Decision number: CCH-D-0000004483-74-05/F Helsinki, 17 September 2014

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

For cyclohexyldimethylamine, CAS No 98-94-2 (EC No 202-715-5), 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 submitted jointly for cyclohexyldimethylamine, CAS No 98-94-2 (EC No 202-715-5), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. ECHA notes that the tonnage band for several members of the joint submission is 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 17 October 2013.

On 22 November 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 23 December ECHA received comments from the Registrant agreeing to ECHA's draft decision. The Registrant acknowledged the information gaps identified by ECHA in section II.A. of that decision and proposed a tiered approach for providing the required information. Regarding the information related to the chemical safety assessment and the chemical safety report required in section II.B., the Registrant had no comments and agreed to update the chemical safety report accordingly.

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, a 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 did not amend the draft decision.

The present decision relates solely to a compliance check examination for:
- *in vitro* gene mutation study in mammalian cells (Annex VIII, 8.4.3.),
- sub-chronic toxicity study (90-day) (Annex IX, 8.6.2.),
- pre-natal developmental toxicity study (Annexes IX and X, 8.7.2),
- DNELs for systemic effects for workers (Annex I, 1.4.1.),
- revised DNELs for local effects via the inhalation route for workers (for acute and long-term exposure), using the methodology recommended by ECHA or a full justification for not using the methodology recommended by ECHA (Annex I, 1.4.1.),
- information on risk management measures and operational conditions for certain exposure scenarios (Annex I, 5.1.1.),
- documentation that risks to the freshwater compartment are adequately controlled for a certain exposure scenario) (Article 14(6))

The other compliance check requirement of two-generation reproductive toxicity study is addressed in a separate decision although all requirements were initially addressed together in the same 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 proposal for amendment. The Member State Committee took the comments of the Registrant on the proposal for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision relating to requirements as indicated above 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 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 VIII and IX 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. *In vitro* gene mutation study in mammalian cells (Annex VIII, 8.4.3.; test method: EU B.17./OECD 476);

2. Sub-chronic toxicity study (90-day), oral route (Annex IX, 8.6.2.; test method: EU B.26./OECD 408) in rats;

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

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

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

1. DNELs for systemic effects for workers (Annex I, 1.4.1.);

2. Revised DNELs for local effects via the inhalation route for workers (for acute and long-term exposure), using the methodology recommended by ECHA
   or
   A full justification for not using the methodology recommended by ECHA (Annex I, 1.4.1.);

3. Information on risk management measures and operational conditions for exposure scenarios ES3 ("Use of DMCHA in flexible foams"), ES4 ("Use of DMCHA in rigid foams") and ES5 ("Use of DMCHA in coatings") (Annex I, 5.1.1.);

4. Documentation that risks to the freshwater compartment are adequately controlled for all exposure scenario ES4 ("Use of DMCHA in rigid foams") (Article 14(6)).

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 **26 September 2016**. The timeline has been set to allow for sequential testing as appropriate.

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

1. *In vitro* gene mutation study in mammalian cells (Annex VIII, 8.4.3.)

An "*In vitro* gene mutation study in mammalian cells" is an information requirement as laid down in Annex VIII, Section 8.4.3. of the REACH Regulation, "*if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2.*" is obtained. ECHA notes that the registration dossier contains negative results for both these information requirements.

Therefore, 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 not provided any study record of an *in vitro* gene mutation study in mammalian cells in the dossier that would meet the information requirement of Annex VIII, Section 8.4.3.

The technical dossier does not contain an adaptation in accordance with column 2 of Annex VIII, Section 8.4.3. or with the general rules of Annex XI for this standard information requirement.

In his comments, the Registrant indicated that he intended to fill the data gap by using the in vivo mammalian erythrocyte micronucleus study available in the dossier in place of the requested study.

ECHA notes that column 2 of Annex VIII, 8.4.3. of REACH indicates that the *in vitro* gene mutation study in mammalian cells could be avoided "*if adequate data from a reliable in vivo mammalian gene mutation test are available*". However, the only available *in vivo* data for mutagenicity comes from a study which is, as pointed out by the Registrant himself, unreliable and which therefore does not meet the above-mentioned column 2 provisions. Furthermore, this study is an *in vivo* mammalian erythrocyte micronucleus test. An in vivo micronucleus test is designed to detect chromosome aberration but not gene mutations. Therefore this test cannot be considered to be a gene mutation test in mammalian cells. In conclusion, the fact that the dossier contains an unreliable *in vivo* study for the endpoint chromosome aberration does not constitute a valid argument to adapt information requirement for the *in vitro* gene mutation study in mammalian cells required by Annex VIII, 8.4.3. of REACH.

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.

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: *In vitro* mammalian cell gene mutation test (test method: EU B.17./OECD 476).

2. Sub-chronic toxicity study (90-day), oral route (Annex IX, 8.6.2.)

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier the Registrant has provided a study record for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD 422) and a two-week study by inhalation. However, these studies do not provide the information required by Annex IX, Section 8.6.2., because exposure duration is less than 90 days.

The Registrant has sought to adapt this information requirement. The justification of the adaptation given by the Registrant is that "*testing DMCHA for sub-chronic repeated dose*

toxicity cannot be justified on scientific grounds due to the lack of systemic toxicity reported in the 28 day study."

The justification of the adaptation given by the Registrant most closely relates to the adaptation possibility of Annex IX, 8.6.2., column 2 according to which no sub-chronic toxicity study needs to be conducted if "*the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit test', particularly if such a pattern is coupled with limited human exposure.*" The Registrant has however not justified or demonstrated with data or information that the cumulative conditions of that adaptation possibility are fulfilled. For example, the Registrant did not demonstrate that the substance is unreactive, insoluble and not inhalable. Furthermore, in the OECD 422 only doses lower than the recommended limit dose (i.e. 1000 mg/kg bw/day) were used, the highest dose tested being approximately 91-104 mg/kg bw/day. Therefore, it is possible that there would be adverse effects at higher dose level.

Therefore, the adaptation of the information requirement suggested by the Registrant cannot be accepted.

In his comments, the Registrant indicated his intention to submit a testing proposal for a repeated dose 90-day oral toxicity study, including full oestrous and sperm analysis.

ECHA notes that the Registrant does not need to submit a testing proposal as this study is already requested in the present decision. The Registrant will have to perform the study after he receives the final version of that decision. Any testing proposal for this endpoint will be treated as administratively inadmissible.

Furthermore, ECHA notes that the Registrant intends to examine extra parameters such as full oestrous and sperm analysis in addition to default recommendations of the test guideline. ECHA would like to remind the Registrant that these extra parameters would not be accepted as a valid adaptation to the requirements of Annex X, 8.7.3. (two-generation reproductive toxicity study) because a repeated dose toxicity study does not cover key parameters required for a two-generation reproduction toxicity study like 10 week pre-mating period, not less than 20 pregnant females per group, post-natal evaluation of the F1 generation and breeding and evaluation of the F2 generation.

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.

In light of the physical-chemical properties of the substance (liquid with low vapour pressure) and the information provided on the uses and human exposure (no uses with spray application), ECHA considers that testing by the oral route is most appropriate.

According to the test method EU B.26/OECD 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

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: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD 408) in rats.

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

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

In the technical dossier the Registrant has provided a study record for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD 422). However, this study does not provide the information required by Annex IX, Section 8.7.2., because it does not cover key parameters of a pre-natal developmental toxicity study like examinations of foetuses for skeletal and visceral alterations.

The Registrant has sought to adapt this information requirement. The justification of the adaptation given by the Registrant is based on animal welfare and the lack of effects in the OECD 422 study.

However, ECHA notes that this adaptation does not meet the specific rules for adaptation of Annex IX, 8.7., column 2 because the substance has toxicological activity: the substance has a classification for acute toxicity, eye damage, and skin corrosion. Furthermore, there is significant worker exposure.

In his comments, the Registrant indicated his intention to submit a testing proposal for a teratogenicity study in rats via the oral route.

ECHA notes that the Registrant does not need to submit a testing proposal as this study is already requested in the present decision. The Registrant will have to perform the study after he receives the final version of that decision. Any testing proposal for this endpoint will be treated as administratively inadmissible.

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

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

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

Notes for consideration by the Registrant

In addition, a pre-natal developmental toxicity study on a second species is part of the standard information requirements as laid down in Annex X, Section 8.7.2. for substances registered for 1000 tonnes or more per year (see sentence 2 of introductory paragraph 2 of Annex X).

The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if weight of evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed. If the Registrant considers that testing is necessary to fulfil this information requirement, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species. If the Registrant comes to the conclusion that no study on a second species is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex X, 8.7.2.

B. 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 (CSR) which shall document the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

1. DNELs for systemic effects for workers (Annex I, 1.4.1.)

Pursuant to Annex I, 1.4.1., a DNEL(s) shall be established for the substance, reflecting the likely routes, duration and frequency of exposure. Alternatively, Annex I, 1.4.2. of the REACH Regulation requires the Registrant to clearly state and fully justify if it is not possible to identify a DNEL.

In the registration dossier, the following DNELs have not been derived for workers:
- acute systemic dermal effects;
- acute systemic inhalation effects;
- acute local dermal effects;
- long-term systemic dermal effects;
- long-term systemic inhalation effects;
- long-term local dermal effects.

Thus, only DNELs for local inhalation effects have been derived for workers. DNELs for local dermal effects and all DNELs for systemic effects have been waived.

ECHA acknowledges that local DNELs cannot be derived for the registered substance for dermal or ocular effects.

However, ECHA disagrees with the waiver on DNELs for systemic effects. As justification for not having derived DNELs for systemic effects, the Registrant claimed that the available data did not indicate systemic toxicity following oral or dermal short-term exposures. However, ECHA notes that in the OECD 422 test provided in the registration dossier (Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test) the limit dose level of 1000 mg/kg_{bw}/day recommended by the test guideline was not achieved due to low palatability of the test substance, and that the substance was only tested up to the level of 100-150 mg/kg_{bw}/day. These tested doses are too low to assess whether the substance could cause systemic toxicity. Therefore, ECHA

believes that the waiver for not providing DNELs for systemic effects is not correct, and that DNELS for systemic effects should be derived.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit in the chemical safety report the following information: DNELs for systemic effects, for workers, and assessment of the related risks. When deriving the DNELs, the Registrant shall take into account the results of the studies requested under section II.A. and he shall use the assessment factors recommended in ECHA's *Guidance on information requirements and chemical safety assessment Volume 8, Chapter R.8: Characterisation of dose [concentration]-response for human health (version 2.1, November 2012)*.

2. Revised DNELs for local effects via the inhalation route for workers (for acute and long-term exposure), using the methodology recommended by ECHA or full justification for not using the methodology recommended by ECHA (Annex I, 1.4.1.)

Annex I, 1.4.1 of the REACH Regulation requires that the following factors shall, among others, be taken into account when deriving DNELs:

a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
b) the nature and severity of the effect;
c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
d) and that the DNELs reflect the likely route(s), duration and frequency of exposure.

The ECHA *Guidance on information requirements and chemical safety assessment* (Volume 8, Chapter R.8) provides further details and specifically provides default factors which should be applied to derive DNELs in the absence of substance specific information.

The starting point for deriving the DNELs for local effects via the inhalation route for workers (for acute and long-term exposure) presented in the registration dossier is a non-guideline repeated dose toxicity study, performed via the inhalation route. The exposure period was only two weeks.

ECHA observes that the Registrant has not followed the recommendations of ECHA's *Guidance on information requirements and chemical safety assessment Volume 8, Chapter R.8: Characterisation of dose [concentration]-response for human health (version 2.1, November 2012)* and has not provided a full justification for the derivation of DNELs in line with Annex I, 1.4.1.

In particular, when deriving the DNELs for local effects via the inhalation route for workers (for acute and long-term exposure), the Registrant has used an assessment factor of 3 for interspecies variation. However, according to the above mentioned ECHA Guidance R.8., no assessment factor is needed for interspecies difference for local DNELs, if the adverse effect is "*simple destruction of membranes*", which seems plausible for a corrosive substance.

In contrast, the Registrant has not applied any assessment factors to take account of the intraspecies variation, the limited exposure duration, and the deficiencies of the available data, and has not provided any justification for that. ECHA Guidance R.8. recommends an assessment factor of at least 5 for intraspecies variation (for workers), and an assessment factor of 6 for the extrapolation from sub-acute to chronic exposure duration (the exposure period of the study used as starting point for deriving the DNEL was only two weeks). Moreover, an additional assessment factor is potentially needed to cover remaining

uncertainties due to the deficiencies of the study used for the assessment (non-guideline study).

As explained above, the information provided on DNELs for the registered substance in the chemical safety report does not fulfil the requirement for preparing a chemical safety report as described in Annex I, 1.4.1. of the REACH Regulation, also considering that the assessment factors used are not in accordance with ECHA *Guidance on information requirements and chemical safety assessment* Volume 8, Chapter R.8. Moreover, those assessment factors are not fully justified, as required in Annex I, 1.4. of the REACH Regulation. Consequently it is necessary to revise the DNELs or to provide a full justification

The Registrant is given two options: The Registrant shall revise the DNELs for workers by applying the assessment factors recommended by ECHA that are appropriate in this case. Subsequently, the Registrant shall re-assess related risks.

In the alternative, the Registrant shall, in accordance with Annex I, 1.4.1, provide a full justification for the DNELs derived for local effects via the inhalation route for workers (for acute and long-term exposure) provided in the chemical safety report by specifying how the following has been taken into account:

a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
b) the nature and severity of the effect;
c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
d) and that the DNELs reflect the likely route(s), duration and frequency of exposure.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit in the chemical safety report either of the following information: Revised DNELs for local effects via the inhalation route for workers (for acute and long-term exposure) using the assessment factors recommended by ECHA and re-assessment of related risks *or* a full justification for not using the recommended assessment factors in DNEL derivation. The results of the studies requested under section II.B. shall be taken into account when revising the DNELs.

3. Information on risk management measures and operational conditions for exposure scenarios ES3 ("Use of DMCHA in flexible foams"), ES4 ("Use of DMCHA in rigid foams") and ES5 ("Use of DMCHA in coatings") (Annex I, 5.1.1.)

Pursuant to Annex I, 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 exposure scenarios provided in the 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. Furthermore, the guidance indicates that sector specific environmental release categories (spERCs) developed by industrial sector organisations can be used in place of the default environmental release categories (ERCs) of ECHA guidance. As far as possible, spERCs have to be linked to the RMM and OC driving the release estimation.

In the present case, in the CSR the Registrant has provided seven exposure scenarios:
- Manufacture of DMCHA (ES1);
- Formulation of DMCHA (ES2);
- Use of DMCHA in flexible foams (ES3);
- Use of DMCHA in rigid foams (ES4);
- Use of DMCHA in coatings (ES5);
- Use of DMCHA in adhesives and sealants (ES6);
- Use of DMCHA in elastomers (ES7).

ECHA notes that by using default input parameters recommended in ECHA Guidance R.16. (first tier assessment), the Registrant calculated risk characterisation ratios (RCRs) that were above 1 for:
- ES3 (Use of DMCHA in flexible foams) with ERC5 (industrial inclusion into or onto a matrix);
- ES4 (Use of DMCHA in rigid foams) with ERC5 (industrial inclusion into or onto a matrix) and ERC3 (Formulation in materials);
- ES5 (Use of DMCHA in coatings) with ERC5 (industrial inclusion into or onto a matrix).

The Registrant subsequently proposed the following refinements:

- For the three exposure scenarios ES3, ES4, and ES5 and for environmental release category ERC5, the Registrant has used a release factor to wastewater of 1%. According to the Registrant, this value of 1% is the highest release factor to wastewater available from different spERCs which the Registrant claims are relevant for the uses considered in these 3 exposure scenarios (i.e. use in flexible foams for ES3, use in rigid foam for ES4, and use in coatings for ES5) and that are applicable to ERC5. The spERC groups considered to be relevant by the Registrant are those for construction chemicals (EFCC), coatings (CEPE), and sealants and adhesives (FEICA). The Registrant indicated that by reviewing all the relevant spERCs from these three groups that are applicable to ERC5, he found that the highest estimated release to water was 1% across all these spERCs. He thus considered that the value of 1% constituted a suitable worst case surrogate for the release factor to wastewater for ERC5. By comparison, the default release factor to wastewater recommended by ECHA Guidance R.16. for ERC5 is 50%.

- For exposure scenarios ES3 and ES5, the Registrant considered that the waste water treatment plant (WWTP) efficiency would be at least 95% for ERC5. For ES4, he assumed a WWTP efficiency of 95% both for ERC5 and ERC3.

ECHA notes that the Registrant has not specified the operating conditions and the risk management measures necessary to attain the release factor to waste water of 1%. Similarly, the Registrant has not provided justifications or actual evidences to support the WWTP efficiency of 95%, as required by Annex I, 5.1.1.

ECHA considers that the Registrant has not provided enough information (e.g. based on RMMs and/or OCs) of the release factors to waste water used in the exposure estimation for ES3 in relation to ERC5, for ES4 in relation to ERC5 and ERC3, and for ES5 in relation to ERC5. There are also no information provided on the techniques necessary to attain a WWTP efficiency of 95%.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to specify RMMs and/or OCs in all exposure scenarios where input parameters used for exposure estimation are deviating from those recommended in ECHA Guidance R.16. The chemical safety report shall be amended accordingly.

4. Documentation that risks to the freshwater compartment are adequately controlled for all exposure scenario ES4 ("Use of DMCHA in rigid foams") (Article 14(6))

Article 14(6) as well as Annex I, Sections 0.1, 5.2.4 and 6.2 to 6.4 of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in the 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. Furthermore, pursuant to Annex VI, Section 5 of the REACH Regulation the information provided in the registration dossier must be consistent with that in the Safety Data Sheet. The requirements of Safety Data Sheets are specified in Annex II of the REACH Regulation.

ECHA notes that risk characterisation ratios above 1 are reported for exposure scenario ES4 (Use of DMCHA in rigid foams) in relation to the exposure release category ERC5 (industrial inclusion into or onto a matrix): RCR is 1.629 for the freshwater compartment (water column and sediment), and 1.637 for the marine compartment (water column and sediment). For this exposure scenario, the release factor to wastewater and the WWTP efficiency have already been modified compared to default values recommended by ECHA guidance R.16 (see Section III. B.3. of this Decision). In the CSR, the Registrant has indicated that the assessment would need "*further refinements or restrictions in the future*". However, the Registrant has not proposed any concrete corrective actions so far.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested either to refine his chemical safety assessment to demonstrate that the risks identified for the aquatic compartment (freshwater and marine) and for exposure scenario ES4 ("Use of DMCHA in rigid foams") are controlled, or to advise against this use of the substance. The chemical safety report and the safety data sheet shall be amended accordingly.

IV. Deadline for submitting the information

In his comments, the Registrant acknowledged the information gaps identified by ECHA in section II.A. and proposed a tiered approach for providing the required information. In particular, the Registrant indicated that he would need to assess the appropriateness of the test methods in view of the corrosive properties of the substance (Tier 1). He mentioned that methodological deviations might be necessary to ensure that administered doses are scientifically relevant and defensible, whilst and not causing undue animal distress. The Registrant explained that, the findings of Tier 1 would help in the design of the most appropriate methodologies to be used in further tests to be performed in Tier 2 (in vitro gene mutation study in mammalian cells, sub-chronic toxicity, pre-natal developmental toxicity) and in Tier 3 (two-generation reproductive toxicity study).

ECHA takes note of the Registrant's intention to perform the studies according to a tiered approach, in particular to account for the corrosive properties of the substance. As already specified in the first version of the decision, the timeline has been set in order to allow sequential testing as appropriate. Therefore, the Registrant will be able to apply a tiered testing strategy for performing the required tests.

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 36 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested another study (Two-generation reproductive toxicity study or Extended one-generation reproductive toxicity study, Annex X, 8.7.3). As this study is not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 24 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

In addition, ECHA would like to point out that the Registrant would not need to submit testing proposals for any of the studies listed in section II.A. of the present decision as these studies are already requested by that decision. Any testing proposals for these endpoints would be treated as administratively inadmissible.

V. Adequate identification of the composition of the tested material

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

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

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

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

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

Leena Ylä-Mononen
Director of Evaluation