

Helsinki, 14 April 2023

Addressee

Registrant of JS_C12-14_Alkylmorpholine as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision

10/06/2016

Registered substance subject to this decision ("the Substance")

Substance name: Morpholine, 4-C12-14-alkyl derivs.

EC/List number: 800-906-3

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 **21 April 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)

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.

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.

Authorised¹ 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)

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Reasons common to several requests*0.1. Data waiver adaptation rejected*

1 You have adapted the following standard information requirements:

- Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., column 2)
- Long-term toxicity testing on fish (Annex VIII, Section 9.1.3, column 2)

2 You have provided the following justification:

- i. the Substance is readily biodegradable;
- ii. the Substance has a low bioaccumulation potential with a calculated log K_{ow} value of 4 and an estimated BCF value of 79.74 L/kg ww.

0.1.1. Your justification to omit the studies has no legal basis

3 A registrant may only adapt the information requirements listed above based on the general rules set out in Annex XI.

4 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH.

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

0.1.2. Conclusion on the adaptation

6 For the reasons above, your adaptation is rejected.

Reasons related to the information under Annex IX of REACH

1. 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.).

1.1. Information provided

8 You have adapted this information requirement by providing data on biodegradation and
bioaccumulation.

1.2. Assessment of the information provided

9 As explained in Section 0.1., your adaptation is rejected.

10 Therefore, the information requirement is not fulfilled.

1.3. Study design and test specifications

11 The Substance is difficult to test due to the adsorptive properties (log K_{oc} 5.8, log K_{ow} 4).
OECD TG 211 specifies that, for difficult to test substances, you must consider the approach
described in 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 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.

12 For multi-constituents/UVCBs, the analytical method must be adequate to monitor
qualitative and quantitative changes in exposure to the dissolved fraction of the test
material during the test (e.g. by comparing mass spectral full-scan GC or HPLC
chromatogram peak areas or by using targeted measures of key constituents or groups of
constituents).

13 If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the
above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most
constituents (or that are consistent with the PEC value). This condition is
mandatory to provide relevant information for the hazard and risk assessment
(Guidance on IRs and CSA, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including,
among others, loading rates, details on the mixing procedure, method to separate
any remaining non-dissolved test material including a justification for the
separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent
manner.

2. Long-term toxicity testing on fish

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

2.1. Information provided

15 You have adapted this information requirement by providing data on biodegradation and bioaccumulation.

2.2. Assessment of the information provided

16 As explained in Section 0.1., your adaptation is rejected.

17 Therefore, the information requirement is not fulfilled.

2.3. Study design and test specifications

18 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.).

19 OECD TG 210 specifies that, for difficult to test substances, 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 1.

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 04 August 2022.

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

ECHA did not receive any comments within the commenting period.

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 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 Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;

Registrant Name	Registration number	Highest REACH Annex applicable to you
████████████████████	████████████████████	██████

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 summaries².
- (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

- (5) Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

 - 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.
- (6) 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. General recommendations for conducting and reporting new tests

2.1. Environmental testing for substances containing multiple constituents

² <https://echa.europa.eu/practical-guides>

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, Section R.11.4.2.2, you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the “known constituents approach” (by assessing specific constituents), or
- the “fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the “whole substance approach”, or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

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