EUROPEAN CHEMICALS AGENCY

~~HIGHLY RESTRICTED~~

Decision number: CCH-D-0000004355-75-05/F Helsinki, 22 August 2014

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

For hexamethylenediamine, CAS No 124-09-4 (EC No 204-679-6), 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 hexamethylenediamine, CAS No 124-09-4 (EC No 204-679-6), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 or more tonnes 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 12 August 2013.

On 31 October 2013 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 28 November 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision for information other than the one required and substantiated in sections II.B.3 and III.B.3 below.

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, proposal for amendment to the draft decision was submitted.

On 10 April 2014 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal for amendment received and modified Section III of the draft decision.

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

By 12 May 2014 the Registrant did not provide any comments on the proposal(s) for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 26 May 2014 in a written procedure launched on 15 May 2014. 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:

1. Spectral data (Annex VI, 2.3.5.)

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 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. Adsorption/desorption screening (Annex VIII, 9.3.1.; test method: Adsorption/desorption using a batch equilibrium method, EU C.18./OECD 106);
2. *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. /OECD 471) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102, as specified in section III.B.2 below;
3. Pre-natal developmental toxicity study (Annex X, 8.7.2.; test method: EU B.31./OECD 414) in rabbits, oral route.

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

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

1. Consideration of the results of toxicity test on *Nitrosomonas sp.* which are reported in OECD SIDS for hexamethylenediamine in the CSA as specified in section III.C.1. below (Annex VIII, 9.1.4. and Annex I, 0.5. and 3.1.5);
2. Revised environmental exposure assessment and risk characterisation as specified in section III.C.2.a) to e) below (Annex I, sections 5 and 6.);

3. Documentation for the recommended personal protective equipment, i.e. gloves to be worn need to be specified clearly when handling the substance or mixture (Article 14(6), Annex I, 5.1.1, in conjunction with Annex II, 0.1.2 and 8.2.2.2(b)), including:
   - The type of material and its thickness, and
   - The typical or minimum breakthrough times of the glove material.

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 **31 August 2015**.

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.

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.

1. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)

"Spectral data" is an information requirement as laid down in Annex VI, Section 2.3.5. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the Registrant did not provide any of the spectral data (ultra-violet (UV), infra-red (IR), nuclear magnetic resonance (NMR) or mass spectrum) required under Annex VI, section 2.3.5 of the REACH Regulation to support the indicated substance identity. ECHA points out that spectral data is a standard requirement of Annex VI, Section 2.3.5 of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit UV and IR, and NMR (such as a ^{1}H-NMR) spectra as specifically explained in the present decision. As an alternative to the NMR spectrum, a mass spectrum of the registered substance can be provided. The Registrant shall also ensure that the composition reported in the dossier is consistent with the provided analytical results.

As for the reporting of the data in the registration dossier, the information should be attached in IUCLID section 1.4.

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

Pursuant to Articles 10(a)(vi) and/or (vii), and 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-X of the REACH Regulation.

1. Adsorption/desorption screening

"Adsorption/desorption screening" is a standard information requirement as laid down in Annex VIII, Section 9.3.1. of the REACH Regulation. According to column 2 of Annex VIII, Section 9.3.1., this study does not need to be conducted if based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient), or if the substance and its relevant degradation products decompose rapidly. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the present case, the Registrant has adapted the standard information requirement on adsorption/desorption using the following justification: *"Based on readily biodegradability and to very low Log Kow, the substance is not expected to adsorb. It further does not show surface active properties. The substance is thus not expected to adsorb onto particles."*

ECHA notes that at environmentally relevant pHs the substance is present in ionised form and for such substances a measured adsorption coefficient is usually needed since it is important to have information on pH-dependence, as explained in Guidance on information requirements and Chemical Safety Assessment Chapter R.7a: Endpoint specific guidance (ECHA, Version 2.1, August 2013).

Furthermore, ECHA points out that if the testing results will indicate a strong binding potential of the substance it might have an impact deciding on terrestrial toxicity testing as both properties, the stability of a substance and adsorption potential of a substance, are taken into account assigning substances to soil hazard categories according to the Table R.7.11-2 (Guidance on information requirements and chemical safety assessment Chapter R.7c: Endpoint specific guidance (ECHA, Version 1.1, November 2012)). According to the CSR provided by the Registrant direct releases to soil are claimed for two exposure scenarios (manufacturing of the substance and use of the substance as intermediate), therefore even for the readily biodegradable, but highly adsorptive substance toxicity testing on terrestrial organisms might become relevant.

ECHA also notes that the Registrant has, contrary to column 2 of Annex VIII, Section 9.3.1. of the REACH Regulation, provided the following statement in the CSR (p. 21): *"However, because other alkyl diamines yet of longer carbon chain length may present high adsorbance to soils, it is suggested to perform an adsorption/desorption test as the OECD 106 to assess its cataionic properties to confirm or infirm our initial statement."*

For the above reasons, ECHA concludes that the Registrant has not met the adaptation criteria of column 2 of Annex VIII, Section 9.3.1. No other adaptation in line with Annex XI to the REACH Regulation has been presented in the registration dossier.

Regarding the test method, as it is noted in the above mentioned Guidance on information requirements and Chemical Safety Assessment Chapter R.7a, batch equilibrium method (EU C.18./OECD 106) uses a range of actual soils and so represents a more realistic scenario than the HPLC (OECD 121) method. ECHA considers this method to be appropriate and suitable test method for addressing the present data requirement for adsorption/desorption screening. It is to be noted that for ionisable substances, soil types should cover a wide range of pHs.

Thus, 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: Adsorption/desorption screening (test method EU C.18./OECD 106). Furthermore, the obtained information on adsorption/desorption potential of the substance is to be used in the chemical safety assessment (CSA) of the registered substance.

2. In vitro gene mutation study in bacteria

An "*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. 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.

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the Commission or ECHA.

Other tests may be used if the conditions of Annex XI are met. More specifically, Section 1.1.2 of Annex XI provides that existing data on human health properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3) may be used if the following conditions are met:

(1) Adequacy for the purpose of classification and labelling and/or risk assessment;
(2) Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
(3) Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
(4) adequate and reliable documentation of the study is provided.

According to paragraph 13 of the current OECD 471 test guideline (updated 1997) at least five strains of bacteria should be used. These should include four strains of S. typhimurium (TA1535; TA1537 or TA97a or TA97; TA98; and TA100) that have been shown to be reliable and reproducibly responsive between laboratories. These four S. typhimurium strains have GC base pairs at the primary reversion site and it is known that they may not detect certain oxidising mutagens, cross-linking agents and hydrazines. Such substances may be detected by E.coli WP2 strains or S. typhimurium TA102 which have an AT base pair at the primary reversion site.

The Registrant has provided a number of tests from the years 1975-1993 according to OECD 471 with an assigned reliability scores of 2-4. The tests used different strains of S. typhimurium, but not E.coli WP2 strains or S. typhimurium TA102. However, since the test was conducted, significant changes have been made to OECD guideline 471 and this means that the study does not meet the current guidelines, nor can it be considered as providing equivalent data according to the criteria in Annex XI.

ECHA concludes that a test using E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102 has not been submitted by the Registrant and that the test using one of these is required to conclude on *in vitro* gene mutation in bacteria.

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: Bacterial reverse mutation test (test method: EU B.13/14. / OECD 471) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102.

3. Pre-natal developmental toxicity study

Pre-natal developmental toxicity studies (OECD 414 or EU test method B.31) on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

ECHA observes that the technical dossier contains data on pre-natal developmental toxicity or similar studies in rats by the oral route using the registered substance as test material. These studies fulfil the standard information requirement for a pre-natal developmental toxicity study in a first species (Annex IX, 8.7.2.).

ECHA observes that the Registrant has provided no study record of a pre-natal developmental toxicity study in a second species in the dossier that would meet the information requirement of Annex X, Section 8.7.2. The technical dossier includes a non-guideline, non-GLP study on fetal growth retardation in mice. ECHA notes that according to Annex XI section 1.1.2 data on human health and environmental experiments not carried according to Good Laboratory Practice (GLP) or test methods referred to in Article 13(3) shall be considered equivalent to data generated by test methods corresponding to test methods referred to in Article 13(3) if the following conditions are met:

(1) adequacy for the purpose of classification and labelling and/or risk assessment;
(2) adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
(3) exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
(4) adequate and reliable documentation of the study is provided.

ECHA notes that the mouse study used only a single dose, intraperitoneal administration and exposure during gestation days 10-14. The Registrant has assigned a Klimisch score 4 and justifies this by "*Details are missing on test animals, test conditions and test results.*" Therefore ECHA concludes that conditions of Annex XI section 1.1.2 are no met and the study does not provide information equivalent to a study conducted according to OECD 414 test guideline.

ECHA further considers that the Registrant has not adapted the present information requirement in line with Annex X, 8.7., column 2 or the general rules for adaptation according to Annex XI. The only note provided by the Registrant that could be interpreted as justification for not providing the study on a second species is following: "*In conclusion, the NOAEL value of* [redacted] *mg/kg b.w./day for maternal toxicity and* [redacted] *mg/kg b.w./day for developmental effects are determined under the test conditions of the developmental study. HMD is not considered as a developmental toxicant.*" This adaptation does not meet the specific rules for adaptation according Annex X, 8.7., column 2 or the general rules for adaptation according to Annex XI. The ECHA Guidance on Information Requirements and

Chemical Safety Assessment, Chapter R.7a: Endpoint Specific Guidance, R7.6.6.4 (ECHA, version 2.1, August 2013) it is stated: *"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. This could be the case if available data demonstrate that for example the rat is the most relevant species for extrapolating to humans or if the rabbit is not a suitable model for testing for developmental toxicity."*

ECHA notes that in a two-generation reproductive toxicity study provided by the Registrant conducted with the registered substance, a reduced litter size was observed in the highest dose group. Although the detail of reporting of these findings does not allow to conclude why this occurred, these data suggest that there may be developmental toxicity. ECHA notes further that despite of the previously mentioned deficiencies, the non-guideline, non-GLP study on fetal growth retardation in mice raises a concern on developmental toxicity by concluding *"According to the authors, these observations were consistent with the hypothesis that putrescine analogues such as HMD are interfering with a primary process, probably protein synthesis, since ornithine decarboxylase activity is usually the result of protein synthesis. Hence, it seems that HMD effects in the developing system may have been mediated at least in part through its influence on fetal ornithiune decarboxylase."*

It is notable that the Registrant has not self-classified the substance for developmental toxicity. The substance does not have an EU harmonised classification for reproductive toxicity.

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.

The test in the first species was carried out by testing a rodent species and ECHA therefore considers that the test in a second species should be carried out in a non-rodent species. According to the test method EU B.31/OECD 414, the rabbit is 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 rabbit as a second species to be used.

In his comments to the draft decision the Registrant agreed that the information requirement for a second species pre-natal developmental toxicity study is currently not met. However, the Registrant considers that *"additional testing on rabbits would not provide more meaningful information on hexamethyldiamine potential developmental toxicity. Therefore, the registrant proposes to perform an adaptation to the present information and to submit it to ECHA in an update of hexamethylenediamine REACH registration dossier."*

ECHA notes that the adaptation to the requested information on pre-natal developmental toxicity study in a second species, noted in Registrant's comment is not currently available in the dossier. ECHA notes further that the Registrant's comment does not contain specific scientific arguments to justify an adaptation of the standard information requirement of a second species pre-natal developmental toxicity study. Therefore the adequacy of such an adaptation cannot be assessed.

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 rabbits by the oral route.

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.

1. Consideration of the results of toxicity test on Nitrosomonas sp.

"Activated sludge respiration inhibition testing" is a standard information requirement as laid down in Annex VIII, Section 9.1.4. of the REACH Regulation. Pursuant to Annex I, Section 0.5. the chemical safety assessment (CSA) shall be based on the information on the substance contained in the technical dossier and on other available and relevant information. Available information from assessments carried out under other international and national programmes shall be included.

Pursuant to Sections 0.6.1. and 3 of Annex I to the REACH Regulation CSA performed by a Registrant shall include an environmental hazard assessment. The hazard identification shall be based on all available information. Based on the available information, the PNEC for each environmental sphere shall be established.

Section 3.1.5 of Annex I of the REACH Regulation specifies that where there is more than one study addressing the same effect, then the study or studies giving rise to the highest concern shall be used to draw a conclusion and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier.

In the present case, ECHA observes that neither all available information was considered in environmental hazard assessment nor justification for not considering available information is provided in the CSR.

More specifically, ECHA notes that there is OECD Screening Information Dataset (SIDS) for hexamethylenediamine (OECD, 8/2002) available where it is concluded that the substance has been shown to inhibit nitrification in *Nitrosomonas sp.* (primary reference: Hockenbury, M. R. and Grady, C. P. Journal of the Water Pollution Control Federation, 768-777, (1977)). Results of this test are not taken into account in the CSA, i.e. not reported and not discussed in the CSR. The results of nitrification inhibition test with *Nitrosomonas sp.*are giving rise to a higher concern than the results of the test with *Pseudomonas putida*, which is provided in the registration dossier and is considered in the CSA.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to consider results of above mentioned toxicity test on *Nitrosomonas sp.* in the CSA and report it in the CSR. In case the Registrant considers that the results of above mentioned study cannot be used in CSA it shall be explained and justified in the CSR.

2. Revised environmental exposure assessment and risk characterisation

According to Article 14(4) of the REACH Regulation, if the substance fulfils the criteria for any of the hazard classes of Annex I to Regulation (EC) No 1272/2008 listed in Article 14(4) of the REACH Regulation or is assessed to be a PBT or vPvB, the chemical safety assessment (CSA) shall include an exposure assessment and risk characterisation. The exposure assessment shall be carried out according to section 5 of Annex I and shall include exposure scenarios and exposure estimations for the registered substance. 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. Annex I, section 6 of the REACH Regulation requires the registrant to characterise the risk for each exposure scenario.

a) Justification of release factors

Pursuant to Annex I, section 5.2.1 of the REACH Regulation the exposure estimation entails three elements: emission estimation, assessment of chemical fate and pathways and estimation of exposure levels. Emission estimation shall be performed under the assumption that the risk management measures (RMMs) and operational conditions (OCs) described in the exposure scenario (ES) have been implemented. These RMMs and OCs should be included in the ESs provided in a CSR.

According to the Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (ECHA, version: 2.1, October 2012) the exposure scenario should contain information (about operational conditions and risk management measures) based on which the assumed release factors and daily use rates can be justified. Exposure scenarios making reference to the A and B tables of the Technical Guidance Document (TGD, 2003) without providing more specific information on the conditions of use are considered insufficient to meet the REACH requirements. Furthermore, the Guidance indicates that sector specific environmental release categories (spERCs) developed by industrial sector organisations can be used in place of the conservative default environmental release categories (ERCs) of ECHA guidance. As far as possible, spERCs have to be linked to the applied RMM and OC driving the release estimation.

In the present case, in the CSR the Registrant has provided 10 ESs: 1) manufacturing of the substance; 2a) use as monomer – specific site No 1; 2b) use as monomer – specific site No 2; 2c) use as monomer – specific site No 3; 2bis) use as monomer at common sites; 3) use as intermediate; 4a) use in dry formulation (formulation); 4b) use in dry formulation (industrial end use); 5a) use in liquid formulation (formulation); 5b) use in liquid formulation (industrial end use).

ECHA notes that, in order to cover any exposures that may be related to the identified hazards, exposure estimation for most of the ESs (except ESs 4a, 4b and 5a) as stated by the Registrant in the CSR is based on "*A&B Table approach according TGD 2003*" or on sector specific environmental release category (spERC) release factors. In some ESs the Registrant stated that "*the relevance of calculated exposure estimation data are checked and validated helping internal measures of releases*", but did not provide any further documentation of this validation.

ECHA considers that clear and detailed justification (e.g. based on RMMs and/or OCs and/or substance properties) for using other than default ERC release factors in exposure estimation is not provided in the CSR (e.g. it is not clear whether not-reduced release factors from A and B tables are used in exposure estimation or whether these factors are reduced by efficiencies of RMMs which are noted in the ESs). Where internal measures of releases are available, the summary of results of these measurements is needed. This summary should be detailed enough for the reader to understand whether or not it covers relevant scenarios for possible releases from the substance processing according to the relevant ES.

Furthermore, ECHA observes that in ES 3 the estimated substance removal from wastewater via sewage treatment is [redacted]%. ECHA notes that this information is not consistent with other information contained in the dossier (e.g. *"wastewater emission controls are not applicable as there is no direct release to wastewater"*) and thus, the information provided by the Registrant is considered as inconsistent. ECHA also notes that it is not clear whether waste water treatment is necessary to work within the scope of ES 3.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide in the relevant ESs (that is, all the other ESs than ESs 4a, 4b and 5a), where non-default ERC release factors are used for exposure estimation, a clear and detailed justification (e.g. based on RMMs and/or OCs and/or substance properties) for any non-default ERC release factors used in the exposure estimation and to specify if waste water treatment is needed for exposure estimation for ES 3. The chemical safety report shall be amended accordingly.

b) Receiving water flow rate

Pursuant to the Annex I, section 5.2.1 of the REACH Regulation the exposure estimation entails three elements: emission estimation, assessment of chemical fate and pathways and estimation of exposure levels. Emission estimation shall be performed under the assumption that the risk management measures (RMMs) and operational conditions (OCs) described in the exposure scenario (ES) have been implemented. ES shall include, where relevant, a descripton of the duration and frequency of emissions of the substance to the different environmental compartments and sewage treatment systems and the dilution in the receiving environmental compartment (Annex I, section 5.1.1).

ECHA states that in line with Annex I, section 5.1.1., one of the OCs which should be included in the ESs provided in the CSR, is in this case the dilution in the receiving environmental compartment, which depends on the receiving surface water (e.g. river) flow rate.

According to the Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (ECHA, version: 2.1, October 2012) the default receiving surface water flow rate is 18000 m3/d (corresponding to a dilution factor of 10). The flow rate or the dilution factor can be changed according to the site specific data. ECHA notes that according to this Guidance in case of site-specific assessments the dilution factor that is applied for calculation of the local concentration in surface water should not be greater than 1000.

In the present case, ECHA notes that the exposure estimation for some exposure scenarios (ES1, ES2b, ES2bis) is based on non-default local receiving water flow rate (e.g. [redacted] m3/d for ES1). Reference for the value of receiving water flow rate used is not provided nor there is any summary (detailed enough to understand whether or not it covers the relevant scenarios for possible substance fate in the environment) of any values measured provided by the Registrant.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide in the above indicated ESs a clear and detailed justification for the non-default receiving surface water flow rate used in the exposure estimation. The chemical safety report shall be amended accordingly.

c) Local predicted environmental concentration (PEC) in freshwater sediment

According to Section 5.0 of Annex I of the REACH Regulation the objective of the exposure assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. Pursuant to Annex I, section 5.2.4 of the REACH Regulation an estimation of the exposure levels shall be performed for all environmental spheres for which exposure to the substance is known or reasonably foreseeable.

In the present case, local PEC in freshwater sediment during emission episode is claimed as "n.a." ("not applicable") for ES 2C (Region 3) although exposure by the substance is reasonably foreseeable. More specifically, ECHA observes that local and regional PECs in surface water were estimated for this ES and they are not equal to zero. For other ESs provided in the CSR, where PECs in surface water are estimated, the PECs in freshwater sediment during emission episode are also estimated by the Registrant. ECHA notes that neither explanation is given on why for this ES PEC in freshwater sediment during emission episode is not relevant nor qualitative exposure estimate is provided for this PEC.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide a justification why for the ES 2C (Region 3) PEC in freshwater sediments is not relevant or he shall, in the alternative, qualitetively or quantitatively estimate relevant PEC. The chemical safety report shall be amended accordingly.

d) Local predicted environmental concentrations in sea water and in marine sediment

According to Section 5.0 of Annex I of the REACH Regulation the objective of the exposure assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. Pursuant to Annex I, section 5.2.4 of the REACH Regulation an estimation of the exposure levels shall be performed for all environmental spheres for which exposure to the substance is known or reasonably foreseeable.

In the present case, ECHA notes that for a number of ESs (e.g. 2bis) local PECs in sea water and marine sediment are claimed as "n.a." ("not applicable") without any further justification or qualitative exposure estimates. For example, in the absence of the data on the location of 'common sites', they may also be placed close to a sea, i.e. the substance may be released to marine environment and exposure of sea water and marine sediments would become relevant. ECHA points out that it has to be explained why these local PECs are not relevant.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide a justification why the local PECs in sea water and marine sediment are not relevant or he has to, in the alternative, qualitatively or quantitatively estimate relevant PECs. The chemical safety report shall be amended accordingly.

e) Risk characterisation

Pursuant to Annex I, section 6 of the REACH Regulation the risk characterisation shall consider the environmental spheres for which exposure to the substance is known or reasonably foreseeable, under the assumption that the risk management measures described under exposure scenario in the Section 5 have been implemented. The risk characterisation consists of a comparison of the PECs in each environmental sphere with the Predicted No-Effect Concentrations (PNECs).

ECHA notes that there is a number of risk characterisation ratios (RCRs) missing while the Registrant claims that these are "n.a." ("not applicable"). However for some of them both PEC and respective PNEC values are available (e.g. marine aquatic and marine sediment RCRs for ES1, freshwater aquatic RCR for ES 2C (Region 3)).

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide all quantitative RCRs where both PEC and respective PNEC values are available. If any of the RCR values is not provided, a detailed justification why this quantitative RCR is not relevant, should be provided in the CSR. The chemical safety report shall be amended accordingly.

3. *Documentation that risks to workers are adequately controlled*

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.

Pursuant to Annex II, section 0.1.2 of the REACH Regulation the information provided in the Safety Data Sheet shall be consistent with that in the CSR. The requirements of Safety Data Sheets are specified in Annex II (amended by Commission Regulation (EU) No 453/2010).

According to section 8.2.2.2(b) of Annex II to the REACH Regulation, the type of gloves to be worn when handling the substance or mixture 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 dermal exposure, including:

- The type of material and its thickness,
- The typical or minimum breakthrough times of the glove material.

The Registrant in the CSR indicated the following for hand protection: "*For processes where the possibility for exposure arises, wear appropriate protective gloves resistant to chemical substances (in accordance with standard EN 374-1). Gloves should be selected according to the application and the duration of use at the work station. Observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. Gloves should be discarded and replaced if there is any indication of degradation or chemical breakthrough.*"

In section 11 of the technical registration dossier in the part for Exposure controls/personal protection, the following is stated: "*Risk management measures are described in the CSR attached.*"

ECHA notes that the substance is classified as causing severe skin burns. To ensure the safe use of a substance it is essential to have detailed guidance on risk management measures, e.g. personal protective equipment. Although the gloves are reported in the CSR as required personal protective equipment to prevent dermal exposure to the substance, the material type of gloves to be worn, its thickness and typical or minimum breakthrough time when handling the substance is not specified.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide documentation for the recommended material type, its thickness and the typical or minimum breakthrough time for the glove type recommended, with regard to the amount and duration of dermal exposure in the CSR.

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 been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation not for all joint registrants.

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://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