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Helsinki, 13 January 2022

Addressees
Registrant(s) of JS_MDI-CHA-DCA as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
03/03/2021

Registered substance subject to this decision ("the Substance")
Substance name: Reaction products of m-tolylidene diisocyanate and cyclohexylamine and cyclohex-1,2-ylenediamine and (Z)-octadec-9-enylamine
List number: 945-075-9
CAS number: NS

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 ***18 October 2023***.

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. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)

Reasons for the request are explained in the appendix entitled "Reasons to request information required under Annexes VII of REACH", respectively.

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 Mike Rasenberg, 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. Growth inhibition study aquatic plants

Growth inhibition study aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

You have provided information on the registered substance :

i. a study according to OECD TG 201 with a test material identified as Reaction product of m-tolylidene diisocyanate and cyclohexylamine and cyclohex-1,2-ylenediamine and (Z)-octadec-9-enylamine, (analogue, List number : 945-075-9), [redacted] 2010.

You have also adapted this information requirement under Annex XI, Section 1.5. ('Grouping of substances and read-across approach'). In support of your adaptation, you have provided the following information:

ii. a study according to OECD TG 201 with a test material identified as "Tetraurea grease 2" (analogue, no list number), [redacted] 2011;
iii. a study according to OECD TG 201 with a test material identified as "Diurea thickener 8" (analogue, no list number), [redacted] 2009;
iv. a study according to OECD TG 201 with a test material identified as "Diurea thickener 8 base grease", (analogue, no list number), [redacted] 2012; and
v. another study as other information, according to OECD TG 201 with the same test material identified as "Diurea thickener 8 base grease", [redacted] 2011;

We have assessed this information and identified the following issues:

A. To comply with this information requirement, the test material in a study must be representative for the substance that is intended to be tested (Article 10 and Recital 19 of REACH; ECHA Guidance R.4.1).

   For studies ii. and iii. to v. above, you have identified the test material as either Tetraurea grease 2 or Diurea thickener 8 or Diurea thickener 8 base grease, without further information, including composition. In the absence of composition information on the test materials, the identity of the test materials and their impurities cannot be assessed and you have not demonstrated that the test materials are representative for the Substances tested.

   Therefore, the information provided is rejected.

B. To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

   Requirements applicable to difficult to test substances

   - if the test material is tested at the saturation concentration, evidence must be provided that all reasonable efforts have been taken to achieve a saturation concentration, which include:
     1) information on the saturation concentrations of the test material in water and in the test solution, and
     2) the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution.

Characterisation of exposure

- a reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (*i.e.* detection and quantification) and working range must be available. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;
- the test media prepared specifically for analysis of exposure concentrations during the test is treated identically to those used for testing (*i.e.* inoculated with algae and incubated under identical conditions).

Your registration dossier provides five OECD TG 201 studies showing the following:

Requirements applicable to difficult to test substances

- you specify that all the test materials tested whether on the Substance or the analogues are poorly soluble in water and hence difficult to test. For none of these studies, the saturation concentration of the test material in the test medium is provided;
- for studies i. to iv., you report that test solutions were prepared following a 23 hours stirring period. You report the results of a preliminary experiment indicating that longer stirring duration led to higher TOC concentrations. For study iii. you have not provided the results of a preliminary solubility experiment;

Characterisation of exposure

- for all the studies i. to v., a non specific analytical method (TOC measurements was used). You have not provided any justification as to why it is not possible to develop an analytical method with adequate specificity and sensitivity;
- for studies i. to v., you report that "*total Organic Carbon (TOC) analysis was performed on the test preparations prepared with the omission of algal cells at 0 and 72 hours*". For all studies including i. and ii. on the Substance and one analogue you report that measured concentration at t=0 and t=72or 75 is <LOD for the limit concentration. For studies iii and iv. the measured TOC at t=0 were well below the results obtained in the preliminary experiment (< LOQ at t=0 *versus* 1.7 mg/L in the preliminary experiment for study iii.; 1.1 mg/L at t=0 *versus* 1.8 mg/L in the preliminary experiment for study iv. For study v., you have not specified if the samples used for TOC measurements were inoculated with algae. In addition, you have not reported the results of TOC measurements for this study.

Based on the above, there are critical methodological deficiencies resulting in the rejection of the results of these studies. More, specifically:

- the corresponding test materials have low solubility. The analytical method used was non specific and had low sensitivity. In addition, the preliminary experiment for studies iii. to v. was conducted based on a shake flask method which is not adequate to estimate the saturation concentration of substances having a water solubility < 10 mg/L (OECD TG 105). Therefore, you have not provided adequate information on the saturation concentration of these test materials in the test medium;
- the analytical determination conducted at t=0 for studies iii. and iv. indicate values that are below the values obtained in the preliminary experiment. Therefore, the test solution preparation was not adequate to maximize the exposure to the test material. For study v., no supporting information is provided to evaluate the validity of the test solutions preparation method;
- the analytical determination of exposure concentrations was done in the absence of algae and therefore does not provide an adequate determination of the

exposure to these test material over the exposure period for all studies.

Therefore, the requirements of OECD TG 201 in conjunction with OECD GD 23 are not met.

In your comments, you agree to conduct the study for this Substance.

On this basis, the information requirement is not fulfilled.

Study design

The Substance is difficult to test due to the low water solubility (estimated with QSAR 6.75e-10 mg/L) and adsorptive properties (with estimated log kow range values between 7.16 and < 11.97). OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.
Furthermore, for multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (ECHA Guidance, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

In your comments you request a clarification on the acceptability of 100mg/L loading rates given the requirement that loading rates are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). ECHA considers that this is already explained in the draft decision and specified in OECD GD 23 but can be repeated here for emphasis.

- if the test material is poorly water soluble, the maximum dissolved concentration that can be achieved in the specific test solution under the test conditions must be determined;
- if the test material is tested at the saturation concentration, evidence must be provided that all reasonable efforts have been taken to achieve a saturation concentration,

which include:

1) an analytical method validation report demonstrating that the analytical method is appropriate, and
2) information on the saturation concentrations of the test material in water and in the test solution, and
3) a description of the method used to prepare the test solution, and
4) the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution;

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

UVCB Substances – with the Substance
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:

a) the variation in compositions reported by all members of the joint submission,
b) the boundary composition(s) of the Substance,
c) 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

a) 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.
b) The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,

With that detailed information, ECHA can confirm 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: General recommendations when conducting and reporting new tests for REACH purposes

A. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

Appendix D: 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 3 February 2021.

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

In the comments to the draft decision, you requested an extension of the deadline to provide information from 9 to 24 months from the date of adoption of the decision. You consider such an extension necessary to allow the CRO to refine the testing procedures for ecotoxicological testing and particularly to allow for development of an analytical method for detection of your difficult to test substance. You also claim that further time is needed to update your category approach and strengthen its plausibility.

ECHA acknowledges the justification from the CRO and the particular difficulties in conducting the test with your substance. Consequently, an additional 9 months is considered appropriate and the deadline is amended accordingly. Additional time for category approach development is not warranted as you will conduct the studies on the Substance.

On this basis, ECHA has granted partially the request and extended the deadline to 18 months.

ECHA took into account your comments and amended the deadline.

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 E: 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)[6]

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[7]

[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] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[7] 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.

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Appendix F: 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]
[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.