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Helsinki, 28 October 2020

Addressees
Registrant(s) of **Imidazolium compounds, 2-C17-unsatd.-alkyl-1-(2-C18-unsatd. amidoethyl)- 4,5-dihydro-N-methyl, Me sulfates, CAS No N/A (EC No 931-745-8)** listed in the last Appendix of this decision

Registered substance subject to this decision (the Substance)
Substance name: **Imidazolium compounds, 2-C17-unsatd.-alkyl-1-(2-C18-unsatd. amidoethyl)- 4,5-dihydro-N-methyl, Me sulfates**
EC number: **931-745-8**
CAS number: Not available

Decision number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F)

DECISION ON SUBSTANCE EVALUATION

Under Article 46 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below using the Substance:

A. Information required to clarify the potential risk related to sediment toxicity.

1. Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment (test method: OECD TG 225).

B. Information required to clarify the potential risk related to toxicity to soil organisms

1. Terrestrial plants, growth test (Test method: ISO 22030)
2. Enchytraeid reproduction test (Test method: OECD TG 220) or Earthworm reproduction test (test method: OECD TG 222)

Deadlines

The information must be submitted by **04 November 2021**.

Conditions to comply with the information requested

To comply with this decision, you must submit the information in an updated registration dossier, by the deadlines indicated above. The information must comply with the IUCLID robust study summary format. You must also attach the full study report for the corresponding study/ies in the corresponding endpoint of IUCLID.

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You must update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You will find the justifications for the requests in this decision in the Appendices entitled 'Reasons to request information to clarify the potential risk'.
You will find the procedural steps followed to reach the adopted decision and some technical guidance detailed in further Appendices.

Appeal

This decision 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] by Christel Schilliger-Musset, 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.

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Basis for substance evaluation

The objective of substance evaluation under REACH is to allow for the generation of further information on substances suspected of posing a risk to human health or the environment ('potential risk').

ECHA has concluded that further information on the Substance is necessary to enable the evaluating Member State Competent Authority (MSCA) to clarify a potential risk and whether regulatory risk management is required to ensure the safe use of the Substance.

The ECHA decision requesting further information is based on the following:

(1) There is a potential risk to human health or the environment, based on a combination of hazard and exposure information;
(2) Information is necessary to clarify the potential risk identified; and
(3) There is a realistic possibility that the information requested would allow improved risk management measures to be taken.

The Appendices entitled 'Reasons to request information' describe why the requested information are necessary and appropriate.

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Appendix A – Reasons to request information to clarify the potential risk related to toxicity to sediment living organisms.

1. Potential risk

1.1 Potential hazard of the Substance

Following its assessment of the available relevant information on the Substance, the evaluating MSCA and ECHA have identified the following potential hazard(s) which must be clarified.

a) Toxicity to sediment living organisms

The available information suggest that the Substance may be hazardous to sediment living organisms.

You have waived sediment toxicity studies with the following argument: *In accordance with column 2 of REACH Regulation, Annex X, section 9.5.1, long- term toxicity testing with sediment organisms does not need to be conducted. Testing shall be proposed if the results of the environmental exposure and risk assessment indicate the need. The need for testing is not indicated.*

ECHA do not agree to your waiving statement. Imidazolium compounds, 2-C17-unsatd.-alkyl-1-(2-C18-unsatd. amidoethyl)-4,5-dihydro-N-methyl, Me sulfates has a high adsorption potential and is emitted to surface water and thus sediment living organisms are exposed. You have derived a PNEC for sediment from the aquatic PNEC of 10 µg/l using the equilibrium partitioning method (EPM) and derived a PNEC for freshwater sediment of 503 mg/kg dw and a PNEC marine sediment of 10.1 mg/kg dw. Using these PNECs you have derived risk characterisation ratios (RCR) for freshswater- and marine sediment. Applying an extra factor of 10 to take account of ingestion of sediment the RCRs for freshwater sediment range from [redacted] to [redacted]. For marine sediment they range from [redacted] to [redacted]. The three highest ratios are [redacted], [redacted] and [redacted] for manufacture of the Substance, manufacture of pulp, paper and paper products and professional use of vehicle cleaning products, respectively.

You derived the aquatic PNEC from a study on a read across substance partially unsaturated IQAC, DMS quaternised CAS No 86088-85-9 for which a chronic NOEC of 0.1 mg/l for algae (*Desmodesmus subspicatus*) was estimated. In this study the algae were exposed to the effluents from a model activated sludge unit fed with the substance.

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The effluents were not characterised and the exposure concentration was only theoretically estimated. The evaluating MSCA considered this study invalid due to the fact that the exposure concentration was unknown and consequently these results should not be used to derive the aquatic PNEC for the substance.

There are three long term studies performed on the Substance. A long-term study on *Daphnia magna* and two studies with the algae *Pseudokirchnerella subcapitata*. The study on Daphnia was semistatic with medium renewals every 48 h. The measured average concentration 48 h after renewal was 66% of the initially measured concentration. ECHA therefore considers that the effect parameters should be based on time weighted average concentrations (TWA). The NOEC for reproduction was 112 µg/ (TWA) which was the highest dose tested. The mortality at highest tested dose was 20% resulting in a NOEC for mortality of 36.7 µg/l (TWA). The NOECs (growth rate) from the the two algae studies were 178 µg/l and 30 µg/l, respectively both based on nominal concentrations. ECHA therefore considers these studies less reliable. The NOEC from the first study may be an underestimation of the toxicity given the decrease in test concentration seen in the Daphnia study. The second study, on the other hand, may overestimate the toxicity. The test substance in the second study contained 24% isopropanol. Isopropanol is virtually non-toxic to algae but may have affected the bioavailability of the test substance. ECHA therefore considers that the NOEC from the Daphnia study of 36.7 µg/l (TWA) should be used for derivation of the aquatic PNEC. Applying an assessment factor of 10 this gives a PNEC of 3.7 µg/l.

The EPM derived PNECs for sediment based on the aquatic PNEC of 3.7 µg/l are 181 mg/kg dw for freshwater sediment and 3.6 mg/kg dw for marine sediment.

Using these PNECs and the PECs estimated by you results in RCRs for freshwater sediment ranging from [redacted] to [redacted]. For marine sediment the RCRs range from [redacted] to [redacted]. The three highest ratios being [redacted], [redacted] and [redacted] for manufacture of the Substance, manufacture of pulp, paper and paper products and professional use of vehicle cleaning products, respectively. Thus, the need for sediment toxicity testing is indicated.

Furthermore, the Substance is a cationic surfactant and ECHA recognises that the equilibrium partitioning method is not recommended for surfactants. This was overlooked in the decision from February 2017. ECHA guidance on information requirements and chemical safety assessment, chapter R7b (v.4.0, June 2017) states: *EPM is based on sorption to organic matter. Therefore, it cannot be used for some classes of substances, e.g. when binding behaviour is not driven by lipophilicity (e.g. aromatic amines forming*

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covalent bonds to sediment components, ionisable substances, surface active substances. The available study on adsorption confirms that the substance has a high adsorption potential and that the adsorption is correlated to the amount of clay and silt of the soils and less so to organic carbon. PNEC sediment derived by applying the EPM is therefore not considered reliable for the Substance.

The testing is needed in order to derive a more reliable $PNEC_{sed}$ and to refine the risk characterisation ratios of the risk assessment. Without the requested information it will not be possible to verify whether there remains an uncontrolled risk with the substance that should be subject to further risk management measures.

The available and current information is not sufficient to draw a conclusion on the hazard. Further information is needed on toxicity to sediment living organisms.

1.2 Potential exposure

According to the information you submitted in all registration dossiers, the aggregated tonnage of the Substance manufactured or imported in the EU is in the range of 100 – 1000 tonnes per year.

Furthermore, you reported that among other uses, the Substance is used in vehicle cleaning products, polishes and wax blends, textiles and in the production of paper. The Substance can be released to the environment as emissions from manufacturing plants, emissions from industrial and professional facilities using the Substance and from consumer uses leading to emissions to municipal waste water treatment plants.

Therefore exposure of sediments cannot be excluded.

1.3 Identification of the potential risk to be clarified

Based on all information available in the registration dossier and information from the published literature, the Substance may constitute a risk for sediment organisms.

The information you provided on manufacture and uses demonstrates a potential for exposure of the environment.

Based on this hazard and exposure information the Substance poses a potential risk to the environment.

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As explained in Section 1.1 above, the available information is not sufficient to conclude on the hazard and in particular on the toxicity to sediment organisms. Consequently further data is needed to clarify the potential risk related to toxicity to sediment living organisms.

1.4 Further risk management measures

If the properties(s) of the Substance are confirmed, the evaluating MSCA will analyse the options to manage the risk(s). New regulatory risk management measures could be restrictions of the use of the Substance for risks for the sediment compartment. This would result in stricter risk management measures, such as improved measures at manufacturing sites, better waste management and revised instructions on safe use, if appropriate.

2. How to clarify the potential risk

2.1 Request A.1 Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment (test method: OECD TG 225)

a) Aim of the study

The aim of the required testing is to provide better information on the toxicity of the Substance to sediment living organisms and thus enable derivation of a more reliable PNEC for sediment.

The OECD TG 225 is a standard information requirement at Annex X, Section 9.5.1 of REACH which may be subject to a compliance check under Article 41 of REACH. However, as you have registered the Substance at the Annex IX level, the study is not a standard information requirement for which a compliance check could be launched. In addition, as you are the only addressee of this decision, your rights and obligations are not prejudiced by the choice of the process. Therefore, the information is requested under the current substance evaluation.

b) Specification of the requested study

Test material and concentration

The test shall be performed with the Substance and the test concentrations must be choosen so that reliable EC50- and NOEC –values can be derived. The test shall be performed with formulated sediment as recommended in the guideline.

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Request for the full study reports

You must submit the full study reports which includes:

- a complete rationale of test design and
- interpretation of the results
- access to all information available in the full study report, such as implemented method, raw data collected, interpretations and calculations, consideration of uncertainties, argumentation, etc.

This will enable the evaluating MSCA to fully and independently assess all the information provided, including the statistical analysis, and to efficiently clarify the potential hazard for sediment organisms.

c) Alternative approaches and how the request is appropriate to meet its objective

The request is:

- Appropriate, because the test is necessary to obtain data on toxicity to sediment living organisms which is needed for a more reliable estimation of the risks to sediment living organisms. The Substance adsorbs strongly to sediment and sediment living organisms that ingest sediment will therefore be exposed not only via the pore water. Testing on Lumbriculus which is a sediment ingesting species is therefore considered appropriate.
- The least onerous measure because there is no equally suitable alternative methodology available that would clarify the potential hazard.

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Appendix B – Reasons to request information to clarify the potential risk related to toxicity to soil organisms.

1. Potential risk

1.1 Potential hazard of the Substance

Following its assessment of the available relevant information on the Substance, the evaluating MSCA and ECHA have identified the following potential hazard(s) which must be clarified.

a. Toxicity to soil organisms

The available information suggest that the Substance may be hazardous to soil organisms.

You have waived terrestrial toxicity studies with the argument that the results of the chemical safety assessment does not indicate a need for testing. The risk assessement is based on a PNEC for soil that you have derived by applying the EPM on the PNEC you have derived for aquatic toxicity. The RCR ratios derived using this PNEC and applying a factor of 10 to take the ingestion of soil into account are all well below 1. You therefore consider that toxicity testing of soil organisms is not necessary. ECHA considers this waiving argumentation invalid.

Imidazolium compounds, 2-C17-unsatd.-alkyl-1-(2-C18-unsatd. amidoethyl)-4,5-dihydro-N-methyl, Me sulfates is a cationic surfactant, highly adsorptive and very toxic to aquatic organsims. Thus it fulfils the criteria of Hazard category 4 according to REACH guidance R.7c. According to this guidance screening assessment based on the equilibrium partitioning method is not recommended for Hazard category 4 substances as the intrinsic properties indicate a high hazard potential to soil organisms. In particular for substances that have a high potential to adsorb to soil or that are very persistent, long-term toxicity testing instead of short-term toxicity testing is recommended.

You have not followed the recommendations in the guidance and have derived a PNEC for soil from the aquatic PNEC of 10 µg/l using the equilibrium partitioning method. Therefore, in the absence of reliable toxicity data on soil organsims the concern remains.

The testing is needed in order to derive a more reliable PNEC for soil and to refine the risk characterisation ratios of the risk assessment. Without the requested information it will not be possible to verify whether there remains an uncontrolled risk with the Substance that should be subject to further risk management measures.

The available and current information is not sufficient to draw a conclusion on the hazard. Further information is needed on toxicity to soil organisms.

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1.2 Potential exposure

According to the information you submitted in all registration dossiers, the aggregated tonnage of the Substance manufactured or imported in the EU is in the range of 100 – 1000 tonnes per year.

Furthermore, you reported that among other uses, the Substance is used in vehicle cleaning products, polishes and wax blends, textiles and in the production of paper. The Substance can be released to the environment as emissions from manufacturing plants, emissions from industrial and professional facilities using the substance and from consumer uses leading to emissions to municipal waste water treatment plants adsorption to sewage sludge and subsequent distribution to agricultural as fertiliser.

Therefore exposure to the soil environment cannot be excluded.

1.3 Identification of the potential risk to be clarified

Based on all information available in the registration dossier and information from the published literature, the Substance may constitute a risk for soil organisms.

The information you provided on manufacture and uses demonstrates a potential for exposure of the environment.

Based on this hazard and exposure information the substance poses a potential risk to the environment.

As explained in Section 1.1 above, the available information is not sufficient to conclude on the hazard and in particular on the toxicity to soil organisms. Consequently further data is needed to clarify the potential risk related to toxicity to soil organisms.

1.4 Further risk management measures

If the properties(s) of the Substance are confirmed, the evaluating MSCA will analyse the options to manage the risk(s). New regulatory risk management measures could be restrictions of the use of the Substance for risks for the soil compartment. This would result in stricter risk management measures, such as improved measures at manufacturing sites, better waste management and revised instructions on safe use, if appropriate.

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2. How to clarify the potential risk

2.2 Request B.1 Toxicity to terrestrial plants (test method: ISO 22030) Request B.2 Enchytraeid reproduction test (test method: OECD TG 220) or Earthworm reproduction test (test method: OECD TG 222)

a) Aim of the studies

The aim of the required testing is to provide better information on the toxicity of the substance to soil organisms and thus enable derivation of a more reliable PNEC for soil.

The requested toxicity to terrerstrial plants (ISO 22030), Enchytraeid reproduction test (OECD TG 220), and Earthworm reproduction test (OECD TG 222) are standard information requirements at Annex IX (Column 2) and Annex X, Section 9.4 of REACH which may be subject to a compliance check under Article 41 of REACH. However, since the information request is based on a potential risk identified, the substance evaluation is an appropriate process in the present case. In addition, as you are the only addressee of this decision, your rights and obligations are not prejudiced by the choice of the process. Therefore, the information is requested under the current substance evaluation.

b) Specification of the requested studies

Test material and concentration

The tests shall be performed with the Substance according to the guidelines. The test concentrations must be chosen so that reliable EC50- and NOEC –values can be derived.

Request for the full study report

You must submit the full study report which includes:

- a complete rationale of test design and
- interpretation of the results
- access to all information available in the full study report, such as implemented method, raw data collected, interpretations and calculations, consideration of uncertainties, argumentation, etc.

This will enable the evaluating MSCA to fully and independently assess all the information provided, including the statistical analysis, and to efficiently clarify the potential risk for soil organsims.

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c) Alternative approaches and how the request is appropriate to meet its objective

The request is:

- Appropriate, because the test is necessary to obtain data on toxicity to soil organisms which is needed for a more reliable estimation of the risks to soil organisms. The Substance adsorbs strongly to soil organisms exposed.
- The least onerous measure, because there is no equally suitable alternative methodology available that would clarify the potential hazard.

d) Consideration of the time needed to perform the requested studies

In your comments on the draft decision, you requested an extension of the timeline to 18 months. You sought to justify this request based on the following time estimation:

Clarification of quotational issues, arrangement of purchase order/ shipment of test sample	2 months
Time needed for planning time in advance of the study	2 months
Pre-test (for the plant study)	2 months
Main study	8 months
Finalisation of draft report	1-2 months
Update of dossier and risk assessment	2-3 months

Furthermore, you provided supporting information from the contract laboratory, which estimates the net time required for the testing, including the pre-test, to be 7-8 months. Additionally, they estimate that the time needed for test item receipt and management would account for a further 2 months. They also consider that COVID 19 may cause unforeseeable delays and therefore estimate the total time to 11-12 months.

The ECHA standard deadline of 9 months for a plant test is based on OECD test guideline 208 "*Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test*". This deadline includes three months for administrative aspects. ECHA acknowledges that the ISO 22030 test including the pre test is more time consuming and requires a test period of 7-8 months, as indicated by the contract laboratory. Adding to this 3 months for the administrative work and considering that the COVID-19 situation may lead to unforeseeable delays, ECHA considers that a deadline of 12 months is justified. Therefore, ECHA has only partially granted the request and set the deadline to 12 months.

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Appendix C: Procedure

This decision does not imply that the information you submitted in your registration dossier(s) are in compliance with the REACH requirements. ECHA may still initiate a compliance check on your dossiers.

12-month evaluation

Due to initial grounds of concern for PBT/vPvB and for environmental exposure and high RCRs for the soil and sediment compartment, the Member State Committee agreed to include the Substance (EC No 931-745-8, CAS RN not available) in the Community rolling action plan (CoRAP) to be evaluated in 2014. Sweden is the competent authority ('the evaluating MSCA') appointed to carry out the evaluation.

In accordance with Article 45(4) of REACH, the evaluating MSCA carried out its evaluation based on the information in the registration dossier(s) you submitted on the Substance and on other relevant and available information.

The evaluating MSCA completed its evaluation considering that further information was required to clarify the following concerns: PBT/vPvB, environmental exposure and high RCRs for the soil and sediment compartment.

Therefore, in accordance with Article 46(1) of the REACH Regulation, a substance evaluation decision was issued on 16 February 2017 requesting further information. You submitted part of the requested information on 23 November 2018. The evaluating MSCA carried out the evaluation of the information in your updated registration(s) and other relevant and available information.

The evaluating MSCA considered that further information was required to clarify the above concerns. Therefore, it prepared a draft decision under Article 46(3) of the REACH Regulation to request further information. It subsequently submitted the draft decision to ECHA on 22 November 2019.

Decision-making

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

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(i) Registrant(s)' commenting phase

ECHA received your comments and forwarded them to the evaluating MSCA.

The evaluating MSCA took your comments into account (see Appendix B). In your comments on the draft decision, you requested an extension of the timeline from 9 months as indicated in the draft decision to 18 months. Therefore, ECHA has partially granted the request and set the deadline to 12 months.

(ii) Proposals for amendment by other MSCAs and ECHA and referral to the Member State Committee

The evaluating MSCA notified the draft decision to the competent authorities of the other Member States and ECHA for proposal(s) for amendment.
As no amendments were proposed, ECHA took the decision according to Articles 52(2) and 51(3) of REACH.

After the deadline set in this decision has passed, the evaluating MSCA will review the information you will have submitted and will evaluate whether further information is still needed to clarify the potential risk, according to Article 46(3) of REACH. Therefore, a subsequent evaluation of the Substance may still be initiated after the present substance evaluation is concluded.

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Appendix D: Technical Guidance to follow when conducting new tests for REACH purposes

Test methods, GLP requirements and reporting

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.

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.

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].

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