~~Confidential~~

Helsinki, 11 June 2021

Addressees
Registrant(s) of JS_3,4-xylenol as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
05/02/2020

Registered substance subject to this decision ("the Substance")
Substance name: 3,4-xylenol
EC number: 202-439-5
CAS number: 95-65-8

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***20 December 2021***.

Requested information must be generated using the Substance unless otherwise specified.

A. Information required from all the Registrants subject to Annex VII of REACH

1. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

Reasons for the request(s) are explained in the following appendix:

- Appendix entitled "Reasons to request information required under Annexes VII of REACH.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the

Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[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 A: Reasons to request information required under Annex VII of REACH

1. Short-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

You have adapted this standard information requirement according to Annex XI, Section 1.2. of REACH (weight of evidence). In support of your adaptation, you have provided the following sources of information:

a. Study on "*50% immobilization concentration at 24 h was determined for Daphnia magna under static conditions*"; data from handbook or collection of data.
b. Study on *Crangon septemspinosa*; data from handbook or collection of data (Original study published in 1979)

Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the (dangerous) property investigated by the required study.

Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach.

However, you have not included a justification for your weight of evidence adaptation, which would include an adequate and reliable (concise) documentation as to why the sources of information provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

In spite of this critical deficiency, which in itself could lead to rejection of the adaptation, ECHA has nevertheless assessed the provided sources of information and identified the following issue(s).

Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 9.1.1. at Annex VII includes similar information that is produced by the OECD TG 202. OECD TG 202 requires the study to investigate the following key parameter:

- The concentration leading to 50% immobilisation of daphnids.

The sources of information (a) and (b) provide relevant information on this key parameter. However the reliability of these sources of information is significantly affected by the following issues:

For a study conducted according to OECD TG 202, the following specifications must be met:

Reporting of the methodology and results

- the test design is reported (*e.g.* static or semi-static test, number of replicates, number of test concentrations and geometric progression used, age of daphnids, feeding of daphnids);
- the test procedure is reported (*e.g.* composition of the test medium, loading in number of *Daphnia* per test vessel);
- the number of immobilised daphnids is determined at 24 and 48 hours. Data are summarised in tabular form, showing for each treatment group and control, the number of daphnids used, and immobilisation at each observation;
- the dissolved oxygen and pH measured at least at the beginning and end of the test are reported;
- adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations are provided;

Technical specifications impacting the sensitivity/reliability of the test

- the test duration is 48 hours or longer;
- young daphnids aged less than 24 hours at the start of the test, are used;
- test animals are not fed during the test;

Characterisation of exposure

- chemical specific analysis of the test solutions is required to demonstrate stability of exposure concentrations during the test;
- the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within 20 % of the nominal or measured initial concentration throughout the test;

Validity criteria

- validity criteria specified in the test guideline must be met:
  - the percentage of immobilised daphnids is ≤ 10% at the end of the test in the controls (including the solvent control, if applicable);
  - the dissolved oxygen concentration is ≥ 3 mg/L in all test vessels at the end of the test;

In your dossier you have provided two studies that did not follow the recommended guideline, showing the following:

Reporting of the methodology and results

- on the test design, you have not specified number of replicates, number of test concentrations and geometric progression used, age and feeding of test organisms for any of the studies, and for study (b) there is no information on test set-up (e.g. static or semi-static)
- on the test procedure, you have not specified composition of the test medium and loading in number of test organisms per test vessel for any of the studies;
- tabulated data on the number of immobilised daphnids after 24 and 48 hours for each treatment group and control are not reported for any of the studies;
- the dissolved oxygen and pH measured at least at the beginning and end of the test are not reported for any of the studies;
- analytical monitoring was conducted for study (b) but information on sampling and analysis, analytical method and the results of the analyses to determine the concentration of the test substance in the test vessels are not reported;

Technical specifications impacting the sensitivity/reliability of the test

- the test duration was 24 hours for study (a);

Characterization of exposure

- no analytical monitoring of exposure was conducted for study (a);
- results are based on nominal concentrations for both studies;

Validity criteria

- you have not specified whether the validity criteria of the test guideline are met for any of the studies.

On this basis there are major deficiencies impacting all sources of evidence provided in support of your weight-of-evidence adaptation, including the following:

- *Reporting of the methodology and results:* In absence of information on the study design and procedure for any of the studies, it is not possible to verify if the test design and test conditions followed the requirements of OECD TG 202. For instance, there is no information on the age and feeding of the tested organisms for any of the studies. This may underestimate the toxicity, because the sensitivity of test organisms may be lower if they are aged more than 24h at test start (ECHA Guidance R.7b) and/or if they are fed during the study. For all these reasons, there is significant uncertainty with regard to the reliability of these studies.
- *Technical specifications impacting the sensitivity/reliability of the test:* the exposure duration was shorter than 48 hours (i.e. 24 hours) for study (a). Shorter test duration generally lead to higher effect values and hence to an underestimation of the toxicity (ECHA Guidance R.7b). Furthermore, there is no information on the age and feeding of the tested organisms for any of the studies. This may underestimate the toxicity, because the sensitivity of test organisms may be lower if they are aged more than 24h at test start (ECHA Guidance R.7b) and/or if they are fed during the study. For all these reasons, there is significant uncertainty with regard to the reliability of these studies.
- *Characterisation of exposure*: in the absence of analytical monitoring for study (a) and in the absence of results of analytical determinations for study (b), you have not demonstrated the stability of the test substance.
- *Validity criteria*: as you have not provided information on dissolved oxygen and tabulated data on the number of immobilised daphnids for any of the studies, it is not possible to verify that the validity criteria are met.

As explained above, there are a number of major deficiencies impacting the reliability of the studies included in your weight-of-evidence. Considering these deficiencies, it cannot be concluded with sufficient confidence what is the concentration of the Substance leading to the immobilisation of 50% of daphnids.

On this basis, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 202 study. Therefore, your adaptation is rejected.

In your comments to the draft decision, you indicate that you agree with the shortcomings of studies (a) and (b) and with the need to fulfil the information requirement (OECD TG 202). You indicate that you plan to explore ways to address this information requirement. However, you have not provided in your comments any new scientific information that could address it.

On this basis the information requirement is not fulfilled.

Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

1. Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

2. Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[2].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

   The Test Material used to generate the new data must be selected taking into account the following:
   - the boundary composition(s) of the Substance,
   - the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

[2] https://echa.europa.eu/practical-guides
[3] https://echa.europa.eu/manuals

Appendix C: Procedure

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

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 28 July 2020.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the request(s).

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix D: List of references - ECHA Guidance[4] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[5]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[5]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[6]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[6] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix E: Addressees of this decision and their corresponding information requirements

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.