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Decision number: CCH-D-0000002118-79-10/F Helsinki, 6 November 2012

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

For Hydrogenated dimerization products of 1-Decene, 1-Dodecene and 1-Octene, List No. 700-308-1, 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 dossier for **Hydrogenated dimerization products of 1-Decene, 1-Dodecene and 1-Octene, List No. 700-308-1** submitted **by** [redacted]

This decision is based on the registration dossier 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 14 June 2012, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the registration at a later stage.

Article 24(1) of the REACH Regulation provides that the notification is regarded as a registration and ECHA has assigned a registration number.

The compliance check was initiated on 9 July 2010.

On 28 June 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

On 28 July 2011 the Registrant provided to ECHA comments on the draft decision. On 6 September 2011 the Registrant updated his registration dossier.

ECHA considered the Registrant's comments received. On basis of the comments, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

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On 14 June 2012 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 18 July 2012 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and decided to amend the draft decision.

On 30 July 2012 ECHA referred the draft decision to the Member State Committee.

The Registrant did not provide any comments on the proposed amendments.

After discussion in the Member State Committee meeting on 19-21 September 2012, a unanimous agreement of the Member State Committee on the draft decision as referred to MSC was reached on 20 September 2012. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

This compliance check decision is interlinked with a testing proposal decision for the same substance (communication number TPE-D-0000002118-79-09/F) for the information requirement of toxicity to terrestrial plants (Annexes IX and X).

II. Information required

ECHA has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of the REACH Regulation.

1) Pursuant to Articles 41(1)(a), 41(3), 3(28), 10(a)(vii) and 12(1)(e), as well as Annexes VII to X to the REACH Regulation, the Registrant shall submit the information using the test method as indicated on:

   a. Melting/freezing point (Annex VII, 7.2.; test method: EU A.1./OECD 102.);
   b. Boiling point (Annex VII, 7.3.; test method: EU A.2./OECD 103.);
   c. Self-ignition temperature (Annex VII, 7.12.; test method EU A.15.);
   d. Developmental toxicity study in rabbits, oral route (Annex X, 8.7.2.; test method EU B.31./OECD TG 414);
   e. Effects on terrestrial organisms (Annex X, 9.4.4.; Test on toxicity to invertebrates; test method: OECD 222 or OECD 220 or OECD 232 or OECD 226);
   f. Effects on terrestrial organisms (Annex X, 9.4.6.; Test on toxicity to terrestrial plants; test method: OECD 208 with at least six species tested using radish and at least five other species of which a minimum with two

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monocotyledonous species and three dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline);

g. Effects on terrestrial organisms (Annex IX, 9.4.2.; Test on toxicity to soil micro-organisms; test method EU C.21./OECD 216); and
h. Long-term toxicity testing to sediment organisms (Annex X, 9.5.1., test method OECD 225).

2) Pursuant to Articles 41(1)(a), 41(3), 10(b), 14(1), 14(3), 14(4) and Annex I of the REACH Regulation, the Registrant shall submit the following information related to Chemical Safety Report (CSR) and update the CSR accordingly:

i. Information on the identification of derived no effects levels DNEL(s) and risk characterisation for worker and consumer by inhalation route (Annex I, Sections 1.0.1. and 1.4.1);
j. PNEC soil and PNEC sediment; exposure assessment for the soil and sediment compartments (taking into account direct and indirect exposure of the soil and sediment compartments) considering all stages of the life-cycle of the substance resulting from the manufacture and identified uses (taking into account, where relevant, the waste life-cycle stage of the substance); and resulting risk characterisation for the soil and sediment compartments.

Pursuant to Article 41(4) of the REACH Regulation, the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **6 November 2013**.

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10, 12 and 13 and with Annexes VII, VIII, IX, X and XI thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

Pursuant to Articles 10 and 12(1)(e) of the REACH Regulation, a registration for a substance produced in quantities over 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

1) The technical dossier submitted by the Registrant contains statements regarding the use of a read-across approach to adapt standard information requirements for the endpoints a to c and g listed below.

Article 13(1) and introductory paragraph of Annexes VII, VIII, IX and X, require to clearly state reasons for adapting the standard information according to the rules in Annex XI. More specifically, Annex XI, section 1.5 provides that substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or 'category' of substances. Application of the group approach requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) by interpolation to other substances in the group (read-across approach).

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The similarities, may, according to Annex XI, section 1.5, be based on:
(1) common functional group;
(2) the common precursors and/or the likelihood of common breakdown products via physical or biological processes, which result in structurally similar chemicals; or
(3) a constant pattern in the changing of the potency of the properties across the category.

In addition, in order to justify the group concept according to Annex XI, section 1.5, it should be clear for which endpoints the suggested read-across is applicable. Annex XI, section 1.5 requires that the results (i) are adequate for the purpose of classification and labelling and/or risk assessment, (ii) have adequate coverage of the key parameters and cover an exposure duration addressed in the corresponding test method referred to in Article 13(3) and (iii) that the documentation of the applied method is adequate and reliable.

ECHA considers that the Registrant does not provide acceptable justification required by Annex XI, section 1.5, as explained above, as to why read-across for the endpoints a to c and g listed below is suggested.

a. Melting/freezing point (Annex VII, 7.2.) and,
b. Boiling point (Annex VII, 7.3)

A melting/freezing point study is a standard information requirement of Annex VII, 7.2 at the present tonnage level. A boiling point study is a standard information requirement of Annex VII, 7.3. at the present tonnage level.

ECHA notes that the technical dossier provided by the Registrant includes two studies for these endpoints; the first has been done with one of the main components of the registered substance, 1-decene dimer with 1-dodecene, hydrogenated and the second study with one of the impurities of the registered substance, 1-dodecene dimer, hydrogenated.

ECHA concludes that the read-across using one of the main components and one of the impurities of the registered substance suggested by the Registrant is not acceptable. Firstly, the Registrant has provided a short description of the justification for read-across. This fails to provide reasons that the properties of the registered substance may be predicted from the properties of the read-across substance. Therefore the requirement of Annex XI, 1.5, that "adequate and reliable documentation of the applied method shall be provided" is not met. In addition, the suggested read-across does not follow the ECHA guidance on read-across (Guidance R.6).

Secondly, the Registrant proposes a read-across to the registered substance, which varies in size from 18- to 24-carbon atoms, from substances which have 22- or 24-carbon atoms. The Registrant has provided no adequate basis for considering that there is a constant pattern in the change of properties of these substances with change in the number of carbon atoms. The read-across from a 22-, or 24-carbon substance to either 18-, or to 20-carbon atom chains is extrapolation, and fails to meet the requirement of Annex XI, 1.5, for interpolation: "*Application of the group*

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concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach)."

For these reasons, the read-across fails to meet the requirements of Annex XI, 1.5, and cannot be considered a valid adaptation of the information requirements concerned. There is no data provided for these endpoints on the registered substance, and so the information requirement for melting/freezing point (Annex VII, 7.2) and for boiling point (Annex VII, 7.3) has not been met.

The Registrant is accordingly requested to submit the missing information for melting/freezing point for the registered substance by using the EU test method A.1 and its boiling point by using the EU test method A.2.

c. Self-ignition temperature (Annex VII, 7.12.)

A self-ignition temperature study is a standard information requirement of Annex VII, 7.12. at the present tonnage level.

ECHA observes that the read-across approach suggested by the Registrant for this endpoint includes one experimental study for 1-dodecene dimer, hydrogenated which is present as an impurity in the registered substance.

ECHA concludes that the read-across from one of the impurity of the registered substance (i.e. 1-dodecene dimer, hydrogenated) suggested by the Registrant is not acceptable. Firstly, the Registrant has provided a short description of the justification for read-across, which fails to provide reasons that the properties of the registered substance may be predicted from the properties of the read-across substance, as specified under point a and b above.

Secondly, the Registrant proposes a read-across to the registered substance, which varies in size from 18- to 24-carbon-atoms, from substance which has 24-carbon atoms. The read-across from a 24-carbon substance to either 18-, 20-, or to 22-carbon atom chains is extrapolation, and fails to meet the requirement of Annex XI, 1.5, for interpolation, as specified under point a and b above.

Moreover, ECHA points out that the substance used for read-across is present at [redacted] concentration in the registered substance and does not account for the bulk composition of the registered substance, including all components.

For these reasons, the read-across fails to meet the requirements of Annex XI, 1.5, and cannot be considered a valid adaptation of the information requirement. There is no data provided for this endpoint on the registered substance, and so the information requirement for self-ignition temperature (Annex VII, 7.12) has not been met.

The Registrant is accordingly requested to submit the missing information for the self-ignition temperature for the registered substance by using of the EU test method A.15.

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d. Reproductive toxicity, Developmental toxicity study in rabbits by oral route (Annex X, 8.7.2.)

In the technical dossier the Registrant has included and referred to several pre-natal developmental toxicity studies in rats that were performed with structurally similar substances. The data provided, especially studies performed with substances from the Solvents category (C9-C14, Aliphatics, <2% Aromatics category and C14-C20 Aliphatics, <2% Aromatics category) fulfil the information requirement for the pre-natal developmental toxicity study, first species i.e. rats, as laid down in Annex IX, section 8.7.2 and according to the Annex XI, section 1.5.

According to section 8.7.2 of Annex X of the REACH Regulation, a further pre-natal developmental toxicity study performed in a second species is required to fulfil the standard information requirements. As explained in the Guidance on information requirements and chemical safety assessment, chapter R.7.6.6.4. *"At ≥1000 t/y, a study in a second species will normally be required when the first study is negative, unless Weight of Evidence assessment or specific data e.g. toxicokinetic data provide scientific justification not to conduct the study in a second species."* The information available on this endpoint for the registered substance in the technical dossier does not meet these information requirements, and the information available from the results obtained using the read-across substances i.e. C9-C14, Aliphatics, <2% Aromatics category and C14-C20 Aliphatics, <2% Aromatics category did not lead to classification as toxic to reproduction category 1A or 1B: May damage the unborn child (H260D). Consequently there is an information gap and it is necessary to generate the data for this endpoint.

The Registrant is accordingly requested to submit the missing information for developmental toxicity for the registered substance, in rabbits, oral route by using the EU test method B.31 (or OECD TG 414).

e, f and g. Effects on terrestrial organisms

Effects on terrestrial organisms is a standard information requirement of Annex IX, 9.4. and Annex X at the present tonnage level.

In order to fulfil the standard information requirements set out in Annex IX and X, section 9.4., the Registrant should provide the following studies: (i) long-term toxicity testing on invertebrates (Annex X, section 9.4.4), (ii) long-term toxicity testing on plants (Annex X, section 9.4.6), and (iii) effects on soil micro-organisms (Annex IX, section 9.4.2). Column 2 of Section 9.4 of Annex X further indicates that this information requirement must be fulfilled unless the chemical safety assessment leads to the conclusion that the information is not needed.

(i) long-term toxicity testing on invertebrates

In its updated dossier (6 September 2011) the Registrant has provided only information on short-term toxicity to terrestrial invertebrates (Acute toxicity test on earthworms according to OECD Guideline 207). The technical dossier does not include an adaptation for the long-term testing toxicity to terrestrial invertebrates as specified in the Annex X, section 9.4.

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ECHA notes that the substance is (highly) adsorptive and according to the Annex IX, section 9.4 (further supported by the Guidance on Information Requirements and Chemical Safety Assessment R.7c section R.7.11.5.3. (May, 2008)), the Registrant shall consider long-term toxicity testing instead of short-term.

ECHA notes that the Registrant has provided a new waiving statement in the dossier for toxicity on sediment organisms (updated 06 September 2011): '*... Soil microorganism toxicity studies as well as additional follow-up terrestrial plant studies in radish have been planned for the registered substance to provide more extensive and definitive data for the soil compartment. The need for further testing in soil or sediment organisms will be re-assessed pending the completion and thorough review of the outcome of the above planned studies.*' .

In the absence of sufficiently adequate information and/or testing proposal(s) on long-term toxicity studies on terrestrial organisms and based on the intrinsic properties of the substance, this justification for data waiving and proposed testing strategy is not considered to be in line with the specific rules for adaptation indicated in column 2 of Annex X, 9.4. Therefore, the Registrant has not fulfilled all the information requirements outlined in Annex X, 9.4.

Therefore, ECHA considers that the long-term testing on terrestrial invertebrates is necessary.

(ii) long-term toxicity testing terrestrial plants

The Registrant proposes to adapt the standard information requirement on long-term toxicity study on terrestrial plants with a following justification "*Further long-term terrestrial planting testing will be considered depending on the results from the additional follow-up short-term studies planned in radish (i.e., terrestrial plants) and a thorough review and evaluation of all relevant information.* "

ECHA notes that the substance is (highly) adsorptive and according to the Annex IX, section 9.4 (further supported by the Guidance on Information Requirements and Chemical Safety Assessment R.7c section R.7.11.5.3. (May, 2008)), the Registrant shall consider long-term toxicity testing instead of short-term.

In the absence of sufficiently adequate information and/or testing proposal(s) on long-term toxicity studies on terrestrial organisms and based on the intrinsic properties of the substance, this justification for data waiving and proposed testing strategy is not considered to be in line with the specific rules for adaptation indicated in column 2 of Annex X, 9.4. Therefore, the Registrant has not fulfilled all the information requirements outlined in Annex X, 9.4.

ECHA notes that the OECD test guideline 208 reflects on the need to choose the number of species to be tested depending on relevant regulatory requirements and on the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing (Annex X, 9.4., column 2) ECHA considers at least six species as the minimum to achieve a reasonably broad selection. The long-term toxicity testing shall be conducted as a minimum with two monocotyledonous species and four dicotyledonous species from different groups, selected according to the criteria indicated in the OECD 208 guideline. The

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Registrant should consider if testing on additional species is needed to cover the information requirement.

In addition to this compliance check decision, the Registrant has submitted a testing proposal on short-term toxicity to terrestrial plants (on one species, radish) in the updated dossier (testing proposal communication number: TPE-D-0000002118-79-09/F) to fulfil the information requirements of Annex IX, 9.4.3. The testing proposal indicates to ECHA that radish is considered by the Registrant to be the most sensitive plant species tested, therefore the radish should be included when testing long-term toxicity testing to plants.

ECHA notes that the test proposed by the Registrant in the testing proposal and the test required under the compliance check refer to the same test methodology. The OECD 208 method generates experimental results which can be used to fulfil the information requirements for the short term and long term toxicity to terrestrial plants.

(iii) effects on soil micro-organisms

The Registrant proposes to adapt the standard information requirement on soil micro-organisms based upon weight of evidence reasoning, and uses read-across as part of his weight of evidence reasoning.

The Registrant provides the following justification: "*Acute toxicity testing to soil microorganisms is not necessary given the read-across data available which indicate that the test substance is not likely to cause toxicity to aquatic microorganisms. Studies are not available to assess the toxicity of the reaction products of 1-decene, 1-dodecene, and 1-octene, hydrogenated to soil microorganisms. However, there are available data indicating that the test substance is not expected to be toxic to aquatic microorganisms (see Section 6.1.7). Hence, based on extrapolation from aquatic microorganisms, the reaction products of 1-decene, 1-dodecene, and 1-octene, hydrogenated would not be expected to produce adverse effects to soil microorganisms. For this reason, toxicity testing to soil microorganisms is not necessary given the available extrapolation data for aquatic microorganisms. See further details and supplied read-across data under the "endpoint summary" entry.*"

ECHA observes that the read-across suggested by the Registrant for this endpoint includes two studies; one with hydrogenated polyalphaolefins (PAO) (Microtox ™ Assay) and one with 1-dodecene trimer (Alkene 4) (Activated Sludge, Respiration Inhibition Test). The Registrant's justification for the read-across is that the above mentioned substances are structurally similar substance to the registered substance.

ECHA concludes that the read-across from hydrogenated PAO and from 1-dodecene trimer, hydrogenated suggested by the Registrant is not acceptable. Firstly, the Registrant has provided a short description of the justification for read-across, which fails to provide reasons that the properties of the registered substance may be predicted from the properties of the read-across substance, as specified under points a and b above.

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Secondly, the read-across to the registered substance from hydrogenated PAO is not acceptable, because the registered substance constituents are only dimers and hydrogenated PAOs can generally be constituted by dimers, trimers or higher oligomers, and the precise composition cannot be predicted by such a generic name. The read-across to the 1-dodecene trimer, hydrogenated (Alkane 4) is not acceptable, because the registered substance constituents are only dimers and the substance used for read-across consist of trimers. Moreover, the read-across to the registered substance, which varies in size from 18- to 24-carbon atoms, from a substance which varies in size around 30- to 40- carbon atoms is extrapolation and not interpolation as specified in Annex IX, section 1.5 of the REACH Regulation. The Registrant has provided no adequate basis for considering that there is a constant pattern in change of properties of these substances with change in the number of carbon atoms. The read-across to 18- to 24-carbon atom chains is extrapolation, and fails to meet the requirement of Annex XI, section 1.5, for interpolation, as specified under point a above.

For the weight of evidence arguments, ECHA notes the following. It is asserted that the registered substance is not expected to be toxic to aquatic micro-organisms and based on extrapolation from aquatic micro-organisms it is not expected that the registered substance is toxic to soil micro-organisms. However, the soil micro-organisms are a different taxonomic level and the provided predictions from aquatic micro-organisms or from terrestrial plants/invertebrates to soil micro-organisms are not acceptable. Moreover, the read-across from the tested substances to the registered substance for the toxicity to aquatic micro-organisms is not acceptable because of the reasons mentioned above.

Furthermore, ECHA notes that the Registrant has identified a number of uses of the substance by workers in industrial settings, by professional workers and by consumers in the registration dossier and direct and/or indirect exposure of the soil compartment is likely. This means that the present information requirement cannot be omitted because exposure to soil compartment is unlikely (Column 2 of Annex IX, 9.4).

ECHA thus considers that there is not sufficient weight of evidence from the totality of these sources of information that could lead to the reliable conclusion that the registered substance does not have effects on soil micro-organisms as measured by toxicity to soil micro-organism study. Consequently, the requirement of Annex XI, 1.2, for a sufficient weight of evidence, has not been met, and this cannot be considered as a valid adaptation of the information requirement.

The Registrant agreed to perform the toxicity to soil micro-organisms test in their comments to the draft decision on 28 July 2011 and in the updated IUCLID dossier submitted on 6 September 2011.

Therefore, pursuant to Article 41(1)(a) the Registrant is required to carry out the following studies:

- Long-term toxicity testing on invertebrates (Annex X, 9.4.4., test method OECD 222 or OECD 220 or OECD 232 or OECD 226)
- Long-term toxicity testing on plants (Annex X, 9.4.6., test method with at least six species tested using radish and least five other species of which a

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minimum two monocotyledonous species and three dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline;

and

- Test on toxicity to soil micro-organisms (Annex IX, 9.4.2., test method: EU C.21/OECD 216);

using the registered substance.

h. Long-term toxicity to sediment organisms

Effects on long-term toxicity to sediment organisms is a standard information requirement of Annex X, 9.5.1. at the present tonnage level.

The Registrant proposes to adapt from the standard information requirement with the following justification (updated 6 September 2011): "'*Soil microorganism toxicity studies as well as additional follow-up terrestrial plant studies in radish have been planned for the registered substance to provide more extensive and definitive data for the soil compartment. The need for further testing in soil or sediment organisms will be re-assessed pending the completion and thorough review of the outcome of the above planned studies.*'

ECHA notes that as toxicity to soil organisms and toxicity to sediment organisms are different information requirements under REACH the proposed testing strategy cannot be agreed. ECHA further notes that the Guidance on Information Requirements and Chemical Safety Assessment R.7b (page 137) clarifies that 'For substances that are highly insoluble and for which no effects are observed in aquatic studies, the application of EPM is not possible. In this case at least one sediment test has to be performed.'

In the absence of sufficiently adequate information and/or testing proposal(s) on long-term toxicity studies on sediment organisms and based on the intrinsic properties of the substance, this justification for data waiving and proposed testing strategy is not considered to be in line with the specific rules for adaptation indicated in column 2 of Annex X, 9.5. Accordingly, the Registrant has not fulfilled all the information requirements outlined in Annex X, 9.5.

Therefore, the Registrant is required to carry out the following study: Long-term toxicity to sediment organisms (Annex X, 9.5.1, test method: OECD 225) using the registered substance.

2) Missing information related to Chemical Safety Report

Articles 10(b) and 14, as well as Annex I set out the general provisions for assessing substances and preparing chemical safety reports (CSR). The following elements are missing from the CSR.

i. Information on the identification of derived no effects levels DNEL(s) and risk characterisation for worker and consumer by inhalation route

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Articles 10(b) and 14(1) as well as Annex I, sections 1.0.1. and 1.4.1. require the registrant to establish DNEL(s) for the registered substance for each relevant human population and for different routes of exposure. If more than one route of exposure is likely to occur, a DNEL shall be established for each route of exposure and for the exposure from all routes combined.

ECHA notes that the CSR (paragraph 5.11, Table 40 and 41) provided by the Registrant contains acute inhalation DNELs for workers and the general population.

In the updated CSR (6 September 2011) the Registrant has described on pp. 100-102 his approach in deriving the DNEL for acute inhalation route for workers and general population. He has made reference to ECHA Guidance on information requirements and chemical safety assessment (ECHA, December 2010) Volume 8: Dose (concentration) – response characterisation, Appendix R.8-8. However, he has derived the DNEL from the LC50 value by using the overall assessment factor of [redacted] for workers and [redacted] for general population. This approach gave as the DNEL for workers a value of 260 mg/m3, which is 22 % of the concentration which killed 50 % of the test animals in the key acute inhalation toxicity study. The Registrant should justify why he considers that the deviations from the Guidance R.8 to derive DNEL is appropriate to guarantee the safe use of the substance. Guidance R.8 (p. 106 of Appendix R.8-8) advices a large assessment factor, a default of 100, to be used when severe effects (lethality) are the basis of the assessment. In the previous version of the CSR (Submission number [redacted]), the Registrant followed the large assessment factor approach as specified in the Guidance R.8 by using assessment factor 100. The Registrant did not justify in the updated CSR why his approach to derive DNELs had changed.

The Registrant shall therefore justify its use of assessment factors where they deviate from those recommended by the Guidance R.8. If substance specific data is not provided to justify the use of assessment factors which deviate from the ones recommended by the Guidance, then the Registrant shall re-calculate the acute inhalation DNELs for workers and consumers, and calculate the risk characterisation ratios for short-term exposure among workers and consumers and suggest risk mitigation measures when risks are identified.

The Registrant is requested to update the registration dossier and the CSR accordingly. For detailed guidance on the calculation of the appropriate DNELs, we invite you to consult the following manual:

Guidance on Information requirements and chemical safety assessment. Chapter R.8: Characterisation of dose [concentration]-response for human health (version 2, December 2010) (http://echa.europa.eu/documents/10162/13632/information_requirements_r8_en.pdf).

j. PNEC soil and PNEC sediment, relevant exposure assessment for the soil and sediment compartments (taking into account, where relevant, the waste life-cycle stage of the substance) and resulting risk characterisation for the soil and sediment compartments

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Pursuant to Articles 10(b) and 14, as well as Annex I, point 3.3.1, the PNEC for each environmental sphere shall be established based on the available information.

Pursuant to Article 14(4) and Annex I, point 0.6 of the REACH Regulation, if the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC or is assessed to be PBT or vPvB, the chemical safety assessment shall also consider the Exposure assessment and Risk characterization steps. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

As described in Guidance on the scope of exposure assessment B.8 (December, 2011) such identified hazards (among others) necessitating exposure assessment are the following: "hazards for which currently no classification criteria exists, but there is information to show that the substance has such hazardous properties".

ECHA notes that the registered substance is self-classified under Regulation (EC) No 1272/2008 as harmful if inhaled (Acute Tox. 4) and for aspiration hazard 1: May be fatal if swallowed and enters airways (H304).

ECHA also notes that the Registrant has waived long-term testing on soil and sediment organisms (as described under sections 1. e, f, g and 1.h above) and the subsequent PNEC derivations. Additionally the Registrant claims in the CSR that environmental exposure assessment is not applicable.

In the absence of sufficiently adequate information and/or testing proposal(s) on long-term toxicity studies on soil and sediment organisms, PNEC derivation on both of these compartments and environmental exposure assessment cannot be established. Based on the (self)-classification of the registered substance the justifications for data waiving cannot be considered to be in line with the information requirement specified in Annex I and with the specific rules for adaptation indicated in Annex X. Accordingly, the Registrant has not fulfilled all the information requirements outlined in those Annexes.

Therefore, pursuant to Articles 10(b) and 14, in line with Annex I and according to Guidance on Information Requirements and Chemical Safety Assessment R.10 (Characterisation of dose(concentration)-response for environment) and Guidance on Scope of Exposure Assessment B.8 (August 2011) the Registrant shall:

- establish PNEC soil and PNEC sediment on the basis of observed effects of the required tests on toxicity to soil and sediment organisms;

and

- perform exposure assessment covering any exposures that may relate to identified hazards to soil and sediment organisms and risk characterisation for the soil and sediment compartments (taking into account direct and indirect exposure of these compartments) considering all stages of the life-cycle of the substance resulting from the manufacture and identified uses (taking into account, where relevant, the waste life-cycle stage of the substance) and on the basis of the established PNECs.

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IV. Adequate identification of the composition of the tested material

In carrying out the studies required by the present decision it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

Furthermore, 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. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
Jukka Malm
Director of Regulatory Affairs