

Decision number: CCH-D-0000002547-70-05/F

Helsinki, 13 November 2012

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006**For Styrene, CAS No 100-42-5 (EC No 202-851-5), 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 Styrene, CAS No 100-42-5 (EC No 202-851-5), submitted by [REDACTED]. (Registrant).

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 6 September 2012, 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 to initiate further compliance checks on the present dossier at a later stage.

The compliance check was initiated on 16 May 2012 and is targeted at the technical dossier information for the standard information requirements of Sections 8.6.2. and 8.7.2. of Annex IX, and of Sections 8.7.2. and 8.7.3. of Annex X of the REACH Regulation as well as at human exposure assessment.

On 25 May 2012 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 20 June 2012 ECHA received comments from the Registrant agreeing to the draft decision and indicating his intention to update the registration dossier by 20 August 2012. However, the Registrant did not update his registration dossier.

On 6 September 2012 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

- 1) Pursuant to Articles 41(1)(a) and (b), 41(3), 10(a)(vii), 12(1)(e), 13 and Annexes IX and X of the REACH Regulation the Registrant shall submit the following information generated with the test methods as indicated on the registered substance subject to the present decision:
 - a. Sub-chronic toxicity study (90-day) in rats, inhalation route (Annex IX, 8.6.2., test method EU B.29/OECD 413);
 - b. Pre-natal developmental toxicity study in rats, inhalation route (Annex IX, 8.7.2., test method EU B.31/OECD 414);
 - c. Second pre-natal developmental toxicity study in rabbits, inhalation route (Annex X, 8.7.2., test method EU B.31/OECD 414);
 - d. Two-generation reproductive toxicity study in rats, inhalation route (Annex X, 8.7.3., EU B.35).
- 2) Pursuant to Articles 41(1)(c), 14 and Annex I of the REACH Regulation the Registrant shall submit in the Chemical Safety Report:
 - a. Derived no effect levels (DNEL(s)) for workers and consumers;
 - b. Human exposure assessment and risk characterisation for the derived exposure scenarios.

ECHA notes that other registrants of the same substance have already submitted in their registration dossiers information from experimental studies involving vertebrate animals in order to fulfil the relevant information requirements. In accordance with Title III of the REACH Regulation, namely the obligations to request access to available information of studies on vertebrate animals (Articles 27 and 30 of the REACH Regulation), the Registrant shall not perform new testing involving vertebrate animals in order to comply with the present decision where such data is already available and is compelled to request this information from other registrants of the same substance.

More specifically, Article 30(1) of the REACH Regulation imposes on the Registrant to request from other substance information exchange forum (SIEF) participants to share the studies involving tests on vertebrate animals already available. The Registrant and the other SIEF participants shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way.

In addition, the Registrant is reminded of the obligation imposed by Article 11 of the REACH Regulation on all the registrants of the same substance to submit registrations for the same substance jointly.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the required information in the form of an updated IUCLID dossier to ECHA by **13 February 2013**.

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information

therein, submitted by the Registrant for registration of the above mentioned substance for the purpose of registration within the applicable tonnage band of above 1000 tonnes per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10, 12 and with Annexes I, IX, X and XI thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

1)a. Sub-chronic toxicity study (90-day)

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, section 8.6.2. of the REACH Regulation. The technical dossier did not contain any studies, study results or robust study summaries for this endpoint. The only information provided in the technical dossier is a brief text stating that the substance is extensively studied and that data are available. No data supporting this text or references to the studies are given.

Consequently there is an information gap and it is necessary to provide information for the endpoint of Annex IX, 8.6.2.. The Registrant is accordingly requested to submit information for this endpoint generated by the following test on the registered substance: 90-day repeated dose toxicity study in the rat, by inhalation tests (EU B.29/OECD 413). The requested route of exposure is by inhalation based on the volatility property of the substance.

The Registrant is requested to update the technical dossier and the CSR with the requested information available in joint submissions for the same substance following sharing jointly this data with the other registrants.

1)b. Pre-natal developmental toxicity study

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, section 8.7.2. of the REACH Regulation.

The technical dossier did not contain any studies, study results or robust study summaries for this endpoint. It only contained a reference to CAESAR QSAR model for Developmental Toxicity v.1.0.0.10, and in the results section a statement "*Predicted Developmental Toxicity Class: Developmental NON Toxicant (refer Appendix 3 to this CSR)*".

The result from the QSAR classification model (i.e. "toxic" or "non-toxic") is not suitable for the purposes of classification and labelling and/or risk assessment for the endpoint for which testing has been proposed to meet the information requirement. The documentation provided is inadequate and it has not been shown if the scientific validity of the model has been established or not. The submitted documents also indicate that the substance might be outside of the applicability domain of the model.

Therefore, ECHA concludes that the information submitted does not meet the conditions for the adaptation on the basis of QSAR models set out in Annex XI, Section 1.3. and it cannot constitute an acceptable adaptation to standard information requirements.

Given that there is no valid adaptation according to Annex XI, 1.3, it follows that the Registrant has an information gap for the endpoint of Annex IX, 8.7.2. and is therefore obliged to fulfil the information requirement. The Registrant is accordingly requested to submit information for this endpoint generated by the following test on the registered

substance: Prenatal developmental toxicity study in the rat, by the inhalation route (EU B.31/OECD 414). The requested route of exposure is by inhalation based on the volatility property of the substance.

The Registrant is requested to update the technical dossier and the CSR with the requested information available in joint submissions for the same substance following sharing jointly this data with the other registrants.

1)c. Second pre-natal developmental toxicity study

A pre-natal developmental toxicity study for a second species is a standard information requirement as laid down in Annex X, section 8.7.2. of the REACH Regulation. Consequently there is an information gap and it is necessary to provide information for the endpoint of Annex X, 8.7.2. and the Registrant is therefore obliged to fulfil the information requirement. The Registrant is accordingly requested to submit the information for this endpoint generated by the following test on the registered substance: Prenatal developmental toxicity study in the rabbit, by the inhalation route (EU B.31/OECD 414). The requested route of exposure is by inhalation based on the volatility property of the substance.

The Registrant is requested to update the technical dossier and the CSR with the requested information available in joint submissions for the same substance following sharing jointly this data with the other registrants.

1)d. Two-generation reproductive toxicity study

A two-generation reproductive toxicity study is part of the information requirements as laid down in Annex X, section 8.7.3. of the REACH Regulation.

The only information on this endpoint in the technical dossier was the following statement "Based on the data summarised here, styrene is not considered as reproductive or developmental toxicant". No summary is available in the technical dossier.

It follows that the Registrant has an information gap for the endpoint of Annex X, 8.7.3. and that he should therefore fulfil the information requirement.

According to the test method EU B.35/OECD 416 the rat is the preferred species. ECHA considers this default species appropriate. The requested route of exposure is by inhalation based on the volatility property of the substance.

The Registrant is requested to submit information on the Annex X, 8.7.3 endpoint generated by the following test on the registered substance: two-generation reproduction toxicity study in the rat, by the inhalation route (EU Method B.35).

The Registrant is requested to update the technical dossier and the CSR with the requested information available in joint submissions for the same substance following sharing jointly this data with the other registrants.

2) Missing information related to the Chemical Safety Report

Annex I sets out the general provisions for assessing substances and preparing chemical safety reports (CSR).

a) Derived no effect levels (DNEL(s)) for workers and consumers

Annex I, section 1.4. of the REACH Regulation, requires the Registrant to establish derived no effect levels (DNEL(s)) for the registered substance. The chemical safety report (CSR) under Chapter 5.9. contains acute and chronic DNELs for worker by inhalation route but the justifications for these derivations remain unclear and the derivation of the DNELs cannot be reproduced. In addition, no DNEL for worker dermal route is derived even though DNEL for worker dermal systemic, long-term effects is a default DNEL to be generated according to ECHA Guidance on information requirements and chemical safety assessment, Volume 8, R8 Characterisation of dose [concentration]-response for human health, May 2008, p. 56 Paper version)¹. Consumer use is mentioned in the CSR and the technical dossier, but no DNELs for consumers are derived.

The Registrant is accordingly requested to reassess and justify the selection for worker inhalation DNELs following ECHA Guidance on information requirements and chemical safety assessment Volume 8, R8 Characterisation of dose [concentration]-response for human health, May 2008². In addition, the Registrant is requested to derive a DNEL for worker dermal route and for all relevant DNELs (oral, inhalation, dermal routes) for consumers.

b) Human exposure assessment and risk characterisation for the derived exposure scenarios

According to Article 14(1) and (3) and Annex I, section 0.6 of the REACH Regulation, 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 categories³ 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 additional steps: Exposure assessment and Risk characterisation in accordance with Annex I, section 0.6.2. 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.

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 section 0.6 of Annex I.

In the technical dossier and in the CSR the Registrant has named three identified uses. The substance has harmonised classification for human health properties (harmful by inhalation, irritant to eyes and skin) and for flammability. However, Section 9 of the CSR includes no exposure assessment (REACH Annex I, section 5). In addition, risk characterisation (Section

¹ Link to ECHA guidance document R.8 is:

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r8_en.pdf?vers=20_08_08

² Link to ECHA guidance document R.8 is:

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r8_en.pdf?vers=20_08_08

³ 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;

10 of the CSR) contains only a very general statement, and it is unclear how risk characterisation has been derived as it is not based on any exposure estimations. The Registrant is accordingly requested to generate exposure estimations and risk characterisation for all identified uses of the substance in and to update the CSR.

IV. Timeline for updating the registration dossier

The present decision requires the Registrant to provide information that in accordance with Article 30(1) of the REACH Regulation he is required to obtain by sharing of information. ECHA considers three months to be sufficient time, (1) to request the studies from the respective data owners, (2) to receive the proof of the costs, (3) to make every effort to ensure that the costs of sharing information are determined in a fair, transparent and non discriminatory way, and (4) to pay and be granted permission to refer to the full study reports after receipt of payment by the respective data owner.

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/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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