EUROPEAN CHEMICALS AGENCY

Helsinki, 17 November 2016

Addressee: [redacted]

Decision number: CCH-D-2114347535-46-01/F
Substance name: 2,3-epoxypropyl o-tolyl ether
EC number: 218-645-3
CAS number: 2210-79-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 24 April 2014
Registered tonnage band: 100-1000T

**DECISION ON A COMPLIANCE CHECK**

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **Composition (Annex VI, Section 2.3.) of the registered substance;**
   - **Nature of impurities, including isomers and by-products**

2. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309) at a temperature of 12 °C with the registered substance;**

3. **Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the registered substance;**

4. **Classification and labelling (Annex VI, Section 4.):**
   - **Apply the harmonised classification and labelling on the registered substance for mutagenicity.**

You 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 and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **24 May 2018**. You shall also update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

## Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

Authorised[1] by Ofelia Bercaru, Head of Unit, Evaluation E3

[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.

**Appendix 1: Reasons**

**1. Composition of the substance (Annex VI, Section 2.3.)**

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.

Annex VI, section 2.3. of the REACH Regulation requires that each registration dossier contains sufficient information for establishing the composition of the registered substance and therefore its identity.
In that respect, according to chapter 4.2 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" thereinafter, you shall note that, for well-defined substances, the following applies:

- Each main constituent (i.e. the constituent present at ≥80% for mono-constituent substance or each constituent present at ≥10% and 80% for multi-constituent substance) shall be identified and reported individually; and

- Each impurity present at ≥1% or relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually.

- For each constituent, the typical, minimum and maximum concentration levels shall be specified regardless of the substance type.

In the present dossier, you identified the registered substance as the well-defined mono-constituent substance *2,3-epoxypropyl o-tolyl ether.* This main constituent was reported without typical concentration and only with the upper level of the concentration range.
In addition, in the remarks field relative to the results of the Liquid Chromatography analysis, in section 1.4, two impurities above 1% (w/w) were mentioned with the following remark "*one impurity was found at* [redacted]*% and a second impurity was detected at a level of approximately* [redacted]*%*". However, these impurities were not identified, and they were reported in section 1.2 as "unknown impurities".

Therefore, ECHA concludes that the compositional information has not been provided to the required level of detail, because the typical and minimum concentration for the main constituent were not provided, and in addition, the impurities >1% (w/w) were not identified and correctly reported in section 1.2.

You are accordingly requested to correct the information provided on the composition of the registered substance, providing the typical and minimum concentration for the main constituent, identifying each impurity >1% (w/w) and reporting such impurities with the typical, minimum and maximum concentration levels.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: you shall report individually any impurity required to be identified and specify at least one of the following identifiers: chemical name, CAS number, EC number and/or molecular formula, as well as the minimum, maximum and typical concentration, in the appropriate fields in Section 1.2 of the IUCLID dossier.

Further technical details on how to report the composition of well-defined substances in IUCLID are available in the Manual How to prepare registration and PPORD dossiers on the ECHA website: http://echa.europa.eu/manuals.

You shall ensure that the composition is verifiable and therefore supported by a description of the analytical methods for the identification and quantification of the constituents required to be reported, as required under Annex VI.2.3.7. of the REACH Regulation. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

ECHA acknowledges your agreement and comment to the draft decision and your intention to update the registration dossier.

**2. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)**

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Simulation testing on ultimate degradation in water" is a standard information requirement as laid down in Annex IX, section 9.2.1.2. 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.

While you have not explicitly claimed an adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement according to Annex XI, Section 1.2 or Annex IX, Section 9.2.1.2, Column 2. You stated: "*The test substance is not readily biodegradable under the conditions of the study. No conclusion on P status can be made*".

However, ECHA notes that your adaptation meets neither the general rule for adaptation of Annex XI, Section 1.2 nor the specific rule in Annex IX, Section 9.2.1.2, Column 2 because the registered substance is clearly not readily biodegradable and it is not insoluble in water (solubility 0.84 g/L). The ready biodegradability tests are screening information only and are insufficient to conclude whether a substance is persistent. Further studies such as simulation tests are needed to confirm whether the substance is persistent or very persistent. ECHA hence considers that with the current information the CSA cannot be used to justify that there is no need to investigate further the degradation of the substance and its degradation products.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA acknowledges your comment to the draft decision and your intention to update the registration dossier. The updated dossier will be assessed after the final decision. ECHA notes that according to the ECHA Guidance R.11 (November 2014) standard approach in PBT/vPvB assessment must cover the substance, its constituents, impurities, additives, and transformation/degradation products. In this case, information on potential biodegradation products needs to be clarified in order to conclude on the PBT status of the substance.

According to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 2.0, November 2014) Aerobic mineralisation in surface water – simulation biodegradation (test method EU C.25. / OECD TG 309) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.2.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of the REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 2.0, November 2014) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-8 (version 3.0 February 2016) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 309. Therefore, the test should be performed at the temperature of 12°C.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD TG 309).

*Notes for your consideration*

Before conducting the requested test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Sections R.7.9.4 and R.7.9.6 (version 2.0, November 2014) and Chapter R.11, Section R.11.4.1.1 (version 2.0, November 2014) on PBT assessment.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the test detailed above is available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

### 3. Identification of degradation products (Annex IX, 9.2.3.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Column 2 of Section 9.2.3. of Annex IX further states that the information does not need to be provided if the substance is readily biodegradable.

The information on identification of the degradation products is not available in the registration dossier and no adaptation for this standard information requirement is provided.

As explained in section (2) above, ECHA considers that with the current information the CSA cannot be used to justify that there is no need to investigate further the degradation of the substance and its degradation products.

Therefore, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA acknowledges your comment to the draft decision and your intention to update the registration dossier. The updated dossier will be assessed after the final decision. ECHA notes that according to the ECHA Guidance R.11 (November 2014) standard approach in PBT/vPvB assessment must cover the substance, its constituents, impurities, additives, and transformation/degradation products. In this case, information on potential biodegradation products needs to be clarified in order to conclude on the PBT status of the substance.

Regarding appropriate and suitable test method, the methods will have to be substance specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition degradation half-life, log Kow and potential toxicity of the metabolite may be investigated. You may obtain this information from the simulation study also requested in this decision, or by some other measure. You will need to provide a scientifically valid justification for the chosen method.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

*Notes for your consideration*

Before providing the above information you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.7.9., Sections R.7.9.2.3 and R.7.9.4. These guidance documents explain that the data on degradation products is only required if information on the degradation products following primary degradation is required in order to complete the chemical safety assessment. Section R.7.9.4. further states that when substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis.

## 4. Classification and labelling (Annex VI, Section 4.)

Pursuant to Article 10(a)(iv) of the REACH Regulation the technical dossier shall include the classification and labelling for the registered substance in accordance with the CLP Regulation, as specified in Annex VI, Section 4 of the REACH Regulation.

The registered substance has a harmonised classification as Muta. 2 with H341 pursuant to Annex VI of the CLP Regulation, which is legally binding (Article 4(3) of the CLP Regulation). However, you have not classified the registered substance as Muta. 2, with this reason: "*The weight-of-evidence demonstrates that there is insufficient in vivo genotoxicity evidence to Classify and Label the test substance as a Mutagen*". The self-classification in the technical dossier proposes a less stringent classification, which is not allowed under to the CLP Regulation.

ECHA acknowledges your comment to the draft decision and your intention to update the registration dossier making the existing harmonised classification prominent.

In your comments you claim that "At the Technical Committee on Classification & Labelling Follow-up III meeting held in Arona on the 4-5 October 2006, it was agreed the substance should instead be classified without the mutagenicity classification (thus not classified for mutagenicity), and this official decision was recommended for inclusion in the next ATP. The decision was based on all relevant and available genotoxicity data."

ECHA notes that the said-modification to the ATP has not taken place. ECHA has not received proposals for revision for the entry in Annex VI of CLP. May you decide to send a revision proposal, you can contact any EU MSCA and ask them to cooperate. The process is described in Section 3.4.3 in our guidance http://echa.europa.eu/documents/10162/13626/clh_en.pdf and in the CLP Regulation, Article 37 (6).

As explained above, the information provided for the registered substance in the technical dossier does not meet the information requirement.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information for the registered substance subject to the present decision: a classification and labelling in accordance with the CLP Regulation.

This information must be provided in Section 2 of the IUCLID dossier.

## Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 27 January 2016.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation.

ECHA notified you of the draft decision and invited you to provide comments. ECHA took into account your comments, which were sent within the commenting period, and they are reflected in the Reasons (Appendix 1).

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

You did not provide any comments on the proposed amendment(s).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-50 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

## Appendix 3: Further information, observations and technical guidance

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

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

3. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

4. In relation to the information required by the present decision, the sample of the substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported 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 the substance tested in the new test(s) 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 or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) 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 test(s) to be assessed.