Helsinki, 5 February 2020

Addressees
Registrants of [redacted] listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
27/09/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: hexamolybdenum(3+) tris((dioctylcarbamothioyl)sulfanide) tris((ditridecylcarbamothioyl)sulfanide) hexahydrate hexasulfanediide
EC number: 441-570-4
CAS number: NS

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

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***10 August 2023***.

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

1. The same long-term toxicity testing on aquatic invertebrates as requested in C.1. (triggered by Annex VII, Section 9.1.5., column 2)

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

1. The same long-term toxicity testing on fish as requested in C.2. (triggered by Annex VIII, Section 9.1.3., column 2;)

2. The same simulation testing on ultimate degradation in surface water as requested in C.3. (triggered by Annex VIII, Section 9.2., column 2)

3. The same soil simulation testing as requested in C.4. (triggered by Annex VIII, Section 9.2., column 2)

4. The same sediment simulation testing as requested in C.5. (triggered by Annex VIII, Section 9.2., column 2)

5. The same identification of degradation products as requested in C.6. (triggered by Annex VIII, Section 9.2., column 2)

6. The same bioaccumulation in aquatic species as requested in C.7. (triggered by Annex I, sections 0.6.1. and 4. in conjunction with Annex XIII, Section 2.1.)

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

1. Long-term toxicity testing on aquatic invertebrates (Annex IX Section 9.1.5; test

method EU C.20./OECD TG 211) with the Substance.

2. Long-term toxicity testing on fish (Annex IX Section 9.1.6; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the Substance;

3. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method EU C.25./OECD TG 309) at a temperature of 12 °C with the Substance; including degradation of each relevant constituent present in concentration at or above 0.1% (w/w).

4. Soil simulation testing (Annex IX, Section 9.2.1.3.; test method EU C.23./OECD TG 307) at a temperature of 12 °C with the Substance; including degradation of each relevant constituent present in concentration at or above 0.1% (w/w).

5. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method EU C.24./OECD TG 308) at a temperature of 12 °C with the Substance; including each relevant constituent present in concentration at or above 0.1% (w/w).

6. Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method among those requested above (3-5) with the Substance.

7. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method OECD TG 305, aqueous exposure) with the Substance; including each relevant constituent present in concentration at or above 0.1% (w/w) and relevant degradation products.

8. Viscosity (Annex IX, Section 7.17.; test method OECD TG 114) with the Substance;

9. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) in rats with the Substance;

10. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route with the Substance;

11. Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test (OECD TG 222) with the Substance;

12. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2; test method: Terrestrial plant test: seedling emergence and seedling growth test, OECD TG 208 with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) with the Substance;

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

Conditions to comply with the requests

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier.

To identify your legal obligations, please refer to the following:

- you have to comply with the requirements of Annexes VII and VIII of REACH, if you have registered a substance at 10-100 tpa;

- you have to comply with the requirements of Annexes VII to IX of REACH, if you have registered a substance at 100-1000 tpa;

Registrants are only required to share the costs of information they are required to submit to fulfil the information requirements for their registration.

The same information, for certain endpoints, is requested in this decision from registrants subject to Annex VII or Annex VIII and Annex IX of REACH. The reasons for triggering of the requested information at each of the Annexes of REACH are provided in the corresponding Appendices, while the testing proposed as well as a design of the requested studies are examined in Appendix C.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and generic recommendations and guidance.

The studies relating to biodegradation and bioaccumulation (request B.2 to B.6 and C.3 to C.7) are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these test are performed and other conditions described in section 5 of Appendix E.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

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 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 for the information required from the Registrants subject to Annex VII of REACH

1. The same long-term toxicity testing on aquatic invertebrates as requested in C.1. (triggered by Annex VII, Section 9.1.1., column 2)

Short-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex VII to REACH. However, according to Annex VII, section 9.1.1, column 2, for poorly water soluble substances (e.g. water solubility below 1 mg/L) long-term toxicity study on aquatic invertebrates (Annex IX, Section 9.1.5) must be considered instead of an acute test. Poorly water soluble substances require longer time to reach steady-state conditions and the short-term tests may not give a true measure of toxicity for this type of substances.

The Substance is poorly water soluble (water solubility below 0.109 mg/L).

Therefore, long-term toxicity testing is needed to accurately define the hazard of the Substance.

The examination of the testing proposed, as well as the selection of the requested test and the test design are addressed in Appendix C, section 1.

Appendix B: Reasons for the information required from the Registrants subject to Annex VIII of REACH

1. The same long term toxicity testing on fish as requested in C.2. (triggered by Annex VIII, Section 9.1.3., column 2)

Short-term toxicity testing on fish is a standard information requirement in Annex VIII to REACH. However, pursuant to Annex VIII, section 9.1.3, column 2, for poorly water soluble substances (e.g. water solubility below 1 mg/L) long-term toxicity study on fish (Annex IX, Section 9.1.6) must be considered instead of an acute test.
Poorly water soluble substances require longer time to reach steady-state conditions and the short-term tests may not give a true measure of toxicity for this type of substances.

The Substance is poorly water soluble (water solubility below 0.109 mg/L).

Therefore, long-term toxicity testing is needed to accurately define the hazard of the Substance.

The examination of the adaptation proposed, as well as the selection of the requested test and the test design are addressed in Appendix C, Section 2.

2.-5. The same simulation testing on ultimate degradation in surface water as requested in C.3., soil simulation testing as requested in C.4., sediment simulation testing as requested in C.5 and identification of degradation products as requested in C.6. (triggered by Annex VIII, Section 9.2., column 2)

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., column 2).

Annex I, Section 4 requires that the CSA includes the PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) assessments. In accordance with Annex XIII, Section 2.1., if the result of the screening tests or other information indicate that the substance may have PBT or vPvB properties, further testing on degradation as set out in Section 3.2 is required. In case the generation of relevant additional information would require information listed in Annexes IX or X, the registrant must submit a testing proposal.

Screening information demonstrating potential PBT or vPvB properties include the following (ECHA Guidance R.11, Sections R.11.4 and Annex XIII):

- the substance is not readily biodegradable and thus potentially persistent; and
- the substance has high potential for bioaccumulation (log Kow > 4.5).

Screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties:

- the Substance is potentially P/vP since it is not readily biodegradable (6% degradation after 28 days in OECD TG 301B); and
- the Substance is potentially B/vB since the Log Kow is above the threshold of 4.5 (Log Kow >4.64)

The available screening information is not sufficient to conclude on the P/vP properties of the Substance, therefore further testing is required.

The examination of the testing (or adaptations) proposed, as well as the selection of the requested tests and the tests design are addressed respectively in in Appendix C, Sections 3-6.

6. The same bioaccumulation in aquatic species as requested in C.7. (Annex I, Sections 0.6.1 and 4 in conjunction with Annex XIII, Section 2.1)

Bioaccumulation in aquatic species is required for the purpose of PBT/vPvB assessment (Annex I, Sections 0.6.1 and 4 to REACH),

Annex I, Section 4 requires that the CSA includes the PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) assessments.
In accordance with Annex XIII, Section 2.1., if the result of the screening tests or other information indicate that the substance may have PBT or vPvB properties, further testing on bioaccumulation as set out in Section 3.2 is required. In case the generation of relevant additional information would require information listed in Annexes IX or X, the registrant must submit a testing proposal.

As described above in Appendix B, section 2 above, screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties. The available screening information is not sufficient to conclude on the B/vB properties of the Substance, and therefore further testing is required.

The examination of the testing proposed, as well as the selection of the requested test and the test design are addressed in in Appendix C, section 7.

Appendix C: Reasons for the information required from the Registrants subject to Annex IX of REACH

1. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)**

Long-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex IX, Section 9.1.5 to REACH.

You have submitted a testing proposal for a Long-term toxicity testing on aquatic invertebrates (*Daphnia magna* reproduction test, OECD TG 211) with the Substance.

ECHA agrees with your proposal.

Under Article 40(3)(a) of REACH, you are requested to carry out the proposed test.

2. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.):**

Long-term toxicity testing on fish is a standard information requirement in Annex IX, Section 9.1.6 to REACH.

You have adapted this information requirement. In your justification, you claim that no further chronic test on fish is needed for the Substance. You indicate that no effects were observed in the available short-term studies with fish and *Daphnia* up to the water solubility limit, but in the studies with Water Accommodated Fraction (WAFs) *Daphnia* was more sensitive than fish. You hence consider that the risk of the test substance to the aquatic compartment can be sufficiently described with the available aquatic toxicity studies and with the proposed long-term *Daphnia* study (Appendix C, section 1 above).

To adapt the information requirement for long-term toxicity testing on fish based on Annex IX, Section 9.1.6., Column 2, the CSA needs to assess and document that risks arising from the Substance are controlled (Annex I, Section 0.1). In particular, as described in Annex I, you need to take into account the environmental hazard assessment including classification and labelling and identification of PNEC.

For the purpose of the hazard assessment, the available toxicity information should at least cover species of three trophic levels: algae/aquatic plants, invertebrates (*Daphnia* preferred) and fish. Regarding long-term toxicity testing, there are no further requirements for fish testing if there is compelling evidence to suggest that the fish is likely to be at least a factor of 10 less sensitive than invertebrates or algae. The data used for comparing the species sensitivity need to be reliable and the effects need to relate to the exact measured concentration. In case the relative sensitivity of fish cannot be predicted, further testing is needed (Section R.7.8.5.3 of ECHA Guidance R.7b).

For hydrophobic and poorly water soluble substances, short-term toxicity studies cannot constitute the compelling evidence to indicate a lack of effects in the long-term studies nor to predict relative species sensitivity. Such substances require longer time to be significantly taken up by the test organisms and as a consequence the steady state conditions are likely not to be reached within the duration of a short-term toxicity test. For this reason, short-term tests may not give a true measure of toxicity for this type of substances.

The Substance is hydrophobic (Log Kow> 4.6) and poorly water soluble (water solubility is below 0.109 mg/L).

You have provided short-term toxicity studies on fish, *Daphnia* and algae, and you have proposed a long-term toxicity study on *Daphnia* (Appendix C, section 1 above).

You have not justified nor provided supporting evidence why *Daphnia* would be more sensitive than fish also in chronic/long-term testing.

Furthermore, in all the available aquatic toxicity studies, you failed to quantify the concentration of the test substance in the test solutions prepared with WAFs with the analytical method used (HPLC-UV, LOQ down to 0.020 mg/L). Since the actual exposure concentrations are not known, it is not possible to compare quantitatively the effect values of the short-term studies.

Due to the reasons above, there is no compelling evidence to predict the relative sensitivity of fish, and long-term testing on fish is needed for the CSA to document that risks to the aquatic environment are controlled.

Therefore, your adaptation is rejected and long-term toxicity study on fish is needed.

Under Article 40(3)(c) of the REACH Regulation, you are requested to carry out the additional test, as indicated above.

3. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.);

Simulation testing on ultimate degradation in surface water is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement by stating that the Substance has extremely low water solubility and that degradation will be investigated in the testing proposed for simulation in sediment.

ECHA has assessed this justification and identified the following issue(s):

A. To adapt the information requirement for simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2), the substance has to be either highly insoluble in water or readily biodegradable.

Based on the information provided, the Substance is not readily biodegradable (6% degradation after 28 days). Furthermore, the Substance is not highly insoluble even if the Substance has a low solubility (below 0.109 mg/L).

B. To assess the degradation of the substance , the P/vP assessment must cover all environmental compartments. Testing should be started with the most relevant compartment which is foreseen to provide the best possibility to conclude the P/vP assessment as being "worst-case" (Section R.11.4.1.1.3 in ECHA Guidance R.11). Since by default the surface water compartment receives a significant amount of emission, testing should start with the OECD TG 309 simulation study, as long as it is technically feasible to conduct the simulation surface water study (Explanatory Notes to Figure R.11-3. Point 4. in ECHA Guidance R.11).

While you proposed simulation studies in sediment and soil (Sections C.4 and C.5, below), you have not justified nor provided supporting evidence on whether results from sediment and/or soil simulation tests would cover the P/vP assessment for all compartments including

the aquatic compartment nor whether you consider that the aquatic compartment is not at all relevant environmental compartment. You have also not provided any evidence showing that the testing in water is not technically feasible (Section R.7.9.2.3 of ECHA Guidance R.7b). On the contrary, the recommended concentrations indicated in the OECD TG 309 (between 1 and 100 µg/L and preferably in the range of <1-10 µg/L) are below the provided water solubility of the Substance. That indicates that low solubility of your Substance does not prevent testing it in water.

Therefore, your adaptation is rejected.

As described above in Appendix B, section 2 of this decision, Screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties (ECHA Guidance R.11 and Annex XIII).

The available screening information is not sufficient to conclude on the P/vP properties of the Substance and simulation testing in water is needed.

Study design

OECD TG 309 is an appropriate method for studying the degradation in surface water. However, when performing the OECD TG 309 test, the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) shall be followed (ECHA Guidance R.11).

Annex XIII indicates that information used for PBT/vPvB assessment shall be obtained under relevant conditions. Therefore, simulation tests should be performed at the temperature of 12 °C, the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8). Performing the test at this temperature is in line with the applicable test conditions of the OECD TG 309.

Quantification of non-extractable residues (NER) needs to be carried out in all simulation studies. The reporting of results shall include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded substance. However, if reasonably justified and analytically demonstrated, a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER. Such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11).

Annex XIII requires assessment of relevant constituents of a substance for PBT/vPvB assessment. The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study. Alternatively, you shall provide a justification for why you consider these as not relevant for the PBT/vPvB assessment.

If you should encounter technical difficulties to perform the requested OECD TG 309 test, such difficulties and attempted solutions should be clearly demonstrated and documented.

Under Article 40(3)(c) of the REACH Regulation, you are requested to carry out the additional test, as indicated above.

4-5. Soil simulation testing (Annex IX, Section 9.2.1.3.) and Sediment simulation testing (Annex IX, Section 9.2.1.4.);

Soil simulation testing and sediment simulation testing are standard information requirements in Annex IX to REACH for substances with a high potential for adsorption to soil.

You have submitted a testing proposal for a Soil simulation testing (Aerobic and Anaerobic Transformation in Soil, OECD TG 307) and for a Sediment simulation testing (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems, OECD TG 308) with the Substance.

Screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties, as explained in Appendix B, section 2 above. The available screening information is not sufficient to conclude on the P/vP properties of the Substance. Additionally, the Substance has low water solubility (<0.109 mg/L), partition coefficient of log Kow > 4.64 and an adsorption coefficient log Koc >3.86, indicating that it has a potential for adsorption to soil and sediment.

Therefore, ECHA agrees with your proposals.

Study design

The requested simulation tests shall be performed under relevant conditions (12°C) and non-extractable residues (NER) must be quantified, for the reasons explained above in section C.3. The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable, shall be assessed. This can be done simultaneously during the same study. Alternatively, you shall provide a justification for why you consider these as not relevant for the PBT/vPvB assessment.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

6. Identification of degradation products (Annex IX, 9.2.3.)

Identification of the degradation products is a standard information requirement in Annex IX to REACH.

You have not provided any information on the identification of degradation products, nor an adaptation in accordance with column 2 of Annex IX, Sections 9.2 or 9.2.3. or with the general rules of Annex XI for this standard information requirement.

Screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties, as explained in Appendix B, section 2 above. Identity and relevance of degradation products must be included in the risk assessment and PBT assessment.

Therefore, information on identification of degradation products is required.

Study selection and design

You shall obtain this information from the simulation studies also requested in this decision (Appendix C, sections 3-5 above). If any other method is used for identification of the

transformation/degradation products, you shall provide a scientifically valid justification for the chosen method.
Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance shall be evaluated and reported, when analytically possible. In addition, degradation half-life, log Kow and potential toxicity of the metabolite must be investigated.

Under Article 40(3)(c) of the REACH Regulation, you are requested to carry out the additional test, as indicated above.

7. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.);

Bioaccumulation in aquatic species, preferably fish is a standard information requirement in Annex IX to REACH.

You have submitted a testing proposal for a Bioaccumulation in aquatic species test (OECD TG 305-I: Aqueous Exposure Bioconcentration Fish Test) with the Substance with the following justification: "*The substance did not exhibit significant toxicity in the available short-term aquatic toxicity tests as well as in the repeat-dose mammalian study. However, the substance has lipophilic properties. Therefore, testing of bioaccumulation in fish is proposed*".

Screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties, as explained in Appendix B, section 2 above. According to the provided information, the Substance is potentially B/vB (reported LogKow >4.64). Therefore, ECHA agrees that a bioaccumulation in aquatic species testing is required.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Bioaccumulation: aquatic. ECHA notes that 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.

Study selection and design

The OECD TG 305 is the appropriate test for testing bioaccumulation in aquatic species. In the testing proposal you specified that the aqueous exposure route is to be used. ECHA agrees that whenever technically feasible, the aqueous route of exposure (OECD TG 305-I) shall be used as the results obtained can be used directly for comparison with the B and vB criteria of Annex XIII of REACH. An aqueous exposure test is preferred for substances that have a high log Kow but still appreciable water solubility with respect to the sensitivity of available analytical techniques, and for which the maintenance of the aqueous concentration as well as the analysis of these concentrations do not pose any constraints. If testing through aquatic exposure is technically not possible, you shall provide scientifically valid justification for the infeasibility. In case you conduct the study using the dietary exposure route (OECD 305-III), you shall also attempt to estimate the corresponding BCF value from the dietary test data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation, ENV/JM/MONO (2017)16. In any case you shall report all data derived from the dietary test as listed in the OECD TG 305-III.

Annex XIII requires assessment of relevant constituents of a substance for PBT/vPvB assessment. The bioaccumulation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically

detectable, shall be assessed. This can be done simultaneously during the same study. Alternatively, you shall provide a justification for why you consider these as not relevant for the PBT/vPvB assessment.
Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

8. Viscosity (Annex IX, Section 7.17.)

Viscosity is a standard information requirement in Annex IX to REACH.

You have submitted a testing proposal for a viscosity study according to OECD TG 114 with the Substance.

ECHA agrees with your proposal.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

9. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

A sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX, Section 8.6.2. to REACH.

You have submitted a testing proposal for a sub-chronic toxicity study (90 day) in rats by the oral route according to OECD TG 408 with the Substance.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Sub-chronic toxicity (90-day): oral. ECHA notes that 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.

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

You proposed testing in rats. ECHA agrees with your proposal.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

10. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

A Pre-natal developmental toxicity study (OECD TG 414) in one species is a standard information requirement in Annex IX to REACH.

The information on this endpoint is not available. You have submitted a testing proposal for a Pre-natal developmental toxicity study in rats according to OECD TG 414 with the Substance.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Reproductive toxicity (pre-natal developmental toxicity). ECHA notes that 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.

You did not specify the route for testing. ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in the ECHA Guidance R.7a, Section R.7.6.2.3.2. Since the Substance is a solid, ECHA concludes that testing should be performed by the oral route.

You proposed testing in rats. According to OECD TG 414 rat is the preferred rodent species and rabbit is the preferred non-rodent species. You may conduct the study in either rats or rabbits.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

11. Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1., column 2)

Effects on terrestrial organisms is a standard information requirement in Annex IX, Section 9.4. to REACH. The requirement must be addressed for different taxonomic groups: invertebrates, soil micro-organisms and terrestrial plants. Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing must be considered instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have submitted a testing proposal for a long-term toxicity test to invertebrates (Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*), OECD TG 222) with the Substance.

According to the provided information, the Substance has a high potential to adsorb to soil (log Kow >4.64, log Koc >3.86) and is potentially very persistent (default setting for non-readily biodegradable substances when half-life in soil is not available, Section R.7.11.5.3 of ECHA Guidance R.7c). Therefore ECHA agrees that a long-term testing is required and the proposed test is appropriate to fulfil the information requirement of Annex IX, Section 9.4.1.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

12. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2)

Effects on terrestrial organisms is a standard information requirement in Annex IX, Section 9.4. to REACH. The requirement must be addressed for different taxonomic groups: invertebrates, soil micro-organisms and terrestrial plants. Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing must be considered instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have submitted a testing proposal for a long-term toxicity test to terrestrial plants (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test, OECD TG 208) with the Substance.

According to the provided information, the Substance has a high potential to adsorb to soil and is potentially very persistent, as explained in section C.4 above. Therefore ECHA agrees that a long-term testing is required and the proposed test is appropriate to fulfil the information requirement of Annex IX, Section 9.4.3.

OECD guideline 208 (Terrestrial plants, growth test) 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 shall 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 208 guideline.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

13. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

Effects on terrestrial organisms is a standard information requirement in Annex IX, Section 9.4. to REACH. The requirement must be addressed for different taxonomic groups: invertebrates, soil micro-organisms and terrestrial plants.

You have submitted a testing proposal for soil micro-organisms test (Soil Microorganisms: Nitrogen Transformation Test, OECD TG 216) with the Substance.

ECHA agrees with your proposal.

Under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

Appendix D: Procedural history

ECHA received your registration containing the testing proposals for examination on 4 October 2018.

ECHA held a third party consultation for the testing proposals from 10 December 2018 until 24 January 2019. ECHA did not receive information from third parties.

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of the REACH.

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification. ECHA did not receive any comments within the 30 days.

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: Observations and technical guidance

1. This testing proposal examination decision does not prevent ECHA from initiating compliance checks at a later stage on the registrations present.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State(s).

3. Test guidelines, GLP requirements and reporting

   Under to Article 13(3) of REACH, all new data generated as a result of this decision needs to be conducted according to the test methods laid down in a European Commission Regulation or according to international test methods recognised by the Commission or ECHA as being appropriate.

   Under to Article 13(4) of REACH ecotoxicological and toxicological tests and analyses shall be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

   Under to 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: 'How to report robust study summaries'[2]

4. Test material

   Selection of the test material(s)

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   While selecting the test material you must take into account the impact of each constituent/impurity is known to have or could have 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.

   Technical reporting of the test material

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

[2] https://echa.europa.eu/practical-guides

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers" on the ECHA website (https://echa.europa.eu/manuals).

5. Strategy for the PBT/vPvB assessment

You are advised to consult ECHA Guidance R.7b, Section R.7.9., R.7c, Section R.7.10 and R.11 on PBT assessment to determine the sequence of the tests and the necessity to conduct all of them. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

You are advised to first conclude whether the Substance may fulfil the Annex XIII criteria of being P or vP, and then continue with the assessment for bioaccumulation. The sequence of the simulation tests also needs to consider the intrinsic properties of the Substance, its identified use and release patterns as these could significantly influence the environmental fate of the Substance. You shall revise the PBT assessment when the new information is available.

6. List of references of the ECHA Guidance documents[3]

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 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[4]

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

[3] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[4] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

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.

Appendix F: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fulfilled
[redacted]	[redacted]	[redacted]