Helsinki, 16 February 2017

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DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For 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)

Addressees: Registrant(s)[1] of Imidazolium compounds, 2-C17-unsatd.-alkyl-1-(2-C18-unsatd. amidoethyl)-4,5-dihydro-N-methyl, Me sulfates, EC No 931-745-8, CAS No not available

This decision is addressed to the Registrant(s) of the above substance with active registrations pursuant to Article 6 of the REACH Regulation on the date on which the draft for the decision was first sent for comments. If Registrant(s) ceased manufacture upon receipt of the draft decision pursuant to Article 50(3) of the REACH Regulation, they did not become addressee(s) of the decision. A list of all the relevant registration numbers of the Registrant(s) that are addressees of the present decision is provided as an Annex to this decision.

Based on an evaluation by the Swedish Chemicals Agency as the Competent Authority of Sweden (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision is based on the registration dossier(s) on 5 May 2015, i.e. the day on which the draft decision was notified to the Registrant(s) pursuant to Article 50(1) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant(s) in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier(s) of the Registrant(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of Sweden has initiated substance evaluation for 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) based on registration(s) submitted by the Registrant(s) and other relevant and available information and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

[1] The term Registrant(s) is used throughout the decision, irrespective of the number of registrants addressed by the decision.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to PBT, environmental exposure and high RCRs for the soil and sediment compartment, Imidazolium compounds, 2-C17-unsatd.-alkyl-1-(2-C18-unsatd. amidoethyl)-4,5-dihydro-N-methyl, Me sulfates was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated 2014. The updated CoRAP was published on the ECHA website on 26 March 2014. The Competent Authority of Sweden was appointed to carry out the evaluation.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 25 March 2015.

On 5 May 2015 ECHA sent the draft decision to the Registrant(s) and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

Registrant(s) commenting phase

By 11 June 2015 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA.

The Registrant(s) questioned the need for a hydrolysis study and suggested that the hydrolysis study should only be performed if the results from the requested test on biodegradation is not sufficient to exclude that the substance is persistent. Furthermore, the Registrant(s) proposed that sediment and soil testing should be performed only if the result of an updated risk characterisation results in a risk characterisation ratio (RCR) >1. The registrant also questioned the timeline which he considered too short.

The evaluating MSCA considered the comments received from the Registrant(s). On the basis of this information section II was amended. The statement of reasons (section III) was changed accordingly.

Commenting by other MSCAs and ECHA

In accordance with Article 52(1) of the REACH Regulation, on 8 September 2016 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, two Competent Authorities of the Member States and ECHA submitted proposals for amendment (PfAs) to the draft decision.

On 14 October 2016 ECHA notified the Registrant(s) of the PfAs to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA reviewed the PfAs received and amended the draft decision accordingly.

Referral to Member State Committee

On 24 October 2016 ECHA referred the draft decision to the Member State Committee.

By 14 November 2016 the Registrant(s)' comments were provided on the proposed amendments. The Member State Committee took these comments into account. The Registrant(s) also provided comments on the draft decision not related to the proposals for amendments. These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

A unanimous agreement of the Member State Committee on the draft decision was reached on 28 November 2016 in a written procedure launched on 17 November 2016.

ECHA took the decision pursuant to Article 52(2) and 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test methods (in accordance with Article 13 (3) and (4) of the REACH Regulation) and the registered substance subject to the present decision:

1. Adsorption/Desorption using a batch equilibrium method (test method: EU C.18/OECD TG 106);

2. Ready biodegradability (test method: OECD 301 B, OECD 301 C, OECD 301 D, OECD 301 F or OECD 310). The Registrant(s) shall make sure that the test is performed at a test concentration that does not exert toxicity to the microorganisms and that adsorption does not significantly affect the bioavailability of the test substance;

3. Daphnia magna reproduction test (test method: EU C.20/ OECD TG 211). The concentrations of the test substance shall be analytically monitored during the test to verify the concentrations and stability of the test substance in the test solutions.

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall also submit the following information regarding the registered substance subject to the present decision:

4. Robust study summary for the BCF of 10.7 that is cited in the registration.

If based on the outcome of request number 2 of this decision the registered substance does not meet the criteria for being classified as ready biodegradable the following information shall be provided:

5. Hydrolysis as a function of pH (test method: EU C.7/ OECD TG 111).

If, based on the information gained as a result of the requested tests under point 1 – 3 of this decision, an updated risk characterisation for the sediment compartment using the equilibrium partitioning method (EPM) results in risk characterisation ratio (RCR) >1 the following information should be provided. The registrant is reminded to take the need for an extra factor of 10 into consideration when applying the EPM:

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

Deadline for submitting the required information

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **23 February 2018** for information requests 1 to 4 or by **23 November 2018** if the

studies according to information requests 5 and/or 6 needs to be performed, an update of the registration(s) containing the information required by this decision[2], including robust study summaries and, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

1. Adsorption/Desorption using a batch equilibrium method (test method: EU C.18/OECD TG 106)

The adsorption potential of Imidazolium compounds, 2-C17-unsatd.-alkyl-1-(2-C18-unsatd. amidoethyl)-4,5-dihydro-N-methyl, Me sulfates, has been measured using the HPLC method described in OECD guideline 121. No test substance related compounds were detected during any of the HPLC trials. The test substance was detected only when the solution was analysed in by-pass mode (i.e. without analytical column). Thus it was not possible to estimate the adsorption coefficient of the test substance. The Koc was therefore given as > 5.63 which was the adsorption coefficient of the reference substance (2,4-DDT) used in the test. A measured adsorption coefficient is considered necessary in order to allow for more reliable predictions of sediment and soil exposure concentration (PECs) for the risk characterisation. Furthermore, a reliable Koc is also necessary when calculating a PNEC for the sediment compartment (PNECsed) applying the equilibrium partitioning method. 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 adsorption/desorption test should cover all main components of the substance and accordingly Koc values for these components should be determined.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the registered substance subject to this decision: **Adsorption/Desorption using a batch equilibrium method (test method: EU C.18/OECD TG 106).**

2. Ready biodegradability (test method: OECD 301 B, OECD 301 C, OECD 301 D, OECD 301 F or OECD 310)

2-C17-unsatd.-alkyl-1-(2-C18-unsatd. amidoethyl)-4,5-dihydro-N-methyl, Me sulfates did not meet the pass level for ready biodegradability in a test according to OECD guideline 301 B. Only between 4.4 and 12.7% mineralisation based on CO_2-evolution was obtained in 28 days. The test substance (Varisoft 3690) had an analytical purity of 75% and the test substance concentration was 10 mg/L based on DOC. No information is given about the remaining 25%. However, according to an evaluation of Varisoft 3690 by Australian authorities (NICNAS, 1999) this formulation contains 25% isopropanol. The study is considered as reliable without restriction by the Registrant(s). However, as 25% of the test material is unknown (possibly isopropanol) and no sterile or toxicity controls were included, the study must be considered as less reliable. Theoretically, the long alkyl chains of the substance would be expected to be degradable and the low CO_2-evolution could be a result of toxicity or adsorption, making the test substance unavailable to the microorganisms, or both.

In a study according to OECD guideline 301 E on the closely related substance Partially unsaturated IQAC, DMS quaternised (CAS 86088-85-9) 76 % DOC removal was measured after 7 days of incubation. However, no further decrease in DOC was seen during the following 21 days of the test. No details on test conditions were given, e.g. it is not known if any abiotic sterile-, adsorption- or toxicity controls were run or if the inoculum was pre

[2] The deadline set by the decision already takes into account the time that registrants may require to agree on who is to perform any required tests and the time that ECHA would require to designate a registrant to carry out the test(s) in the absence of the aforementioned agreement by the registrants (Article 53(1) of the REACH Regulation).

adapted. This study is therefore considered invalid and unsuitable for drawing conclusions on the degradability of the substance as the DOC removal seen may as well be the result of adsorption.

The substance with CAS No 86088-85-9 has also been tested in an inherent test corresponding to OECD 302 B. After 28 days of incubation > 90% of the test substance had been eliminated based on COD measurements indicating that the substance is inherently biodegradable. The reliability of the study cannot be assessed as very little information is given about the study performance. Consequently it is not possible to assess to what extent adsorption contributes to the decreasing COD. Regarding the applicability of the method the following is stated in OECD guideline 302 B: "*Chemicals which are non-volatile and are soluble in water to at least 50 mg DOC/l may be assessed by this method, provided also that they do not significantly adsorb, are not lost by foaming and do not inhibit bacteria at the concentration tested.*" The water solubility of the test substance is 2.6 mg/l. In addition the test substance is highly adsorbing indicating that OECD 302 B is not a suitable test method for this substance. Furthermore, the quality of the study is unassignable due to the lack of information in the study report. The results can therefore not be used to conclude on the biodegradability of the registered substance.

Furthermore, the registration dossier also contains reference to a study conducted similar to OECD Guideline 303 A (Simulation Test - Aerobic Sewage Treatment. A: Activated Sludge Units). In this study Partially unsaturated IQAC, DMS quaternised (CAS 86088-85-9) with an analytical purity of [redacted]% was eliminated for > 90%, based on DOC removal, in a modified activated sludge unit during 63 days of incubation. However as no details on the test design is given in the robust study summary it is not possible to judge if the elimination seen was a result of adsorption to the sludge only or if degradation also occurred.

The Registrant(s) conclude that the registered substance is inherently biodegradable and uses this assumption to derive half-lives for the exposure modelling and in his PBT-assessment to conclude that the P-criterion is not fulfilled. This is based on the available data not considered justified. The available degradation data does not allow a firm conclusion to be drawn on the degradability of the registered substance. Further studies are therefore needed to enable a proper assessment of the P-properties of the substance and also for deriving half lives to be used in the exposure assessment.

The Registrant(s) shall make sure that the test is performed at a test concentration that does not exert toxicity to the microorganisms and that adsorption does not significantly affect the bioavailability of the test substance. The registrant is advised to consult Appendix R.7.9-3 of the ECHA Guidance on information requirements and chemical safety assessment Chapter R7b, version 3.0, February 2016 for possible modifications. The test can be enhanced by prolonging the test duration to 60 days provided that a slow degradation without reaching a plateau has started within 28 days. (See section R.7.9.4. to chapter R.7.b of the ECHA's Guidance on information requirements and chemical safety assessment, version 3.0, February 2016). The Registrant(s) may optionally conduct measurements of primary degradation of the relevant constituents and formation of relevant transformation products during the ready biodegradation test. 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.

Due to the adsorptive nature of the substance test methods where the decrease in dissolved organic carbon (DOC) is used as a measurement of degradation (OECD 301 A and 301 E) are not considered appropriate.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the registered substance subject to this decision:
Ready biodegradability (test method: OECD 301 B, OECD 301 C, OECD 301 D, OECD

301 F or OECD 310).

3. Daphnia magna reproduction test (test method: EU C.20/ OECD TG 211)

The request is relevant to the concerns regarding PBT assessment and derivation of the PNECaq and PNECsed values and thus necessary for allowing a more reliable risk assessment for aquatic organisms as well as for the sediment compartment.

There are no aquatic long term studies available for the registered substance. The registration dossier contains, however, one study on a similar substance, Partially unsaturated IQAC, DMS quaternised, CAS No 86088-85-9. In this study three generations of Daphnia magna were exposed during 63 days to the effluents from a model activated sludge unit fed with the substance. The effluents were not characterised and the exposure concentration 0.1 mg/l was only theoretically estimated. The evaluating Member State therefore considers the results of this study invalid and consequently these results can not be used for PNEC derivation. The Registrant(s) consider this study reliable and uses the NOEC of 0.1 mg/l as the basis for his PNEC derivation even though lower NOECs for algae are available. Since NOECs for algae are also available, the Registrant(s) have derived an aquatic PNEC of 2 µg/l using an assessment factor of 50.

The available acute toxicity data are all of questionable reliability as in most cases test concentrations have not been measured and the results are based on nominal concentrations and thus, may underestimate the toxicity. However, the evaluating Member State considers that a preliminary estimation of the aquatic PNEC can currently only be performed using the acute ecotoxicity data. Using the lowest acute toxicity available for the registered substance i.e. an EC_{50} of 0.065 mg/l for Daphnia magna and an assessment factor of 1000 according to Echa Guidance R.10 gives a PNECaq = 0.065 µg/l. When this PNEC is used in combination with the Registrant(s)'s current exposure data, RCRs > 1 for a number of Emission Scenarios are identified.

Testing is needed in order to derive a Predicted No Effect Concentration for the aquatic compartment (PNECaq) and to refine the risk characterisation ratios of the risk assessment for the aquatic compartment. The information is also needed in order to enable derivation of a more reliable PNEC for the sediment compartment using the equilibrium partitioning method. In addition, information on long term toxicity to aquatic invertebrates is required in order to enable the evaluating MSCA to assess the properties of the substance and to decide whether it is toxic (T) in accordance with Annex XIII of the REACH Regulation. This information is thus also needed to establish whether the suspected concern (PBT properties) may be realised or not. 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 two main components, which makes up approx. 90% of the registered substance, are very similar and differ only in that one of those (ca. [redacted]% of the UVCB) is a quaternary ammonium surfactant and the other (ca. [redacted]% of the UVCB), lacking a methyl group, is a tertiary ammonium surfactant. Both components are in themselves UVCB substances with two unsaturated carbon chains of varying length from below C14 to above C18 with a majority(80-90%) being C18. The third largest component (ca. [redacted]%) is also a quaternary ammonium surfactant with one carbon chain being similar to the two main components but with the quaternary ammonium in another position.

The minor components, N-(2-(2-C-17-unsatd.-alkyl-4,5-dihydro-1H-imidazol-1-yl)ethyl)2-C18-unsatd.alkanamide (ca. [redacted]% of the UVCB), octadec-9-enoic acid ([redacted]% of the UVCB) and methyl octadec-9-enoate ([redacted]% of the UVCB) are not expected to have ecotoxicological effects below their water solubility according to ECOSAR predictions.

Information on the toxicity of other cationic quaternary ammonium surfactants indicates that the toxicity increases with increasing carbon chain lengths see e.g. Sandbacka et al., 2000, "The acute toxicity of surfactants on fish cells, daphnia magna and fish – a comparative study". Toxicol. in vitro 14, 61-68. This relationship between carbon chain length and toxicity is also utilised in the SARs available for estimation of acute toxicity of cationic surfactants to aquatic organisms in ECOSAR. It is plausible that this relationship between carbon chain length and toxicity could be applicable also to the imidazolium class of cationic quaternary ammonium surfactants.

Considering that the major part, ca. 80% of the UVCB consists of cationic quaternary and tertiary ammonium surfactants with carbon chain lengths of C18 which, based on information on other cationic quaternary ammonium surfactants, are expected to be more toxic than those with a shorter carbon chains, testing of the registered substance as a whole is appropriate.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the registered substance subject to this decision: **Daphnia magna reproduction test (test method: EU C.20/ OECD TG 211).**

The Registrant(s) shall take measures to minimise any losses that occur due to the adsorptive nature of the substance. In particular they should refer to the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures. It is particularly important to base the effect concentrations on measured concentrations of the test substance.

Once results of the proposed test on long-term toxicity to aquatic invertebrates are available, the Registrant(s) shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to investigate further the effects on aquatic organisms, the evaluating Member State will consider requesting a long-term toxicity test on fish in the follow-up evaluation.

4. Robust study summary for the BCF-value of the 10.7 cited in the registration dossier

No experimental studies on bioaccumulation of Imidazolium compounds, 2-C17-unsatd.-alkyl-1-(2-C18-unsatd. amidoethyl)-4,5-dihydro-N-methyl, Me sulfates are available. Instead the registrant has used BCFBAF v3.01 to calculate BCF values. The calculation gave the following result: "Arnot-Gobas calculation method (upper trophic) gives a BCF 1. This model is however not applicable to ionic substances. Regression-based calculation method: BCF 71 L/kg wet-wt (Episuite uses a calculated Log Kow of 12.94 which is outside the domain of the model)."

However, the registration dossier also refers to an experimental BCF value of 10.7 for the similar compound Imidazolium compounds, 2-(C15-17(odd numbered), C17-unsatd. alkyl)-1-[2-(C16-18(even numbered), C18-unsatd. amido)ethyl]-4,5-dihydro-N-methyl, Me sulfates) CAS No: 68122-86-1. The value is cited from an evaluation performed by Australian authorities (NICNAS, 1999). No details on the study are given besides that it was a flow through test and the test species was bluegill sunfish. To allow an assessment of the reliability and relevance of this BCF-value for the B-assessment of the registered substance a robust study summary is needed.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide **a robust study summary** for the measured BCF-value of 10.7 referred to in the registration dossier.

5. Hydrolysis as a function of pH (test method: EU C.7/ OECD TG 111)

The hydrolysis of Imidazolium compounds, 2-C17-unsatd.-alkyl-1-(2-C18-unsatd. amidoethyl)-4,5-dihydro-N-methyl, Me sulfates, has been measured using the method described in OECD guideline 111. The measured half-lives were > 1 year at pH 4 and 25°C, 2.9 days at pH 7 and 20°C, and 1.2 days at pH 9 and 20°C. The study is given reliability score 1 by the registrant. However, hydrolysis products were not identified. No information was given if measures were taken to avoid adsorption to the test vessels. It is therefore possible that the disappearance of the test substance from the test solutions at least in part is due to adsorption to the test vessels. The study is therefore considered not reliable by the evaluating Member State. Identification of hydrolysis products is considered necessary to adequately evaluate the hydrolysis behaviour of the substance and for identifying if hydrolysis products that may have relevance for the PBT assessment are formed.

In their comments to the draft decision the Registrant(s) question the need for a hydrolysis study and suggest a stepwise approach. They propose that only if the results from the (enhanced) ready biodegradation test indicate that the substance does not meet the persistent criterion a hydrolysis study is needed.

ECHA accepts the reasoning and agrees to make the hydrolysis study conditional depending on the outcome of the (enhanced) ready biodegradability test. According to ECHA Guidance Chapter R.7b, section R.7.9.5.2 results from an enhanced biodegradation test can be used in a screening P/vP assessment. The normal pass levels of the OECD guidelines (60% ThOD or ThCO2) can be applied without the 10-day window for the purpose of assessing persistence.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the registered substance subject to this decision: **Hydrolysis as a function of pH (test method: EU C.7/ OECD TG 111)** including identification of hydrolysis products.

The Registrant(s) do not need to perform the study if, based on the results from the biodegradation study requested under item 2 of this decision, applying the pass levels of the OECD guidelines (60% ThOD or ThCO2), it can be concluded that the substance (and its relevant constituents and/or degradation products) is not persistent. If the Registrant(s) consider that the substance can be concluded not persistent on the basis of the ultimate degradation result in the ready biodegradability test, the Registrant(s) need to include (in PBT/vPvB assessment part of the registration dossier(s)) a justification why in this specific case (e.g. due to structural similarity of the constituents) sufficient information can be obtained from biodegradation result based on the CO_2 production or O_2 consumption of the registered (UVCB) substance that the substance (and its relevant constituents and/or degradation products) is not persistent. This justification is needed because the different constituents (depending on their degradability and carbon content/theoretical oxygen demand) may have degraded to a varying extent when the pass level is achieved at the level of test substance. Therefore, it is possible that the degradation of some of the constituents have not reached the pass level. In addition, to support their conclusion the Registrant(s) may use the measurements of primary degradation of the relevant constituents and formation of relevant transformation products during the ready biodegradation test, if available. 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.

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

Sediment toxicity studies have been waived by the Registrant(s) 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.*

The evaluating Member State does not agree to this waving 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. The Registrant(s) have derived a PNEC for sediment from the aquatic PNEC of 2 µg/l using the equilibrium partitioning method. However, the aquatic PNEC derived by the Registrant(s) are not considered valid. Furthermore, the Registrant(s) have not applied the extra factor of 10 to the $PEC_{sed}/PNEC_{sed}$ ratio in order to take uptake via ingestion of sediment into account as prescribed in ECHA Guidance R.10, chapter R.10.5.2.1 for highly adsorptive substances. When this extra factor is applied in combination with the Registrant(s)'s current exposure data, RCRs between 1 and 10 for a number of Emission Scenarios are identified.

As explained under point 3 above it is considered that a preliminary aquatic PNEC can currently only be derived from the acute ecotoxicity data (therefore PNECaq = 0.065 µg/l). Using this PNECaq to derive a sediment PNEC applying the equilibrium partitioning method will result in even higher RCR ratios (up to 300) for the sediment compartment.

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.

In their comment to the draft decision the Registrant(s) propose to employ a stepwise approach. They suggests that a sediment test should be performed only if a risk characterisation based on the results of the data requested in the draft decision would give a risk characterisation ratio (RCR) > 1. ECHA accepts the reasoning and agrees to make the sediment test conditional depending on the outcome of a revised sediment risk characterisation.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the registered substance subject to this decision: **Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment (test method: OECD TG 225)**.

The Registrant(s) do not need to perform the study if a revised sediment risk characterisation based on the information gained as a result of the studies requested under item 1 – 3 of this decision results in risk characterisation ratio (RCR) < 1 using the equilibrium partitioning method (EPM). The registrant is reminded to take the need for an extra factor of 10 into consideration when applying the EPM.

IV. Adequate identification of the composition of the tested material

In relation to the required experimental stud(y/ies), the sample of the substance to be used shall have a composition that is within the specifications of the substance composition that are given by all Registrant(s). It is the responsibility of all the Registrant(s) to agree on the tested material to be subjected to the test(s) subject to this decision and to document the

necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation. Finally, the test(s) must be shared by the Registrant(s).

V. Avoidance of unnecessary testing by data- and cost-sharing

In relation to the experimental stud(y/ies) the legal text foresees the sharing of information and costs between Registrant(s) (Article 53 of the REACH Regulation). Registrant(s) are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who is to carry out the study on behalf of the other Registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at:
https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

Further advice can be found at http://echa.europa.eu/regulations/reach/registration/data-sharing

If ECHA is not informed of such agreement within 90 days, it will designate one of the Registrants to perform the stud(y/ies) on behalf of all of them.

VI. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[3] by Leena Ylä-Mononen, Director of Evaluation

Annex: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.

[3] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.