~~Confidential~~

Helsinki, 16 February 2022

Addressees
Registrant of RECONSILE EC# 219-137-4 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
23/02/2021

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 2,4,6,8-tetramethylcyclotetrasiloxane
EC number: 219-137-4

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

DECISION ON TESTING PROPOSAL(S)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the requested information listed below by ***23 May 2024***.

The requested information must be generated using the **Substance (99.5% purity) unless otherwise specified.**

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

1. Extended one-generation reproductive toxicity study also requested below (triggered by Annex IX, Section 8.7.3., column 1)

2. Long-term toxicity to terrestrial invertebrates also requested below (triggered by Annex IX, Section 9.4.1., column 2)

B. Information required from the Registrants subject to Annex X of REACH

1. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: EU B.56./OECD TG 443) by oral route, in rats, specified as follows:

   - Ten weeks premating exposure duration for the parental (P0) generation;
   - The highest dose level in P0 animals must be determined based on clear evidence of an adverse effect on sexual function and fertility without severe suffering or deaths in P0 animals as specified further in Appendix B.1. or follow the limit dose concept. The reporting of the study must provide the justification for the setting of the dose levels;
   - Cohort 1A (Reproductive toxicity);
   - Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation; and
   - Cohorts 2A and 2B (Developmental neurotoxicity).

   You must report the study performed according to the above specifications. Any expansion of the study must be scientifically justified.

2. Long-term toxicity testing on terrestrial invertebrates (Annex X, Section 9.4.4.; test

method: OECD TG 222) on the hydrolysis product methylsilanetriol with EC No. 219-489-9 (CAS RN 2445-53-6).

Reasons for the request(s) are explained in the following appendices entitled "Reasons to request information required under Annexes IX to X 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 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.

For certain endpoints, ECHA requests the same study from registrants at different tonnages. In such cases, only the reasoning why the information is required at lower tonnages is provided in the corresponding Appendices. For the tonnage where the study is a standard information requirement, the full reasoning for the request including study design is given. Only one study is to be conducted; the registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants under Article 53 of REACH.

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 can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to 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.

Approved[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 IX of REACH

This decision is based on the examination of the testing proposals you submitted.

1. Extended one-generation reproductive toxicity study

An extended one-generation reproductive toxicity (EOGRT) study (OECD 443) is an information requirement under Annex IX to REACH (Section 8.7.3.) if the available repeated dose toxicity studies indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity.

Your dossier contains repeated dose toxicity studie(s) which indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity:

- Reduced fertility or litter size: The OECD TG 422 study with the Substance showed a lower number of corpora lutea at the high dose (11.3 vs. 13.6 in the control group). The value at high dose was below the historical control range. You consider that the reduction of the number of corpora lutea and consequent reduction of number of pups is an adverse effect.
- Histopathology of the thyroid: The OECD TG 408 and 422 studies with the Substance show effects in histopathology of the thyroid. In the OECD TG 408 study, thyroid follicular cell hypertrophy was present in 9/10 males and 8/10 females at the high dose. In OECD TG 422 study, amorphous materials in the colloid were observed in males of all treatment groups with dose-dependency in its severity and incidence.

Therefore, the concern for reproductive toxicity must be further investigated.

ECHA agrees that an EOGRTS is necessary to address the identified concerns in relation with reproductive toxicity.

For the study specifications, see Appendix B.1.

2. Long-term toxicity testing on terrestrial invertebrates

Short-term toxicity to invertebrates is an information requirement under Annex IX to REACH (Section 9.4.1). Long-term toxicity testing must be considered (Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

Based on the information in your registration dossier the Substance is considered as not readily bioavailable. Furthermore, based on data on analogues, you state that the "*Initial rates of degradation in soil simulation tests ranged from 0.16 to 2.1% per month*".

Therefore, the Substance is considered potentially highly persistent in soil. On this basis information on long-term toxicity on terrestrial invertebrates must be provided.

Your registration dossier includes a testing proposal on long-term toxicity on terrestrial invertebrates.

For the assessment of the testing proposal and for the test selection and study specifications, see Appendix B.2.

Appendix B: Reasons to request information required under Annex X of REACH

This decision is based on the examination of the testing proposals you submitted.

1. Extended one-generation reproductive toxicity study

The basic test design of an extended one-generation reproductive toxicity study (EOGRTS) is a standard information requirement under Annex X to the REACH Regulation. Furthermore, column 2 of Section 8.7.3. defines when the study design needs to be expanded.

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for an EOGRTS according to OECD TG 443 with the Substance.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Toxicity to reproduction. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

ECHA agrees that an EOGRTS is necessary.

1.2. Specification of the study design

Species and route selection

You proposed testing by oral route in rats. ECHA agrees with your proposal.

Pre-mating exposure duration

You proposed ten weeks pre-mating exposure duration. ECHA agrees with your proposal. Ten weeks pre-mating exposure duration is required because there is no substance specific information in the dossier supporting shorter pre-mating exposure duration (ECHA Guidance R.7a, Appendix R.7.6-3).

Dose-level setting

For the dose level setting, you make a '*Preliminary proposal: 0, 50, 250 and 1000 mg/kg bw*' in the document attached in IUCLID section 7.8.1. This proposal is '*based on the limit dose (OECD 443 and OECD Guidance Document 151) and having ~4 fold intervals between the dose levels.*' In the same document you also note that '*all proposals related to the study design should be re-evaluated after the completion of the ECHA mandated 90-day toxicity study via the oral route'*. ECHA agrees that all available information should be taken into account.

The aim of the requested test must be to demonstrate whether the classification criteria of the most severe hazard category for sexual function and fertility (Repr. 1B; H360F) and developmental toxicity (Repr. 1B; H360D) under the CLP Regulation apply for the Substance (OECD TG 443, paragraph 22; OECD GD 151, paragraph 28; Annex I Section 1.0.1. of REACH and Recital 7, Regulation 2015/282), and whether the Substance meets the criteria for a Substance of very high concern regarding endocrine disruption according to Art.57(f) of

REACH as well as supporting the identification of appropriate risk management measures in the chemical safety assessment.

To investigate the properties of the Substance for these purposes, the highest dose level must be set on the basis of clear evidence of an adverse effect on sexual function and fertility, but no deaths (i.e., no more than 10% mortality; Section 3.7.2.4.4 of Annex I to the CLP Regulation) or severe suffering such as persistent pain and distress (OECD GD 19, paragraph 18) in the P0 animals.

In case there is no clear evidence of an adverse effect on sexual function and fertility, the limit dose of at least 1000 mg/kg bw/day or the highest possible dose level not causing severe suffering or deaths in P0 must be used as the highest dose level. A descending sequence of dose levels should be selected to demonstrate any dose-related effect and aiming to establish the lowest dose level as a NOAEL.

In summary: Unless limited by the physical/chemical nature of the Substance, the highest dose level in P0 animals must be as follows:

(1) in case of clear evidence of an adverse effect on sexual function and fertility without severe suffering or deaths in P0 animals, it must be determined based on such clear evidence or
(2) in the absence of such clear evidence, the highest dose level in P0 animals must be set to be the highest possible dose not causing such severe suffering or death or
(3) there is such clear evidence but the highest dose level set on that basis would cause severe suffering or death, it must be set to be the highest possible dose not causing such severe suffering or death or
(4) it must follow the limit dose concept.

You have to provide a justification with your study results demonstrating that the dose level selection meets the conditions described above.

Numerical results (i.e. incidences and magnitudes) and description of the severity of effects at all dose levels from the dose range-finding study/ies shall be reported to facilitate the assessment of the dose level section and interpretation of the results of the main study.

Cohorts 1A and 1B

Cohorts 1A and 1B belong to the basic study design and must be included.

<u>Histopathological investigations in Cohorts 1A and 1B</u>

In addition to histopathological investigations of cohorts 1A, organs and tissues of Cohort 1B animals processed to block stage, including those of identified target organs, must be subjected to histopathological investigations (according to OECD TG 443, paragraphs 67 and 72) if

- The results from Cohort 1A are equivocal,
- If the test substance is a suspected reproductive toxicant or
- If the test substance is a suspected endocrine toxicant.

<u>Splenic lymphocyte subpopulation analysis</u>

Splenic lymphocyte subpopulation analysis must be conducted in Cohort 1A (OECD TG 443, paragraph 66; OECD GD 151, Annex Table 1.3).

Investigations of sexual maturation

To improve the ability to detect rare or low-incidence effects, all F1 animals must be maintained until sexual maturation to ensure that sufficient animals (3/sex/litter/dose) are available for evaluation of balano-preputial separation or vaginal patency (OECD GD 151, paragraph 12 in conjunction with OECD TG 443, para. 47). For statistical analyses, data on sexual maturation from all evaluated animals/sex/dose must be combined to maximise the statistical power of the study.

Cohorts 2A and 2B

The developmental neurotoxicity Cohorts 2A and 2B must be conducted in case of a particular concern on (developmental) neurotoxicity.

Existing information on the Substance itself derived from available *in vivo* studies (OECD TG 408 and 422) show effects indicative of thyroid toxicity[2]. More specifically,

- Changes in histopathology of the thyroid gland were observed in males and females at high dose in the OECD TG 408 study (follicular cell hypertrophy) and in males of all treatment groups in the OECD TG 422 study (amorphous materials in the colloid with dose-dependency in its severity and incidence).
- Changes in thyroid hormone levels were observed in the OECD TG 408 study. At high dose, TSH levels were significantly increased: 372% of controls in males and 198% in females. The changes in T3 and T4 were slight.

The thyroid effects raise of concern for developmental neurotoxicity.

You proposed not to include Cohort 2A and 2B, however in the document attached in IUCLID section 7.8.1., you consider that '*this should be re-evaluated after the ECHA mandated oral 90-day study data is available.*'

For the reasons stated above, including effects observed in the OECD TG 408 (90-day) study, the developmental neurotoxicity Cohorts 2A and 2B must be conducted.

1.3. Outcome

Under Article 40(3)(b) your testing proposal is accepted under modified conditions and you are requested to conduct the test with the Substance, as specified above.

Based on the information provided in your dossier, to ensure that the relevant hazard property of the Substance is appropriately identified, ECHA requests that the study is conducted with the Substance with 99.5% purity.

Further expansion of the study design

The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no triggers for the inclusion of Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including the extension of Cohort 1B or Cohort 3 if relevant information becomes available from other studies or during conduct of this study. Inclusion is justified if the available information meets the criteria and conditions which are described in Column 2, Section 8.7.3., Annex IX/X. You may also expand the study due to other scientific reasons in order to avoid a conduct of a new study. The study design, including

[2] OECD GD 150

any added expansions, must be fully justified and documented. Further detailed guidance on study design and triggers is provided in ECHA Guidance R.7a, Section R.7.6.

2. Long-term toxicity testing on terrestrial invertebrates

Long-term toxicity to invertebrates is an information requirement under Annex X to REACH (Section 9.4.4).

2.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for an Earthworm Reproduction Test (test method: EU C.33 / OECD TG 222) with the following justification: "*The soil hazard category 3 (ECHA 2017, guidance part R7(c) Table R.7.11—2) has been derived for the substance based on the expected persistence of the silanol hydrolysis product, methylsilanetriol. In accordance with the screening assessment for soil hazard category 3 substances, a PNECsoil has been calculated from the aquatic data on the basis of the equilibrium partitioning method. The PNEC calculated by Equilibrium Partitioning has been derived for the purpose of chemical safety assessment and the risk characterisation ratios are below 1. In addition, a confirmatory long-term soil toxicity test should be conducted. A chronic earthworm reproduction test with methylsilanetriol is proposed to fulfil the testing requirements for soil hazard category 3*".

You intend to test the following hydrolysis product of the Substance: methylsilanetriol (EC No. 219-489-9, CAS No. 2445-53-6). ECHA understand that you intend to fulfil this information requirement through an adaptation under Annex XI, Section 1.5 ('Read-across and grouping of substances').

You have also provided an adaptation under Annex XI, Section 1 ('Testing does not appear scientifically necessary'). In support of your adaptation, you provided the following justification: "[the] *study does not need to be conducted because the substance hydrolyses rapidly in water and the breakdown products are also unstable. The available toxicity studies in algae and daphnia demonstrate that the hydrolysis products are not toxic to aquatic organisms at the limit concentrations suitable for these tests. The substance hydrolyses rapidly and the final hydrolysis product methylsilanetriol has a log Kow of -2.4. PNECsoil for methylsilanetriol has been calculated from PNECfreshwater on the basis of the equilibrium partitioning method; the risk characterisation ratios (RCR) based on PNECsoil derived from this method are <1. In addition, the substance is only used in industrial settings in closed systems under controlled conditions and emissions to surface waters are unlikely. Therefore, further studies are not scientifically justified*".

ECHA notes that your justification does not relate to any of the adaptation possibilities specified under Annex XI, Section 1. Therefore, your adaptation is rejected.

As far as you further refer to exposure based considerations, ECHA points out that in your registration dossier you neither report that the substance is used in a rigorously contained system with minimisation of release to the environment nor did you provide any description of strictly controlled conditions under IUCLID Section 13. Moreover, as specified by you in your justification for the testing proposal, the Substance falls under the soil hazard category 3 and in this context a confirmatory long-term toxicity test on terrestrial organisms is required (ECHA Guidance R.7.11.5.3., Table R.7.11-3).

Based on the above, ECHA agrees that an appropriate study on long-term toxicity to terrestrial invertebrates is needed as specified in your testing proposal.

2.2 Grouping of substances and read-across approach

ECHA understands that you intend to fulfil the information required for Long-term toxicity on terrestrial invertebrates, by way of adaptation under Annex XI, Section 1.5 ('Read-across and grouping of substances').

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents[3,4].

You have provided some justification for the read-across in IUCLID Section 6.3. and Section 7.2. of your CSR.

You intend to read-across between the main hydrolysis product of the Substance, methylsilanetriol, EC No. 219-489-9 (CAS RN 2445-53-6) as source substance and the Substance as target substance.

You have provided the following reasoning for the prediction of the terrestrial toxicity to be based on testing the hydrolysis product:

- In IUCLID Section 6.3., you state that "*The substance hydrolyses rapidly"* and that the main hydrolysis product is methylsilanetriol. You state that "*Due to the rapid hydrolysis of the substance, the chemical safety assessment is based on the silanol hydrolysis product methylsilanetriol*";
- In IUCLID Section 5.1.2., you provide a non-guideline experimental study ([redacted] *2011*) showing that the hydrolysis half-life of the Substance (based on degradation of the parent substance by ring-opening) was determined to be 4.2 minutes at pH 7. You further state that full hydrolysis takes longer (approximately 1 day).

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which is based on the rapid formation of a transformation product that corresponds to the selected source substance. The properties of your Substance are predicted to be quantitatively equal to those of the selected source substance.

ECHA agrees that the information you provided indicates that the Substance hydrolyses fast to form the selected source substance. Based on the available hydrolysis data, the Substance is expected to be unstable over the duration of terrestrial toxicity tests. With a half-life of 4.2 minutes at pH 7 (based on ring opening) and a full hydrolysis to methylsilanetriol in approximately 1 day, the loss of the parent substance is expected to be fast and testing of the parent substance is unlikely to be technically feasible. It can be assumed that any (transient) intermediate hydrolysis products are unlikely to have an impact as, by the time the Substance reaches the soil, hydrolysis would have already taken place. In this context, ECHA Guidance R.7.11.4.3 specifies that the terrestrial hazard assessment needs to consider the properties (including toxic effects) of degradation products that may be formed in soil. ECHA also notes that hydrogen gas would also be formed during the hydrolysis, but this

[3] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

[4] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

substance is partitioning to the atmosphere and is not expected to remain in the soil compartment.

Conclusion on the read-across approach used to predict ecotoxicological properties

Considering the above, ECHA concludes that the read-across is plausible and that testing the main known hydrolysis product is acceptable.

2.3. Specification of the study design

The proposed Earthworm Reproduction Test (test method: OECD TG 222) is appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (ECHA Guidance R.7.11.3.1).

2.4. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with methylsilanetriol EC No. 219-489-9 (CAS RN 2445-53-6), as specified above.

Appendix C: 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[5].

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 in relation to request B.1. 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.

   For request B.2. (see Appendix B, section 2), ECHA considers the read-across from the hydrolysis product, methylsilanetriol with EC No. 219-489-9 (CAS RN 2445-53-6) as plausible.

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, such as the purity of the Substance.

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[6].

[5] https://echa.europa.eu/practical-guides
[6] https://echa.europa.eu/manuals

Appendix D: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 27 March 2020.

ECHA held a third party consultation for the testing proposal(s) from 25 May 2020 until 9 July 2020. ECHA did not receive information from third parties.

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

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 E: List of references - ECHA Guidance[7] 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)[8]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)[9]

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.

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

OECD Guidance documents[10]
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.

[10] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix F: 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]

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.