ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114300145-68-01/F Helsinki, 30 June 2015

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

For 2-phenylpropene, CAS No 98-83-9 (EC No 202-705-0), 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).

ECHA notes that in the joint submission covering the current registration, the Chemical Safety Report (CSR) is not provided by the lead registrant on behalf of the member registrants. The scope of this compliance check is limited to the standard information requirements of Annex I and Section 2 of Annex VI, while the compliance check concerning the information requirements laid down in Annexes VII to X was done on the lead registrant dossier of this joint submission.

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for 2-phenylpropene, CAS No 98-83-9 (EC No 202-705-0), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more tonnes per year. This decision does not take into account any updates submitted after 15 January 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 28 October 2013.

On 28 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 13 January 2014 ECHA received comments from the Registrant agreeing to ECHA's draft decision. The Registrant acknowledged the information gaps identified by ECHA with regard to the chemical safety assessment and the chemical safety report, and agreed to update the chemical safety report accordingly.

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 15 January 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.

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

On 20 February 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 2 March 2015 ECHA referred the draft decision to the Member State Committee.

By 23 March 2015 the Registrant did not provide any comments on the proposals for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 7 April 2015 in a written procedure launched on 26 March 2015.

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

II. Information required

A. 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:

1. Revised derived no effect levels (DNEL) for workers and for the general population (Annex I, Section 1.4.1.), as specified in section III.C.1. below;
2. Revised predicted no effects levels (PNEC) for aquatic (Annex I, section 3.3.1.), as specified in section III.C.2. below;
3. Revised exposure assessment and risk characterisation for environment (Annex I, sections 5 and 6), as specified under section III.C.3. below.

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 **7 January 2016**.

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 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. According to Article 14(3) and Annex I section 0.6.1., the chemical safety assessment shall include human health, physicochemical and environmental hazard assessments.

Further, according to Article 14(4) and Annex I section 0.6.2, if the substance fulfils the criteria for any of the hazard classes or categories referred to in Article 14(4) and Annex I section 0.6.3. of the REACH Regulation, the chemical safety assessment shall also include exposure assessment including the generation of exposure scenarios (or the identification of relevant use and exposure categories if appropriate) and exposure estimation, as well as risk characterisation.

1. Revised derived no effect levels (DNEL) for workers and for the general population (Annex I, Section 1.4.1.)

Article 14(3)(a) and Annex I, Section 1.4.1. of the REACH Regulation require the Registrant to establish DNEL(s) for the registered substance for each relevant human population using the study giving rise to the highest concern.

Further, Annex I, 1.4.1 of the REACH Regulation also requires that the following factors shall, among others, be taken into account when deriving DNELs:

a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
b) the nature and severity of the effect;
c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
d) and that the DNELs reflect the likely route(s), duration and frequency of exposure.

A full justification shall be given specifying, inter alia, the choice of the information used, the routes of exposure (oral, dermal, inhalation) and the duration and frequency of exposure to the substance for which the DNEL is valid.

The ECHA *Guidance on information requirements and chemical safety assessment* Volume 8, Chapter R.8 states that "*when an EU IOEL exists the registrant may, under conditions as described below, use the IOEL in place of developing a DNEL. Alternatively the registrant should, in accordance with the requirements of REACH, derive a DNEL following the steps outlined in the hazard assessment section of REACH Annex I.*" More specifically, it is stated that "*a registrant is allowed to use an IOEL as a DNEL for the same exposure route and duration*". Further, it also states that "*when the registrant is using a substance in a way that leads to other exposure routes or exposure durations than the exposure route and duration on which the IOEL is based (typically derived for inhalation exposure over 8 hours per working day (TWA) and/or short term exposures, typically of 15 minutes duration (STEL)) or if other human populations are exposed, the relevant DNELs should be derived. For example, in the case when the use may lead to dermal or oral exposure of the population at large or vulnerable sub-populations, DNELs to cover these situations will be required.*"

The Registrant has done a route-to-route extrapolation using an OEL value for long-term systemic effects via inhalation to derive a DNEL for long-term systemic effects via dermal route. In addition, the Registrant has also used the OEL value to derive DNELs for the general population.

ECHA notes that the Registrant has used the OEL value to derive a DNEL for another route of exposure, i.e. dermal, and DNELs for other human population, i.e. general population,

than the route of exposure and human population on which the OEL is based. Therefore, the Registrant has derived incorrectly the DNELs for dermal route for workers and for all routes for general population.

In his comments, following the procedure set out in Article 50(1) of the REACH Regulation, the Registrant indicated his intention to address the identified issues and appropriately amend the CSR.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit a revised DNEL for dermal route for workers and revised DNELs for the general population, considering the deficiencies pointed out above and the hazard data provided in the registration dossier and re-assessment of related risks. The chemical safety assessment and the chemical safety report shall be amended accordingly.

For the derivation of DNELs, the Registrant is reminded to use the assessment factors recommended in the ECHA Guidance on information requirements and chemical safety assessment, R.8. (Version 2.1, November 2012).

2. Revised predicted no effects levels (PNEC) for aquatic (Annex I, section 3.3.1.)

Article 14(3)(c) and Annex I, Section 3.3.1. of the REACH Regulation requires to establish a PNEC for each environmental sphere based on the available information and to use an appropriate assessment factor to the effect values.

Annex I, Section 3.1.5. of the REACH Regulation states that "*where there is more than one study addressing the same effect, then the study or studies giving rise to the highest concern shall be used to draw a conclusion and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust summaries will be required of all key data used in the hazard assessment. If the study or studies giving rise to the highest concern are not used, then this shall be fully justified and included as part of the technical dossier, not only for the study being used but also for all studies reaching a higher concern than the study being used.*"

The ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.10 (version May 2008) provides further details and specifically provides default factors which should be applied to derive PNECs.

The Registrant has provided four study summaries for growth inhibition tests on aquatic plants:

1. Alga growth inhibition test (OECD 201): key study providing a 72h-NOEC of 2.26 mg/L with *Desmodesmus subspicatus*.
2. Alga growth inhibition test (OECD 201): supporting study providing a 72h-NOEC of 0.3 mg/L with *Pseudokirchnerella subcapitata*.
3. Alga growth inhibition test (OECD 201): supporting study with *Pseudokirchnerella subcapitata*, providing a 72h-NOEC of 40 mg/L.
4. Supporting study with several species of algae, no guideline followed and without providing a NOEC.

The Registrant has used study No. 1 as the key study for this endpoint. Also, the Registrant has stated for study No. 2 that "*the study was conducted according to guideline: original report in Japanese (a few details reported in English); for the preparation of test solutions HCO-30 was used as solubilizing agent although the water solubility of AMS is ca. 100 mg/L;*

furthermore, the concentration of solubilizing agent was not found in the Japanese report and the results thereof were not reported" as the reason to low the reliability of the study and, as a consequence, not qualifying it as a key study.

ECHA points out that the fact that only "*a few details* [are] *reported in English*" does not constitute a sufficient justification for not using this study to draw a conclusion for this endpoint since it is the one giving rise to the highest concern. Thus, the justification provided by the Registrant does not fulfil the requirements of Annex I, section 3.1.5.

In addition, ECHA notes that if the study No. 2 is the key study, the NOEC value from this study (0.3 mg/L) shall be used for the derivation of PNECs for freshwater and marine water compartments. According to the OECD Guidance Number 23[1], page 43, for static and semi-static tests, where the concentrations do not remain within 80-120% of nominal, the effect concentrations could be determined and expressed relative to the geometric mean of the measured concentrations, if available.

In his comments, following the procedure set out in Article 50(1) of the REACH Regulation, the Registrant indicated his intention to address the identified issues and appropriately amend the CSR once the final decision is received.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit revised PNECs for freshwater and marine water, considering the deficiencies pointed out above, and re-assessment of related risks <u>or</u> a full justification for not using the results coming from the study giving raise to the highest concern. The chemical safety assessment and the chemical safety report shall be amended accordingly.

3. Revised exposure assessment and risk characterisation for environment (Annex I, sections 5 and 6)

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.

Further, Annex I, Section 5.2. of the REACH Regulation requires the Registrant to provide exposure estimation for each scenario. The exposure estimation entails three elements: emission estimation, assessment of chemical fate and pathways and estimation of exposure levels. In addition, the emission estimation shall consider the emissions during all relevant parts of the life-cycle of the substance resulting from the manufacture and each of the identified uses and the estimation of exposure levels shall be performed for all environmental spheres.

ECHA's *Guidance on information requirements and chemical safety assessment* Chapter R.16 (version 2.1, October 2012) provides recommended default release factors. In this guidance it is stated that "*the exposure scenario should contain information (about operational conditions and risk management measures) based on which the assumed release factors and daily use rates can be justified. Exposure scenarios making reference to the A and B tables of the Technical Guidance Document (TGD, 2003) without providing more specific information on the conditions of use are considered insufficient to meet the REACH requirements.*"

[1] OECD Series On Testing And Assessment: Number 23. Guidance Document On Aquatic Toxicity Testing Of Difficult Substances And Mixtures. ENV/JM/MONO(2000)6. OECD, December 2000.

Annex I section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario and shall 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 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.

ECHA observes that section 3.5. of the IUCLID dossier is incomplete and not consistent with the CSR and other sections of IUCLID, e.g. in sections 3.2 and 3.3 of IUCLID the Registrant declares that he is manufacturing the substance but in section 3.5 "Manufacture" is not declared. ECHA further observes that, in order to cover any exposures that may be related to the identified hazards, the Registrant has provided only one exposure scenario. This scenario seems to be for the manufacturing of the substance and the Registrant considers 6 manufacturing sites called Site A, B, C, D, E and F. The assessment for each of the 6 individual sites is partly based on "*special information from manufacturer*" and partly "*based on default assumptions*". The Registrant states that "*the default release factors are 0.003 for waste water and 0.0001 for the air (TGD, Tab. A1.2, MC 1b, vp 100 – 1000 Pa, B1.6)*".

The Registrant has also provided a tool called as "[redacted]" as an attached file called "[redacted]". This spreadsheet-based tool calculates the maximum use volumes corresponding to the situation where the PEC values equals the PNEC. This tool has been developed "*in order to provide downstream users with information to assess their local conditions*". The tool is said to be based on EUSES "*but with some simplifications to improve the user friendliness and to concentrate on the key parameters*". All default parameters are said to be taken from EUSES and the release factors are apparently taken from ECHA's *Guidance on information requirements and chemical safety assessment*, Chapter R.16 (version 1.0, May 2008).

ECHA observes the following deficiencies in the exposure assessment and risk characterisation of the registered substance:

- The Registrant has not used the correct format for the CSR as it is required in Annex I, Section 7 of the REACH Regulation. In particular, sections 9 (Exposure assessment) and 10 (Risk characterisation) are provided in the form of an attached document that do not follow the format specified in Annex I, section 7 of the REACH Regulation.
- For the exposure scenario for manufacturing of the substance, the Registrant has not provided a clear and detailed justification (e.g. based on RMMs and/or OCs and/or substance properties) for the use of release factors for waste water and air (0.003 and 0.0001 respectively) from A and B tables of the outdated Technical Guidance Document (TGD, 2003) instead of the ones recommended in ECHA's *Guidance on information requirements and chemical safety assessment* Chapter R.16 (0.06 and 0.05 respectively). ECHA notes that the release factors used by the Registrant are less protective than the ones recommended and, as stated in the guidance, "*without providing more specific information on the conditions of use are considered insufficient to meet the REACH requirements*".
- The dilution factor applied in the receiving water is set to 13400 for site A and 2300 for site F. ECHA notes that the dilution factors applied by the Registrant in sites A and F exceed the maximum value of 1000 recommended in ECHA's

Guidance on information requirements and chemical safety assessment Chapter R.16. In the environment, dilution is in practice not complete near the point of discharge. In the mixing zone, higher concentrations will occur. The distance from the point of discharge where complete mixing may be assumed will vary between different locations. For situations with very high dilution factors, the mixing zones may be very long and the overall area that is impacted by the effluent before it is completely mixed can be very substantial. Therefore, in case of site-specific assessments, Guidance R.16. recommends that the dilution factor that is applied for calculation of the local concentration in surface water should not be greater than 1000.

- The Registrant has not provided environmental exposure assessment and risk characterisation for any downstream uses of the substance. According to Annex I, Section 5 of the REACH Regulation, "*the exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses*". Therefore, ECHA notes that the REACH requirements have not been fulfilled.

  Instead, the Registrant has provided downstream users with a spreadsheet-based tool that calculates the maximum permissible use volumes corresponding to the situation where the PEC values equal the PNEC. ECHA notes that this approach does not demonstrate that the risk is controlled for downstream users but rather provides a way to back-calculate the maximum use volumes for not having RCRs above 1. In addition, some of the release factors used by the tool are outdated since they are apparently taken from version 1 (May 2008) of the ECHA's *Guidance on information requirements and chemical safety assessment* Chapter R.16. Therefore, the Registrant has not fulfilled the requirements of Annex I, Section 5. Although it would be possible for downstream users to scale the exposure scenarios, it is responsibility of the Registrant to consider all stages of the life-cycle of the substance in the exposure assessment, the risk management measures and the risk characterisation.

In his comments, following the procedure set out in Article 50(1) of the REACH Regulation, the Registrant indicated his intention to address the identified issues and appropriately amend the CSR.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation of the REACH Regulation, the Registrant is requested to revise the exposure assessment and risk characterisation for the environment addressing the issues identified above:

- Use the format specified in Annex I, section 7 of the REACH Regulation.
- Use the default ERC release factors recommended in ECHA's *Guidance on information requirements and chemical safety assessment* Chapter R.16 *or* provide a clear and detailed justification (e.g. based on RMMs and/or OCs and/or substance properties) for the non-default release factors used in the exposure estimation.
- Use of dilution factors not greater than 1000 according to ECHA's *Guidance on information requirements and chemical safety assessment* Chapter R.16.
- Provide a clear description of operational conditions for manufacture and the supported uses based on ECHA's Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12.
- Provide the exposure assessment and risk characterisation for all identified uses.

The chemical safety report shall be amended accordingly.

IV. 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.

[redacted]
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