EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 21 May 2021

Addressees
Registrants of JS_3007-53-2 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
18/09/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: N,N-dimethyldodecanamide
EC number: 221-117-5
CAS number: 3007-53-2

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 information listed below by ***30 May 2022***.

The requested information must be generated using the Substance unless otherwise specified.

A. 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)

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)

3. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., column 2; test method: OECD TG 222)

4. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216 and test method: EU C.22./OECD TG 217)

5. Long-term toxicity to terrestrial plants (triggered by Annex IX, Section 9.4.3., column 2; test method: EU C.31./OECD TG 208 with at least six species)

Reasons for the requests are explained in the appendix entitled "Reasons to request information required under Annex IX 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, VIII and IX to REACH, for registration at 100-1000 tpa.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

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

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

This decision 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 to request information required under Annex IX of REACH

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

1. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a *Daphnia magna* reproduction test (test method: EU C.20/OECD TG 211).

Your registration dossier does not include any information on long-term toxicity on aquatic invertebrates.

ECHA agrees that an appropriate study on long-term toxicity study on aquatic invertebrates is needed.

1.2. Test selection and study specifications

The proposed *Daphnia magna* reproduction test (test method: EU C.20/OECD TG 211) is appropriate to cover the information requirement for long-term toxicity on aquatic invertebrates (ECHA Guidance R.7.8.4.1.).

The Substance is difficult to test due to the low water solubility (28.02 mg/L) and its adsorptive properties (log kow = 4.43). OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.

1.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

2. 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.).

2.1. Information provided to fulfil the information requirement

You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification:

- You consider that as "*the most sensitive species are the invertebrates*", the OECD 211 chronic daphnia test that you propose to conduct will be sufficient allow classification for chronic effects;
- You also state that "*a preliminary environmental risk assessment based on the acute ecotoxicity data for the most sensitive species (daphnia) and an assessment factor of 1000 does not indicate a risk for the aquatic compartment (Risk Characterization Ratio (RCR) < 1)*".

We have assessed this information and identified the following issue:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected.

In your comments on the draft decision, you stated that you believe that for the registered substance there is sufficient weight of evidence from several independent sources available, leading to the assumption/conclusion that the substance has no dangerous property regarding long-term aquatic effects on fish and that therefore, you consider that in accordance to Annex XI, paragraph 1.2, further testing on vertebrate animals (i.e. fish) for that property is scientifically not necessary. You also stated that you would update the registration dossier for N,N-dimethyldodecanamide (EC 221-117-5) accordingly. However, you have not provided any details in your comments on the information you intend to provide to justify your adaptation.

Therefore, the information in your comments is not sufficient for ECHA to make an assessment.

Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation").

On this basis, the information requirement is not fulfilled.

2.2. Test selection and study specifications

The Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210) is appropriate to cover the information requirement for long-term toxicity on fish (ECHA Guidance R.7.8.4.1.).

OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained under Appendix A.1, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix IX.

2.3. Outcome

Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement on Aquatic toxicity at Annex IX covers both long-term toxicity on invertebrates (Section 9.1.5.) and on fish (Section 9.1.6.).

However, you have provided a testing proposal for long-term toxicity on aquatic invertebrates only. As explained above, the information requirement for long-term testing on fish is not fulfilled.

Therefore, Under Article 40(3)(c) of REACH, you are requested to carry out the additional test with the Substance, as specified above.

3. Long-term toxicity testing on terrestrial invertebrates

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

As specified under Annex IX, Section 9.4., column 2, in the absence of toxicity data to soil organisms, the equilibrium partitioning method (EPM) may be applied to assess the hazard to soil organisms. The choice of the appropriate tests depends on the outcome of the chemical safety assessment.

In this context, ECHA Guidance R.7.11.6. describes an integrated testing strategy (ITS) for soil toxicity, which rely on the assignment of the Substance to a "soil hazard category" and on an initial screening assessment using the EPM, in order to decide the information needed for the chemical safety assessment.

Based on the information from your registration dossier:
- the Substance is considered to have high adsorption potential to soil as you report a log Kow value of > 5 based on OECD TG 117;
- the Substance is considered to be very toxic to aquatic organisms as the lowest short-term EC50 is < 1 mg/L for the Substance.

The Substance falls into the soil hazard category 4 (HC4) described in the ITS for soil toxicity, which indicates a high hazard potential to soil organisms. For such substance, long-term terrestrial toxicity tests according to the standard information requirements Annex X (i.e. both on invertebrates and plants) must be provided.

3.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for an Earthworm Reproduction Test (test method: OECD TG 222).

Your registration dossier does not include any information on long-term toxicity on terrestrial invertebrates.

ECHA agrees that an appropriate study on long-term toxicity to terrestrial invertebrates is needed.

3.2. Test selection and study specifications

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).

3.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

4. Effects on soil micro-organisms

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

As already explained in Appendix A.3., the Substance falls into the soil hazard category 4 (HC4) described in the ITS for soil toxicity (ECHA Guidance R.7.11.6.), which indicates a high hazard potential to soil organisms. For such substance, long-term terrestrial toxicity tests must be provided. ECHA Guidance R.7.11.3.1. specifies that a NOEC/ECx from a microbial assay such as the OECD TG 216 and/or OECD TG 217 is considered as a long-term result for microbial populations.

4.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a Soil Microorganisms: Carbon Transformation Test (EU C.22/OECD TG 217).

Your registration dossier does not include any information on effects on soil microorganisms.

ECHA agrees that appropriate information on long-term adverse effects on soil microorganisms is needed.

4.2. Test selection and study specifications

ECHA Guidance R.7.11.3.1. specifies that the 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. However, as specified in OECD TG 216 and 217, if agrochemicals (e.g. crop protection products, fertilisers, forestry chemicals) are tested, both the carbon transformation and the nitrogen transformation tests must be conducted. Your report that the substance is used as co-formulant in plant protection products. Therefore, information on both carbon transformation and nitrogen transformation must be provided.

4.3. Outcome

Your testing proposal for the Soil Microorganisms: Carbon Transformation Test (EU C.22./OECD TG 217) is accepted under Article 40(3)(a).

Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. As explained above, if agrochemicals are tested, both the carbon transformation and the nitrogen transformation tests must be conducted. However, you have provided a testing proposal for Carbon Transformation Test only.

Therefore, in addition to the test proposed by you, under Article 40(3)(c) of REACH, you are requested to carry out a Soil Microorganisms: Nitrogen Transformation Test (EU C.21./OECD TG 216). Both tests must be performed with the Substance as specified above.

5. Long-term toxicity to 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 (Annex IX, Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

As already explained in Appendix A.3., the Substance falls into the soil hazard category 4 (HC4) described in the ITS for soil toxicity (ECHA Guidance R.7.11.6.), which indicates a high hazard potential to soil organisms. For such substance, long-term terrestrial toxicity tests must be provided.

5.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test (test method: OECD TG 208) with a suitable study design for addressing long-term assessment.

Your registration dossier does not include any information on long-term toxicity on terrestrial plants.

ECHA agrees that an appropriate study on long-term toxicity testing on terrestrial plants is needed.

5.2. Test selection and study specifications

The proposed 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.

5.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

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

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

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[2].

B. Test material

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 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.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

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

Appendix C: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 20 July 2020.

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

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix D: List of references - ECHA Guidance 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)[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.

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.

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[5]
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.

[4] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[5] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix E: 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.