~~Confidential~~

Helsinki, 17 August 2021

Addressees
Registrants of RECONSILE EC# 205-492-2 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
26/02/2021

Registered substance subject to this decision ("the Substance")
Substance name: Dodecamethylpentasiloxane
EC number: 205-492-2
CAS number: 141-63-9

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 ***22 November 2022***.

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

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

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats.

Reasons for the request(s) are explained in the following appendix entitled "Reasons to request information required under Annex IX 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 Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa
- the information specified in Annexes VII to X to REACH, for registration at more than 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 IX of REACH

1. Sub-chronic toxicity study (90-day)

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement applying a read-across approach in accordance with Annex XI, Section 1.5. You read-across between the structurally similar substances, Decamethyltetrasiloxane (L4), EC No. 205-491-7 (CAS No. 141-62-8) as source substance and the Substance (L5) as target substance. Your dossier contains:

i. A read-across justification document in IUCLID Section 13, together with 28-day repeated-dose toxicity studies via oral (OECD TG 407) and inhalation (OECD TG 422) routes for the source substance and 28-day repeated-dose toxicity study via oral route (OECD TG 407) for the Substance as supporting information; and a
ii. A 90-day repeated-dose toxicity study via inhalation route according to OECD TG 413, with the source substance ([redacted] 2010b).

ECHA has assessed this information and identified the following issue with the submitted 90-day inhalation study with the source substance:

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should:

- be adequate for the purpose of classification and labelling and/or risk assessment.

The overall objective of toxicity testing is to determine the potential hazard of the test substance to human beings. A repeated dose toxicity study must be performed by either the oral, inhalation or dermal route. To decide on a specific route, it requires first to identify the appropriate routes.[2]

According to Annex IX, 8.6.2., Sub-chronic toxicity study (90-day) should be performed using the most appropriate route of administration. According to ECHA Guidance R.7a, R.7.5.4.3.2, "*the oral route is the default one because it is assumed to maximise systemic availability (internal dose) of most substances.*"

To identify the potential hazards following 90-day exposure to the Substance, you have provided a 90-day repeated-dose toxicity study conducted via inhalation route using the source substance L4 (study ii above). You stated that in this study, the observed changes at the high dose of 400 ppm, corresponding to approximately 1500 mg/kg bw/d (recalculated from 5.1 mg/L, 6h/day) in serum chemistry and haematology parameters, urinary volumes and organ weights (absolute and relative, including the increase in relative liver weight of +7.9%) may be treatment-related, but are not toxicologically significant. You concluded in the robust study summary for this study that "*these increases in organ weights (liver, uterus) may be treatment-related and were not considered adverse as there were no histopathological correlates*."

The lack of toxicity following exposure via inhalation route was supported by a combined repeated-dose toxicity study with the reproduction/developmental toxicity screening test following the OECD TG 422 ([redacted] 2007) conducted with the source substance**.** No treatment-related effects were observed at the highest attainable concentration 400 ppm.

[2] ECHA Guidance R.7a, R.7.5.6.3.4

You have also provided a 28-day repeated-dose toxicity study conducted according to the OECD TG 407 ([redacted], 2010a) with the source substance L4. In this oral study, the NOAEL reported at 25 mg/kg bw/day based on significantly elevated mean absolute liver weights, mean liver-to-body weight ratios and mean liver-to-brain weight ratios together with brown pigment accumulation in the liver at 250 mg/kg bw/d.

Based on above information, testing via the inhalation route does not maximise the systemic availability of the source substance. More severe effects - liver toxicity accompanied by histopathological correlates - at much lower nominal doses were observed after oral administration in an OECD TG 407 study. After inhalation administration in OECD TG 413 or OECD TG 422 studies no histopathological changes were found in the liver. This indicates that administration of the source substance via oral route causes more severe systemic toxicity than administration of this substance via inhalation route. While you have not provided toxicokinetic information for the source substance (or the Substance) to compare the absorption of the substance via oral and inhalation routes, the more severe systemic toxicity observed following oral administration of the source substance indicates that exposure via the oral route maximises the systemic availability (internal dose) of this substance.

Therefore, the available 90-day inhalation source study (OECD TG 413) with the source substance L4 (study ii) is not considered adequate for identification of the toxicological profile of the source substance. Consequently, the information from this study is not adequate neither for purpose of the identification of the systemic toxicological properties of the Substance, nor for the purpose of classification and labelling and/or risk assessment.

Therefore, the information requirement is not fulfilled.

Information on the design of the study to be performed (route/ species/ strain)

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity, because although the information indicate that human exposure to the Substance by the inhalation route may occur due to spraying applications, the oral administration is expected to maximise the systemic availability systemic availability (internal dose) of the Substance, as explained above.

Therefore the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance

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[3].

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[4].

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

Appendix C: Procedure

The information requirements Extended one-generation reproductive toxicity study (EOGRTS; Annexes IX or X, Section 8.7.3.) and Pre-natal developmental toxicity study in a second species (PNDT, OECD 414, Annex X, 8.7.2) are not addressed in this decision. Your related testing proposals will be addressed in a separate decision once the information from the Sub-chronic toxicity study (90-day) requested in the present decision is provided. This is due to the fact that the results from the 90-day study is needed for the assessment of the testing proposal design of the EOGRTS.

As an EOGRTS may cover the same parameters as in a test for Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.), also this latter endpoint was excluded from the scope of this compliance check.

In any case, this decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations.

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

The compliance check was initiated on 04 September 2020.

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

ECHA did not receive any comments within the commenting period.

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[5] 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)[6]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[7]

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[8]

[5] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[6] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[7] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[8] 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 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) data requirements to be fulfilled
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[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.