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Helsinki, 24 November 2022

Addressees
Registrant(s) of MAA Joint Submission as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
15/11/2017

Registered substance subject to this decision ("the Substance")
Substance name: Allylamine
EC/List number: 203-463-9

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 the deadline of ***29 August 2025***.

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

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

1. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. D/E/F/OECD TG 301C/D/F or EU C.29./OECD TG 310)

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

2. Adsorption/ desorption screening (Annex VIII, Section 9.3.1.; test method: EU C.18/OECD TG 106)

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

3. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 413) by inhalation route, in rats

4. 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). Due to reasons explained in Section 6., the test sample must be chosen to minimise gastrointestinal irritation and to allow investigation of intrinsic properties at adequate dose levels. This could be achieved by testing a neutral salt of the Substance.

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

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

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

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Reasons related to the information under Annex VII of REACH

1. Ready biodegradability

1 Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

1.1. Information provided

2 You have adapted this information requirement by using weight of evidence based. In support of your adaptation, you provided the following sources of information:

i. a ready biodegradability study according to OECD TG 310 with the Substance.

ii. an adaptation based on Annex XI, Section 1.3. ('QSAR') using the BIOWIN model.

3 To support your adaptation, you have also provided the following statement: "*In a weight-of-evidence approach, considering that many test vessel replicates at each time point achieved the desired degradation levels to consider allylamine and readily biodegradable, supported by the high probability of ready biodegradability predicted by BIOWIN, the registrant has considered allylamine as readily biodegradable for the purpose of the Chemical Safety Assessment*".

1.2. Assessment of information provided

4 Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information enabling, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement.

5 The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement.

6 According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude on the corresponding information requirement.

7 Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach. This documentation must include robust study summaries of the studies used as sources of information and a justification explaining why the sources of information together provide a conclusion on the information requirement.

8 You have not included a justification for your weight of evidence adaptation, which would include an adequate and reliable (concise) documentation as to why the sources of information provide sufficient weight to conclude on the information requirements under consideration.

9 In spite of this critical deficiency, ECHA has nevertheless assessed the validity of your adaptation.

10 Relevant information that can be used to support weight of evidence adaptation for the information requirement of Annex VII, Section 9.2.1.1 includes similar information that is produced by the OECD TG 301 or 310. OECD TG 301 or 310 requires the study to investigate the following key element:

- the ultimate aerobic biodegradation (as measured by parameters such as DOC removal, CO2 production and oxygen uptake) of the test material under low inoculum concentration is measured at sufficiently frequent intervals to allow the identification of the beginning and end of biodegradation

11 The source of information (i.) and (ii.) may provide relevant information on the above key element.

12 However, the reliability of these sources of information is significantly affected by the following deficiency:

1.2.1. The experimental study (i.) provides inconsistent results

13 The Introduction to the OECD Guidelines for Testing of Chemicals Section 3, Part 1 on the Principles and strategies Related to the Testing of Degradation of Organic Chemicals (July 2003) specifies that ready biodegradability tests must be designed so that positive results are unequivocal. This is, for example, reflected in the OECD TG 301 which specifies that the difference of extremes of replicate values of the removal of the test material at the plateau, at the end of the test or, if appropriate, at the end of the 10-d window must be ≤ 20%.

14 In the provided OECD TG 310 study (i), highly variable results were obtained among replicates both in terms of degradation kinetics but also in terms of % of degradation reached during the test. In addition, while degradation is expected to be a continuous process leading to observing (eventually) a plateau, all three replicates for which degradation was monitored throughout the test period showed a decrease in the % degradation in the last phase of the test. You consider that the observed variability is due to the volatility of the test material and state that "*this study is considered to not be conclusive regarding the ready biodegradability of* [the Substance]". You have provided no explanation as to why the % degradation decreased at the end of the study period or whether the design was such that positive results are unequivocal.

15 ECHA concludes that this study cannot be regarded as providing unequivocal results as regard to whether the Substance may be regarded as readily biodegradable or not. While the high variability of the test results is a major deficiency affecting the reliability of this study, you also have not explained why the % degradation decreased from an average 58% on day 21 to an average 36% by day 28. Therefore the provided study cannot be considered a reliable source of information that could contribute to the conclusion on the above key element.

1.2.1. (Q)SAR results (ii) do not provide a reliable basis to conclude that a substance is readily biodegradable

16 Guidance on IRs and CSA, Section R.7.9.5.1. specifies that (Q)SARs for predicting ready biodegradation (such as the BIOWIN model) are not yet sufficiently accurate to predict rapid degradation. However, when no useful information on degradability is available (either experimentally derived or estimated), (Q)SAR predictions can be used as supporting evidence of that the substance is not rapidly degradable.

17 Your have provided the results of QSAR calculation based on the BIOWIN model. You consider that in addition to the experimental study discussed above, this information supports the conclusion that the substance should be regarded as readily biodegradable.

18 However, as explained above, (Q)SARs predictions does not provide a reliable basis to conclude that a substance degrades fast. Therefore the provided information cannot be considered a reliable source of information that could contribute to the conclusion on ready biodegradability.

19 In summary, the sources of information (i) to (ii) provide to some extent relevant information on ultimate aerobic biodegradation. However, these sources of information have significant reliability issues as described above and cannot contribute to the conclusion on the information requirement for ready biodegradability.

20 It is not possible to conclude, based on any source of information alone or considered together, on the information requirement for ready biodegradability. Therefore, your adaptation is rejected

21 On this basis, the information requirement is not fulfilled.

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

Reasons related to the information under Annex VIII of REACH

2. Adsorption/ desorption screening

23 Adsorption/desorption screening is an information requirement in Annex VIII to REACH (Section 9.3.1.).

2.1. Information provided

24 You have adapted this information requirement under Annex, VIII, Section 9.3.1., column 2. In support of your adaptation, you provided the following justification: "*In accordance with REACH Annex VIII, Section 9.3.1, Column 2, adsorption/desorption screening does not need to be conducted if the substance can be expected to have a low potential for adsorption. ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R7, indicates that a cut off of log Pow = 3 is acceptable, for which this substance has a log Pow = < 3. In addition, a prediction of the log Koc using KOCWIN v2.00 estimates that the log Koc = 1.1, indicating that the substance would have a low potential for adsorption*".

2.2. Assessment of information provided

2.2.1. The log Kow is not a valid descriptor of the bioaccumulation potential of the Substance

25 Under Section 9.3.1., Column 2, first indent of Annex VIII to REACH, the study may be omitted if based on the physicochemical properties the substance can be expected to have a low potential for adsorption. A low log Kow (i.e. log Kow < 3) may be used to support low potential for adsorption. However, the study may not be waived on the basis of low log Kow alone, unless the potential for adsorption of the substance is solely driven by lipophilicity. For instance, the study may not be waived on the basis of low octanol-water partition coefficient alone if the substance is surface active or ionisable at environmental pH (pH 4 – 9).

26 Your registration dossier provides an adaptation stating that the log Kow is < 3. Your further states that, based on a QSAR using log Kow (KOCWIN v2.00) as input variable, the log Koc of the Substances is predicted to be 1.1. Under Section 4.21 of your technical dossier, you report that the pKa of the Substance is 9.7.

27 The Substance is ionisable environmental pH (pH 4 – 9; footnote 21 in Guidance on IRs and CSA, Section R.7.1.17.). Therefore, log Kow is not a valid descriptor of the bioaccumulation potential of the Substance. This equally applies to QSAR predictions based on log Kow. As a result your adaptation is rejected.

28 In the comments to the draft decision, you indicate that you agree that the Substance is ionisable at environmental pH. You indicate that you plan to explore ways to address this information requirement. In particular, you state that "*the n-octanol/water partition coefficient was determined to be 0.13 at pH 10.2. At this pH, the partition coefficient is considered as a logD on a partially ionised species. On the other hand, due to the relationship between logD and pH4, logD of ionised forms are generally lower than non-ionised forms. When pH increase, logD increases too, meaning that the more NH3+ form we have, the less hydrophobic and adsorptive the substance is. As the non-ionised form, considered more adsorptive, is only expected at a pH > 10.7 (>pKa+1), and considering natural waters are not anticipated to have a pH greater than this value, the measured logD*

value at 0.13 can be regarded as a worst-case, sufficient for purpose, to conclude on the low potential for adsorption". You "*propose to recalculate the log Kow value based on the relationship between logD and logKow for bases and include a QSAR prediction to determine the adsorption coefficient of the non-ionised form of the substance, considering as a worst-case estimation". You conclude that "the performance of an adsorption / desorption study on the registered substance is not scientifically relevant*".

29 ECHA notes that LogD refers to the the water:octanol partition coefficient at a specific pH. While it accounts for the effect of pH on the ability of ionisable substances to partition to octanol, it does not take into account other mechanisms impacting the adsorption potential, in particular ionic binding to negatively charge soil particles. In the absence of justification that ionic binding will not lead to higher adsorption potential that that predicted based on logD alone, the proposed QSAR prediction will be regarded as inadequate to meet information requirement.

30 On this basis, the information requirement is not fulfilled.

Reasons related to the information under Annex IX of REACH

3. Sub-chronic toxicity study (90-day)

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

3.1. Information provided

32 You have provided the following studies on the Substance:

i. a non-GLP dose range finding study (2013)
ii. a GLP subacute inhalation toxicity study (28 days) according to OECD TG 412 (2013)
iii. a non-GLP and non-guideline "*sub-chronic exposure study*" (1960)

3.2. Assessment of the information provided

33 We have assessed this information and identified the following issues:

3.2.1. Study not adequate for the information requirement: not the correct type of study

34 (Eco)toxicological studies must comply with a recognised test method (Art. 13(3) of REACH), in this case OECD TG 413. Such study must cover the specifications of the corresponding OECD test guideline (Art. 13(3) of REACH).

35 The studies (i. and ii.) are described as respectively "*dose range finder*" and "*according to OECD TG 412*".

36 Dose range finding studies, like study (i.), are used to determine acceptable top dose levels for e.g. sub-chronic toxicity studies. The study (ii.) conducted as per OECD TG 412 investigates short-term repeated dose toxicity (28 days) rather than sub-chronic (90 days) repeated dose toxicity. In any case, the studies (i. and ii.) do not cover the specifications for the corresponding of the OECD TG 413 such as an exposure duration of at least 90 days; clinical observations; body weight and food/water consumption measurements; haematology and clinical biochemistry; bronchoalveolar lavage analysis, lung burden measurements for particles likely to be retained in the lung, as well as gross necropsy and histopathology of the organs listed in the OECD TG 413 at the end of the study. Therefore, the studies are rejected.

3.2.2. Study not adequate for the information requirement: various deviations from the test guideline

37 To fulfil the information requirement, a study must comply with the OECD TG 413 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a. the highest dose level should aim to induce toxicity or reach the limit dose;
b. at least 10 male and 10 female animals for each test and control group;
c. dosing of the Substance for a minimum of 6h/day, on a 5 day per week basis for a period at least 90 days;
d. at least weekly food consumption measurements;
e. haematological and clinical biochemistry tests as specified in paragraphs 48-49 of the test guideline.

38 The study (iii.) is described as a "*sub-chronic exposure study*".

39 However, the following specifications are not according to the requirements of the OECD TG 413:

a. No justification for the dose setting. The highest concentration tested was 40 ppm, and you do not explain how this relates to the limit value stated in the test guideline (20 mg/L for vapours). You express the concentration with the unit ppm, which is according to the test guideline to be used for gases, whereas you test a vapour (to be expressed in mg/L);
b. no females were used in each concentration and control group;
c. the exposure duration was only 50 days;
d. data on food consumption are missing;
e. data on haematology and clinical biochemistry findings are missing (i.e. incidence and severity with relevant baseline values).

40 The information provided does not cover the key parameter(s) required by the OECD TG 413.

41 On this basis, the information requirement is not fulfilled.

42 In the comments to the draft decision, you state that the Substance is corrosive (Skin Corr. 1A), and that therefore "*appropriate OCs/RMMs/PPE*" are in place to "*protect the workers in line with the requirements for a highly corrosive substance*". You explain how the only use of the Substance is "*Polymerisation of Monomer*", and you describe the PROCs you consider applicable for workers. In turn you claim that "*exposure is proven to be negligible*" and "*the substance is of really low concern for human health once the appropriate OCs/RMMs/PPE are in place*". However, you conclude that "*the substance does not meet the standard waiver options as listed in Annex IX of the REACH Regulation (EC) No 1907/2006 nor the Annex XI criteria (point 2 and 3)*".

43 Following this discourse, you indicate your intention to adapt this information requirement by means of weight of evidence according to Annex XI, Section 1.2, of the REACH Regulation.

44 You state that "*further testing will not change the outcome of the risk assessment as the substance is already classified in the "high hazard band" and will lead to unnecessary animal suffering due to the corrosive properties of the substance*".

45 However, the information in your comments is not sufficient for ECHA to make an assessment, because while you have described your intentions, you have not provided any new scientific information addressing the information requirement. You remain responsible for complying with this decision by the set deadline.

3.3. Specification of the study design

46 Following the criteria provided in Annex IX, Section 8.6.2, Column 2, the inhalation route is the most appropriate route of administration to investigate repeated dose toxicity of the Substance (Guidance on IRs and CSA, Section R.7.5.6.3.2), because the Substance is a liquid of very high vapour pressure (>10 kPa at 25 °C).

47 According to the OECD TG 413, the rat is the preferred species.

48 Therefore, the study must be performed according to the OECD TG 413, in rats and with inhalation administration of the Substance.

3.3.1. Concentration-level setting

49 The aim of the requested test is to collect suitable information for hazard identification (i.e. classification and labelling [specifically for specific target organ toxicity – repeated exposure (STOT RE) and for reproductive toxicity], for characterising the major toxic effects and

target organs of the substance and, hence, for detecting triggers for further studies), and for risk assessment (*i.e.*, for assessing a no-observed-adverse-effect level (NOAEL) and the dose-response relationship)[2].

50 To investigate the properties of the Substance for these purposes, the highest concentration level must be set on the basis of clear evidence of toxicity without causing lethality or persistent signs that might lead to lethality or prevent a meaningful evaluation of the results (OECD TG 413, paragraph 20).

51 In case there is no clear evidence of an adverse effect, the limit dose of at least 20 mg/L for vapours (OECD TG 413, paragraph 13) or the highest possible dose level not causing severe suffering or deaths must be used as the highest dose level. A descending sequence of dose levels should be selected to demonstrate any dose-related effect and aiming to establish the lowest dose level as a NOAEL.

52 You have to provide a justification with your study results demonstrating that the concentration level selection meets the conditions described above.

4. Pre-natal developmental toxicity study in one species

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

4.1. Information provided

54 You have adapted this information requirement without referring to a specific provision of Annexes VII to XI. To support the adaptation, you have provided following information:

i. a statement where you waive the need for a pre-natal developmental toxicity study with the Substance on the premise that there is "*no scientific basis*." Furthermore, you state that "*No effects on reproductive organs, fertility, or offspring were noted in the reproductive/developmental toxicity screening test* […]".

55 In addition, you have also provided:

ii. a GLP reproduction/Developmental Toxicity Screening Test according to OECD TG 421 (2013) with the Substance.

56 We have assessed this information and identified the following issues:

4.1.1. Adaptation not based on an existing provision

57 A registrant who submits an adaptation must set out clearly, in the relevant part of its registration dossier, the provision of Annexes VII to XI on which the adaptation is based, the grounds for the adaptation, and the scientific information which substantiates those grounds.

58 Your statement under (i.) above does not refer to a specific adaptation as per Annex IX column 2 or Annex XI. Therefore, your have not demonstrated that this information requirement can be omitted.

4.1.2. Study not adequate for the information requirement

[2] Advice on dose-level selection for the conduct of sub-acute and sub-chronic assays under REACH (ECHA, January 2022)

59 To fulfil the information requirement, a study must comply with OECD TG 414 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) at least 20 female animals with implantation sites are included for each test and control group;
b) the foetuses are examined for sex and body weight/external, skeletal and soft tissue alterations (variations and malformations)/number of resorptions and or live foetuses/ measurement of anogenital distance in live rodent foetuses.

60 The study (ii.) is described as a "reproduction/developmental toxicity screening test". This study has been conducted using the OECD TG 421 which is a screening tests rather than a conclusive developmental toxicity study.

61 That study does not cover the key parameters of the OECD TG 414 such as:

a) a statistical power equivalent to the OECD TG 414, as the study provided has 10 animals in each group but only 8 with implantation sites;
b) skeletal and soft tissue alterations (variations and malformations).

62 The study (ii.) is not adequate for the information requirement and is therefore rejected.

63 On this basis, the information requirement is not fulfilled.

64 In the comments to the draft decision, you state that the Substance is corrosive (Skin Corr. 1A), and that therefore "*appropriate OCs/RMMs/PPE*" are in place to "*protect the workers in line with the requirements for a highly corrosive substance*". You explain how the only use of the Substance is "*Polymerisation of Monomer*", and you describe the PROCs you consider applicable for workers. In turn you claim that "*exposure is proven to be negligible*" and "*the substance is of really low concern for human health once the appropriate OCs/RMMs/PPE are in place*". However, you conclude that *"the substance does not meet the standard waiver options as listed in Annex IX of the REACH Regulation (EC) No 1907/2006 nor the Annex XI criteria (point 2 and 3)*".

65 Following this discourse, you indicate your intention to adapt this information requirement by means of weight of evidence according to Annex XI, Section 1.2, of the REACH Regulation.

66 You state that "*further testing will not change the outcome of the risk assessment as the substance is already classified in the "high hazard band" and will lead to unnecessary animal suffering due to the corrosive properties of the substance*".

67 However, the information in your comments is not sufficient for ECHA to make an assessment, because while you have described your intentions, you have not provided any new scientific information addressing the information requirement. You remain responsible for complying with this decision by the set deadline.

4.2. Specification of the study design

68 The Substance is a corrosive liquid and you apply a self-classification as Skin Corr. 1A (H314). ECHA Guidance R.7.6.2.3.2. specifies that corrosive or highly irritating substances must be tested for reproductive toxicity preferably via the oral route. However, testing at concentration/dose levels causing corrosivity must be avoided. Testing of neutral salts of alkaline or acidic substances is therefore more appropriate as it allows the investigation of intrinsic properties at adequate dose levels.

69 Therefore, a PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral administration (ECHA Guidance R.7.6.2.3.2). The test sample must be chosen to minimise gastrointestinal irritation and to allow

investigation of intrinsic properties at adequate dose levels. This could be achieved by testing a neutralised salt of the Substance.

70 If the PNDT study submitted in response of this decision does not deliver reliable results because of gastrointestinal irritation, further testing may be considered necessary in order to investigate the intrinsic properties at adequate dose levels. Therefore, if the Member State competent authorities consider that a concern must be clarified in that respect, they may decide to require further testing under Substance Evaluation.

5. Long-term toxicity testing on aquatic invertebrates

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

5.1. Information provided

72 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following justification: "*The Chemical Safety Assessment for this substance confirms that no unacceptable risks to aquatic organisms exist under the defined conditions of use, based on the PNECs derived from the available data-set, which consists of acute toxicity studies on aquatic invertebrates. No long-term testing on invertebrates is therefore proposed*."

5.2. Assessment of the information provided

73 We have assessed this information and identified the following issue:

5.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

74 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

75 Your adaptation is therefore rejected.

76 On this basis, the information requirement is not fulfilled.

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

5.3. Study design and test specifications

78 The Substance is difficult to test due its high vapour pressure (32 kPa at 25°C) and ionisable properties (pKa = 9.7). 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.

6. Long-term toxicity testing on fish

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

6.1. Information provided

80 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following justification: "*The Chemical Safety Assessment for this substance confirms that no unacceptable risks to aquatic organisms exist under the defined conditions of use, based on the PNECs derived from the available data-set, which consists of acute toxicity studies on fish. No long-term testing on fish is therefore proposed*."

6.2. Assessment of the information provided

6.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

81 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

82 Your adaptation is therefore rejected.

83 On this basis, the information requirement is not fulfilled.

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

6.3. Study design and test specifications

85 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.).

86 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 5.3.

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

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 06 July 2021.

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

ECHA took into account your comments and amended the deadline.

In your comments, you requested an extension of deadline from 18 months to 30 months. The deadline of the draft decision was 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: 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 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]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[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[3].

(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[4].

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