~~Confidential~~

Helsinki, 16 November 2023

Addressees
Registrants of JS_Carbodiimide as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
14 March 2023

Registered substance subject to this decision ("the Substance")
Substance name: Bis(2,6-diisopropylphenyl)carbodiimide
EC/List number: 218-487-5

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)

Under Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***21 October 2025***.

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

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

1. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., column 2; test method: EU C.33/OECD TG 222)

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

3. Long-term toxicity on 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)

The reasons for the decision(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressee(s) of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 requirements for testing and reporting new tests under REACH, see Appendix 4.

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

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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 1: Reasons for the decision

Contents

0. Reasons common to several requests

0.1. Substance-tailored exposure-driven testing adaptation rejected

1 You have adapted the following standard information requirement(s) under Annex XI, Section 3.2 (a) substance-tailored exposure-driven testing, for the following information requirements:

- Effects on soil microorganisms (Annex IX, 9.4.2)
- Long-term toxicity on terrestrial plants (triggered by Annex IX, Section 9.4.3.)

2 A substance-tailored exposure-driven testing adaptation must fulfil the cumulative conditions set out under Annex XI, Sections 3(1) as well as 3(2)(a), (b) or (c).

0.1.1. The Substance is a potential PBT/vPvB substance.

3 In accordance with Section 3.1 of Annex XIII, the results from the screening tests or other information might indicate that the substance may have PBT or vPvB properties. This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as it is not readily biodegradable (*i.e.* <60/70% degradation in an OECD 301F and B), and
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - it has a calculated BCF > 2000;
  - it meets the criteria vB as set out in Annex XIII (*i.e.* BCF > 5 000);
- it meets the T criteria set in Annex XIII: NOEC or EC_{10} < 0.01 mg/L or classification as carc. 1A or 1B, muta. 1A or 1B, repro. 1A, 1B or 2, or STOT RE 1 or 2.

4 Your registration dossier provides the following:

- the Substance is not readily biodegradable (1% degradation after 28 days in OECD TG 301F and 3% degradation after 28 days in OECD TG 301B;
- the Substance meets the vB criteria: BCF of 14631.8 in an OECD 305 III study;
- the Substance meets the T criteria: The substance is classified as STOT RE 1 and as toxic for reproduction (category 1B). In addition is toxic to the aquatic environment with an EC_{50}(48h) or 0.0040 mg/L in an OECD 202.

Under section 2.3 of your IUCLID dossier and section 8 of your CSR ('PBT assessment'), you conclude that the Substance is vB (and B) and T. You also note that no conclusion for the persistence of the substance in the environment can be reached yet as testing in ongoing.

5 Based on the above, the available information on the Substance indicates that it is a potential PBT/vPvB substance.

0.1.2. Lack of appropriate PNEC

6 Under Annex XI, Section 3.2 (a)(ii) and (iii), a relevant and appropriate predicted no effect concentration (PNEC) must be derived and the results of the exposure assessment must show that exposures are always well below the PNEC, i.e. risk characterisation ratios RCRs must always be well below 1.

7 For substances satisfying the PBT and vPvB criteria of Annex XIII long-term effects and the estimation of the long-term exposure cannot be carried out with sufficient reliability (Annex I, Section 4.0.1). As a result, for such substances, PNECs and PECs cannot be derived with sufficient reliability to demonstrate that the ratio between PECs and the PNEC are always well below 1.

8 As explained above in point 0.1.1., the information from your dossier does not allow excluding that the Substance is PBT/vPvB.

9 Therefore, you have neither demonstrated that an appropriate PNEC can be derived nor that RCRs are well below 1.

0.2. Conclusion on the substance-tailored exposure driven testing adaptation

10 Based on the above, your substance-tailored exposure driven testing adaptation under Annex XI, Section 3, is rejected.

Reasons for the decision(s) related to the information under Annex IX of REACH

1. Long-term toxicity testing on terrestrial invertebrates

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

1.1. Triggering of the information requirement

12 Under Annex IX, Section 9.4., column 2, for substances that have a high potential to adsorb to soil or that are very persistent, long-term toxicity testing must be considered instead of short-term. Guidance on IRs and CSA, Section R.7.11.5.3. clarifies that a substance is considered to be very persistent in soil if it has a half-life >180 days. In the absence of specific soil data, high persistence is assumed unless the substance is readily biodegradable.

13 Based on the information from your registration dossier the Substance is considered to be highly persistent in soil as it is considered not readily biodegradable based on an OECD 301 F and OECD 301 B study.

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

1.2. Information provided to fulfil the information requirement

15 You have submitted a testing proposal for an Earthworm Reproduction Test (EU C.33/OECD TG 222).

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

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

1.3. Test selection and study specifications

18 The proposed Earthworm Reproduction Test (EU C.33/OECD TG 222) is appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (Guidance on IRs and CSA, Section R.7.11.3.1).

1.4. Outcome

19 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. Effects on soil micro-organisms

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

21 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 for Effects on terrestrial organisms at Annex IX covers short-term toxicity to invertebrates (Section 9.4.1.), effects on soil

micro-organisms (Section 9.4.2.) and short-term toxicity to plants (Section 9.4.3.). However, you have provided a testing proposal for long-term toxicity to invertebrates only.

2.1. Information provided to fulfil the information requirement

22 Your registration dossier does not include any information on effects on soil microorganisms, instead you have submitted an adaptation under Annex XI, Section 3.2 (a). To support the adaptation, you have provided the following justification: 'Nonetheless, as a robust justification of "unlikely exposure" based on Col. 2 of REACH Annex IX cannot be delivered because of the insufficient documentation on downstream uses available to the registrant, it is deemed as reasonable to undertake an Annex XI.3.2. (a) route based on derived PNEC'.

23 As explained under the section 0.1, your substance-tailored exposure driven testing adaptation under Annex XI, Section 3. is rejected.

24 On this basis information on the effects on soil microorganisms must be provided.

25 ECHA concludes that an appropriate study on Effects on soil microorganisms is needed.

2.2. Test selection and study specifications

26 Guidance on IRs and CSA, Section Guidance on IRs and CSA, Section 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.

2.3. Outcome

27 On the basis of Article 40(3)(c), you are requested to conduct the additional test with the Substance, as specified above.

3. Long-term toxicity to terrestrial plants

28 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.

3.1. Triggering of the information requirement

29 Under Annex IX, Section 9.4., column 2, for substances that have a high potential to adsorb to soil or that are very persistent, long-term toxicity testing must be considered instead of short-term. Guidance on IRs and CSA, Section R.7.11.5.3. clarifies that a substance is considered to be very persistent in soil if it has a half-life >180 days. In the absence of specific soil data, high persistence is assumed unless the substance is readily biodegradable.

30 As already explained in request 1, the Substance is considered to be highly persistent in soil as it is considered not readily biodegradable.

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

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.

3.2. Information provided to fulfil the information requirement

32 Your registration dossier does not include any information on Long-term toxicity to terrestrial plants, instead you have submitted an adaptation under Annex XI, Section 3.2 (a). To support the adaptation, you have provided the following justification: 'Nonetheless, as a robust justification of "unlikely exposure" based on Col. 2 of REACH Annex IX cannot be delivered because of the insufficient documentation on downstream uses available to the registrant, it is deemed as reasonable to undertake an Annex XI.3.2. (a) route based on derived PNEC'.

33 As explained under the section 0.1, your substance-tailored exposure driven testing adaptation under Annex XI, Section 3. is rejected.

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

35 ECHA concludes that an appropriate long-term toxicity study on terrestrial plants is needed.

3.3. Test selection and study specifications

36 Guidance on IRs and CSA, Section Guidance on IRs and CSA, Section R.7.11.3.1. specifies that the Terrestrial Plant Test (EU C.31./OECD TG 208, with at least six species) is appropriate to cover the information requirement for long-term toxicity on terrestrial plants.

37 The OECD TG 208 (EU C.31.) 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.

3.4. Outcome

38 On the basis of Article 40(3)(c), you are requested to conduct the additional test with the Substance, as specified above.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).
Guidance for monomers and polymers; ECHA (2012).
Guidance on intermediates; ECHA (2010).

All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs); ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

The Substance is listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2024.

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 11 August 2022.

ECHA held a third-party consultation for the testing proposal(s) from 22 September 2022 until 7 November 2022. ECHA did not receive information from third parties on this testing proposal.

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

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 6 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the requests.

In your comments on the draft decision, you requested an extension of the deadline to provide information from 15 to 20 months from the date of adoption of the decision. You have provided evidence on laboratory capacity indicating significant lead in time is expected for the requested studies at the testing facility. On this basis, ECHA has extended the deadline to 20 months.

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 3: Addressee(s) of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- 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.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third-party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. 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].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. 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.

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

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[3].

[3] https://echa.europa.eu/manuals