EUROPEAN CHEMICALS AGENCY

Helsinki, 05 August 2020

Addressees
Registrants of JS_30618-84-9 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
14/11/2018

Registered substance subject to this decision ("the Substance")
Substance name: Mercaptoacetic acid, monoester with propane-1,2,3-triol
EC number: 250-264-8
CAS number: 30618-84-9

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 ***13 May 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. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: EU B.13/14. / OECD TG 471)

The reasons for the request are explained in the following appendix:

- Appendix entitled "Reasons to request information required under Annex 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.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

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. In vitro gene mutation study in bacteria

An *in vitro* gene mutation study in bacteria is a standard information requirement in Annex VII to REACH.

You have provided a key study and supporting study in your dossier:

i. In vitro gene mutation study in bacteria (1992), a key study, with the following strains, TA 98, TA 100, TA 1535, TA 1537, and TA 1538 which all gave negative results.
ii. In vitro gene mutation study in bacteria (1987), a supporting study, with the following strains, TA 1537, TA 1537, and TA1538 which all gave negative results.

We have assessed this information and identified the following issues:

A. Key study

To fulfil the information requirement, the study has to meet the requirements of OECD TG 471 (1997). The key parameters of this test guideline include:

a) The test must be performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101)
b) At least 5 doses must be evaluated, in each test condition.
c) Triplicate plating must be used at each dose level.
d) The number of revertant colonies per plate for the concurrent negative control must be inside the historical control range of the laboratory.
e) The mean number of revertant colonies per plate must be reported for the treated doses and the controls.

The reported data for the key study (i) you have provided did not include:

a) results for the appropriate 5 strains, that is in the required fifth strain, *S. typhimurium TA102* or *E. coli* WP2 uvrA or *E.coli* WP2 uvrA (pKM101).
b) the evaluation of at least 5 doses in each test condition as you did not provide information how many and what doses were tested.
c) information on whether triplicate plating was used at each dose level.
d) whether the number of revertant colonies per plate for the negative control was inside the historical control.
e) data on the number of revertant colonies per plate for the treated doses and the controls

In your comments on the draft decision, you fully agreed with ECHA on the deficiencies listed above and why the dossier does not comply with this information requirement. However, you do not see any value of having a new OECD TG 471 test based on the following reasons:

- The Substance is used as a reducing agent in cosmetic formulation and the strains *S. typhimurium TA102* or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101) are detecting oxidizing mutagens. Therefore, the outcome of the test can be predicted to be negative for e.g. TA102 based on chemical reactivity.

- Looking at all test results regarding genotoxicity, even in case of a positive result as a worst-case prediction, the overall conclusion will not change. The overall assessment of the test battery will remain the same: not genotoxic.
- The negative prediction of the outcome with e.g. TA102 is confirmed for the whole group of SH-bearing compounds produced and REACH-registered by you.

ECHA notes that the lack of 5th strain (e.g. TA102) is not the only shortcoming in the provided study, as explained above. Based on the information you have provided and due to all the identified deficiencies in the *in vitro* gene mutation study in bacteria, it is not possible to reliably assess mutagenic properties of the Substance in bacteria as required by OECD TG 471.

Moreover, according to Annex VII Section 8.4. (column 2) "*further mutagenicity studies shall be considered in case of a positive result*". Therefore, you cannot simply conclude that the Substance is not genotoxic if there is a "*positive result as a worst-case prediction*".

Therefore, the information provided does not cover all the key parameters required by OECD TG 471.

B. Supporting study

You considered the supporting study (ii) as not reliable (reliability 3, non-GLP) based on incomplete strain selection and lack of method description. Consequently, ECHA has not considered this study.

In your comments to the draft decision you also stated that instead of experimental testing with e.g. TA102, you suggest summarizing all available data regarding the information requirement for genotoxicity based on ECHA's Read-Across Assessment Framework. You indicated also a general need to improve your read-across. At the end, you expect to conclude that a risk for genotoxicity of this group of chemicals cannot be identified at all. You claim that newly conducted tests will have a negative outcome regarding the induction of gene mutations (mutagenicity).

We note that currently there is no specific read-across adaptation in your dossier and/or comments to the draft decision to adapt this information requirement. ECHA notes that you may, under your own responsibility, provide a read-across adaptation to waive this information requirement. However, if it fails you remain responsible for complying with this decision by the set deadline.

Therefore, considering the above, the information requirement is not fulfilled.

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471) is considered suitable.

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 variation in compositions reported by all members of the joint submission,
   - 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 and whether it is suitable for use by all members of the joint submission.

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 03 July 2019.

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 and the deadline.

With reference to your comments, the timeline indicated in the draft decision to provide the information requested is 6 months from the date of adoption of the decision.

In your comments to the draft decision, you requested an extension of the timeline as you intend to improve the read-across approach. Also, you invoke your nature of SME and the fact that read-across/grouping and waiving approaches are complex and therefore require time to be developed.

However, in your comments you have not indicated any issues (including laboratory capacity) related to the performance of the studies requested in this decision. Therefore, the arguments provided above do not justify your request to extend the timeline and ECHA has not modified the deadline of the decision.

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]

[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 aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

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 the corresponding information requirements applicable to them

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]
[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.