ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000005118-76-02/F Helsinki, 17 September 2014

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

For 2-ethylhexyl acetate, CAS No 103-09-3 (EC No 203-079-1), 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 2-ethylhexyl acetate, CAS No 103-09-3 (EC No 203-079-1), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VII, Section 8.3, Annex I, Sections 5.2.4. and 6.3. of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of [redacted]. This decision does not take into account any updates submitted after 12 June 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2015.

The compliance check was initiated on 5 September 2013.

On 19 November 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 10 December 2013 the Registrant updated his registration dossier with the submission number [redacted]. On 19 December 2013 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments and the dossier update. On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed to reflect this amendment and other comments provided.

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.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Information related to chemical safety assessment and chemical safety report

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

> Environmental exposure assessment and risk characterisation (Annex I, Sections 5.2.4. and 6.3.).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **24 March 2015.**

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.

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.

Environmental exposure assessment and risk characterisation (Annex I, Sections 5.2.4. and 6.3.)

According to Article 14(1) and (4) and Annex I, section 0.6., the Registrant is required to perform a chemical safety assessment (CSA) for the registered substance. The CSA shall cover 1) Human health hazard assessment, 2) Human health hazard assessment of physicochemical properties, 3) Environmental hazard assessment and 4) PBT and vPvB assessment. If as a result from these steps, the substance meets the criteria for any hazard classes or categories[1] set out in Annex I to Regulation (EC) No 1272/2008 (CLP Regulation), or is assessed to be a PBT or vPvB, the CSA shall also include the additional steps: Exposure assessment, including generation of exposure scenario(s) and exposure estimation, and Risk characterisation. The additional steps of the CSA shall be carried out in accordance with Sections 5 (for Exposure assessment) and 6 (for Risk characterisation) of Annex I of the REACH Regulation.

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- hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F.
- hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10.
- hazard class 4.1:
- hazard class 5.1;

Further, according to Annex I, section 5.0., the objective of the Exposure assessment is to make quantitative or qualitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. The assessment shall consider all stages of the life-cycle of the substance and shall cover any exposures that may relate to the hazards identified in Sections 1 to 4 of chapter 0.6 of Annex I.

The Registrant has waived the exposure assessment and risk characterisation for the environment on the basis that no hazard has been identified in the chemical safety assessment.

ECHA notes that the registered substance has a harmonized classification for human health as Skin Irritant 2 according to the CLP Regulation. Therefore, according to Article 14(4) and Annex I, section 0.6, as the substance meets the criteria for classification the CSA shall include two additional steps, meaning that Exposure assessment and Risk characterisation is required.

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 of Annex I of REACH Regulation.

It is clear from the dossier that the Registrant has identified a hazard for the environment: effects (mortality) are seen in the short term fish test at concentrations as low as 8 mg/L (LC50 fish=8.27 mg/L with fish being the most sensitive species). Therefore, the Registrant is required to carry out the exposure assessment and subsequent risk characterisation also for the environment in order to address the hazard identified for the environment. As further outlined in Guidance on information requirements and chemical assessment, Part B: Hazard assessement 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". Moreover, the above mentioned guidance specifies further (in Section 8.4.2.2) that "If there are ecotoxicity data showing effects in aquatic organisms, but the substance is not classified as dangerous for the aquatic environment, an aquatic PNEC can nevertheless be derived thus indicating a hazard to the aquatic environment. /.../ Hence, quantitative exposure assessment, i.e. derivation of PECs, is mandatory for the water, sediment and soil environmental compartments."

In his comments on the draft decision the Registrant challenged the request for exposure assessment for i.a. not being consistent in the understanding of the term 'hazard' in the provisions of the REACH and CLP Regulation. ECHA points out the following:

Generally, two of the main purposes of both the REACH and CLP Regulation are to ensure a high level of protection of human health and the environment (Article 1(1) of the REACH and CLP Regulation respectively). The additional steps in a chemical safety assessment of exposure assessment and risk characterisation serve this objective as they allow estimating and characterising any risk to mankind or the environment. The formal arguments of the Registrant that this shall be done only for CLP-classified hazards ignore this overall context.

Both the REACH and CLP Regulation distinguish between the terms 'hazard', 'hazardous' and 'hazard classes'. The legislator would have used the term 'hazard classes' only if that was his intention for Annex I, Section 5 to the REACH Regulation. This becomes clear from the disctinct references used in Article 3 of the CLP Regulation, Article 14(4) and Annex I, Sections 0.6.3. and 5. to the REACH Regulation. Under REACH, a hazard is identified by the results generated from the tests used to fulfil the information requirements set out in Annexes VII to XI. Pursuant to Article 13(3) of the REACH Regulation tests define endpoints/effects to be observed and reported for identification of (no)effect levels/concentrations as well as a limit dose and therefore, if a hazard is identified it is when an adverse effect is observed below that limit dose.

The REACH and CLP Regulations can be interpreted in a coherent and consistent way without reducing unnecessarily their respective scopes. The chemical safety assessment/report is regulated by law in order to assess and document that any risks arising from a substance are adequately controlled during manufacture and use. The burden of safe use lies with operators. ECHA therefore considers the additional steps of exposure assessment and risk characterisation for any identified hazard irrespective of classification as a measure in line with the precautionary principle that is underpinning the REACH Regulation (Article 1(3)) and which the Registrant seems to ignore.

Pursuant to Annex I, Section 3.0.2. of the REACH Regulation five environmental spheres shall be assessed for hazards. Annex I, Sections 5 and 6 require an exposure assessment and risk characterisation for the "environmental spheres for which exposure to the substance is known or reasonably foreseeable". Following the Registrant's argumentation, the environmental exposure assessment and risk characterisation would only be possible for the aquatic environmental sphere since the results for a number of standard data requirements for the other environmental spheres (e.g. information on soil/sediment toxicity,) do not lead to the classification of substances as hazardous, as no hazard classes or classification criteria exist. It cannot be correct that a large part of standard data requirements set out in the REACH Annexes would become irrelevant. Instead, the legislator has a clear intention to use the standard information required in Annexes VII to X of the REACH Regulation for the hazard assessment without prejudice of classification needs.

For reasons of proportionality, the requirement of two additional steps in the chemical safety assessment is limited to those substances meeting the criteria for classification of any hazard class/category set out in Article 14(4) of the REACH Regulation/Annex I CLP Regulation. In that regard the request by ECHA to understand exposure and risk of the substance subject to the present decision is not exceeding of what is appropriate and necessary to attain the objectives of the legislation. The identified hazard in this case has been demonstrated by mortality of fish as outlined in above. At the same time, as ECHA is not requiring exposure assessment and risk characterisation on all environmental endpoints, it does not exceed what is necessary to address the concern.

ECHA respects the principle of equal treatment as it requires for any substance meeting the criteria for classification in any of the hazard classes/categories an exposure assessment and risk characterisation.

Finally, in response to the Registrant's claim that ECHA's action would jeopardise legal certainty, ECHA points out that it has issued guidance on when exposure assessment and risk characterisation are expected (Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health; Version: 2.1; November 2012).

In conclusion, the arguments by the Registrant cannot lead to omit the required data that is needed in order to comply with the REACH Regulation.

Therefore, the Registrant is requested to perform an environmental exposure assessment covering all life-cycle stages of the registered substance originating from manufacture and identified uses, and subsequently perform risk characterisation for each exposure scenario to demonstrate the safe use of the substance, and update the dossier accordingly.

IV. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 12 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested a skin sensitization study (Annex VII, 8.3). 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 registration is 6 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

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

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