ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114315377-50-01/F Helsinki, 18 February 2016

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For n-(2-hydroxyethyl)-n,n-dimethyl alkyl-c12-14-(even numbered)-1-aminium chloride, EC No 931-275-3, registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for n-(2-hydroxyethyl)-n,n-dimethyl alkyl-c12-14-(even numbered)-1-aminium chloride, CAS No NS (EC No 931-275-3), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after the deadline for updating (13 March 2015) communicated to the Registrant by ECHA on 4 February 2015.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 20 November 2013.

On 14 November 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 19 December 2014 ECHA received comments from the Registrant on the draft decision.

The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made

On 3 September 2015 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, proposals for amendment to the draft decision were submitted.

On 9 October 2015 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 19 October 2015 ECHA referred the draft decision to the Member State Committee.

By 9 November 2015 the Registrant did not provide any comments on the proposals for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 23 November 2015 in a written procedure launched on 12 November 2015.

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

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

Description of the analytical methods (Annex VI, 2.3.7.)

B. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vi) and/or (vii), 12(1)(e), 13 and Annexes IX and X of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. Pre-natal developmental toxicity study (Annex IX, 8.7.2.; test method: EU B.31./OECD 414) in rats or rabbits, oral route;

2. Effects on terrestrial organisms – Long-term toxicity testing on plants (Annex X, 9.4.6.; test method: Terrestrial plants, growth test, OECD 208), with at least four species tested (with as a minimum one monocotyledonous species and three dicotyledonous species, other than *Avena sativa* and *Lactuca sativa*) , or Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030).

Pursuant to Articles 41(1), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, once the results of the above terrestrial study are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including an updated derivation of the terrestrial PNEC.

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

C. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1)(c), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

3. Documentation for the recommended personal protective equipment (Annex I, 5.1.1. in conjunction with Annex II, 0.1.2. and 8.2.2.2(b)), as specified under Section III point C below.

D. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **27 February 2017** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

Description of the analytical methods (Annex VI, section 2.3.7.)

"Description of the analytical methods" is an information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA observes that the Registrant has not included a sufficient description of the quantitative analysis that would enable the composition of the registered substance to be verified.

More specifically, ECHA notes that the Registrant did not provide the description of an appropriate method for the quantification of chloride ion present in the registered substance. This information is essential to confirm the identity and composition of the registered substance.

In line with Annex VI, 2.3.7, the Registrant is accordingly requested to provide the description of an analytical method that is specific for the quantification of the chloride ion present in the substance. The description shall be sufficient for the method to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

As for the reporting of the above data in the registration dossier, the information should be attached in IUCLID section 1.4. The Registrant shall ensure that the composition reported in the dossier is consistent with the analytical results obtained.

In their comments the Registrant stated their intention to include the report on the quantification of chloride and the description of the analytical method in a dossier update.

Note for consideration by the Registrant:

ECHA notes that the EC number used by the Registrant for pre-registering the substance corresponds to EC no 288-474-7 (C12-C18-alkyl(hydroxyethyl)dimethyl, chlorides). ECHA understands that such identifiers have been used initially for identifying the substance and have been subsequently amended to the name n-(2-hydroxyethyl)-n,n-dimethyl alkyl-c12-14-(even numbered)-1-aminium chloride. The Registrant should consider examining these inconsistencies to provide clarity to the registration dossier.

B. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

Pre-natal developmental toxicity study (Annex IX, 8.7.2.)

A "pre-natal developmental toxicity study" for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier the Registrant has provided a study record for an OECD Guideline 414 (Prenatal Developmental Toxicity Study) on an analogue substance C8-C10 alkyl dimethyl hydroxyethyl ammonium chloride. The justification of the adaptation given by the Registrant is: "*The use of this substance data as surrogate is justified as it is seen as a worst case, i.e. based on the shorter chain length, its lower molecular weight and thus its higher chemical reactivity.*"

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated by means other than tests. Such other means include the use of information from structurally related substances (grouping of substances and read-across), "*provided that the conditions set out in Annex XI are met*".

ECHA notes that the Registrant has based the one-to-one read-across on structural similarity. In the initial draft decision issued to the Registrant, ECHA indicated that the Registrant had failed to provide adequate information to support their claim of higher reactivity of the source substance. As a consequence of this omission, ECHA considered that the Registrant had failed to demonstrate that "human health effects may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach)", as required by Annex IX, section 1.5 of the REACH Regulation.

The Registrant has submitted comments on the ECHA draft decision further elaborating the read-across approach.

In his comments to the draft decision, the Registrant outlines structural similarities and differences between the source and target substances and considers that the substances follow the principles of a chain-length category as well as a metabolic pathway category. The Registrant also points out similarities in the physico-chemical properties of the substances, refers to similarities in metabolic pathways and considers that the metabolites/catabolic end-products are identical for the source and the registered substances. The Registrant concludes on that basis that "*there are good reasons to assume that each category member exhibits the same toxic mode of action*". The Registrant further considers that "*following accepted scientific opinion, shorter chain length molecules from the same chemical class exhibit generally a higher chemical reactivity compared to longer chain-length analogues*" and therefore formulates the hypothesis that, "*based on the shorter chain length, its lower molecular weight and thus its higher chemical reactivity*", the source substance can be seen as a worst-case compared to the "longer chain length" registered substance.

In order to support this hypothesis, the Registrant claims that existing data confirm that the registered substance does not have embryo/foetotoxic or teratogenic properties at applicable dose levels. The Registrant also explains why toxicity data from the repeated dose toxicity studies cannot be considered as conflicting with the read-across hypothesis due to differences in experimental design and associated differences in the nature of the effects observed.

The Registrant concludes that he considers that the requirements of Annex XI section 1.5. are met and disagrees with ECHA's opinion that the adaptation of the information requirement does not fulfil the criteria set in Annex XI, section 1.5. The Registrant also indicates its intention to update the technical dossier to reflect in more detail on the arguments presented above "*and to include a read-across justification according to curent standards as soon as possible*".

ECHA has analysed the information and documentation provided in the registration dossier and in the Registrant's comments to the draft decision in light of the requirements of Annex XI, Section 1.5. of the REACH Regulation and concludes that these requirements are not met for the reasons below.

In his comments to the draft decision, the Registrant outlines similarities in the chemical structures between the source and target substances, points out at similarities in their physico-chemical properties and indicates that "*both substances are considered to be biologically equivalent because they follow the same (main) metabolic pathways of enzymatic oxidation and glucuronidation and the anticipated metabolites and/or catabolic end products are considered to be identical for both compounds*". ECHA considers that these arguments do not constitute, in general or in this specific case, a sufficient basis to demonstrate that toxicological properties of the registered substance can be predicted from a source substance. ECHA notes that, according to the requirements of Annex XI, section 1.5 of the REACH Regulation, structural similarity is necessary for the use grouping and read-across approaches. Similarity in physico-chemical properties may contribute to increasing the robustness of the read-across hypothesis. However, structural similarity and similarity in physico-chemical properties do not constitue, either on their own or together, a sufficient basis for establishing that the toxicological properties can be predicted using information from analogue substances. ECHA also points out that similarities in chain length or metabolic pathways do not necessarily correlate with similarities in toxicological properties of the substances and therefore such arguments without adequate supporting information do not establish that the toxicological properties can be predicted. Therefore, ECHA considers that the information provided by the Registrant does not constitute a sufficient basis to demonstrate that "human health effects may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach)", as required by Annex XI, 1.5 of the REACH Regulation.

The Registrant has stated in his comments that the source molecule C8-10 alkyl dimethyl hydroxyethyl ammonium chloride *"based on the shorter chain length, its lower molecular weight and thus its higher chemical reactivity"* can be seen as a worst case (compared to the longer chain-length target molecule C12-14 alkyl dimethyl hydroxyethyl ammonium chloride). The Registrant supports this argument with a comparison of the repeated dose toxicity of the source substance and a combined repeated dose toxicity study/screening study for reproductive/developmental toxicity (OECD 422) conducted with the registered substance.

ECHA notes that the Registrant has not provided case-specific data to support the argument of higher chemical reactivity of the source substance, nor justified that this reactivity determines the toxicity of the target substances. ECHA considers that the arguments provided of shorter chain length, the lower molecular weight and consequent proposed higher reactivity of the source substance do not constitute, in the asbence of additional mechanistic information linking these arguments with the property under consideration, an adequate basis on which to draw conclusions on the human health properties of the registered substance. ECHA considers there is insufficient supporting information comparing the human health properties of the source and registered substance such that a reliable prediction of properties can be made. Moreover there is no specific consideration as to why the pre-natal developmental toxicity of the registered substance can be predicted from the information available on the source substance.

ECHA points out that the investigations performed in a screening study differ significantly from those conducted in a pre-natal developmental toxicity study. In particular, parameters such as skeletal alterations, which were the type of effects reported to be the leading developmental toxicity effect observed in the high dose group in the pre-natal developmental toxicity study performed with the source substance, are not investigated in the screening study which is available for the target substance. ECHA also observes that the highest dose level used in the screening study, i.e. 60mg/kg bw/day, is lower than the dose level causing effects in the PNDT study, i.e. 100 mg/kg bw/day. ECHA considers that the possibility that the registered substance itself causes skeletal effects or other developmental toxicity cannot be dismissed on the basis of the information provided in the registration dossier. As this effect (skeletal alterations) is not measured in the screening study, it is also not possible to draw any conclusions on the dose at which, potentially, such effect would be observed if the target substance was tested in a pre-natal developmental toxicity study and which would allow comparison with the dose-response of this effect observed for the source substance. Therefore, ECHA is of the opinion that the data obtained from the screening study conducted with the registered substance does not constitute robust supporting evidence of a higher reactivity of the source substance making it a worst-case for the prediction of the pre-natal developmental toxicity of the registered substance.

ECHA considers that the Registrant's arguments above, by themselves or in combination, are insufficient to demonstrate that the human health effects (prenatal developmental toxicity) of the registered substance may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group, as required by Annex XI, Section 1.5 of the REACH Regulation. As the requirements of Annex XI, Section 1.5 of the REACH Regulation have not been fulfilled, the adaptation by the Registrant cannot be accepted, and it is necessary to perform testing on the registered substance.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method EU B.31/OECD 414, as referred to in in Annex IX, Section 8.7.2. of the REACH Regulation, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rats or rabbits by the oral route.

ECHA observes that the Registrant has indicated in his comments to the draft decision that "species differences in the toxicological profile are not expected" and therefore considers that this adaptation of the information requirements of Annex IX, 8.7.2 can also be used to adapt the information requirement of Annex X, 8.7.2. This decision does not address the Annex X, 8.7.2 requirement for a pre-natal developmental toxicity study on a second species. However, please see the 'Note for consideration by the Registrant'.

Note for consideration by the Registrant:
You are reminded that before performing a pre-natal developmental toxicity study in a second species you must consider the specific adaptation possibilities of Annex X, Section 8.7.2., column 2 and general adaptation possibilities of Annex XI. If the results of the test in the first species enable such adaptation, testing in the second species should be omitted and the registration dossier should be updated containing the corresponding adaptation statement.

Terrestrial Plants (Annex X, 9.4.6.)

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, section 9.4., of the REACH Regulation. Long-term toxicity testing on plants (Annex X, section 9.4.6.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

The Registrant has provided adequate information on effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.) and long-term toxicity testing on invertebrates (Annex X, section 9.4.4.).

The Registrant has provided two study records describing the same study on terrestrial plants conducted according to OECD 208 (in 1993), in two different species; [redacted] (monocotyledonous species) and [redacted] dicotyledonous species). Concerning the study on terrestrial plants ECHA notes that according to the original OECD guideline 208 (Terrestrial plants, growth test; as published in 1984) a minimum of three species were required. ECHA concludes that whilst the information provided by the Registrant is considered as scientifically valid for two different species, with only two species tested, it is neither sufficient to fulfil all the requirements of the original OECD 208 Test guideline, nor the requirements of section 9.4.6 of Annex X of the REACH Regulation.

As explained above, the information available on the endpoints of toxicity to terrestrial plants (Annex X, 9.4.6.) for the registered substance in the technical dossier does not meet all of the information requirements. Consequently there is a partial information gap and it is necessary to provide information for this endpoint.

According to section R.7.11.5.3., Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 1.1, November 2012), substances that are ionisable or have a log Kow/Koc >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil (logKoc = 5.1).

Based upon the available aquatic toxicity information and the physicochemical properties of the substance, and in relation to section R.7.11.6. of the above-mentioned guidance, ECHA considers that the substance would fall into soil hazard category 4. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates that the lowest value obtained from the long-term toxicity tests should be used to derive the PNEC soil.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. However, as stated above the Registrant has performed valid testing on two different species in accordance with OECD 208 guideline. Thus, in this specific case due to the available adequate information, ECHA considers that further testing of four species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with one monocotyledonous species and three dicotyledonous species. The Registrant can consider if testing on additional species is required to cover the information requirement (see the Evaluation Progress Report 2012 pp 34-35; http://echa.europa.eu/documents/10162/13628/evaluation_report_2012_en.pdf).

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Terrestrial plants, growth test (test method: OECD 208), with at least four species tested (with as a minimum one monocotyledonous species and three dicotyledonous species, other than [redacted] and [redacted], or, Soil Quality – Biological Methods – Chronic toxicity in higher plants (test method: ISO 22030).

In their comments, the Registrant presents three arguments against performing the requested long-term terrestrial plants study (OECD 208 with 4 additional species). These are based on 1) persistency in soil, 2) terrestrial hazard assessment, and 3) terrestrial safety assessment.

1) Persistency

In his comments to the draft decision, the Registrant claims that the half-life of the substance in soils is limited ("rapid median aerobic degradation half-life of 6.2 d at 20°C"). In addition, the Registrant has provided in the dossier three different DT50 values for 3 different soils ranging from 6.0 to 13.6. ECHA disagrees with including bound residues in the half-life calculations as done by the Registrant and notes that *degradation* half-lives should only account for actual degradation of the parent compound. This is especially important in the present case as the Registrant has indicated in IUCLID section 5.2.3 that bound residue levels started to *decrease* again towards the end of the study, indicating either de-sorption (or degradation) of initial bound residues. However, ECHA is also of the opinion that the overall weight of evidence does not suggest a half-life of the parent compound in soil that would meet the persistency criterion. Therefore, the substance could be considered as 'not persistent' (in soil). However, Guidance R.7c, Table R.7.11-2 mentions high adsorption as a parameter to decide on the soil hazard category. In his comments, the Registrant did not disagree with ECHA's conclusion that the logKoc of the substance (5.1) indicates a 'high adsorption' potential.

2) Terrestrial hazard data

The Registrant lists the studies available in the dossier, including an OECD 208 study with 2 species. The Registrant also indicates that "*(...) the number of species to be tested is dependent on the relevant regulatory requirements, therefore it is not specified in the Guideline"* and continues that *"Neither Annex IX or X nor the REACH Guidance Document R.7c do specify the number of species to be justified in the plant test and the request from ECHA to test 4 additional plant species is not justified."* ECHA disagrees with the Registrant and has outlined in the draft decision why it considers an OECD 208 study as a valid chronic study fulfilling the information requirement of Annex X, 9.4.6. This includes a reference to ECHA's Evaluation Progress Report 2012 pp 34-35 where it is explained that ECHA's Member State Committee has established its understanding on how compliance with the endpoint on terrestrial plants is to be achieved (e.g. p. 34-35: '*OECD TG 208 (Terrestrial plants, growth test) considers the need to determine the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution:* [...] *In general, both OECD TG 208 with a minimum of six species and ISO 2230 are, in principle, suitable for covering long-term testing requirements on plants...*'). ECHA notes that inter-species variability, particularly among dicotyledonous species, is expected to cover several orders of magnitude, hence a minimum of 6 species (two monocotyledons and four dicotyledons) is needed in the OECD TG 208 to cover this.

3) Terrestrial safety assessment

The Registrant states in his comment that the PECsoil using a median half-life of 6.2d is low and that the RCRs are all <1. The Registrant also notes that '*If the plant test is regarded as incomplete the PNEC soil can be derived from the two other chronic studies (earthworm and soil microorganisms) using an assessment factor of 50 instead of 10.'* ECHA further notes that some of the RCRs in the current dossier would be close to 1 if the Registrant would have applied and AF = 50 which further indicates the relevance of providing a compliant long-term study on terrestrial plants and ECHA therefore disagrees with the statement of the Registrant that '*...further testing on plants... will not change the outcome of the safety assessment*'. ECHA is of the opinion that such conclusion cannot be drawn from the current dossier.

Importantly, ECHA notes that Guidance R.10, Table R.10.10, cannot be used in isolation. Considering the available terrestrial *toxicity* data: the Registrant should *first* assess the other information on the substance in accordance with Guidance R.7c, Table R.7.11-2, and in this particular case, assess the high aquatic toxicity and high adsorption potential. Based on this assessment the Registrant should provide the required hazard data (or have submitted the appropriate testing proposals) and only then derive the correct AF according to Guidance R.10. The request therefore for a long-term study on terrestrial plants according to REACH, Annex X, 9.4.6 remains. According to Guidance R.7c, Table R.7.11-2 the substance falls under soil hazard category 4, and terrestrial *long-term* studies are required for *3 trophic levels* for such substances.

C. Information related to the chemical safety assessment and chemical safety report

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

Documentation for the recommended personal protective equipment, Skin protection (Article 14(6), Annex I, section 5.1.1, in conjunction with Annex II, 0.1.2 and 8.2.2.2 (b)(i).

Article 14(6) as well as Annex I, 0.1., 5.1.1., 5.2.4. and 6.2. of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in a CSR. The exposure shall be estimated and risks shall be characterised in the CSR under the assumption that relevant risk management measures have been implemented.

According to Annex I, 0.3., 0.5. and 5.1.1. the applied Risk Management Measures (RMM) have to be described in the CSR. The CSR needs to contain sufficient information to allow ECHA to gain assurance that the risks are adequately controlled and that appropriate risk management measures can be prescribed by actors in the supply chain. Accordingly, the supplier is required to describe the relevant RMM in detail in the Safety Data Sheet in order to minimise the exposure for workers handling the registered substance (e.g. the type of gloves to be worn, protection equipment for parts of the body other than the hand or respiratory protection shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of exposure in accordance with Annex II, section 8.2.2.2.(b)(i), (ii) and 8.2.2.2.(c) respectively). The information provided in the Safety Data Sheet (SDS) shall be consistent with information in the Chemical Safety Report (Annex II, section 0.1.2. of the REACH Regulation).

ECHA notes that specific detailed information on the recommended personal protective equipment is missing both from the CSR and from the information on safe use within the IUCLID dossier. In the CSR, the Registrant indicated "substance/ task appropriate gloves" and "chemically resistant gloves conforming to EN374" for hand protection, while in IUCLID Section 11 the registrant has reported no information on glove specification.

To ensure the safe use of a substance, Annex I Section 5.1.1 requires a description of the risk management measures to reduce or avoid direct and indirect exposure of humans. Gloves are to be reported in the CSR and IUCLID Section 11 as required personal protective equipment to prevent dermal exposure to the substance. Generally, gloves that are capable of preventing exposure to the skin for a pre-determined duration shall be specified. Typically, this information has to specify the glove material, breakthrough time and thickness of the glove material.

Therefore, pursuant to Article 41(1)(c) the registrant is required to provide in the CSR a description of the gloves to be used when handling the pure substance. The information provided by the Registrant shall be sufficiently detailed to allow suppliers to fulfil their obligations specified under Annex II for the compilation of the safety data sheets.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation

In relation to the information required by the present decision, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 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 ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised1 by Ofelia Bercaru , Head of Unit, Evaluation E3

[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.