~~Confidential~~

Helsinki, 08 June 2022

Addressees
Registrant(s) of JS_Amides_C22_unsaturated as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
02/06/2015

Registered substance subject to this decision ("the Substance")
Substance name: (Z)-docos-13-enamide
EC number: 204-009-2

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 ***15 September 2025***.

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) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102

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

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

1. If negative results are obtained in test performed for the information requirement of Annex VII, Section 8.4.1. then in vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490)

2. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., column 2)

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

1. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

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

3. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216)

4. Long-term toxicity to terrestrial plants also requested below (triggered by Annex IX,

Section 9.4.3., column 2)

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

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

   - Ten weeks premating exposure duration for the parental (P0) generation;
   - Dose level setting shall aim to induce systemic toxicity at the highest dose level;
   - Cohort 1A (Reproductive toxicity);
   - Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation.

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

2. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) by oral route, in a second species (rabbit)

3. Long-term toxicity testing on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: EU C.33/OECD TG 222 or EU C.32/OECD TG 220)

4. Long-term toxicity to terrestrial plants (Annex X, Section 9.4.6.; test method: EU C.31/OECD TG 208 with at least six species tested or ISO 22030)

5. Long-term toxicity testing to sediment organisms (Annex X, Section 9.5.1.; test method: EU C.35/OECD TG 225 or EU C.40/OECD TG 233 using spiked sediment)

Reasons for the request(s) are explained in the following appendices entitled "Reasons to request information required under Annexes VII 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 Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- 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.

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". 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. In vitro gene mutation study in bacteria

An *in vitro* gene mutation study in bacteria is an information requirement under Annex VII to REACH (Section 8.4.1.).

You have provided a key study in your dossier:

i. a study according to OECD TG 471 on the Substance.

We have assessed this information and identified the following issue:

To fulfil the information requirement, the study has to meet the requirements of OECD TG 471[2] (1997). One of the key parameters of this test guideline includes:

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)

However, the reported data for the study (i.) you have provided did not include:

a) the required fifth strain, *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

The information provided does not cover one of the key parameters required by OECD TG 471.

On this basis, 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) should be performed using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102.

2. 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 the following information:

i. a study according to OECD TG 201 with the Substance

We have assessed this information and identified the following issue:

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:

Additional requirements applicable to difficult to test substances

a) 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 is determined;
b) 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] ECHA Guidance R.7a, Table R.7.7–2, p.557

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;

Characterisation of exposure

c) 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);
d) the concentrations of the test material are measured at least at the beginning and end of the test:
   1) at the highest, and
   2) at the lowest test concentration, and
   3) at a concentration around the expected EC_{50}.
   For volatile, unstable or strongly adsorbing test substances, additional samplings for analysis at 24 hour intervals is required;

Reporting of the methodology and results

e) the test conditions are reported (*e.g.*, composition of the test medium, biomass density at the beginning of the test);
f) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;
g) adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided.

Your registration dossier provides an OECD TG 201 showing the following:

Additional requirements applicable to difficult to test substances

a) the test material is poorly water soluble (water solubility determined to be < 0.738 µg/L based on OECD TG 105). However, you have not provided an estimate of the maximum dissolved concentration that can be achieved in the specific test solution under the conditions of this test;
b) you report that nominal concentrations of [redacted] µg/L were tested which indicates that you intended to test the test material at its saturation concentration. However, you have provided none of the information listed under point b) above to support that saturation was achieved;

Characterisation of exposure

c) you report that "*duplicate samples were taken from the test media of all test concentrations at the start of the test (without algae) and at the end of the test (containing algae)*". Therefore, the measurements at the start of the test were not conducted under identical conditions to those used for testing as the test solutions were not inoculated with algae;
d) the test material is highly adsorptive (log Kow of c.a. 8 based on OECD TG 117). However, you have not conducted determination of exposure concentrations at 24h intervals;

Reporting of the methodology and results

e) you have not reported the test conditions adequately. In particular, no information is available on the composition of the test medium and on biomass density at the beginning of the test;

f) the results of algal biomass determined in each flask at least daily during the test period is not provided;
g) you have provided no information on the analytical method (including performance parameters of the method). In addition, the results of the analytical determination of exposure concentration is not reported in an unambiguous way (i.e. table showing measured values in each replicate for each test material concentration and each interval of sampling)

Based on the above,

- the Substance is difficult to test (low water solubility and high adsorptive properties) and there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, you have not provided information on the saturation concentration of the test material in the test medium used to conduct testing and you have not provided any information to support that the test procedure was adequate to maximize exposure to the test material. In addition, the analytical determination of exposure concentrations was not adequate as measured values at the start of the test were conducted without algae and the frequency of analytical determinations was too low;
- independent of the above issue, the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, you have not provided adequate information on the test procedure. Also, no information is provided on the performance parameters of the analytical method and the reporting of measured test material concentrations is unclear. Finally, as you have not provided the results of algal biomass determined in each flask at least daily during the test period, it is not possible to make an independent assessment of whether or not the study met the validity criteria specified in the OECD TG 201.

Therefore, this study does not meet the requirements of OECD TG 201 in conjunction with OECD GD 23.

On this basis, the information requirement is not fulfilled.

Study design

The Substance is difficult to test due to its low water solubility (< 0.738 µg/L based on OECD TG 105) and high adsorptive properties (log Kow of c.a. 8 based on OECD TG 117). OECD TG 201 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 201. 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 solution.

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

1. In vitro gene mutation study in mammalian cells

An *in vitro* gene mutation study in mammalian cells is an information requirement under Annex VIII to REACH (Section 8.4.3.) in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

i. Triggering of the study

Your dossier contains (i) a negative result for *in vitro* cytogenicity study in mammalian cells, and (ii) inadequate data for the other study (*in vitro* gene mutation study in bacteria).

The *in vitro* gene mutation study in bacteria provided in the dossier is rejected for the reasons provided in Appendix A.1.

The result of the request for information in Appendix A.1. will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

ii. Assessment of information provided

You have provided a key study in your dossier:

i. A study according to OECD TG 476 with the Substance

We have assessed this information and identified the following issue:

To fulfil the information requirement, the *in vitro* gene mutation study on mammalian cells has to meet the requirements of OECD TG 476 or OECD TG 490[3]. Therefore, the following specifications must be met:

a) At least 4 concentrations must be evaluated, in each test condition.
b) The response for the concurrent negative control must be inside the historical control range of the laboratory.

The reported data for the study you have provided do not include:

a) the evaluation of at least 4 concentrations in each test condition. In Experiment I, the reported data include 6 concentrations in each test condition and in each culture. However, precipitation of the test material was observed for 4 out of 6 concentrations, i.e. only 2 concentrations were evaluated. In Experiment II, the reported data include 6 concentrations in each test condition and in each culture. However, the culture was not continued for 1 out of 6 concentrations and precipitation of the test material was observed for 2 out of 6 concentrations, i.e. only 3 concentrations were evaluated.
b) the historical control range of the laboratory.

The information provided does not cover the specifications required by the OECD TG 476.

On this basis, the information requirement is not fulfilled.

Consequently, you are required to provide information for this endpoint if the *in vitro* gene mutation study in bacteria provides a negative result.

[3] ECHA Guidance R.7a, Table R.7.7–2, p.557

Study design

To fulfil the information requirement for the Substance, either the *in vitro* mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) or the thymidine kinase gene (OECD TG 490) are considered suitable.

2. Long-term toxicity testing on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.). Long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7.8.5).

In an OECD TG 105 study (based on the column elution method), the saturation concentration of the Substance in water was below the limit of detection of the analytical method (*i.e.* 0.738 µg/L).

Therefore, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Appendix C.1.

Appendix C: Reasons to request information required under Annex IX of REACH

1. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

You have provided the following information:

i. a study similar to OECD TG 215 with the Substance

We have assessed this information and identified the following issue:

The Fish Early Life Stage (FELS) toxicity test (test method: OECD TG 210) is the most suitable test guideline for addressing long-term toxicity on fish for most substances (ECHA Guidance R.7.8.2.). As specified in ECHA Guidance R.7.8.2., the Fish, Juvenile Growth Test (test method: OECD TG 215) is only considered as an acceptable test method if the following cumulative conditions are met:

a) a well-founded justification is provided to support that growth inhibition is the most relevant effect in fish, and
b) the substance has a log Kow < 5.

Otherwise, OECD TG 215 could underestimate long-term toxicity in fish and not achieve the REACH objective of protection of the environment nor would the study be appropriate for classification and labelling and risk assessment.

You have provided no justification as to why growth inhibition is the most relevant effect in fish for the Substance. Further, in section 4.7 of your technical dossier, you report that the log Kow of the Substance is > 6.5. You also state that by extrapolation you consider the log Kow to be c.a. 8.

Therefore, the OECD TG 215 is not regarded as an acceptable test method for the Substance and a Fish Early Life Stage (FELS) toxicity test (test method: OECD TG 210) needs to be provided.

On this basis, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A.2.

2. Long-term toxicity 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 from your registration dossier:

- the Substance is considered to have high adsorption potential to soil as you report log Kow and log Koc values > 6.5 and > 5 respectively for the Substance.

On this basis information on long-term toxicity on terrestrial invertebrates must be provided.

The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed respectively in Appendix D.3.

3. Effects on soil micro-organisms

Effects on soil microorganisms is an information requirement under Annex IX to REACH (Section 9.4.2).

You have omitted this information with the following justification: "*The compound is virtually insoluble in water which limits its bioavailability. It is readily biodegradable and not toxic to any species tested including aquatic plants, aquatic invertebrates, aquatic vertebrates and mammals*".

We have assessed this information and identified the following issue:

> A registrant may only adapt this information requirement based on the specific rules for adaptation from column 1 set out in the second column of Annex IX, Section 9.4 or the general rules set out in Annex XI.
>
> Your justification to omit this information does not refer to any legal ground for adaptation under the second column of Annex IX, Section 9.4 or Annex XI to REACH.
>
> In any case the information provided on most of the elements of your justification are rejected for the reasons already described above. Therefore, you have not demonstrated that this information can be omitted.

On this basis, the information requirement is not fulfilled.

Study design

ECHA Guidance R.7.11.3.1. specifies that Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) is considered suitable for assessing long-term adverse effects on soil microorganisms for most non-agrochemicals.

4. Long-term toxicity on terrestrial plants

Short-term toxicity to terrestrial plants is an information requirement under Annex IX to REACH (Section 9.4.3). 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 from your registration dossier:

- the Substance is considered to have high adsorption potential to soil as you report log Kow and log Koc values > 6.5 and > 5 respectively for the Substance.

On this basis information on long-term toxicity on terrestrial plants must be provided.

The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed respectively in Appendix D.4.

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

1. Extended one-generation reproductive toxicity study

The basic test design of an Extended one-generation reproductive toxicity (EOGRT) study (OECD TG 443) is an information requirement under Annex X to REACH (Section 8.7.3.). Furthermore, Column 2 of Section 8.7.3. defines when the study design needs to be expanded.

You claim that the information requirement is not triggered under Annex IX, 8.7.3, column 1.

We have assessed this information and identified the following issue:

This claim is not an adequate adaptation under Annex X (Section 8.7.3, column 2) or Annex XI to omit the information requirement for EOGRTS at Annex X.

Based on the above, the information you provided does not fulfil the information requirement.

Study design:

Premating exposure duration and dose-level setting

The length of premating exposure period must be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

Ten weeks premating exposure duration is required to obtain results adequate for classification and labelling and /or risk assessment. There is no substance specific information in the dossier supporting shorter premating exposure duration (ECHA Guidance R.7.6.).

Therefore, the requested premating exposure duration is ten weeks.

In order to be compliant and not to be rejected due to too low dose levels, the highest dose level shall aim to induce systemic toxicity, but not death or severe suffering of the animals, to allow comparison of reproductive toxicity and systemic toxicity. The dose level selection should be based upon the fertility effects. A descending sequence of dose levels should be selected in order to demonstrate any dose-related effect and to establish NOAELs.

If there is no relevant data to be used for dose level setting, it is recommended that range-finding results are reported with the main study.

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

Cohorts 1A and 1B

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

Species and route selection

The study must be performed in rats with oral administration (ECHA Guidance R.7.6.2.3.2.).

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 Cohorts 2A and 2B (developmental neurotoxicity) and/or Cohort

3 (developmental immunotoxicity) were identified. However, you may expand the study by including the extension of Cohort 1B, Cohorts 2A and 2B and/or Cohort 3 if relevant information becomes available from other studies or during the 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 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 any added expansions, must be fully justified and documented. Further detailed guidance on study design and triggers is provided in ECHA Guidance R.7.6.

2. Pre-natal developmental toxicity study in a second species

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is an information requirement under Annex X to REACH (Section 8.7.2.).

You have provided a key study in your dossier:

i. a study according to OECD TG 414 via oral route in rats with the Substance.

We have assessed this information and identified the following issue:

> You have not provided information on a second species. In order to be compliant and enable concluding if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 in two species.
>
> Based on the above, the information you provided does not fulfil the information requirement.

Study design

A PNDT study according to the OECD TG 414 should be performed in the rabbit or rat as the preferred species. The test in the first species was carried out by using a rodent species (rat). Therefore, a PNDT study in a second species must be performed in the rabbit as preferred non-rodent species.

The study must be performed with oral administration (ECHA Guidance R.7.6.2.3.2) of the Substance.

3. Long-term toxicity testing on terrestrial invertebrates

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

You have omitted this information with the following justification: "*The compound is virtually insoluble in water which limits its bioavailability. It is readily biodegradable and not toxic to any species tested including aquatic plants, aquatic invertebrates, aquatic vertebrates and mammals*".

For the reasons already explained under Appendix C.3., you adaptation is rejected.

On this basis, the information requirement is not fulfilled.

Study design

ECHA Guidance R.7.11.3.1. specifies that the earthworm reproduction test (OECD TG 222), the Enchytraeid reproduction test (OECD TG 220), and the Collembolan reproduction test

(OECD TG 232) are appropriate to cover the information requirement for long-term toxicity testing on terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol since this decision is dependent upon species sensitivity and substance properties. However, when log Kow >5 and log Koc >4, as in this case, the test OECD 232 is not appropriate as the dominant route of exposure for Collembolans is via pore water.

4. Long-term toxicity testing on terrestrial plants

Long-term toxicity to terrestrial plants is an information requirement under Annex X to REACH (Section 9.4.6).

You have omitted this information with the following justification: "*The compound is virtually insoluble in water which limits its bioavailability. It is readily biodegradable and not toxic to any species tested including aquatic plants, aquatic invertebrates, aquatic vertebrates and mammals*".

For the reasons already explained under Appendix C.3., you adaptation is rejected.

On this basis, the information requirement is not fulfilled.

Study design

The Terrestrial Plant Test (test method: OECD TG 208) is appropriate to cover the information requirement for long-term toxicity on terrestrial plants.

The OECD TG 208 considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing must be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208.

5. Long-term toxicity to sediment organisms

Long-term toxicity to sediment organisms is an information requirement under Annex X to REACH (Section 9.5.1.).

You have omitted this information with the following justification: "*the substance is readily biodegradable, poorly water soluble and no toxicity has been observed at 100 times the water solubility of the test material*".

We have assessed this information and identified the following issue:

> A registrant may only adapt this information requirement based on the specific rules for adaptation from column 1 set out in the second column of Annex X, Section 9.5.1. or the general rules set out in Annex XI.
>
> Your justification to omit this information does not refer to any legal ground for adaptation under the second column of Annex X, Section 9.5.1 or Annex XI to REACH.
>
> In any case the information provided on most of the elements of your justification are rejected for the reasons already described above. Please also note that ECHA Guidance

R.7.8.10.3 specifies that substances that do not exhibit a toxic effect when tested in water-only test systems because equilibrium was not reached during the exposure phase may nevertheless exert significant toxic effects in sediment tests. This may be especially true for poorly water soluble substances with high adsorption potential as the exposure duration in aquatic studies can in some cases be too short to reach steady state conditions for such substances. Therefore, if no effects are observed in pelagic tests, extrapolation from pelagic data to sediment data is not possible.

Therefore, you have not demonstrated that this information can be omitted.

On this basis, the information requirement is not fulfilled.

Study design

Sediment-Water Chironomid Toxicity Test Using Spiked Sediment (test method: EU C.27/OECD TG 218) is only appropriate to cover the information requirement for long-term toxicity to sediment organisms for substances which equilibration time (time to reach steady state in the body) is not anticipated to be very long (e.g. not highly lipophilic substance such as substance with log Kow < 5 and log Koc < 3; ECHA Guidance R.7.8.9.1. and R.7.8.14.2.) such as the Substance.

Under section 4.7 of your registration dossier you provide a Log Kow value for the Substance of >6.5 (based on OECD TG 117). Under section 5.4.1 of your registration dossier you provide a Log Koc value for the Substance of >5 (based on OECD TG 121).

Therefore, the equilibration time for the Substance is anticipated to be very long. For such substance, the Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (test method: EU C.40/OECD TG 233), which is an extension of the proposed test, must be conducted (ECHA Guidance R.7.8.9.1. and R.7.8.14.2.). Alternatively, you may also consider conducting a Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment (test method: EU C.35/OECD TG 225).

ECHA Guidance R.7.8.10.1 specifies that spiking the water phase does not accurately represent accumulation processes within the sediment lasting longer than the test period and is only regarded as applicable to simulate pesticide spray drift event and other type of exposure (e.g. chemical spill). For industrial chemicals with continuous and intermittent release, spiking the sediment must be conducted as this approach is intended to simulate accumulated levels of substance persisting in the sediment.

ECHA notes that the Substance has multiple industrial uses (not all of which are closed processes), as well as Article Service Life for both Professional and Consumer uses. Considering the environmental release pattern for the Substance, ECHA concludes that the study must be conducted by spiking the sediment phase.

Appendix E: 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[4].

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[5].

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

Appendix F: 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 22 March 2021.

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

ECHA took into account your comments and did not amend the requests.

In your comments on the draft decision, you requested an extension of the deadline from 30 to 51 months from the date of adoption of the decision.

First, you justified the request by additional time required to complete the testing due to limited testing capacities of one laboratory. ECHA has partially granted the request since the request is based on a single laboratory statement and no substantiation was provided for such high extension of the deadline. ECHA has extended the deadline by 6 months.

Second, you considered that additional time is needed as the Subsance is difficult to test due to its poor water solubility. ECHA acknowledges the difficulties in conducting the test including the study design and the development of analytical method. You have not indicated any specific time to address this issue, which is limited to aquatic testing, and such tests are significantly shorter than, and can be carried out in parallel to, human health testings. Therefore, ECHA has not granted more time for that purpose.

Third, you argue that the extension is needed due to legal uncertainty regarding the reliability of the extended one generation reproductive toxicity study (EOGRTS). As you indicated, in July 2021, in ongoing review on performed EOGRT studies, ECHA has identified several critical issues in the study designs. The published note (*Critical aspects for designing and conducting extended one-generation reproductive toxicity (EOGRT) studies under REACH*, July 2021) is clear and stand-alone, and, at this stage, no follow-up update is expected. Therefore, a further extension of the deadline set in the decision to accommodate the "legal uncertainty regarding the reliability of the EORGTS" is considered unjustified.

Fourth, you request three more months to finalise the reports and to include them in the IUCLID dossier. The period for such activities is, however, already included in the original timeline. Therefore, this justification for extension is rejected.

On this basis, ECHA has partially granted the request and extended the deadline to 36 months.

In your comments on the draft decision, you do not provide any endpoint-specific comments. You agree that some additional toxicology testing is needed to satisfy the data requirements for the Substance and agree to generate further data. You also stated "*Nevertheless, especially with regard to single higher tier tests, we intend to refine the testing strategy by applying a tiered approach.*".

While ECHA acknowledges your intention to refine the testing strategy, we note that the deadline in the adopted decision is legally binding.

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 G: List of references - ECHA Guidance[6] 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)[7]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[8]

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[9]

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