EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003640-81-06/F Helsinki, 25 September 2014

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

For 2,2,4(or 2,4,4)-trimethylhexane-1,6-diamine, CAS No 25513-64-8 (EC No 247-063-2), 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 2,2,4(or 2,4,4)-trimethylhexane-1,6-diamine, CAS No 25513-64-8 (EC No 247-063-2), 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 submitted after 6 March 2014, 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 from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 23 August 2013.

On 28 November 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments by the 13 January 2014.

On 13 January 2014 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 6 March 2014 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 10 April 2014 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 22 April 2014 ECHA referred the draft decision to the Member State Committee.

By 12 May 2014, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant on the proposals for amendment into account.

After discussion in the Member State Committee meeting on 10-13 June 2014, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 12 June 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

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

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annexes VII, VIII, IX, 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. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Algae, growth inhibition test, EU C.3./OECD 201);
2. Long-term aquatic toxicity testing on invertebrates (Annex IX, Section 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20./OECD 211);
3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD 210);
4. Effects on terrestrial organisms:
   a) Long-term toxicity testing on terrestrial invertebrates (Annex X, 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222, or Enchytraeid reproduction test, OECD 220, or Collembolan reproduction test in soil, OECD 232);
   b) Long-term toxicity testing on plants (Annex X, 9.4.6.; test method: Terrestrial Plant Test: Seedling Emergence and Seedling Growth, OECD 208, with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030); and
   c) Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD 216).
5. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.; test method: Hydrolysis as a Function of pH, EU C.7./OECD 111).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **2 October 2015**. The timeline has been set to allow for possible sequential testing as indicated under section III.A.4.d below.

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 derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(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.

1. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

"Growth inhibition study aquatic plants" is a standard information requirement as laid down in Annex VII, Section 9.1.2. 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.

The Registrant has submitted a study with *Scenedesmus subspicatus* (new name: *Desmodesmus subspicatus*). ECHA notes that the study has several deficiencies: there is no information provided on test temperature and pH; analytical monitoring of the test concentrations has not been performed; it is not clear whether the validity criteria are fulfilled; as well as no results are provided on the basis of growth rate.

In accordance with Section 1.1.2. of Annex XI of the REACH Regulation, data from experiments not carried out according to the test methods referred to in Article 13(3) shall only be considered equivalent to data generated from the standard test method if they fulfil the cumulative conditions outlined in that provision. As test temperature, pH and fulfillment of validity criteria are relevant key parameters of the standard toxicity study with algae, and they have not been provided, the second of the listed conditions is not fulfilled by the submitted study (i.e. there is no adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3)). Furthermore, ECHA observes that there is no adequate and reliable documentation of the study provided in the IUCLID registration dossier (i.e. the fourth of the listed conditions is not fulfilled). As two out of four conditions, which have to be fulfilled cumulatively, are not met, ECHA needs not to assess the fulfilment of the other conditions to conclude that the toxicity study on algae provided in the registration dossier does not fulfil the conditions for an adaptation of the standard testing regime as set out in Annex XI, Section 1.1.2.

Thus, 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.

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: Algae, growth inhibition test (test method: EU C.3./OECD 201).

2. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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.

The Registrant has waived testing on long-term aquatic toxicity study with invertebrates using the following justification: *"According to Annex IX, 9.1, column 2 of the REACH regulation long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The chemical safety assessment does not indicate a need for long-term tests with aquatic invertebrates."* Furthermore, ECHA notes that the Registrant has submitted a short-term study with *Daphnia magna*, and has reported deviations from the standard procedure as follows: "*Exposure period only 24 hours, incomplete documentation*". The standard duration of *Daphnia* sp. Acute immobilisation test (EU C.2. and OECD 202) is 48 hours.

In accordance with Section 1.1.2. of Annex XI of the REACH Regulation, data from experiments not carried out according to the test methods referred to in Article 13(3) shall only be considered equivalent to data generated from the standard test method if they fulfil the cumulative conditions outlined in that provision. As exposure duration is a relevant parameter of the short-term study, the third of the listed conditions is not fulfilled by the submitted short-term study. Furthermore, ECHA observes that as there is no information provided in the IUCLID registration dossier on the pH and dissolved oxygen concentration of the test solutions, which are relevant key parameters of the standard short-term toxicity study with *Daphnia*, the second of the listed conditions is not fulfilled by the submitted study (i.e. there is no adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3)). As two out of four conditions, which have to be fulfilled cumulatively, are not met, ECHA needs not to assess the fulfilment of the other conditions to conclude that the toxicity study on *Daphnia* provided in the registration dossier does not fulfil the conditions for an adaptation of the standard testing regime as set out in Annex XI, Section 1.1.2.

Furthermore, ECHA considers that, bearing in mind unrealibility of all short-term aquatic toxicity studies provided in the dossier (as indicated in sections III.1, III.2. and III.3.), there is no information available in the dossier justifying that there is no concern for aquatic environment. Thus, the justification for waiving long-term toxicity to aquatic invertebrates endpoint provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.1, or the general adaptation rules of Annex XI. Therefore, the adaptation cannot be accepted. 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 long-term aquatic toxicity to invertebrates endpoint.

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: *Daphnia magna* reproduction test, (test method: EU C.20./OECD 211).

3. Long-term toxicity testing on fish (Annex IX, 9.1.6.1.)

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has waived testing on long-term aquatic toxicity study with fish using the following justification: *"According to Annex IX, 9.1, column 2 of the REACH regulation long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. As Daphnia magna and algae were observed to be the more susceptible to trimethylhexane-1,6-diamine (EC50 31.5 and 29.5 mg/L, respectively) no long-term toxicity testing with fish is needed/proposed."* Furthermore, ECHA notes that the Registrant has submitted a short-term study with *Leuciscus idus*, and has reported deviations from the standard procedure as follows: *"Exposure period only 48 hours, incomplete documentation, no analytical monitoring*". The standard duration of Fish, acute toxicity test (EU C.1. and OECD 203) is 96 hours.

In accordance with Section 1.1.2. of Annex XI of the REACH Regulation, data from experiments not carried out according to the test methods referred to in Article 13(3) shall only be considered equivalent to data generated from the standard test method if they fulfil the cumulative conditions outlined in that provision. As exposure duration is a relevant parameter of the short-term study, the third of the listed conditions is not fulfilled by the submitted short-term study. As one out of four conditions, which have to be fulfilled cumulatively, is not met, ECHA needs not to assess the fulfilment of the other conditions to conclude that the short-term toxicity study on *Leuciscus idus* provided in the registration dossier does not fulfil the conditions for an adaptation of the standard testing regime as set out in Annex XI, Section 1.1.2.

Furthermore, ECHA considers that, bearing in mind unreliability of all short-term aquatic toxicity studies provided in the dossier (as indicated in sections III.1, III.2. and III.3.), there is no information available in the dossier justifying that the fish is less sensitive species than aquatic plants/invertebrates and that there is no concern for aquatic environment. Thus, the justification for waiving long-term toxicity to fish endpoint provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.1, or the general adaptation rules of Annex XI. Therefore, the adaptation cannot be accepted. 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 long-term toxicity to fish endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b (Section 7.8.4.1.) and OECD Test Guideline 210, Fish, Early-Life Stages (FELS) is considered as the most sensitive of the fish tests currently available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth.

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: Fish, early-life stage (FELS) toxicity test (test method: OECD 210).

4. Effects on terrestrial organisms (Annex X, 9.4.)

The Registrant must address the standard information requirements set out in Annexes IX and X, section 9.4., for different taxonomic groups: effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.).

a. Terrestrial invertebrates (Annex IX, 9.4.1. and Annex X, 9.4.4.)

Toxicity to terrestrial invertebrates is a standard information requirement under Annex IX, 9.4.1. and Annex X, 9.4.4. of the REACH Regulation. The registration dossier does not contain data for these endpoints. Instead, the Registrant has waived short- and long-term toxicity testing on effects on terestrial invertebrates using the following justification: "*Waiving of soil toxicity tests according to Column 2 of Annex IX and X of Reach Regulation 1907/2006: direct or indirect exposure of soil compartment is unlikely to occur*".

ECHA considers that in contrast to the statement of the Registrant the potential exposure to soil cannot be considered as unlikely. ECHA notes that according to the information provided in the technical registration dossier, application of the substance via sludge could be expected. For monomer use of the substance by professional users (indoor and outdoor) the Registrant assumes the local municipal sewage treatment plant (STP) as risk management measure (RMM). Furthermore for the exposure estimation he assumes that sludge from STP is applied to soil. ECHA considers that this is a correct assumption as for not known municipal STPs, the assumption of sludge application to the soil should be conservative. In addition, ECHA notes that the substance is not volatile and is not rapidly degradable with log Koc of 1.40. Based on these physico-chemical and fate properies, the presence of the substance in the sludge of municipal STP is highly expected. In addition, ECHA notes that indirect exposure levels via air/wastewater releases were also estimated by the Registrant for other exposure scenarios.

In his comments to the draft decision the Registrant stated that exposure via sewage sludge would not be relevant for the substance subject to the present decision due to its physico-chemical properties and fate considerations. The Registrant claimed that the adsorption potential of the substance would be very low. The Registrant specified that a fate estimations by the EPI Suite model show low adsorption of the substance to a sludge (1.78% of the amount entered sewage treatment plant which in practice "*will be much lower*"). Furthermore, the Registrant referred to ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.16 (Version 2.1, October 2012) stating that the amount of the substance bound to a sludge would be zero.

ECHA notes that according to the REACH Regulation and further explanations provided in the ECHA Guidance on information requirements and Chemical Safety Assessment, Chapter R.7C (version 1.1, November 2012) toxicity testing with terrestrial organisms might be relevant not only for substances with high adsorption potential. ECHA understands that EPI Suite estimated values do not provide accurate simulation of the fate of the substance in sewage treatment plant, but rather give an indication that the substance will also be adsorbed to a sewage sludge. Based on ECHA's estimations by EPI Suite (version 4.1) model, approximately 1.7-1.9% of the substance entering wastewater treatment plant can be expected to be adsorbed to a sewage sludge. Furthermore, it should be noted that tables in Appendix R.16-3 of the Guidance, Chapter R.16 are based on the water-octanol partitioning coefficient, while according to the Guidance on information requirements and Chemical Safety Assessment, Chapter R.7a (version 2.3, December 2013) "caution should be exercised in using this criterion, as substances that are water soluble and have a low octanol-water partition coefficient do not necessarily always have a low adsorption potential. A *measured* adsorption coefficient is usually needed for ionising substances, since it is important to have information on pH-dependence (cationic substances in particular generally adsorb strongly)." On the basis of information provided in the dossier, the registered substance is present in the ionised form at environmentally relevant pHs. Thus, the above referred tables are not directly applicable to the substance. Therefore, ECHA considers that a portion of the substance entering sewage treatment system will be adsorbed to the sludge.

Therefore, in the absence of measured adsorption data and/or a sewage simulation study proving otherwise, ECHA considers that exposure of soil is likely and the long-term toxicity testing cannot, according to Column 2 of Annex IX, or Annex X, section 9.4, be waived on this basis. Thus, the adaptation of the standard information requirement cannot be accepted.

As explained above, the information available on these endpoints for the registered substance in the registration dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for toxicity on terrestrial invertebrates.

The earthworm reproduction test (OECD 222), Enchytraeid reproduction test (OECD 220), and Collembolan reproduction test (OECD 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. Each of these tests is suitable to also address the information requirement of Annex IX, section 9.4.1, as specified above. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

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:

Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (test method: OECD 222), or Enchytraeid reproduction test (test method: OECD 220), or Collembolan reproduction test in soil (test method: OECD 232).

b. Toxicity testing on terrestrial plants (Annex IX, 9.4.3. and Annex X, 9.4.6.)

Toxicity to terrestrial plants is a standard information requirement under Annex IX, 9.4.3. and Annex X, 9.4.6. of the REACH Regulation. The registration dossier does not contain data for these endpoints. Instead, the Registrant has waived short- and long-term toxicity testing on effects on terrestrial plants using the following justification: "*Waiving of soil toxicity tests according to Column 2 of Annex IX and X of Reach Regulation 1907/2006: direct or indirect exposure of soil compartment is unlikely to occur*".

As already outlined above under III.A.4.a. the adaptation is not justified and therefore the information available on these endpoints for the registered substance in the registration dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for toxicity on terrestrial plants.

Both the Terrestrial plants, growth test (OECD 208, in the configuration as explained below) and the Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030) are considered capable of generating information appropriate for the fulfilment of the information requirement for long-term toxicity testing on plants. Each of these tests is suitable to also address the information requirement of Annex IX, section 9.4.3, as specified above. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

OECD guideline 208 (Terrestrial Plant Test: Seedling Emergence and Seedling Growth) 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. The long-term toxicity 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. The Registrant should consider if testing on additional species is required to cover the information requirement.

In his comments to the draft decision, as for the terrestrial invertebrate testing, the Registrant stated that exposure via sewage sludge would not be relevant for the substance subject to the present decision due to its physico-chemical properties and fate considerations. The same ECHA's considerations reported above under Section III.A.4.a for the terrestrial invertebrate testing apply.

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 Plant Test: Seedling Emergence and Seedling Growth (test method: OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants (test method: ISO 22030).

c. Effects on soil micro-organisms (Annex IX, 9.4.2.)

The hazard to soil microbial communities is a standard information requirement under Annex IX, section 9.4.2. of the REACH Regulation. The registration dossier does not contain data for this endpoint. Instead, the Registrant has waived testing on effects on soil microorganisms using the following justification: "*Waiving of soil toxicity tests according to Column 2 of Annex IX and X of Reach Regulation 1907/2006: direct or indirect exposure of soil compartment is unlikely to occur*".

As it is explained above under III.A.4.a, ECHA considers that exposure of soil is likely and information on effects on soil micro-organisms cannot, according to Column 2 of Annex IX, section 9.4 or Annex XI, be waived on this basis. Thus, the adaptation of the standard information requirement cannot be accepted.

In addition, ECHA notes that toxic effects of the substance on aquatic microorganisms were observed and are reported in the dossier, section 6.1.7: "*the EC50 (16 hours) was determined as 89 mg/L indicating that the test substance may be harmful to aquatic microorganisms*". It is indicated in the Guidance on information requirements and chemical safety assessment, Chapter R. 7c (ECHA, November 2012) that where inhibition of sewage sludge microbial has been observed in Annex VIII testing, a test on soil microbial activity will additionally be necessary for a valid PNEC to be derived.

In his comments to the draft decision the Registrant stated that effects on the growth of *Pseudomonas putida* observed in the study reported in the registration dossier are related to the pH value and their relevance in natural environments is questionable. The Registrant refers to a study where pH was adjusted and results of study showed that effects on test organisms can be observed only at very high concentrations. ECHA notes that no robust study summary of the study with pH adjustment is currently available in the dossier. Therefore ECHA can neither assess the reliability of this study nor conclude that there would be no need to obtain information on effects on soil micro-organisms purusant to Annex IX, 9.4.2. Furthermore, as it is noted below, intrinsic properties of soil microbial communities are not addressed through the Equilibrium Partitioning Method (EPM).

In addition, as for the terrestrial invertebrate testing, the Registrant stated that exposure via sewage sludge would not be relevant for the substance subject to the present decision due to its physico-chemical properties and fate considerations. The same ECHA's considerations reported above under Section III.A.4.a for the terrestrial invertebrate testing apply.

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

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:

Soil microorganisms: nitrogen transformation test (test method : EU C.21./OECD 216).

d. Notes for consideration by the Registrant

ECHA observes that in chemical safety report (CSR) the Registrant has summarised following: "*Screening tests on biodegradation in water showed that the substance is neither readily nor inherently degradable. Based on the information available at the moment, the substance has to be classified as persistent and very persistent respectively*". In addition, ECHA notes that based on the data on aquatic toxicity the Registrant should consider whether or not the substance is very toxic to aquatic organisms. The Registrant needs to consider the above mentioned Guidance R. 7c to decide on the relevance of screening assessement for soil as provided in Table R.7.11-2 of that Guidance. If the Registrant concludes that some of the above required tests are not necessary to further investigate effects on terrestrial organisms, he should update his technical dossier by clearly stating the reasons for adapting the information requirement for the soil toxicity test(s) which he has – on the basis of the new information – found to be no longer necessary.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4.1. does not apply for the present endpoint. Further, ECHA notes that the requested tests under subsections (a), (b) above are not sufficient to address this standard information requirement.

5. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.)

"Hydrolysis as a function of pH" is a standard information requirement as laid down in Annex VIII, Section 9.2.2.1 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.

The Registrant has waived testing on hydrolysis using the following justification: "*There are no functional groups in the molecular structure with a relevant liability to hydrolysis. Therefore hydrolysis under environmental conditions can be excluded without testing based on structural considerations.*"

ECHA firstly notes that the reason given by the Registrant for waiving testing on hydrolysis is not among adaptation possibilities of Column 2 of Annex VIII, section 9.2.2.1. Secondly, the Registrant has not justified its claim, and ECHA is of the opinion that it cannot be ruled out that amines can be susceptible for hydrolysis. For the above reasons the waiving of the study by the Registrant cannot be accepted. Consequently there is an information gap and it is necessary to provide information on this endpoint.

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: Hydrolysis as a Function of pH, (test method: EU C.7./OECD 111).

6. Further notes for consideration by the Registrant

ECHA notes that before the Member State Committee (MSC) meeting where the decision was discussed and agreement was reached the Registrant informed ECHA that he has misinterpreted ECHA's communication letter inviting the Registrant to provide comments on the proposals for amendment received from Member State Competent Authorities. In response to that ECHA noted to the Registrant that he may provide his oral remarks on the proposals for amendment during the MSC meeting. ECHA understands that during the MSC meeting the Registrant noted that he agrees performing short-term toxicity testing on aquatic invertebrates, but does not agree on performing other aquatic toxicity studies immediately, and would like to consider the outcome of the short-term toxicity testing on aquatic invertebrates first. Furthermore, the Registrant does not agree on performing study on hydrolysis as a function of pH. Instead the Registrant noted that he intends to cover other short- and long-term- aquatic toxicity endpoints as well as information requirement on hydrolysis as a function of pH by an improved weight of evidence argumentation and/or other adaptation possibilities as foreseen in the columns 2 of relevant sections of Annexes VII-IX and Annex XI.

ECHA considers that at the moment of adoptiong the decision there was no relevant information in the dossier which would allow to consider the information requirements of Annex VII, section 9.1.1., Annex VII, section 9.1.2., Annex VIII, section 9.1.3., Annex VIII, section 9.2.2.1., Annex IX, section 9.1.5. and Annex IX, section 9.1.6. as fulfilled. Therefore, the above mentioned information requirements are requested to be fulfilled by provision of information as specified in section II of the present decision.

However, ECHA notes that 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 requests 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.

7. Timeline for submitting the requested information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 9 months from the date of adoption of the decision. ECHA has taken note of the new requests included in the decision based on proposals for amendment and considers that 12 months from the date of adoption of the decision is a reasonable time period for providing the required information in the form of an updated dossier. The decision was therefore modified accordingly.

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. 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/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
Leena Ylä-Mononen
Director of Evaluation