~~Confidential~~

Helsinki, 03 May 2023

Addressee(s)
Registrant(s) of EC_275-662-9 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
26/11/2020

Registered substance subject to this decision ("the Substance")
Substance name: m-(2,3-epoxypropoxy)-N,N-bis(2,3-epoxypropyl)aniline
EC number/List number: 275-662-9

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 ***10 November 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 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. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25/OECD TG 309) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided;

4. Identification of degradation products (Annex IX, 9.2.3.; test method: EU C.25/OECD TG 309).

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 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.
In addition, the studies relating to biodegradation and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in this Appendix.

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 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 IX of REACH

1. Long-term toxicity testing on aquatic invertebrates

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

1.1. Information provided

2 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on the following experimental data:

(i) a long-term toxicity study on *Daphnia magna* (2012) with the source substance p-(2,3-epoxypropoxy)-N,N-bis(2,3-epoxypropyl)aniline, EC 225-716-2 // p-isomer.

3 You provide a read-across justification document in IUCLID Section 13.2.

4 You provide the following reasoning for the prediction of this information requirement: "*Based on the results mentioned above on physico-chemical properties and environmental fate and given that short term toxicity on Fish and Algae species are very similar, it is highly likely that the p-isomer substance will show the same acute toxicity to aquatic invertebrate than the m-isomer and that the m-isomer will have the same chronic toxicity to Daphnia Magna in a reproduction test than the p-isomer. Consequently, we consider scientifically justified to read-across from the m-isomer to the p-isomer and vice versa*."

5 ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

1.2. Assessment of the information provided

1.2.1. Read-across adaptation rejected

6 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

7 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

8 We have identified the following issue(s) with the prediction of ecotoxicological properties:

1.2.1.1. Lack of relevance of the supporting information

9 Annex XI, Section 1.5. requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties.

10 According to the Guidance on IRs and CSA, Section R.6.2.2.1.f., "it is important to provide supporting information to strengthen the rationale for the read-across approach. Thus, in addition to the property/endpoint being read across, it is also useful to show that additional properties, relevant to the endpoint, are also (qualitatively or quantitatively) similar between the source and target chemicals".

11 In order to support your claim that the Substance and source substance(s) have similar properties for the endpoints under consideration, you refer to studies relating to the short-term toxicity to fish and growth inhibition on algae and environmental fate properties of the Substance and the source substance. Short-term toxicity studies from three trophic levels (Daphnia, fish and algae) are available for the m-isomer (the Substance) and for two trophic levels (fish and algae) for the p-isomer substance (the source substance). Additionally, a chronic study on daphnia reproduction is available on the p-isomer (the source substance) which is used to fulfil this information requirement.

12 However, the short-term studies do not inform on the sublethal effects assessed in the long-term toxicity studies on aquatic invertebrates (e.g. reproduction) and thus cannot be used to compare the properties of the Substance and of the source substance based on your reasoning. Furthermore, you have not provided reasoning why similar toxicity can be supported by studies with different test organisms (e.g. from fish and algae to Daphnia) considering that the mechanisms impacting toxicity, or toxicokinetics, between different organimsm are not the same. Accordingly, this information is not considered as relevant to support your read-across hypothesis and you have not provided supporting information to scientifically justify the read-across explanation for prediction of properties.

13 As explained above, you have not established that relevant properties of the Substance can be predicted from data on the source substance. On this basis, your read-across approach under Annex XI, Section 1.5. is rejected and the information requirement is not fulfilled.

1.3. Study design and test specifications

14 The Substance is difficult to test due to hydrolysis (half-life 5 days, pH 7). In addition, for short-term toxicity to fish ([redacted], 2013) and short-term toxicity to aquatic invertebrates ([redacted], 2013) you state under details on the test material that the Substance is volatile and not completely soluble in water. The OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in the 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 the 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 solution.

2. Long-term toxicity testing on fish

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

2.1. Information provided

16 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following information: *"In accordance with REACH (regulation No 1927/2006) Annex IX, long-term toxicity testing does not need to be performed (required in section 9.1.6) as the chemical safety assessment indicates there is no need to investigate further the effects on aquatic organisms : The substance is neither PBT nor vPvB."*

2.2. Assessment of the information provided

17 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to fish referred to under Column 1, Section 9.1.6.

18 Your adaptation is therefore rejected and the information requirement is not fulfilled.

2.3. Study design and test specifications

19 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

20 The OECD TG 210 specifies that, for difficult to test substances, the OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in "Study design and test specifications" under request 2.

3. Simulation testing on ultimate degradation in surface water

21 Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

3.1. Information provided

22 You have adapted this information requirement by using

a) Column 2 of Annex IX, Section 9.2. stating that the Chemical Safety Assessment does not indicate the need to conduct the study; and

b) Annex XI, Section 1.5. (grouping of substances and read-across approach) and provided a simulation study on ultimate degradation in surface water (2020), conducted with the source substance p-(2,3-epoxypropoxy)-N,N-bis(2,3-epoxypropyl)aniline, EC 225-716-2 // p-isomer.

3.2. Assessment of information provided

3.2.1. Annex IX, Section 9.2., Column 2 is not a valid basis to omit the study

23 You have provided the following justification to support your adaptation: *"In accordance with column 2 of REACH (Regulation (EC) No 1907/2006) Annex IX, the simulation testing on ultimate degradation in surface water, and sediment simulation testing (required in section 9.2.1.2, and 9.2.1.4) do not need to be conducted based on the findings of the Chemical Safety Assessment; the substance does not fulfil classification criteria according to the applicable regulations and does not fulfil the criteria for vPvB or PBT."*

24 Annex IX, Section 9.2., Column 2 provides that "further" biodegradation testing must be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. That

provision allows a registrant to propose, or ECHA to require, biotic degradation testing not covered by the information on degradation listed under Annex IX, section 9.2., Column 1. Therefore, this provision cannot be used as a justification for omitting the submission of information on simulation testing on ultimate degradation in surface water required under Annex IX, Section 9.2.1.2, Column 1.

25 Therefore, your adaption is rejected.

3.2.2. Read-across adaptation rejected

26 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

27 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

28 To support your adaptation you provide a read-across justification document in IUCLID Section 13.2. In this document you present your read-across hypothesis based on a) structural considerations, b) physical chemical properties, c) toxicological considerations, and d) environmental fate/ecotoxicological considerations.

29 With regard to the prediction of environmental fate properties you state: "*While both chemicals are not considered to be readily biodegradable in OECD 301F or OECD 301B, the p-isomer substance was only degraded up to 4% within 28 days and the m-isomer substance up to 11%. The m-isomer is also not considered to be inherently biodegradable in a OECD 302B study*."

30 The read-across justification document does not provide any further reasoning for the prediction of the environmental fate properties.

31 ECHA understands that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

32 We have identified the following issue(s) with the prediction of environmental fate properties:

33 Annex XI, Section 1.5. requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must include an information requirement specific explanation why the properties of the Substance may be predicted from other substances in the group, i.e. a read-across hypothesis. This hypothesis should be based on recognition of the structural similarities and differences between the substances (Guidance on IRs and CSA, Section R.6.). It should explain why the differences in the chemical structures should not influence the environmental fate properties or should do so in a regular pattern.

34 Your read-across hypothesis is based on structural similarities and similarities in the physico-chemical properties of the Substance and the source substance.

35 You have not provided any relevant read-across justification specific to this information requirement. Furthermore, you have not explained how structural and physico-chemical similarity would explain similarity in the predicted information requirement(s) and thus be sufficient to justify the environmental fate predictions.

36 In particular, you have not demonstrated how your claim that the Substance and source substance are are not readily biodegradable in OECD 301F or OECD 301B tests could be relevant to support the prediction of the properties of the Substance for this information requirement from data on the source substance.

37 Physico-chemical similarity alone does not necessarily lead to predictable or similar environmental fate properties or confirm that the degradation products would be the same for the source and the target substance. You have not provided a well-founded hypothesis to establish a reliable prediction for a environmental fate property.

38 As explained above, you have not established that relevant properties of the Substance can be predicted from data on the source substance. On this basis, your read-across approach under Annex XI, Section 1.5. is rejected and the information requirement is not fulfilled.

3.3. Study design and test specifications

39 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1):

(1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

(2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

40 You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (Guidance on IRs and CSA, Section R.11.4.1.1.3.).

41 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

42 As specified in Guidance on IRs and CSA, Section R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test material concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Therefore, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

43 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; Guidance on IRs and CSA, Section R.11.4.1.).

4. Identification of degradation products

44 Identification of abiotic and biotic degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

4.1. Information provided

45 You have provided:

i. simulation study on ultimate degradation in surface water (2020), conducted with p-(2,3-epoxypropoxy)-N,N-bis(2,3-epoxypropyl)aniline, EC 225-716-2 // p-isomer.

46 While you have not identified this information as a read-across approach for identification of degradation products, the test material used is different than the Substance. Therefore, the studies conducted with this substance (hereafter referred to as the "source substance") will be evaluated as a read-across adaptation under Annex XI, Section 1.5 of REACH.

4.2. Assessment of information provided

47 We have assessed this information and identified the following issue(s):

48 As explained under request 3, you have provided a read-across justification document in IUCLID Section 13.2. In this document you present your read-across hypothesis based on a) structural considerations, b) physical chemical properties, c) toxicological considerations, and d) environmental fate/ecotoxicological considerations.

49 However, as explained under request 3, you have not provided a well-founded hypothesis to establish a reliable prediction for environmental fate properties and you have not explained how degradation products can be predicted from data on the source substance. For the reasons explained under request 3 your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5 is rejected.

50 Therefore, the information requirement is not fulfilled.

4.3. Study design and test specifications

51 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

(1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
(2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

52 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported. In addition, identified transformation/degradation products must be considered in the CSA including PBT assessment.

53 You must obtain this information from the degradation study requested in request 4.

54 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request 4) must be conducted at 12°C and at a test concentration < 100 µg/L. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline, e.g. 20°C) and at higher application rate (i.e. > 100 µg/L).

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. In particular, this decision does not consider the information requirements for mutagenicity which may be addressed at a later time.

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

The compliance check was initiated on 01 February 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.

ECHA did not receive any comments within the commenting period.

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

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.

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

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