~~Confidential~~

Helsinki, 20 June 2022

Addressees
Registrant of JS_835-183-3 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
29/03/2021

Registered substance subject to this decision ("the Substance")
Substance name: N4,N4'-hexane-1,6-diylbis[N-butyl-6-chloro-N,N'-bis(2,2,6,6-tetramethylpiperidin-4-yl)-1,3,5-triazine-2,4-diamine]
EC number: 835-183-3

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 ***3 January 2024.***

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

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

1. Bioaccumulation in aquatic species (triggered by Annex I, sections 0.6.1. and 4.; Annex XIII, Section 2.1.; test method: EU C.13./OECD TG 305, aqueous exposure)

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

2. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats

3. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit)

4. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: EU C.13./OECD TG 305, aqueous exposure)

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 addressees 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

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

1. Bioaccumulation in aquatic species

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

2 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential vPvB substance (Guidance on IRs and CSA, Section R.11.4.).

3 This is the case if the Substance itself, or any of its constituents or impurities which are present in concentrations ≥ 0.1% (w/w), or relevant transformation/degradation product meet the following criteria:

1) it is potentially persistent or very persistent (P/vP), for example because:
   - it is not readily biodegradable (*i.e.* <60% degradation in an OECD TG 310);
2) it is potentially bioaccumulative or very bioaccumulative (B/vB) for example because:
   - it has a high potential to partition to lipid storage (*e.g.* log K_{ow} > 4.5).

4 Your registration dossier provides the following:

- The Substance is not readily biodegradable (2% degradation after 28 days in OECD TG 310);
- The Substance has a high potential to partition to lipid storage (Log K_{ow} > 4.72 based on OECD TG 107).

5 ECHA notes that under section 2.3 of your IUCLID dossier ('PBT assessment'), you refer to a predicted BCF result (EPI Suite BCFBAF of 4.465 L/kg wet weight). However, we agree with your conclusions under section 5.3.1. of your IUCLID dossier (see also section "4." of this appendix below) that the predicted BCF result is not reliable.

6 Furthermore, the information in your dossier is currently incomplete and therefore, it is not possible to conclude on the toxicity of the Substance (see sections "2." and "3." of this appendix).

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

8 Therefore, information on bioaccumulation in aquatic species must be provided.

9 The examination of the information provided, the selection of the requested test and the test design, as well as your comments on the draft decision, are addressed under section 4 of this Appendix.

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

2. Sub-chronic toxicity study (90-days)

11 A sub-chronic toxicity study (90 day) is an information requirement under Annex IX to REACH (Section 8.6.2.).

2.1. Information provided to fulfil the information requirement

12 You have submitted a testing proposal for a Sub-chronic toxicity study (90 day) according to OECD TG 408 with the Substance.

13 ECHA requested your considerations for alternative methods to fulfil the information requirement for Repeated dose toxicity. 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.

14 ECHA agrees that a 90-day study is necessary.

2.2. Specification of the study design

15 You proposed testing in the rat. ECHA agrees with your proposal because the rat is the preferred species according to the OECD TG 408. Therefore, the study must be conducted in the rat.

16 You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is appropriate to investigate systemic toxicity; Guidance on IRs and CSA, Section R.7.5.4.3.2.

2.3. Outcome

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

18 In the comments to the draft decision, you agree to perform the requested study.

3. Pre-natal developmental toxicity study in a first species

19 A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is an information requirement under Annex IX to REACH (Section 8.7.2.).

3.1. Information provided to fulfil the information requirement

20 You have submitted a testing proposal for a PNDT study according to OECD TG 414 by the oral route with the Substance.

21 ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. 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.

22 ECHA agrees that a PNDT study in a first species is necessary.

3.2. Specification of the study design

23 You proposed testing in the rat as a first species. You may select between the rat or the rabbit because both are preferred species under the OECD TG 414 (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

24 You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is the most appropriate to investigate reproductive toxicity (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

3.3. Outcome

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

26 In the comments to the draft decision, you agree to perform the requested study.

4. Bioaccumulation in aquatic species

27 A bioaccumulation study in aquatic species is an information requirement under Annex IX to REACH (Section 9.3.2.).

4.1. Information provided to fulfil the information requirement

28 You have submitted a testing proposal for Bioaccumulation in Fish: Aqueous Exposure test (OECD TG 305-I, aqueous exposure).

29 Your dossier does not provide information on Bioaccumulation in aquatic species.

30 ECHA requested your considerations for alternative methods to fulfil the information requirement for bioaccumulation in fish. 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. Especially, you concluded that "*In the EPI suite BCFFBAF v3.01, the result of BCF= 4.465 L/kg wet-wt. But it has exceeded the molecular weight range of this model. So, this QSAR result may be not reliable and QSAR could not be applied for the aquatic bioaccumulation endpoint for this substance*."

31 ECHA agrees that the provided QSAR data for the bioaccumulation endpoint is not reliable and that an appropriate study on Bioaccumulation in aquatic species (fish) is needed.

32 In the comments to the draft decision, you agree to perform the study, however, you question the necessity to perform the test because:

a. the Substance has a low water solubility (< 0.02 mg/L);

b. you consider that the uptake of the Substance could be hindered because of its molecular weight of 1040.78;

c. you consider that there is no or little exposure to human or the environment within the EU, as the Substance is entering the EU market as a polymer.

33 ECHA has assessed your comments and identified the following issues:

a. ECHA acknowledges the properties of the Substance, however, a low water solubility does not prevent the OECD TG 305 to be performed. Please note

that you may conduct the study using the dietary exposure route (OECD 305-III) if you justify and document that testing through aquatic exposure is not technically possible (see section 4.2. below);

b. The molecular weight itself is not sufficient as indicator of limited bioaccumulation. It should be considered along with the average maximum diameter and information derived from toxicokinetic and/or chronic mammalian studies in a weight-of-evidence approach (Guidance on IR & CSA R.11);

c. There is currently no sufficient information to assess whether your adaptation fulfils the requirements of Section 3 of Annex XI to the REACH Regulation, as you have not provided a thorough and rigorous exposure assessment.

34 Therefore, you have not demonstrated that this information can be omitted, and you remain responsible for complying with this decision by the set deadline.

4.2. Test selection and study specifications

35 The proposed Bioaccumulation in Fish: Aqueous and Dietary Exposure test (EU C.13/OECD TG 305) is appropriate to cover the information requirement for Bioaccumulation in aquatic species (Guidance on IRs and CSA, Section R.7.10.3.1).

36 Exposure via the aqueous route (OECD TG 305-I) must be conducted unless it can be demonstrated that:

- a stable and fully dissolved concentration of the test substance in water cannot be maintained within ± 20% of the mean measured value, and/or
- the highest achievable concentration is less than an order of magnitude above the limit of quantification (LoQ) of a sensitive analytical method.

37 This test set-up is preferred as it allows for a direct comparison with the B and vB criteria of Annex XIII of REACH.

38 You may only conduct the study using the dietary exposure route (OECD 305-III) if you justify and document that testing through aquatic exposure is not technically possible as indicated above. You must then 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).

4.3. Outcome

39 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the 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).

All Guidance on REACH is 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

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 23 August 2021.

ECHA held a third party consultation for the testing proposal(s) from 30 September 2021 until 15 November 2021. ECHA did not receive information from third parties.

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

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

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

> In your comments on the draft decision, you requested an extension of the deadline to provide information from 18 to 24 months from the date of adoption of the decision. You considered that the extension of 6 months is needed because the studies could be delayed due to current limited capacity of the test laboratories. However, you did not provide any documentary evidence of the limited test laboratory capacity.
>
> On this basis, ECHA has not modified the deadline to provide the information requested.

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: Addressees 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 Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

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.

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) 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 shall ensure that the data generated are adequate for hazard identification and risk assessment

1.2. 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 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. General recommendations for conducting and reporting new tests

References to Guidance on REACH and other supporting documents can be found in Appendix 1.

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