hence the observed effects per individual animal are required in order to allow an independent assessment of the study results. Furthermore, information related to the recovery or irreversibility of effects observed in iris and conjuctiva were not included in the study report.

In its comments to the draft decision, the Registrant expressed its intention to update the registration dossier with a robust study summary for an *in vivo* eye iritation study. The information proposed to be submitted by the Registrant may be sufficient to bring the Registration into compliance for this requirement. However, as indicated in the notification letter of the draft decision from 25 August 2015, ECHA does not take into account any dossier updates after the notification of this draft decision. Any such update will be examined by ECHA after the deadline set in the adopted decision has passed.

Consequently, the Registrant is requested to complete the robust study summary for the endpoint with the missing information, as indicated above.

Guidance on the preparation of study summaries is provided in the Practical Guide 3: How to report robust study summaries", which is available on the ECHA website under the following link:
http://echa.europa.eu/documents/10162/13643/pg_report_robust_study_summaries_en.pdf

C. Information in the technical dossier related to the classification and labelling of the substance

Pursuant to Article 10(a)(iv) of the REACH Regulation the technical dossier shall contain information on classification and labelling of the substance as specified in Annex VI, Section 4 of the REACH Regulation in conjunction with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation).

5. Hazard classification for skin effects, or a justification, why the hazard classification for Skin Irritant Category 2 is not applied

Annex VI, Section 4 of the CLP Regulation clarifies that the hazard classification of the substance shall result from the application of Title I and II of the CLP Regulation. According to Article 5(1) of Title I and recitals 20 and 21 of the CLP Regulation, a substance shall be classified on the basis of available information.

Furthermore, the technical dossier must include the resulting hazard label for the substance in line with Title III of the CLP Regulation (Annex VI, Section 4.2. of the REACH Regulation).

The criteria for classification as skin irritant Category 2 are defined in Annex I of CLP, 3.2.2.7.1. and presented in Table 3.3.2 as follows:

"(1) Mean value of ≥ 2,3 - ≤ 4,0 for erythema/ eschar or for oedema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions; or
(2) Inflammation that persists to the end of the observation period, normally 14 days, in at least 2 animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia, and scaling; or
(3) In some cases where there is pronounced variability of response among animals, with very definite positive effects related to chemical exposure in a single animal but less than the criteria above."

The Registrant reported in the technical dossier a key study for skin irritation/corrosion (in vivo) study according to OECD test guideline 404 and with a reliability code of 1 ([redacted]).

The following results were reported in the dossier: "Topical application of isooctanol produced only signs of mild irritation in the rabbit following a 4 hour semi-occluded dermal patch exposure. Dermal observations were conducted 45 minutes, 24, 48 and 72 hours and 7 days after exposure. All animals survived the exposure. Well defined erythema was noted in one animal at the 45 minute point while the other animals had very slight erythema. Erythema increased after the 45 minute interval. Five animals were noted with well-defined erythema at the 24 and 48 hour intervals. At the 72 hour interval, all animals were noted with well-defined erythema. Erythema increased again at the day 7 interval; two animals were noted with severe erythema and four animals were noted with well-defined erythema. The mean skin irritation scores between 24 and 72 hours were: erythema 1.89 and oedema 1.22."

ECHA notes that the provided *in vivo* skin irritation/corrosion is a reliable study and conducted according to OECD 404 except that duration of the study observation period was not sufficient enough to see the full reversibility of the effects observed. Nevertheless from the report it is evident that the severity of erythema persisted and even increased in severity until the end of observation period, day 7, and sever erythema was observed in 2/6 animals and well defined erythema in 4/6 animal at this time point. Hence this information seem to fulfill the classification criteria, number 2, stated in Table 3.3.2.
However, the Registrant indicated that the registered substance is "not classified" for skin irritation "according to the general classification and labeling requirements for dangerous substances and preparations (Directive 67-548-EEC) or the classification, labeling and packaging (CLP) regulation (EC) No 1272/2008".

Consequently, ECHA concludes that the aforementioned information available in the technical dossier is not consistent with the classification and labelling used (no classification and labelling) by the Registrant.

In its comments to the draft decision, the Registrant expressed its intention to update the registration dossier by reviewing the study data that was included to fulfill the skin irritation/corrosion criteria and provide additional information. Following review of the data if the substance meets CLP criteria for this endpoint, the Registrant will submit a hazard classification and labelling for skin effects. Alternatively, the Registrant will provide justification why the hazard classification for skin effects (CAT 2) is not applied.

The information proposed to be submitted by the Registrant may be sufficient to bring the Registration into compliance for this requirement. However, as indicated in the notification letter of the draft decision from 25 August 2015, ECHA does not take into account any dossier updates after the notification of this draft decision. Any such update will be examined by ECHA after the deadline set in the adopted decision has passed.

Therefore, pursuant to Article 41(1) (a) and (3) of the REACH Regulation, the Registrant is requested to submit a hazard classification and labelling for skin effects of the registered substance, that is consistent with the data available in the registration dossier and the CLP criteria Annex I, 3.2., especially table 3.2.2.

Alternatively, the Registrant is requested to submit a justification, why the hazard classification for skin irritation category 2 is not applied in view of the data presented in the registration dossier.

D. Information related to the chemical safety assessment and chemical safety report

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

6. Environmental exposure assessment and risk characterisation (Annex I, Sections 5 and 6)

Pursuant to Article 14(4) of the REACH Regulation, the chemical safety assessment shall include exposure assessment (Annex I, Section 5) and risk characterisation (Annex I, Section 6) if the substance fulfils the criteria for certain hazard classes of Annex I to Regulation (EC) No 1272/2008 (the CLP Regulation) or it is assessed to be a PBT or vPvB. Annex I, Section 5 of the REACH Regulation requires the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

Annex I, Section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario and to consider the human population (exposed as workers, consumer or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonable foreseeable, under the assumption that the risk management measures described under exposure scenario in the Section 5 have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

In the CSR provided by the Registrant the exposure assessment for the environment is missing. The Registrant claims that no exposure assessment is necessary by stating that exposure assessment is "Not applicable, since exposure scenarios are not required for this substance (not classified as dangerous according to Directive 67/548/EEC and assessed to be not PBT/vPvB)".

ECHA notes that the registered substance meets the criteria for classification as Skin irritant, Category 2 (see Section III C of this draft decision) and thus, is fulfilling the criteria set out in Article 14(4) of the REACH Regulation triggering a requirement to provide an exposure assessment and a risk characterisation in the chemical safety assessment.

With regard to the scope of the required exposure assessment, as stated above and in accordance with Annex I, Section 5.0, it has to cover all hazards that have been identified according to Sections 1 to 4 on Annex I. As further outlined in Guidance on information requirements and chemical assessment, Part B: Hazard assessment 2011, version 2.1, such identified hazards (among others) necessitating exposure assessment are the "hazards for which there are classification criteria and there is information on these properties of the substance showing that it does have these properties, but the severity of the effects is lower than the criteria for classification and so the substance is not classified".

The above guidance document, Section B.8.4. (pages 47 and 48) further provides that the Registrant should consider whether adverse effects have been observed in studies conducted at the highest practicable and biologically-relevant concentration on environmental toxicity, e.g. according to OECD and EU Guidelines, taking into account the properties of the substance determining the environmental fate. For instance, regarding acute aquatic toxicity 100 mg/l is an effect limit value in the relevant OECD guideline. This means that acute aquatic toxicity results below 100 mg/l are considered as a hazard.

The above guidance document also provides that if no adverse effects have been observed in studies at the highest recommended concentration/doses tested, this would normally indicate that no hazard has been identified and no DNEL or PNEC can be derived and hence exposure assessment for that route of exposure, type of effect or protection target would not be needed.

It is clear from the dossier that the Registrant has identified a hazard for the environment. ECHA notes that effects were observed in some environmental toxicity studies. In particular, e.g. in the short-term toxicity studies to aquatic invertebrates provided by the Registrant an EC50 of 31.8 mg/L was obtained and reported in the technical dossier, which is well below the effect limit value of 100 mg/L.

In its comments to the draft decision, the Registrant expressed its intention to update the registration dossier by submitting an Environmental exposure assessment and risk characterization in the chemical safety report (CSR). The information proposed to be submitted by the Registrant may be sufficient to bring the Registration into compliance for this requirement. However, as indicated in the notification letter of the draft decision from 25 August 2015, ECHA does not take into account any dossier updates after the notification of this draft decision. Any such update will be examined by ECHA after the deadline set in the adopted decision has passed.

Under the Registrant's interpretation of the scope of a member State Competent Authority proposal for amendment, the Registrant stated that he "*did not agree that the substance represents an environmental hazard based on acute aquatic toxicity warranting an exposure assessment*" because Annex I, Section 0.6.3. would provide that an exposure assessment and risk characterization are only required if certain hazard classes under Regulation (EC) No 1272/2008 apply that are not met by the substance. ECHA notes that the rationale for requesting exposure assessment and risk characterisation has been set out above and that the Registrant has not provided arguments that would change this assessment.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to generate an exposure assessment and risk characterisation for the environment representative for each relevant group of homologous constituents of the registered substance. The chemical safety report shall be amended accordingly.

Notes for consideration by the Registrant

The requested exposure assessment and risk characterisation for the environment also need to include sediment and terrestrial compartments taking into account the the information generated following ECHA Decision CCH-D-2114289310-53-01/F from 30 January 2015 and the integrated testing strategy (ITS) for assessing toxicity to these compartments according to *ECHA Guidance on information requirements and chemical safety assessment* (Version 2.0, November 2014) Sections R.7.8 and R.7.11.6, respectively.

Under the Registrant's intepertation of the scope of a member State Competent Authority proposal for amendment, the Registrant outlined that "*The registered substance is currently being tested/evaluated for chronic aquatic toxicity pursuant to final decision CCH-D-2114289310-53-01/F (30 Jan 2015). If required preparation of an Exposure assessment per Annex I, Section 5.0 of the REACH Regulation will be based on the outcome of this testing*". ECHA notes that the Registrant will need to re-evalaute and where relevant, update the Chemical Safety Report, due to the outcome of further testing.

IV. Adequate identification of the composition of the tested material

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. 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 Claudio Carlon, Head of Unit, Evaluation E2

[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.