EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114294439-34-01/F Helsinki, 31 March 2015

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

For 2-mercaptoethanol, CAS No 60-24-2 (EC No 200-464-6), 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 2-mercaptoethanol, CAS No 60-24-2 (EC No 200-464-6), 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 tonnes per year. This decision does not take into account any updates submitted after 24 July 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 1 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 7 January 2014 ECHA received comments from the Registrant agreeing to ECHA's draft decision. On 17 January 2014 the Registrant updated his registration dossier (submission number [redacted]).

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

On 24 July 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 29 August 2014 ECHA notified the Registrant of the proposal(s) 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 8 September 2014 ECHA referred the draft decision to the Member State Committee.

By 1 October 2014 in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. In addition, the Registrant provided comments on the draft decision. The Member State Committee took the comments on the proposals for amendment of the Registrant into account. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5).

The present decision does not address the information requirement for two-generation reproductive toxicity study (Annex X, Section 8.7.3.) although also this request was initially addressed together in the same draft decision. That information requirement is addressed in a separate decision.

After discussion in the Member State Committee meeting on 28-29 October 2014, a unanimous agreement of the Member State Committee on the draft decision was reached on 29 October 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 IX and X of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. Effects on terrestrial organisms
   a) Short-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1.; test method: Earthworm, acute toxicity tests, EU C.8./OECD 207), as specified in Section III.A.2.a. below;
   b) Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil micro-organisms: nitrogen transformation test, EU C.21./OECD 216), as specified in Section III.A.2.b. below;

2. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD 309).

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. Revised DNELs for workers 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 (Annex I, 1.4.1.) The results of the study requested under section II.A.1 above shall be taken into account when revising the DNELs.

2. Documentation for the recommended personal protective equipment, i.e. gloves to be worn need to be specified clearly when handling the substance (Article 14(6), Annex I, 5.1.1.:

Notes 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.

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 **7 October 2016**.

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 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. Effects on terrestrial organisms (Annex IX, 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.).

According to column 2 of section 9.4. of Annexes IX and X, these studies do not need to conducted if direct and indirect exposure of the soil compartment is unlikely. The registrant

may also seek adapt the information requirements following the general rules for adaptation in accordance with Annex XI to the REACH Regulation.

a. Short-term toxicity to terrestrial invertebrates

ECHA notes that the Registrant has adapted information requirement on terrestrial organisms using the following justification:" *The substance is not readily biodegradable. However, as the logKoc is below 3 and the substance has no cationic properties, a low adsorption potential is indicated. Therefore, binding to sewage sludge is unlikely and as a consequence a transfer to the soil compartment is not expected. As a consequence, no tests on terrestrial organisms are provided."*

ECHA considers that the justification for waiving provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2, section 9.4 of Annexes IX or X, or the general adaptation rules of Annex XI, as referred to in this section above. Therefore, the adaptation cannot be accepted.

ECHA further refers to the criteria from Table R.7.11-2 from the Guidance on information requirements and chemical safety assessment, Vol 6, Chapter R7c, under which the substance would fall into soil hazard category 2 (HC2). The substance is toxic to *Daphnia* (EC50 is 0.4 mg/L), the substance has been considered by the Registrant as potentinaly persistent (P), but based on the degradation studies, the substance does not fulfil the P criteria (according to Annex XIII), as the DT50 < 60 days, and logKoc is 0.122. Release of the substance to soil, and exposure via the soil can occur and has not been excluded by the Registrant (PNECsoil 0.29mg/kg dw). In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory short-term soil toxicity test for substances of HC2 at the Annex X level.

ECHA also observes that while the Registrant did not provide any terrestrial studies, for the PNECsoil calculation the Registrant uses an EC50 for terrestrial plants and an assessment factor of 1000 (PNECsoil 0.29 mg/kg dw). Thus, it seems that the Registrant has not provided all the available information.

Since the terrestrial tests recommended by the above Guidance are missing in the present registration dossier, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Following the draft decision the Registrant submitted comments on partitioning behaviour and on quantitative exposure assessment. On the partitioning behaviour, the Registrant claims that "*Although 2-mercaptoethanol is not readily biodegradable, it can be easily eliminated from water and is biodegradable after prolonged exposure. The substance reached 69% biodegradation after 60 days exposure in an OECD 310 study (*[redacted]*), with additional studies showing between <10 and 90% removal after 28 days (*[redacted]*) . The rate constant for the photodegradation of 2-mercaptoethanol in water is 6.8E+09 L/mol.sec, indicating that it would have a half-life in water of between 4.7 and 393 days depending on the concentration of hydroxyl radicals (*[redacted]*).*
Based on its Henry's Law Constant of 0.013 Pa m3/mol ([redacted]*), 2- mercaptoethanol would not partition to the atmosphere in significant quantities. When in the atmosphere, the substance is expected to undergo indirect photodegradation, with a half-life of approximately 8.4 hours (*[redacted]*), and, as such, indirect exposure of soil via atmospheric deposition is expected to be negligible.*

2-mercaptoethanol is unlikely to partition out of the aquatic compartment based on its low log Kow (-0.056) ([redacted]) and log Koc (0.1221) ([redacted]) and absence of cationic properties. Transfer in the environment from water to sludge, sediment or soil is expected to be unlikely. In addition, 2-mercaptoethanol is predicted to remain predominantly in the water phase during treatment at an STP, with the potential for exposure of soils via the spreading of STP sludges to agricultural land consequently being extremely low. The modelled distribution between environmental compartments shows 99.7 % would distribute to water over time, with only 0.31 % in air and none in the other environmental compartments ([redacted]). 2-mercaptoethanol will biodegrade after prolonged exposure and also be removed by indirect photodegradation and therefore indirect exposure to soil via water or air is expected to be negligible. "
Furthermore the Registrant discusses the quantitative exposure assessment:
"*A quantitative environmental exposure assessment was performed for all identified uses. Exposure based waiving for the terrestrial environment, based on this quantitative exposure assessment, takes into account direct as well as indirect exposure. Exposure modelling includes a fugacity approach as well as indirect exposure pathways such as wet or dry deposition from the atmosphere or sewage sludge application.*
The 2-mercaptoethanol dossier will be updated with the results of the long term toxicity to Daphnia study. The results of this study will be used to refine the PNEC for freshwater and consequently those for marine water as well as fresh and marine sediment and soil using equilibrium partitioning. For the terrestrial environment, exposure modelling using the updated soil PNEC indicates that all identified uses are safe, with RCRs well below [redacted] (maximum RCR for soil of [redacted]). Therefore novel testing is not considered to be necessary."
The Registrant concludes that 2-mercaptoethanol is unlikely to partition to soil based on its physico-chemical properties and quantitative exposure assessment with RCRs well below 1 for the soil compartment and no novel terrestrial toxicity testing is deemed necessary

ECHA appreciates that the partitioning behaviour of the substance would indicate that the potential for binding to organic matter in the soil is very low. ECHA observes, however, that based on its (bio)degradation potential, the substance is considered HC2. The Registrant has provided information relating to the unlikely exposure of the terrestrial compartment to the substance and indicated that further refinement of exposure assessment based on new aquatic toxicity data will be included in a dossier update. Based on exposure considerations, it is possible that further testing for terrestrial organisms may not be needed. In the dossier update submitted by the Registrant on 17 January 2014 (submission number [redacted]) no evidence was found of the CSR being updated, nor evidence of additional information on exposure being included. As such, ECHA concludes that the Registrant did not meet their commitment, outlined in their comments, to provide further refinement of the hazard and exposure assessments. Thus, it is not possible to conclude on the Registrant's claim that there is no risk to the soil compartment, since the provisions outlined in ECHA Guidance relating to HC2 substances have not been fulfilled.

In view of the observations above, given the substance properties and that the invertebrates proved the most sensitive species in the aquatic studies, testing on soil invertebrates is appropriate.

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, acute toxicity test (test method: EU C.8./OECD 207).

However, ECHA considers that presently it is not possible to determine whether results obtained from the above required short-term test (Annex IX, 9.4.1.) could be used to adequately justify an adaptation of the standard information requirement of Annex X, 9.4.4.

for long-term testing. Additionally, ECHA notes that long-term tests are suitable to simultaneously address the information requirement of Annex X, section 9.4.4. and Annex IX, section 9.4.1. Therefore, the Registrant is granted the option to carry out a long-term test as an alternative to the short-term test requested by this decision.

The earthworm reproduction test (OECD 222) and Enchytraeid reproduction test (OECD 220) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. 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 40(1) and(3), as alternative to the short-term test requested above, the Registrant can opt to carry out one of the following studies: Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1. and Annex X, 9.4.4.); test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222, or Enchytraeid reproduction test OECD 220 using the registered substance subject to the present decision.

As the Guidance advocates performing an initial screening assessment based upon the EPM, together with a confirmatory short-term soil toxicity test (the short-term toxicity to terrestrial invertebrates test, specified above), which the Registrant is requested to carry out by the present decision, ECHA considers that at this stage it is not possible to determine whether a test will be required to fulfil the standard information requirements of Annex IX, 9.4.3. and Annex X, 9.4.6. of the REACH Regulation.

The Registrant shall determine the need to perform further terrestrial toxicity tests on plants based on the outcome of the requested toxicity test on terrestrial invertebrates and the considerations set out in Table R.7.11.-2, section R7.C. of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008).

b. Effects on soil micro-organisms

The Registrant has waived testing on effects on soil micro-organisms using the following justification: *"In accordance with Column 2 of REACH Annex IX, the effects on terrestrial organisms studies (required in Section 9.4) do not need to be conducted as the chemical safety assessment according to Annex I indicates that this is not necessary."*

ECHA considers that the justification for waiving provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.4, or the general adaptation rules of Annex XI, as referred to above in this section (Section III). Therefore, the adaptation of the information requirement by the Registrant cannot be accepted.

ECHA further refers to to criteria from Table R.7.11-2 from the Guidance on information requirements and chemical safety assessment, Vol 6, Chapter R7c, according to which the substance would fall into hazard category 2 (HC2). The effects on soil micro-organisms is a standard information requirement for the substances from HC2. Therefore data on this endpoint need to be available.

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

According to ECHA Guidance on information requirements and chemical safety assessment (version 1.1, November 2012), Chapter R.7C, R.7.11.3.1. p115, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

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: Effects on soil micro-organisms: nitrogen transformation test (test method : EU C.21./OECD 216).

The Registrant is reminded that there is a ECHA final decision accepting a long-term toxicity study proposed by the Registrant on *Daphnia* with a deadline of 20 January 2014. The results of this study may affect the PNECsoil derived using the EPM. The substance is not highly adsorbtive to soil and shows some biodegradation potential suggesting that there will not be significant partitioning to soil. However, if there is a risk to soil following the results of the new data on *Daphnia*, soil invertebrates and soil micro-organisms, the Registrant shall submit a testing proposal for long-term plant toxicity testing.

2. Simulation testing on ultimate degradation in water (Annex IX, 9.2.1.2.)

"Simulation testing on ultimate degradation in water" is a standard information requirement as laid down in Annex IX, section 9.2.1.2. 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 waived the simulation test on ultimate degradation in surface water with the justification: *"The biodegradability under anaerobic and aerobic conditions as well as the elimination are well investigated for 2-mercaptoethanol. The substance is considered to be biodegradable after prolonged exposure and well eliminable from water by testing. Therefore, no further testing on biodegradation is deemed necessary."*

The Registrant based this waiving on a GLP key study conducted according to OECD guideline 310 (CO2-Headspace test) with a prolonged test duration (60 days). At the end of the exposure period 69% of the substance has been biodegraded – the Registrant thereof assessed the registered substance as being "biodegradable". The (simplified) criteria for judging a substance being readily biodegradable is reaching the pass level after the test duration. The duration of the test in Guideline OECD 301A-F and OECD 310 is 28 days and the pass level depends on the parameter measured in the test system (pass level: DOC-removal = 70% degr.; O2-uptake & CO2-Evolution 60% degr.). The Registrant prolonged the test duration to 60 days (based on the test guideline, prolongation is not an option) and also failed to provided information on degradation rates at different sampling points during the test duration. Because of this it is not possible to assess the degradation kinetics and the necessary degradation rate to determine if the 10-day window criteria is achieved. As a result there is sufficient evidence that the key study does not fulfill the validity criteria of test guideline OECD 310 and it thus cannot be used for the assessment of ready biodegradation.

The Registrant also provided information on 4 supporting studies which in his opinion underline his assessment that the registered substance is biodegradable. The registration dossier contains two additional tests on ready biodegradation (according to: OECD 301C – Modified MITI (I), Rel. 1; OECD 301 A – DOC die away test, Rel. 2) showing clear deviation in results (after 28 days: 15-21% degr. via O2-consumption; <10% degr. via DOC-removal) when compared with the key study. Both test results match the criteria for defining a substance being "not readily biodegradable". The third test is a test on inherent biodegradation (OECD 302 C – Modified MITI (II)) showing 90% degradation (measured

parameter: TOC) after 28 days. According to the criteria of the test guideline the substance is judged being inherently biodegradable. The last test is a test on anaerobic degradation (no test guideline followed) showing 29% degradation after 55 days (measured parameter: COD).
Finally, the Registrant concluded: "*The test substance is not readily biodegradable according to OECD criteria and poorly biodegradable under anaerobic conditions. Nevertheless, it can be easily eliminated from water and is biodegradable after prolonged exposure.*"

ECHA notes that high degradation rates in a test on inherent biodegradation cannot be seen as a subtitute for a test on ready biodegradation as the design of the test methods clearly differ.

According to Annex IX, 9.2.1.2, Column 2 the study need not be conducted if
a) the substance is highly insoluble in water or
b) the substance is readily biodegradable.
Condition a) is not fulfilled as the water solubility has been determined being 1000 g/l.
Condition b) is also not fulfilled because of the above stated reasons:

Having assessed all of the provided information from screening tests on biodegradation ECHA concludes that the registered substance cannot be regarded as being readily biodegradable and the justification for waiving the simulation study provided by the Registrant is thus not valid.

As explained above, the information available on this endpoint for the registered substance in the technical 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: Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD 309).

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 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. Revised DNELs for workers 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 (Annex I, 1.4.1.)

Annex I, 1.4.1 of the REACH Regulation requires DNELs to be established for the substance, reflecting the likely route(s), duration and frequency of exposure. 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) the DNELs reflect the likely route(s), duration and frequency of exposure.

A full justification shall be given specifying, inter alia, the choice of information used, the route of exposure (oral, dermal, inhalation) and the duration and frequency of exposure to the substance for which the DNEL is valid.

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

The assessment factors (AF) applied by the Registrant and the default assessment factors recommended in the ECHA Guidance[1] are given in detail in Annex I attached to this decision.

ECHA observes that the Registrant has not followed recommendations of ECHA's Guidance R.8 and has not provided a full justification for the derivation of worker relevant DNELs in line with Annex I, 1.4.1. In particular, concerning the systemic long-term DNELs for dermal route, for interspecies differences a reccommended AF of 2.5 for remaining differences is missing, and for intraspecies worker an AF of 3 was used instead of the recommended AF of 5.

Also, concerning the systemic long-term DNELs for inhalation route, for interspecies differences a reccommended AF of 2.5 for remaining differences is missing, and for intraspecies worker an AF of 3 was used instead of the recommended AF of 5.

In addition the AF accounting for differences between sub-acute to chronic was 3 instead of the recommended AF of 6 for both systemic long-term dermal and inhalation route.

As several RCRs in the dossier are between 0.83-0.99, the use of the AFs recommended in the ECHA Guidance will have an impact on the assessment of risk management measures required to ensure safe use.

As explained above, the information provided on DNEL for the registered substance in the chemical safety report does not meet the general provisions for preparing a chemical safety report as described in Annex I, 1.4.1. because the assessment factors used are not in accordance with ECHA *Guidance on information requirements and chemical safety assessment* Volume 8, Chapter R.8. or are not fully justified. 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 Guidance 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 workers 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.

[1] Link to ECHA guidance document R.8 is: http://echa.europa.eu/documents/10162/17224/information_requirements_r8_en.pdf

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 workers using the assessment factors recommended by ECHA Guidance and re-assessment of related risks *or* a full justification for not using the recommended assessment factors in DNEL derivation.

ECHA also notes that in the current dossier the Registrant has used ECETOC TRA to estimate exposure for a variety of worker exposure scenarios using efficiency for gloves of 98% to estimate the exposure via dermal route. However, ECHA notes that according to the guidance for the model used (ECETOC TR 114) the maximum pre-defined values are 95% for industrial users. , The Registrant is reminded that in case of deviation from the prescribed effectiveness factors for gloves in using ECETOC TRA, the CSR should include a justification (e.g. related to the substance or the specific recommended or implemented personal protection measures or based on relevant biomonitoring data) for the deviation. This is in particular important as, already with the current DNEL, use of a 95% value for glove effectiveness will generate RCRs above 1 in those scenarios where 98% has been used by the Registrant.

The results of the studies requested under section II.A.1 shall be taken into account when revising the DNELs.

2. Documentation for the recommended personal protective equipment, i.e. gloves to be worn need to be specified clearly when handling the substance need to be specified clearly (Article 14(6), Annex I, 5.1.1.:

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

According to Annex I, 0.3., 0.5. and 5.1.1. the applied Risk Management Measures (RMM) have to be described in the CSR. The CSR needs to contain sufficient information to allow ECHA to gain assurance that the risks are adequately controlled and that appropriate risk management measures can be prescribed by actors in the supply chain. Accordingly, the supplier is required to describe the relevant RMM in detail in the Safety Data Sheet in order to minimise the exposure for workers handling the registered substance (e.g. the type of gloves to be worn 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 in accordance with Annex II, section 8.2.2.2. (b)(i)). The information provided in the Safety Data Sheet (SDS) shall be consistent with information in the Chemical Safety Report (Annex II, section 0.1.2. of the REACH Regulation).

ECHA notes that specific detailed information on the recommended personal protective equipment is missing both from the CSR and from the information on safe use within the IUCLID dossier. In the CSR, the Registrant indicated the following for hand protection: *"wear chemical resistant gloves (EN374)in combination with intensive management supervision controls"*, while in IUCLID Section 11 has reported*: "hand protection: chemical resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary"*.

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

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

Notes for consideration by the Registrant:

It is the responsibility of the Registrant to ensure consistency of the information within the CSR, and between the CSR, IUCLID section 11 and the safety data sheet.

C. Deadline for submitting the information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 24 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also included a request for a two-generation reproductive toxicity study (Annex X, 8.7.3.). As this endpoint 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 18 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. Adequate identification of the composition of the tested material

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

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

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

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

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
Ofelia Bercaru
Head of Unit, Evaluation

Annex I.

Assessment factors (AF) applied by the Registrant:

For workers - systemic long term – inhalation route:
- interspecies: 1
- intraspecies: 3
- exposure duration: 3
  (overall AF: 9)

For workers - systemic long term – dermal route:
- interspecies: 4
- intraspecies: 3
- exposure duration: 3
  (overall AF: 36)

The default assessment factors recommended in the ECHA Guidance[2]:

For workers - systemic long term – inhalation route:
- interspecies: 2.5 (remaining differences between species non related to allometry)
- intraspecies: 5 (workers)
- exposure duration: 2 (sub-chronic to chronic)
  (overall AF: 25)

For workers - systemic long term – dermal route:
- interspecies - allometric correction: 4 (rat to human)
- interspecies - remaining differences: 2.5 (non-related to allometry)
- intraspecies: 5 (workers)
- exposure duration: 2 (sub-chronic to chronic)
- absorption difference dermal-oral[3]: 1
  (overall AF: 100)

[2] Link to ECHA guidance document R.8 is: http://echa.europa.eu/documents/10162/17224/information_requirements_r8_en.pdf
[3] In the absence of substance specific information, the ECHA Guidance R.8 (section R.8.4.2) recommends that a factor of 1 be applied for the extrapolation of the results from the oral route to the dermal route. In general, dermal absorption will not be higher than oral absorption and by default, the same bioavailability for experimental animals and humans should be assumed.