~~Confidential~~

Helsinki, 01 September 2023

Addressee(s)
Registrant(s) of JS_26591-72-0 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
20/07/2022

Registered substance subject to this decision ("the Substance")
Substance name: 3-methyl-1-vinyl-1H-imidazolium methyl sulphate
EC number/List number: 247-832-2

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 ***8 December 2026***.

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

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

1. Growth inhibition study on aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3/OECD TG 201).

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

2. Simulation testing on ultimate degradation in surface water, also requested below (triggered by Annex VIII, Section 9.2.);

3. Identification of degradation products, also requested below (triggered by Annex VIII, Section 9.2.);

4. Bioaccumulation in aquatic species, also requested below (triggered by Annex VIII, Section 9.3., Column 2.).

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

5. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats;

6. 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);

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

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

9. 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;

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

11. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: EU C.13/OECD TG 305), aqueous or dietary exposure.

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.

In the requests above, the same study has been requested under different Annexes. This is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the standard information requirement is not met and the specification of the study design are provided. Only one study is to be conducted; all registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 of REACH.

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

[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)
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

Appendix 1: Reasons for the request(s)

Contents

Reasons common to several requests

0.1. Substance-tailored exposure-driven testing adaptation rejected

1 You have adapted the following standard information requirement(s) under Annex XI, Section 3.2 (b) substance-tailored exposure-driven testing, for the following information requirements:

- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Simulation testing on ultimate degradation in surface water (triggered by Annex VIII, Section 9.2., Column 2)
- Identification of degradation products (triggered by Annex VIII, Section 9.2., Column 2)
- Bioaccumulation in aquatic species (triggered by Annex VIII, Section 9.3., Column 2)
- Long-term toxicity to aquatic invertebrates (Annex IX, Section 9.1.5.)
- Long-term toxicity to fish (Annex IX, Section 9.1.6.)
- Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)
- Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

2 Furthermore, based on your comments to the draft decision, although not explicitly claimed, ECHA understands that you also intend to apply Annex XI, Section 3.2(b) adaptation for:

- Identification of degradation products (Annex IX, Section 9.2)

3 To support your adaptation you have provided the following information:

(i) *"According to section 3.2 (b)(…), testing in accordance with (…) Annex IX and Annex X may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report, if the manufacturer demonstrates and documents for all relevant scenarios throughout the life cycle strictly controlled conditions as set out in Article 18 (4) (a) to (f) apply. In accordance with article 18 (4) of REACH, means of rigorous containment, minimization technologies are applied by the registrant to minimize emissions into the environment during the manufacturing and use process which are further described in the document attached (…)"*;

(ii) A justification document in which you further describe:

- Processes applied in the manufacture and the use of the Substance as monomer for polymerisation
- Means of rigorous containment and minimisation technologies
- Technical equipment to rigorously contain the Substance
- Operative measures and management systems to minimize emissions
- Special procedures applied for sampling, filling as well as before cleaning and maintenance
- PPE used when handling hazardous substances
- Emergency and incident responses
- Waste information

(iii) You further state: *"According to Article 18 (4 a-f) of REACh Regulation (EC) No. 1907/2006 throughout the life cycle of the substance strictly controlled conditions are applied. Consequently, an environmental-related exposure assessment and risk characterization is not required."*

4 A substance-tailored exposure-driven testing adaptation must fulfil the cumulative conditions set out under Annex XI, Sections 3(1) as well as 3(2)(b).

0.1.1. Lack of or incomplete exposure assessment

5 Under Annex XI, Sections 3(1) and (2), testing may be omitted based on the exposure scenario(s) developed in the chemical safety report (CSR) by providing an adequate and scientifically supported justification based on a thorough and rigorous exposure assessment.

6 This also applies to monomers in polymer for which the justification must cover in particular absence of unreacted monomers and demonstration that the polymer does not degrade to monomers under use or waste stage (see Guidance for monomers and polymers, April 2012, Version 2.0), in particular Sections 2.2, 3.2.1 and 4.2, and the decision of Board of Appeal for A-001-2020 (in particular paragraphs 109 and 110).

7 You state that the Substance is only used as monomer in the production of polymers.

8 Your claim that "traces of the substance will remain as an unwanted impurity in the final polymer in concentrations typically below 100 ppm" (i.e. <0.01%). You have not claimed nor provided documentary evidence (e.g. laboratory report or reference to literature) confirming that the total concentration of the residual unreacted monomer in the polymer is absent.

9 Furthermore, you have not demonstrated that the polymer does not degrade into the registered monomer under normal use, environmental conditions and/or waste stage.

10 You have not considered the presence of, and exposure to, unreacted (unbound) monomer which may remain or could be re-formed in the polymer, i.e. the quantities of the monomer substance which did not react during the polymerisation reaction and remained in the composition of the polymer or can be formed as a result of degradation of the polymer.

11 Therefore, the CSR does not contain a chemical risk assessment covering all relevant exposures of the entire life cycle of the (monomer) substance subject to this decision.

12 You have not provided an adequate and scientifically supported justification.

13 In your comments to the draft decision you provide further theoretical explanations based on thermodynamics and actual measurements of the Substance in polymer products covering production batches in the period 2008 to 2023.

14 The additionally provided information addresses the issue above. However, since the information is currently not available in your dossier, the issue remains. You remain responsible for complying with this decision by the set deadline.

0.1.2. Strictly controlled conditions not demonstrated

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

16 You have provided a claim of strictly controlled conditions. Among others, you describe the following conditions of use:

- The substance is transferred mainly via pipes. However, you state that transfer could also happen via filling into sealed packaging. There is no explicit information on whether the Substance is contained during filling. In your comments to the draft decision, you explain that the Substance is not volatile and that therefore evaporation to air is negligible. You also state that "*technical measures are in place to avoid aerosol formation during filling*". However, you do not explain further what exactly those technical measures are. You indicate that filling is done at a filling station, but without further details the absence of releases during filling is not demonstrated.
- Flexible hose connections are used for the transfer to the filling stations. Flexible hose connections are unlikely to guarantee strictly controlled conditions. No information is provided on how much and how often filling into sealed packaging is used instead of transfer via pipes.
- The off gas of the reactor as well as the waste gas from the sampling systems and filling stations are treated with scrubbers. However no details are provided, e.g. on the type of scrubbers (e.g. wet or dry, based on water). There is also no information provided on how the scrubber solution or adsorber is treated. In your comments to the draft decision, you explain that the Substance is not volatile at room temperature and that therefore evaporation to air is negligible at room temperature. Therefore, the Substance is not expected to end-up in scrubbers. The additional information can address this part of the issue. However, since the information is currently not available in your dossier, the issue remains.
- Part of the waste gas from the sampling systems and filling stations can be vented into the atmosphere, without treatment. This contradicts the requirements for SCC. Details on how much and how often venting into the atmosphere could happen are not provided. In your comments to the draft decision, you refer, as above, to the substance not being volatile and that evaporation to air is negligible. However, contrary to the previous point, it is not clear at what temperature the Substance is handled or how aerosol formation is avoided in practice. Therefore, you did not demonstrate that the Sustance is absent from the waste gas.
- During cleaning, the vessels are rinsed, and residual materials are emptied. No information is provided on how the cleaning medium and the residual materials are further handled and treated. In your comments to the draft decision, you explain that some of the wastewater generated during cleaning processes is sent to incineration. However, you also mention that some wastewater is not subject to incineration and can be released to a sewage treatment plant. Therefore, the issue remains.
- No information is provided on whether wastewater is generated and on how it is treated. Based on the documentation provided, potential releases to wastewater cannot be ruled out (e.g. from cleaning/maintenance or from scrubber solutions). In your comments to the draft decision, you provide some information as explained under the previous point. In particular, you mention that part of the wastewater from cleaning processes can end up in a sewage treatment plant.
- For the handling of waste, you indicate that the "*requirements from European and National waste legislation*" are followed. However, no information is provided on the exact procedures applied, e.g. on how waste is collected and treated. In the comments to the draft decision, you provide information as explained under the previous point and the additional information does not address the issue. Therefore, the issue remains.

- You state that "*the production processes are continuously monitored (in safety and environmental terms)*". However, no actual monitoring data are provided to demonstrate the absence of environmental releases. In your comments to the draft decision, you explain that wastewater is monitored continuously via TOC measurement. However, TOC measurement is neither a substance specific nor a sensitive analytical method. It is therefore insufficient to demonstrate the absence of the Substance in the wastewater.
- No mass balance is provided (e.g. how much of the Substance is transformed into the other manufactured substance(s), how much is recycled, disposed as waste etc.). In your comments to the draft decision you do not provide a mass balance and the information provided is insufficient to establish a mass balance and therefore the issue is not addressed.

17 Based on the above, the provided information on operational conditions are either not described in sufficient detail to allow a conclusion on whether strictly controlled conditions are met or they even contradict with those.

18 Moreover, the additional information provided in your comments to the draft decision do not address all issues as listed above.

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

0.1.3. Conclusion on the substance-tailored exposure driven testing adaptation

20 Based on the above, your substance-tailored exposure driven testing adaptation under Annex XI, Section 3. is rejected.

Reasons related to the information under Annex VII of REACH

1. Growth inhibition study aquatic plants

21 Growth inhibition study on aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

1.1. Information provided

22 You have provided:

(i) a growth inhibition study on aquatic algae (1990) with the Substance.

1.2. Assessment of the information provided

1.2.1. The provided study does not meet the specifications of the test guideline(s)

23 To fulfil the information requirement, a study must comply with OECD TG 201 (Article 13(3) of REACH). Therefore, the following specifications must be met:

Validity criteria

a) at least 16-fold increase in biomass is observed in the control cultures by the end of the test;

b) the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;

c) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Desmodesmus subspicatus*;

Characterisation of exposure

d) analytical monitoring must be conducted. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;

Reporting of the methodology and results

e) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;

f) microscopic observation performed to verify a normal and healthy appearance of the inoculum culture are reported. Any abnormal appearance of the algae at the end of the test is reported;

24 In study (i):

Validity criteria
No information is provided on:

a) the biomass at the start and end of the test, respectively;

b) the mean coefficient of variation for section-by-section specific growth in the control;

c) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures;

Characterisation of exposure

d) no analytical monitoring of exposure was conducted;

Reporting of the methodology and results

e) tabulated data on the algal biomass determined daily for each treatment group and control are not reported;

f) microscopic observations to verify a normal and healthy appearance of the inoculum culture are not reported;

25 Based on the above,

- ECHA is not in the position to assess whether the validity criteria of OECD TG 201 listed under a) to c) are met
- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, in the absence of analytical monitoring of the exposure concentrations (d) it cannot be confirmed that test concentrations were stable during the course of the study. Therefore, the derived effect concentrations based on nominal concentrations are not reliable and the hazard can be underestimated.
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, in the lack of information on e) and f) ECHA cannot verify that the specifications of OECD 201 were met.

26 On this basis, the specifications of OECD TG 201 are not met.

27 Therefore, the information requirement is not fulfilled.

Reasons related to the information under Annex VIII of REACH

2. Simulation testing on ultimate degradation in surface water

28 Under Annex VIII, Section 9.2., Column 2, further information on degradation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the degradation of the substance.

2.1. Triggering of the information requirement

29 Therefore, this information requirement is triggered in case if for example additional information on degradation as set out in Annex XIII, point 3.2.1, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex. This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as:
  - it is not readily biodegradable (i.e. <60/70% degradation in an OECD TG 301 study), and
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - for some groups of substances (e.g. organometals, substances present in their ionised form, surfactants) other partitioning mechanisms may drive bioaccumulation (e.g. binding to protein/cell membranes) and high potential for bioaccumulation cannot be excluded solely based on its potential to partition to lipid.

30 Your registration dossier provides the following:

- the Substance is not readily biodegradable (25% degradation after 28 days in a study similar to OECD TG 301 E);
- the Substance is present in its ionised form at environmentally relevant conditions and therefore high potential for bioaccumulation cannot be excluded based on available information.

31 Furthermore:

- it is not possible to conclude on the bioaccumulation potential of the Substance (see request 11 of this decision), and
- it is not possible to conclude on the toxicity of the Substance (see request 5, 6, 7, 8 of this decision).

32 Based on the above, the available information on the Substance indicates that it is a potential PBT/vPvB substance.

33 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

2.2. Information requirement not fulfilled

34 The information provided, its assessment and the specifications of the study design are addressed under request 9.

3. Identification of degradation products

35 Under Annex VIII, Section 9.2., Column 2, further information on degradation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the degradation of the substance.

3.1. Triggering of the information requirement

36 Therefore, this information requirement is triggered in case if for example additional information on degradation as set out in Annex XIII, point 3.2.1, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex.

37 As already explained in request 2, the Substance is a potential PBT/vPvB substance.

38 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

3.2. Information requirement not fulfilled

39 The information provided, its assessment and the specifications of the study design are addressed under request 10.

4. Bioaccumulation in aquatic species

40 Under Annex VIII, Section 9.3., Column 2, further information on bioaccumulation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the bioaccumulation properties of the substance.

4.1. Triggering of the information requirement

41 Therefore, this information requirement is triggered in case if for example additional information on bioaccumulation as set out in Annex XIII, point 3.2.2., is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1. of that Annex.

42 As already explained in request 2, the Substance is a potential PBT/vPvB substance.

43 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, soil represents a relevant environmental compartment.

4.2. Information requirement not fulfilled

44 The information provided, its assessment and the specifications of the study design are addressed under request 11.

Reasons related to the information under Annex IX of REACH

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

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

5.1. Information provided

46 You have adapted this information requirement by using Annex XI, Section 3. (substance-tailored exposure-driven testing). To support the adaptation, you have provided the information summarised under section 0.1.

5.2. Assessment of the information provided

5.2.1. Substance-tailored exposure-driven testing adaptation rejected

47 As explained in Section 0.1., your adaptation based on exposure-based waiving under Annex XI, Section 3. is rejected.

48 Therefore, the information requirement is not fulfilled.

5.3. Specification of the study design

49 Following the criteria provided in Annex IX, Section 8.6.2., Column 2, and considering the Guidance on IRs and CSA, Section R.7.5.6.3.2., the oral route is the most appropriate route of administration to investigate repeated dose toxicity of the Substance.

50 According to the OECD TG 408, the rat is the preferred species.

51 Therefore, the study must be performed in rats according to the OECD TG 408 with oral administration of the Substance.

6. Pre-natal developmental toxicity study in one species

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

6.1. Information provided

53 You have adapted this information requirement by using Annex XI, Section 3. (substance-tailored exposure-driven testing). To support the adaptation, you have provided the information summarised under section 0.1.

6.2. Assessment of the information provided

6.2.1. Substance-tailored exposure-driven testing adaptation rejected

54 As explained in Section 0.1., your adaptation based on exposure-based waiving under Annex XI, Section 3. is rejected.

55 Therefore, the information requirement is not fulfilled.

6.3. Specification of the study design

56 A PNDT study according to the test method OECD TG 414 should be performed in rat or rabbit as preferred species.

57 As the Substance is a solid, the study must be conducted with oral administration of the Substance (Annex IX, Section 8.7.2, Column 1).

58 Therefore, the study must be conducted in rats or rabbits with oral administration of the Substance.

7. Long-term toxicity testing on aquatic invertebrates

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

7.1. Information provided

60 You have adapted this information requirement by using Annex XI, Section 3. (substance-tailored exposure-driven testing). To support the adaptation, you have provided the information summarised under section 0.1 of this decision.

7.2. Assessment of the information provided

7.2.1. Substance-tailored exposure-driven testing adaptation rejected

61 As explained in Section 0.1., your adaptation based on exposure-based waiving under Annex XI, Section 3. is rejected.

62 Therefore, the information requirement is not fulfilled.

8. Long-term toxicity testing on fish

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

8.1. Information provided

64 You have adapted this information requirement by using Annex XI, Section 3. (substance-tailored exposure-driven testing). To support the adaptation, you have provided the information summarised under section 0.1 of this decision.

8.2. Assessment of the information provided

8.2.1. Substance-tailored exposure-driven testing adaptation rejected

65 As explained in Section 0.1., your adaptation based on exposure-based waiving under Annex XI, Section 3. is rejected.

66 Therefore, the information requirement is not fulfilled.

8.3. Study design and test specifications

67 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.).

9. Simulation testing on ultimate degradation in surface water

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

9.1. Information provided

69 You have adapted this information requirement by using Annex XI, Section 3. (substance-tailored exposure-driven testing). To support the adaptation, you have provided the information summarised under section 0.1 of this decision.

9.2. Assessment of the information provided

9.2.1. Substance-tailored exposure-driven testing adaptation rejected

70 As explained in Section 0.1., your adaptation based on exposure-based waiving under Annex XI, Section 3. is rejected.

71 Therefore, the information requirement is not fulfilled.

9.3. Study design and test specifications

72 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.

73 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.).

74 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.

75 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. Paragraph 52 of the OECD TG 309 provides that the "total recovery (mass balance) at the end of the experiment should be between 90% and 110% for radiolabelled substances, whereas the initial recovery at the beginning of the experiment should be between 70% and 110% for non-labelled substances". NERs contribute towards the total recovery. Therefore, the quantity of the (total) NERs must be accounted for the total recovery (mass balance), when relevant, to achieve the objectives of the OECD TG 309 to derive degradation rate and half-life. The reporting of results must include a scientific justification of the used extraction procedures and solvents.

76 For the persistence assessment by default, total NERs is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NERs may be differentiated and quantified as irreversibly bound or as degraded to biogenic NERs, 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 (NER - summary 2019 (europa.eu)).

77 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.).

10. Identification of degradation products

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

79 You have not submitted any information for this requirement.

80 In your comments to the draft decision, although not explicitly stated, ECHA understands that you intend to adapt this information requirement under Annex XI, Section 3(2)(b).

81 As explained in section 0.1.2 of this decision, you have not demonstrated that the conditions of strictly controlled conditions are met for the Substance. Consequently, the conditions of Annex XI, Section 3(2)(b) are not met and your adaptation is rejected.

82 Therefore, the information requirement is not fulfilled.

10.1. Study design and test specifications

83 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.

84 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.

85 You must obtain this information from the degradation study requested in request 9.

86 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request 9) 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).

11. Bioaccumulation in aquatic species

87 Bioaccumulation in aquatic species is an information requirement under Annex IX to REACH (Section 9.3.2.).

11.1. Information provided

88 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.3.2.(low potential for bioaccumulation). To support the adaptation, you have provided following information:

(i) "*The study does not need to be conducted because the substance has a low potential for bioaccumulation based on log Kow <=3 and a low potential to cross biological membranes*";

(ii) "*Due to the ionic properties of this ionic liquid under environmental relevant conditions (pH 5 to 9), the log D was calculated (…). The log D was calculated to be clearly below 3 at pH 5 to 9. Regarding these values, accumulation of the test substance in organisms is not to be expected.*"

89 In addition, you have adapted this information requirement by using Annex XI, Section 3. (substance-tailored exposure-driven testing). To support the adaptation, you have provided the information summarised under section 0.1 of this decision.

11.2. Assessment of the information provided

11.2.1. The log K_{ow} or the log D is not a valid descriptor of the bioaccumulation potential of the Substance

90 Under Section 9.3.2., Column 2, first indent of Annex IX to REACH, the study may be omitted if the substance has a low potential for bioaccumulation and/or a low potential to cross biological membranes.

91 A low log K_{ow} (i.e. log K_{ow} < 3) on its own may be used to show low potential for bioaccumulation only if the potential for bioaccumulation of the substance is solely driven by lipophilicity. This excludes, for example, situations where the substance is surface active or present in ionised form at environmental pH (pH 4 – 9).

92 Your registration dossier provides an adaptation stating that the log K_{ow} is < 3 and log D is < 3 at pH 5 – 9.

93 The Substance is as salt and hence present in ionised form at environmentally relevant conditions.

94 Therefore, log K_{ow} as well as log D, derived therefrom, are not valid descriptors of the bioaccumulation potential of the Substance. This is because other bioaccumulation mechanisms than partition to lipid cannot be ruled out based on these values. Therefore, your adaptation is rejected.

11.2.2. Substance-tailored exposure-driven testing adaptation rejected

95 As explained in Section 0.1., your adaptation based on exposure-based waiving under Annex XI, Section 3. is rejected.

96 Therefore, the information requirement is not fulfilled.

11.3. Study design and test specifications

97 Bioaccumulation in fish: aqueous and dietary exposure (Method EU C.13 / OECD TG 305) is the preferred test to investigate bioaccumulation (Guidance on IRs and CSA, Section R.7.10.3.1.). Exposure via the aqueous route (OECD TG 305-I) must be conducted unless it can be demonstrated that:

- a stable and fully dissolved concentration of the test material in water cannot be maintained within ± 20% of the mean measured value, and/or
- the highest achievable concentration is less than an order of magnitude above the limit of quantification (LoQ) of a sensitive analytical method.

98 This test set-up is preferred as it allows for a direct comparison with the B and vB criteria of Annex XIII of REACH.

99 You may only conduct the study using the dietary exposure route (OECD 305-III) if you justify and document that testing through aquatic exposure is not technically possible as indicated above. You must then estimate the corresponding BCF value from the dietary test data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO(2017)16).

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

The compliance check was initiated on 02 May 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 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: Addressee(s) of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[2].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. Test material

(1) Selection of the Test material(s)

The 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.

(2) Information on the Test Material needed in the updated dossier

- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers (https://echa.europa.eu/manuals).

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

2. General recommendations for conducting and reporting new tests

2.1. Strategy for the PBT/vPvB assessment

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. You must assess the PBT properties of each relevant constituent of the Substance present in concentrations at or above 0.1% (w/w) and of all relevant transformation/degradation products. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

You are advised to consult Guidance on IRs & CSA, Sections R.7.9, R.7.10 and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

In particular, you are advised to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation. When determining the sequence of simulation degradation testing you are advised to consider the intrinsic properties of the Substance, its identified uses and release patterns as these could significantly influence the environmental fate of the Substance. You must revise your PBT assessment when the new information is available.