~~Confidential~~

Helsinki, 16 March 2023

Addressees
Registrant(s) of JS_233-634-3 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
09/12/2021

Registered substance subject to this decision ("the Substance")
Substance name: Ethyl 4-dimethylaminobenzoate
EC/List number: 233-634-3

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)

Under Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***23 September 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. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats

2. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

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

4. 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)

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

6. 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 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 IX of REACH

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

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

1.1. Information provided to fulfil the information requirement

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

3 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.

ECHA agrees that a 90-day study is necessary.

1.2. Specification of the study design

4 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.

5 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.

1.3. Outcome

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

2. Long-term toxicity testing on aquatic invertebrates

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

2.1. Information provided to fulfil the information requirement

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

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

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

2.2. Test selection and study specifications

11 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 (Guidance on IRs and CSA, Section R.7.8.4.1.).

2.3. Outcome

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

3. Long-term toxicity testing on fish

13 Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

3.1. Information provided to fulfil the information requirement

14 You have submitted a testing proposal for a Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210).

15 Your registration dossier does not include any information on long-term toxicity on fish.

16 ECHA requested your considerations for alternative methods to fulfil the information requirement for long-term toxicity on 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.

17 ECHA agrees that an appropriate study on long-term toxicity on fish is needed.

3.2. Test selection and study specifications

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

3.3. 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.

4. Long-term toxicity testing on terrestrial invertebrates

20 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.

21 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.

22 Based on the information from your registration dossier the Substance is potentially very persistent. Under Section 5.2.1 of your technical dossier, you have provided an OECD TG 301B study where the biodegradation of the Substance was 40% after 28 days. You also provide a QSAR estimation which predicts the Substance as non readily biodegradable. Your

technical dossier currently does not include any specific simulation data for biodegradation in soil.

23 Therefore, the Substance is considered to be potentially very persistent and information on long-term toxicity on terrestrial invertebrates must be provided.

24 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 of the REACH Regulation (Article 40(3)(c) of REACH). The information requirement for Effects on terrestrial organisms at Annex IX includes toxicity to invertebrates (Section 9.4.1.), effects on soil microorganisms (Section 9.4.2.) and toxicity to plants (Section 9.4.3.). You have submitted a testing proposal regarding effects on terrestrial organisms limited to the effects on soil micro-organisms. For the following reasons ECHA considers that additional information on toxicity to invertebrates must be provided.

4.1. Information provided to fulfil the information requirement

25 You have adapted this information requirement referring to Section 1 of Annex XI to REACH. To support the adaptation, you have provided the following justification: "…the toxicity to soil macroorganisms study required in Section 9.4 does not appear scientifically necessary" as "the data are not required as the risk assessment performed concludes that the substance is of no immediate concern to the environment" and "direct and indirect exposure of the soil compartment is unlikely, according to the physicochemical properties of the registered substance (log Koc < 3) and to its uses (no releases to non-agricultural soil)".

4.2. Assessment of the information provided

4.2.1. The provided adaptation does not follow any of the general rules for adaptation under Section 1 of Annex XI to REACH or the specific rules set out in Annex IX, Section 9.4., Column 2

26 A registrant may only adapt this information requirement based on the general rules set out in Annex XI or the specific rules set out in Annex IX, Section 9.4., Column 2.

27 Your justification to omit this information does not refer to any of the general rules for adaptation under Section 1 of Annex XI to REACH, and you do not provide any pertinent supporting documentation.

28 With the view of possible adaptation under Annex IX, Section 9.4., Column 2, ECHA notes that in your registration dossier you report uses for the Substance under the following environment release categories: ERC2, ERC5, ERC10a and ERC11a. Under the section 10 of your CSR you report total releases to the soil of a total 320 kg/year of the Substance from all the exposure scenarios. Therefore, exposure of the soil compartment is expected.

29 Therefore, you have not demonstrated that this information can be omitted.

30 ECHA concludes that an appropriate long-term toxicity study on terrestrial invertebrates is needed.

Test selection and study specifications

31 The 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).

4.3. Outcome

32 Therefore, under Article 40(3)(c), you are requested to conduct the additional test with the Substance, as specified above.

5. Effects on soil micro-organisms

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

5.1. Information provided to fulfil the information requirement

34 You have submitted a testing proposal for a Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216).

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

36 ECHA agrees that an appropriate study on effects on soil microorganisms is needed.

5.2. Test selection and study specifications

37 The proposed Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) is appropriate to cover the information requirement on effects on soil microorganisms (Guidance on IRs and CSA, Section R.7.11.3.1.).

5.3. Outcome

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

6. Long-term toxicity to terrestrial plants

39 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.

40 As explained in the Request 4 the Substance is considered to be potentially very persistent and information on long-term toxicity on terrestrial plants must be provided.

41 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 of the REACH Regulation (Article 40(3)(c) of REACH). The information requirement for Effects on terrestrial organisms at Annex IX includes toxicity to invertebrates (Section 9.4.1.), effects on soil microorganisms (Section 9.4.2.) and toxicity to plants (Section 9.4.3.). You have submitted a testing proposal regarding effects on terrestrial organisms limited to the effects on soil micro-organisms. For the following reasons ECHA considers that additional information on toxicity to terrestrial plants must be provided.

6.1. Information provided to fulfil the information requirement

42 You have adapted this information requirement referring to Section 1 of Annex XI to REACH. To support the adaptation, you have provided the following justification: "…the toxicity to terrestrial plants study required in Section 9.4.3 does not appear scientifically necessary" as "the data are not required as the risk assessment performed concludes that the substance is of no immediate concern to the environment" and "direct and indirect exposure of the soil compartment is unlikely, according to the physicochemical properties of the registered substance (log Koc < 3) and to its uses (no releases to non-agricultural soil)".

6.1. Assessment of the information provided

6.1.1. The provided adaptation does not follow any of the general rules for adaptation under Section 1 of Annex XI to REACH or the specific rules set out in Annex IX, Section 9.4., Column 2

43 As explained in the above reasons for Request 4, you have not demonstrated that this information can be omitted.

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

6.2. Test selection and study specifications

45 The Seedling Emergence and Seedling Growth Test (test method: OECD TG 208) is appropriate to cover the information requirement for long-term toxicity to plants (Guidance on IRs and CSA, Section R.7.11.3.1.).

46 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.

6.3. Outcome

47 Therefore, under Article 40(3)(c), you are requested to conduct the additional test with the Substance, as specified above.

48 In your comment to the draft decision, you state that you will consider adaptation of this information requirement on the basis of column 2, Section 9.4 of Annex IX. As indicated in your comment, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made.

49 Based on the above, you remain responsible for complying with this decision by the set deadline.

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

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 15 March 2022.

ECHA held a third party consultation for the testing proposal(s) from 10 May 2022 until 27 June 2022. ECHA did not receive information from third parties.

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 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.

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 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) 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.

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].

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