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Helsinki, 02 June 2023

Addressee
Registrant of JS_761-65-9 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
05/01/2021

Registered substance subject to this decision ("the Substance")
Substance name: N,N-dibutylformamide
EC number/List number: 212-090-0

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***9 June 2025***.

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

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

1. Short-term repeated dose toxicity study (28 days) (Annex VIII, Section 8.6.1.; test method: EU B.7/OECD TG 407) by oral route, in rats

The reasons for the request(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 of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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.

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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 request(s)
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 request(s)

Contents

Reasons related to the information under Annex VIII of REACH

1. Short-term repeated dose toxicity (28 days)

1 A short-term repeated dose toxicity study (28 days) is an information requirement under Annex VIII, Section 8.6.1.

1.1. Information provided

2 You have adapted this standard information requirement under Annex XI, Section 3.2 (b) ('Substance-tailored exposure-driven testing').

1.2. Assessment of the information provided

1.2.1. Substance-tailored exposure-driven testing adaptation rejected

3 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).

1.2.1.1. Strictly controlled conditions not demonstrated

4 Under Annex XI, Section 3(2)(b)), it must demonstrated and documented for all relevant scenarios that throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f) apply (see further Guidance on Intermediates and Practical Guide 16).

5 You have provided a claim of strictly controlled conditions: "*According to REGULATION (EC) No 1907/2006, Annex VIII, testing for repeated dose toxicity (section 8.6) may be omitted, if relevant human exposure can be excluded in accordance with Annex XI section 3. Furthermore and in accordance with section 3.2 (b) of Annex XI (as amended by Regulation 134/2009), testing can be omitted when the substance is not incorporated in an article and the manufacturer can demonstrate and document for all relevant scenarios that throughout the life cycle strictly controlled as well as rigorously contained conditions as set out in Article 18(4)(a) to (f) (Regulation 1907/2006) apply. The Registrant demonstrates and documents for all relevant exposure scenarios as given by the life-cycle stages covered (PROCs) that throughout the whole life-cycle strictly controlled conditions as set out in "Article 18(4) [a to f] apply, by giving a detailed process description*"). while providing limited information on use and exposure in the CSR.

6 However, the information on use and exposure in your CSR does not demonstrate that the Substance is handled under strictly controlled conditions. More specifically:

- Condition (a) as set out in Article 18(4) is not fulfilled because it has not been demonstrated that the substance is rigorously contained by technical means during its whole lifecycle, including purification, cleaning and maintenance of equipment. You state that the Substance is transported "[redacted]". However, you do not clarify if this is also the case for the following step: "[redacted]". Furthermore, you state that "[redacted]". However, without identifying the type of "[redacted]" and the specifics of the sampling procedure, the claim for rigorous containment cannot be considered acceptable. In

addition, you do not clarify how the substance remains rigorously contained in the event that extensive system maintenance is required.

- Condition (c) as set out in Article 18(4) does not appear to be fulfilled because you state that "[...] *only a small, well-defined and trained group of workers will be exposed occasionally to low levels using appropriate risk management measures to minimize exposure*." This implies that human exposure cannot be excluded.
- Condition (d) as set out in Article 18(4) is not fulfilled because you have not explained whether cleaning and maintenance works are required and whether there are procedures in place that ensure strictly controlled conditions in the event of cleaning and maintenance.
- Condition (e) as set out in Article 18(4) is not fulfilled because you have not specified which procedural and/or control technologies are in place to prevent exposure in the event of accidental release.
- Condition (f) as set out in Article 18(4) is not fulfilled because you do not describe whether any record-keeping is in place to document substance-handling and there is no indication if and how such procedures are supervised by the site operator.

7 In addition to the above, the exposure estimations listed in your CSR for both the dermal and inhalation routes (0.165 mg/kg bw/day and 0.197 mg/m^3, respectively) contradict your claim that relevant human exposure can be excluded in accordance with Annex XI Section 3.

8 Therefore, the use of the Substance under strictly controlled conditions is not demonstrated.

9 Therefore, the information requirement is not fulfilled.

10 In your comments to the draft decision, you agree to conduct the study.

1.3. Specification of the study design

11 Following the criteria provided in Annex VIII, Section 8.6.1., Column 2, and considering the Guidance on IRs and CSA, Section R.7.5.6.3.1., the oral route is the most appropriate route of administration to investigate repeated dose toxicity of the Substance.

12 According to the OECD TG 407, the rat is the preferred species.

13 Therefore, the study must be performed according to the OECD TG 407, in rats and with oral administration of the Substance.

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

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

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

The compliance check was initiated on 09 June 2022.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 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 request or the deadline.

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]

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

(1) Selection of the Test material(s)

- 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.

With that detailed information, ECHA can confirm 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 (https://echa.europa.eu/manuals).

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