Decision number: CCH-D-2114313519-50-01/F Helsinki, 15 February 2016

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

**For sodium xylenesulphonate, CAS No 1300-72-7 (EC No 215-090-9), 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 sodium xylenesulphonate, CAS No 1300-72-7 (EC No 215-090-9), 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 per year. This decision does not take into account any updates submitted after 3 September 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 11 June 2013.

On 10 February 2014 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 12 March 2014 ECHA received comments from the Registrant on the draft decision.

On 02 June 2014 the Registrant updated his registration with the submission number [redacted]

ECHA received comments and update concerning the information requirements of Annex IV, Sections 2.1. 2.2, 2.3.5, 2.3.6 and 2.3.7; Annex VII, Section 7.5; and Annex X, Sections 8.7.2. and 8.7.3. The compliance check requirement to submit information of a two-generation reproductive toxicity study (EU B.35, OECD TG 416) or an extended one-generation reproductive toxicity study (EU B.56, OECD TG 443) has been removed from this draft decision due to the legislative amendments to the REACH Regulation regarding Annex X, Section 8.7.3. In light of this, ECHA Secretariat did not consider further the Registrant's comments and update concerning the information requirement of Annex X, Section 8.7.3. However, ECHA Secretariat did consider further the Registrant's comments and/or update concerning the information requirement of Annex X, Sections 8.7.2. On the basis of all this

information and change of scope, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 3 September 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, a proposal for amendment to the draft decision was submitted.

On 9 October 2015 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal for amendment received and amended the draft decision.

On 19 October 2015 ECHA referred the draft decision to the Member State Committee.

By 9 November 2015, in accordance to Article 51(5), the Registrant provided comments on the proposal for amendment. The Member State Committee took the comments on the proposal for amendment of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 23 November 2015 in a written procedure launched on 12 November 2015.

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

## II. Information required

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

Pursuant to Articles 41(1), 41(3), 10(a)(vi) and/or (vii), 12(1)(e), 13 and Annex X of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the registered substance subject to the present decision:

1. Pre-natal developmental toxicity study (Annex X, 8.7.2.; test method: EU B.31./OECD 414) in rabbits, oral route.

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 request in this decision, or to fulfil otherwise the information requirement with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.*

**B. 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:

1. Documentation for the recommended personal protective equipment (Annex I, 5.1.1. in conjunction with Annex II, 0.1.2. and 8.2.2.2(b)), as specified under Section III point B.1 below.

**C. Deadline for submitting the required information**

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit the information required by this decision in the form of an updated registration to ECHA by **22 February 2017**, including, where relevant, an update of the Chemical Safety Report.

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 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.

1. Pre-natal developmental toxicity study (Annex X, 8.7.2.)

Pre-natal developmental toxicity studies on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1; Annex X, Section 8.7.2., column 1; and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

There is information available on this endpoint only for a pre-natal developmental toxicity study in a first species in the technical dossier. However, there is no information available for a pre-natal developmental toxicity study in a second species. Consequently there is an information gap for Annex X, Section 8.7.2. and it is necessary to provide information for this endpoint.

The technical dossier contains information on a pre-natal developmental toxicity study in rats by the oral route using the analogue substance calcium xylenesulphonate as test material. The read-across from calcium xylenesulphonate to the registered substance sodium xylenesulphonate is considered acceptable due to the chemical identity of the xylenesulphonate anion, whereas the different cations (presence of calcium instead of sodium) are not expected to alter the results of the prenatal developmental toxicity study.

However, there is no information available for a pre-natal developmental toxicity study in a second species and the technical dossier does not contain an adaptation in accordance with column 2 of Annex X, Section 8.7. or with the general rules of Annex XI for this standard information requirement.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement for a pre-natal developmental toxicity study in a second species. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The test in the first species was carried out by testing a rodent species and ECHA therefore considers that the test in a second species should be carried out in a non-rodent species. According to the test method EU B.31/OECD 414, the rabbit is the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rabbit as a second species to be used.

The Registrant provided comments and updated the technical dossier. The updated dossier includes an endpoint study record to waive the second-species information requirement (study scientifically unjustified) based on the argumentation presented in his comments.

ECHA understands that the Registrant does not agree that a pre-natal developmental toxicity study on a second species is a standard information requirement because he states "*that according to Annex X, 8.7.2, column 1 of the REACH Regulation, the pre-natal developmental toxicity study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data according to Annex IX, 8.7.2, column 2 of the REACH Regulation. The registrant performed the pre-natal developmental study on rodents to fulfill the required information for a substance registered for 1000 tonnes or more per year.*" In this respect, ECHA emphasises that the pre-natal developmental toxicity study is a standard information requirement pursuant to Section 8.7.2., Annex X. This follows from the cumulative nature of the requirements contained in Column 1 to the testing Annexes and was confirmed by the ECHA Board of Appeal in decision A-004-2012 of 10 October 2013.

Furthermore, the Registrant states that the study is scientifically unjustified because

- In a pre-natal developmental toxicity study on the rat "*no treatment- related or dose-related indications of developmental toxicity up to 3000 mg/kg day dose were observed*";
- "*Repeated dose toxicity studies with sodium xylenesulphonate gave no hints for any reproductive or developmental toxicity*"; and
- "*In the absence of any indications of the substance affecting rat development in the pre-natal study, there is no reason to suggest that any effects on development are likely in other species*"; and
- "*In terms of animal welfare, noting testing on vertebrate animals for the purposes of Article 25 of the REACH regulation shall be undertaken only as a last resort*".

ECHA emphasises that according to column 2 of Section 8.7. , Annex X, the pre-natal developmental toxicity study on a second species does "*not need to be conducted if:*

- *the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented, or*
- *the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented, or*
- *the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure.*
- *If a substance is known to cause developmental toxicity, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.*"

ECHA notes that the waiving statement provided by the Registrant does not comply with any of the abovementioned specific adaptation possibilities according to column 2 of Section 8.7. of Annex X.

ECHA also observes that the waiving statement provided by the Registrant does not comply with any of the general adaptation possibilities according to Annex XI. In this respect, ECHA notes that the Registrant's argumentation can be interpreted as a Weight-of-Evidence adaptation according to Section 1.2., Annex XI. ECHA emphasises that if Weight-of-Evidence is applied, the Registrant should address all the parameters of the endpoint concerned that may give rise to a conclusion that a substance has or has not a particular dangerous property. In this specific case, the documentation and justification should therefore address all the relevant parameters of the endpoint "second-species pre-natal developmental toxicity" (rabbit). The general statements relating to (1) the results of the pre-natal developmental toxicity study in rat and repeated-dose toxicity studies, (2) no indications that developmental effects are likely in other species, (3) general animal welfare considerations do not address said relevant parameters. ECHA therefore concludes that the presented documentation and justification does not address the specific parameters of this endpoint.

Based on the information provided by the Registrant, ECHA concludes that none of the aforementioned specific nor general adaptation possibilities are currently met and, therefore, information on pre-natal developmental toxicity on a second-species (rabbit) must be provided.

With respect to the Registrant's statement that "*In any case, an OECD 414 test using rabbits should not be carried out until the OECD 416 test is complete and available data regarding pre-natal development toxicity has been re-evaluated*", ECHA emphasises that the scope of the compliance check has changed and the request for an OECD 416 study has been removed from the decision.

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: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rabbits by the oral route.

## B. 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.

1. Documentation for the recommended personal protective equipment, hand protection / respiratory protection (Article 14(6), Annex I, section 5.1.1, in conjunction with Annex II, 0.1.2 and 8.2.2.2 (b)(i) / (c).

Article 14(6) as well as Annex I, 0.1., 5.1.1., 5.2.4. and 6.2. of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in a CSR. The exposure shall be estimated and risks shall be characterised in the CSR under the assumption that relevant risk management measures have been implemented.

According to Annex I, 0.3., 0.5. and 5.1.1. the applied Risk Management Measures (RMM) have to be described in the CSR. The CSR needs to contain sufficient information to allow ECHA to gain assurance that the risks are adequately controlled and that appropriate risk management measures can be prescribed by actors in the supply chain. Accordingly, the supplier is required to describe the relevant RMM in detail in the Safety Data Sheet in order to minimise the exposure for workers handling the registered substance (e.g. the type of gloves to be worn, protection equipment for parts of the body other than the hand or respiratory protection shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of exposure in accordance with Annex II, section 8.2.2.2.(b)(i), (ii) and 8.2.2.2.(c) respectively). The information provided in the Safety Data Sheet (SDS) shall be consistent with information in the Chemical Safety Report (Annex II, section 0.1.2. of the REACH Regulation).

ECHA notes that specific detailed information on the recommended personal protective equipment is missing both from the CSR and from the information on safe use within the IUCLID dossier. In the CSR, the Registrant indicated the following for hand protection / respiratory protection: Chemical resistant gloves with basic training / Respiratory protection capable of offering 90% reduction in inhaled concentration of the substance. While in IUCLID Section 11 he has reported generic information on hand and respiratory protection.

To ensure the safe use of a substance, Annex I Section 5.1.1 requires a description of the risk management measures to reduce or avoid direct and indirect exposure of humans. Gloves are reported in the CSR and IUCLID Section 11 as required personal protective equipment to prevent dermal exposure to the substance. Generally, gloves that are capable of preventing exposure to the skin for a pre-determined duration shall be specified. Typically, this information has to specify the glove material, breakthrough time and thickness of the glove material. Respiratory protection is reported in the CSR and IUCLID Section 11 as required personal protective equipment to prevent inhalation exposure to the substance. Generally, filters that are capable of preventing inhalation exposure for a pre-determined duration shall be specified.

Therefore, pursuant to Article 41(1)(c) the registrant is required to provide in the CSR a description of the gloves/ respiratory equipment to be used when handling the pure substance. The information provided by the Registrant shall be sufficiently detailed to allow suppliers to fulfil their obligations specified under Annex II for the compilation of the safety data sheets.

### C. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 36 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also contained a two-generation reproductive toxicity study (EU B.35, OECD TG 416) or an extended one-generation reproductive toxicity study (EU B.56, OECD TG 443) (Annex X, Section 8.7.3.). As these studies are not addressed in the present decision, ECHA Secretariat considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 12 months from the date of the adoption of the decision. The decision was therefore modified accordingly. Concerning the inclusion of the request for the "Documentation for the recommended personal protective equipment (Annex I, 5.1.1. in conjunction with Annex II, 0.1.2. and 8.2.2.2(b))", no additional time is necessary. The decision's deadline was therefore not modified.

## 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 Guilhem de Seze, Head of Unit, Evaluation E1

[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.