ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114336559-39-01/F Helsinki, 19 July 2016

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

For Reaction product of propylidynetrimethanol, propylene oxide and ammonia, EC No 500-105-6, 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 Reaction product of propylidynetrimethanol, propylene oxide and ammonia, EC No 500-105-6, 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 per year. This decision does not take into account any updates after the date when the draft decision was notified to the Registrant under Article 50(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. ECHA notes, in particular, that the information requirement of Annex X, Section 8.7.3 has not been addressed in this decision.

The compliance check was initiated on 15 December 2014.

On 24 March 2015 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 29 April 2015 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. The statement of reasons (Section III) was changed accordingly.

On 3 March 2016 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 proposal(s) for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, proposal for amendment to the draft decision were submitted.

On 8 April 2016 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 amended the draft decision.

On 18 April 2016 ECHA referred the draft decision to the Member State Committee.

By 10 May 2016, 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 was reached on 23 May 2016 in a written procedure launched on 13 May 2016.

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

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

3. 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).

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 requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

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 exposure assessment for the dermal route (Annex I, Section 5.2.4.) as specified in section III.B.1 below.
2. 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)(i))., including:
   - The type of material and its thickness, and
   - The typical or minimum breakthrough times of the glove material.
3. Risk characterisation for local dermal effects (Annex I, Section 1.4.1., Annex I, Section 6.5.) as specified in section III.B.3 below.
4. Revised exposure assessment and risk characterisation for the inhalation route (Annex I, Sections 5. and 6.) as specified in section III.B.4. below.
5. Revised environmental exposure assessment (Annex I, Section 5) as specified in section III.B.5 below.

C. Information in the technical dossier related to the manufacture and use(s) of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(iii) and Annex VI, Section 3 of the REACH Regulation, the Registrant shall submit the following information for the registered substance subject to the present decision:

1. A revised life cycle description considering the inclusion of consumer uses, if relevant (Annex VI, sections 3.5, 3.6 and 3.7), as specified in section III point C below.

D. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **26 July 2018** an update of the registration dossier containing the information required by this decision. 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 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. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

A "sub-chronic toxicity study (90 day)" using the most appropriate route of administration 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 as key study a sub-chronic 90-day dermal toxicity study in rats, performed by [redacted] according to OECD guideline 411. He has also provided as supporting study a non-guideline oral 31-day study in rats with the substance "Polyoxypropylenetriamine 403", performed by [redacted] That later study was flagged as unreliable by the Registrant.

The Registrant has sought to adapt the information requirement for a sub-chronic toxicity study (90 day) via the oral route with the following justification:
"*This study does not need to be performed, since a 90 day repeated dose toxicity study is available (dermal) (REACH regulation, Annex IX, Column 2 Adaptation). Moreover, the oral/inh. route is not expected to be the main route of exposure.*"

ECHA is of the opinion that the conditions for adaptation set out in Annex IX, 8.6.2, column 2 are not met in this case, as the dermal route of administration used in the provided sub-chronic toxicity is not appropriate.

In this respect, column 2 of Annex IX, Section 8.6.2 specifies that testing by the dermal route is appropriate if:

(1) skin contact in production and/or use is likely; and
(2) the physicochemical properties suggest a significant rate of absorption through the skin; and
(3) one of the following conditions is met:
- toxicity is observed in the acute dermal toxicity test at lower doses than in the oral toxicity test, or
- systemic effects or other evidence of absorption is observed in skin and/or eye irritation studies, or
- in vitro tests indicate significant dermal absorption, or
- significant dermal toxicity or dermal penetration is recognised for structurally-related substances.
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ECHA believes that the dermal route is not the most appropriate route of administration for the following reasons:

- physicochemical properties (in particular a molecular weight >400 $g.mol^{-1}$) does not suggest high dermal absorption,
- toxicity in the acute dermal study was not observed at lower doses than in the acute oral study (dermal acute LD50=1000 mg/ kg bw, oral acute LD50=550 mg/kg bw),
- there is no conclusive evidence of systemic effects in the provided skin/eye irritation studies or in the dermal 90-day repeated dose toxicity study that would suggest absorption via the dermal route,
- the dossier does not contain information on toxicokinetics/dermal absorption and there is no evidence of dermal absorption, either for the registered substance or for a related substance.

The substance is a liquid with a low vapour pressure but used in industrial spray application (PROC 7) at concentrations up to [redacted]%. The substance is classified as Eye Damage 1 and skin irritation was reported in the dermal repeated dose toxicity study. Therefore, respiratory tract irritation cannot be excluded if inhalation exposure occurs. However, in the Chemical Safety Report it is indicated that for industrial spraying, additional respiratory tract protection ([redacted]% efficiency) is required: a full face respirator conforming to EN140 with Type A filter or better should be used. Based on the risk management measures indicated by the Registrant for spray application, inhalation exposure is deemed to be limited and the risk for respiratory tract irritation after inhalation seems to be sufficiently addressed.

Therefore ECHA considers that testing by the oral route is most appropriate.

In his comments to the draft decision, the Registrant disagreed with performing the requested study, arguing that the dossier already contained a repeated dose toxicity study in rats by the dermal route. He claimed that it could not be demonstrated with certainty that the dermal LD50 is higher than the oral LD50; thus the dermal route would be a relevant route for occupational exposure.

ECHA notes that, as mentioned above, a provided study by the dermal route can only be considered appropriate to fulfil the standard information requirement if the criteria as specified in column 2 of Annex IX, Section 8.6.2. are met. As mentioned above, the criteria require (1) that skin contact in production and/or use is likely *and* (2) that the physicochemical properties suggest a significant rate of absorption through the skin *and* that one of conditions listed under (3) are met. ECHA notes that the first criterion is met but that the physicochemical properties do not suggest a significant rate of absorption through the skin. Furthermore, the findings in the provided sub-chronic dermal toxicity study indicate local irritating effects at the site of administration but no other histopathological alterations attributable to the administration of the substance. Hence, as assumed based on the physicochemical properties of the substance, no significant rate of absorption through the skin could be demonstrated. In addition, as indicated above, none on the criteria listed under (3) are met. With respect to the Registrant's comment on the LD50 values for dermal and oral route, ECHA notes that the information provided in the dossier does not indicate that toxicity might be observed in the acute dermal toxicity study at lower doses than in the oral toxicity study. Hence, the criteria for the appropriateness of the dermal route of Annex IX, Section 8.6.2., column 2 are not met.

Furthermore, ECHA notes that a sub-chronic toxicity study (90 day) using the dermal route with the registered substance does not provide the same level of information on identification of a hazard for repeated dose toxicity as a sub-chronic toxicity study by the oral route would provide. More specifically, the doses that can be administered dermally are limited by the irritating property of the substance whereas usually higher doses can be administered in an oral toxicity study. Hence, a sub-chronic toxicity study (90 day) using the dermal route with the registered substance is not suitable for hazard identification of systemic toxicity.

ECHA further disagrees with the Registrant's comments that the pre-natal developmental toxicity study, which is also requested within the decision, will be sufficient to detect any unexpected systemic effect. More specifically, in a pre-natal developmental toxicity study no histopathological examinations of organs and other examinations will be performed as required in a sub-chronic toxicity study. Hence, a pre-natal developmental toxicity study is not suitable to detect hazards for repeated dose toxicity and to classify accordingly.

Finally, the Registrant argues that a new test via the oral route is not relevant because the current DNEL long term systemic via the dermal "*could be seen as sufficiently protective for occupational exposure.*" ECHA notes that results of the dermal toxicity study are suitable to derive a DNEL for long-term *local* effects by the dermal route. However, those results are not suitable to derive such a DNEL for *systemic* effects or to perform a route-to-route extrapolation to oral or inhalation route with regard to systemic effects.

In conclusion, the Registrant's comment did not give reasons to change the information required in the draft decision.

Therefore the information available in the dossier does not meet the information requirement of Annex IX, Section 8.6.2. Consequently there is an information gap and it is

necessary to provide information for a sub-chronic toxicity study (90 day) using the oral route.

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.

2. Pre-natal developmental toxicity study (Annex IX, Section 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.

The Registrant has not provided a study record of a pre-natal developmental toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.7.2. but has sought to adapt this information requirement based on the following justification:
"*A reproductive / developmental toxicity screening study (according to OECD 421) has been performed. No adverse effects were observed at the highest dose tested (dermal exposure of 100 mg/kg bw/d). Results from the OECD 422 screening assessment study conclude that there is no developmental toxicity at the highest concentration tested of 100 mg/kg/day. The substance is classified as a mild skin irritant (CLP cat 3) and showed moderate to severe irritation in the 90 d dermal repeated dose test at resp. 50 and 160 mg/kg bw/d dose levels. Therefore, testing at higher concentrations is not justifiable. In addition, reproductive tissues (including gonads, uterus, epididymides, prostate, and if present, seminal vesicles) were examined for gross pathology in the 90 day repeated dose study and no adverse effects were noted.*
Huntsman considers that this endpoint has been adequately tested through the use of the screening study and that no additional studies are required. Moreover, exposure to this substance is considered to be limited".

In the technical dossier the Registrant has provided a study record for a "reproduction/ developmental toxicity screening test" (test method: OECD 421). 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.

Therefore the information available in the dossier does not meet the information requirement of Annex IX, Section 8.7.2. Consequently there is an information gap and it is necessary to provide information for a pre-natal developmental toxicity study.

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.

In his comments, the Registrant agreed to perform a pre-natal developmental toxicity study, oral route, in rats according to OECD 414 and said he would submit a testing proposal for this study. ECHA takes note of the Registrant's agreement to perform the test but highlights that no testing proposal is necessary since the study is already formally requested in the present decision.

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, Section 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, Section 8.7.2.

3. 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.

Further, Annex IX section 9.2.3. of the REACH Regulation requires the identification of the degradation products.

The Registrant has sought to adapt the standard information requirement of simulation testing on ultimate degradation in water by using the following justification:
"*Based on results from screening studies, the test substance is not expected to biodegrade. Moreover, emissions to the environment are not expected to occur, since all processes are performed in a closed system*".

According to Annex IX, section 9.2.1.2., column 2 of the REACH Regulation, the simulation testing on ultimate degradation in water does not need to be conducted if the substance is highly insoluble in water or the substance is readily biodegradable. The data provided by the Registrant indicates for the registered substance a water solubility of 562 g/L at 20 °C and less than 5% biodegradation after 28 days. Therefore the registered substance can neither be considered to be highly insoluble nor readily biodegradable and consequently the specific rules for adaption presented in column 2 of Annex IX, section 9.2.1.2.of the REACH Regulation do not apply.

The Registrant claims that emissions to the environment are not expected to occur and that all processes are performed in closed system. ECHA notes that for exposure scenario ES4

(Professional use and service life of solvent-based coatings and specialities containing the registered substance at construction sites) the substance is used outdoors on construction sites and thus not in a closed system. Furthermore, ECHA notes that strictly controlled conditions as set out in Article 18(4)(a) to (f) of the REACH Regulation apply for none of the exposure scenarios presented in Section 9 of the Chemical Safety Report. The Registrant's claim that there is no release to the environment is not properly justified in the Chemical Safety Report, as explained in section III.B.5 below. Therefore the Registrant failed to demonstrate that the environment was unlikely to be exposed to the substance under normal or reasonably foreseeable conditions of use and exemptions and consequently the general rules for adaptions presented in Annex XI.3. of the REACH Regulation do not apply.

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

Finally, ECHA notes that in Section 8 of his Chemical Safety Report, the Registrant indicates that "*further simulation testing at lower concentrations should be performed in order to definitively conclude on the persistence of this substance*".

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.

In his comments, the Registrant disagreed to perform the requested test arguing that he had already considered his substance to be not readily biodegradable and that this constituted a worst-case assumption. He further explained that, should the test material be radiolabelled, it would be difficult to define precise positions of the labelled atoms since the registered substance is a complex mixture of unknown or variable composition (the registered substance is a UVCB). He proposed to perform instead an inherent biodegradation test (OECD 302) to conclude on whether the registered substance is persistent or not. He also mentioned that QSAR models could be used to investigate possible degradation pathways and to gain an insight on the properties of the degradation products.

Column 2 of Annex 9.2 of the REACH Regulation states that "*further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the chemical safety assessment and may include simulation testing in appropriate media (e.g. water, sediment or soil)*". On this basis, ECHA considers that the need for simulation test(s) and for the identification of degradation products can be triggered: 1/ by the PBT/vPvB assessment, 2/ by the risk assessment or 3/ by the information requirements on the degradation products.

1/ ECHA acknowledges that the registered substance per se is not B and not T. However, pursuant to Annex XIII of the REACH Regulation "*the identification* [of PBT and vPvB substances] *shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products*". ECHA notes that the registration dossier does not contain any information on the degradation products and on whether they could be PBT/vPvB or not.

2/ ECHA considers that the exposure assessment and therefore also the risk assessment need revision as indicated in section III.B.5. of this decision. Therefore it is not possible to conclude whether the chemical safety assessment demonstrates the absence of risk.

3/ ECHA notes that information on degradation products is in itself required for the PBT/vPvB assessment as Annex XIII of the REACH Regulation explicitly requires that PBT/vPvB properties of degradation products need to be taken into account, as explained above. Information on degradation products shall also be taken into account for the exposure assessment (Annex I 5.2.4. of the REACH Regulation) and for the hazard assessment (e.g. see column 2 of Annex X 9.4 and Annex X 9.5.1 of the REACH Regulation). Finally, ECHA further points out that information on degradation products is required for the preparation of Section 12 of the safety datasheet (Annex II of the REACH Regulation).

The requested simulation test in surface water (OECD 309) is a validated standard international test laid down in the Test Methods Regulation 440/2008 (section C.25) and, therefore, it meets the requirements of Article 13(3) of the REACH Regulation. Furthermore, this test is the most appropriate for identifying degradation products because it is designed to simulate the degradation behaviour of substances in natural water whereas the OECD 302 test proposed by the Registrant in his comments is a screening test performed under artificial conditions (i.e. adapted inoculum, high inoculum concentration, high test substance concentrations).

Registrant further argues that the OECD 309 test is not technically feasible because "*the structural properties of the substance, being a UVCB, do not permit the respective test to be conducted*. [...] *If the test material is to be radiolabelled, it will be difficult to define the precise position(s) of the labelled atom(s)*". ECHA acknowledges that the position of the radio-label within the test substance is very important for the study design. The radio-label will need to be positioned in the part of the molecule which is the least susceptible to biodegradation in order to be able to trace as much of the metabolites as possible. The most common isotope used for radiolabelling is ^{14}C but additional labelling e.g. with ^{13}C or ^{15}N may facilitate the identification of the degradation products.

In particular, the Registrant refers to the possibility of using unspecified QSARs. However, in the absence of any further information, this proposed adaptation does not meet the requirements of Annex XI, Section 1.3 of the REACH Regulation. Therefore, this adaptation is rejected.

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).

Notes for consideration by the Registrant
Annex IX, Section 9.2.3. of the REACH Regulation requires the identification of the degradation products unless the substance is readily biodegradable. The Registrant has not provided this information and has not provided a justified adaptation for it. Therefore, this constitutes a further information gap in the registration. ECHA notes that the test required for fulfilling the standard information requirement of Annex IX, Section 9.2.1.2. is suitable for providing information on the degradation products. Therefore, the Registrant should use the information to be generated by test method EU C.25/OECD 309 to also fulfil the information requirement of Annex IX, 9.2.3., i.e. he should include information on the degradation products in his technical dossier.

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.

Pursuant to Article 41(1)(c) of the REACH Regulation ECHA may verify that any required Chemical Safety Assessment and Chemical Safety Report comply with the requirements of Annex I and that the proposed risk management measures are adequate.

1. Revised exposure assessment for the dermal route (Annex I, Section 5.2.4.)

Pursuant to Sections 0.6.2 and 0.6.3 of Annex I of the REACH Regulation, the CSA performed by a Registrant shall include an exposure assessment according to Section 5 of Annex I. Annex I, Section 5.2.4, of the REACH Regulation requires the Registrant to perform an estimation of the exposure levels for all human populations (workers, consumer and humans liable to exposure via the environment) for which exposure to the substance is known or reasonably foreseeable. Each relevant route of exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure) shall be addressed. In addition, Annex I, section 5.2.5 of the REACH Regulation indicates that appropriate models can be used for the estimation of exposure levels.

ECHA notes that the Registrant has used the ECETOC TRA model[1], version 2, to estimate exposure for occupational exposure scenarios. A variety of permutations of operational conditions and risk management measures have been assumed when using the model.

In particular, for estimating dermal exposure, ECHA notes that the Registrant has in some situations assumed the use of personal protective equipment (PPE), in particular gloves, as risk management measures, but that he has otherwise used the local exhaust ventilation (LEV) exposure modifier of the ECETOC TRA model. The Registrant has identified the potential for acute exposure leading to local effects as a trigger for using gloves. However, he has not applied this logic to all exposure scenarios where dermal contact is likely. For long term dermal exposure, in some cases the Registrant has used the LEV modifier but has not included gloves to predict the exposure. In other cases the LEV modifier has not been used whereas gloves have been included. Sometimes he has included both the LEV modifier and gloves. This inconsistent approach leads to a confused picture and possibly to risk management measures being inadequately specified.

Furthermore ECHA underlines that the Guidance on information requirements and chemical safety assessment, R.14 version 2.1, November 2012 (section R.14.4.8, page 21) advises against the use of the LEV modifier for dermal exposure estimation. Research projects (e.g. the RISKOFDERM project) have indeed shown that the ECETOC TRA model underestimates dermal exposure for some situations with local exhaust ventilation compared to measured data. Moreover, ECHA notes that the registered substance is a liquid with a vapour pressure of 682 Pa at 20 °C. On this basis, ECHA notes that LEV will have almost no actual impact on the potential for skin exposure to the registered substance as this occurs largely, other than at high volume spraying, through contact with residues and splashing. Therefore ECHA considers that the use of the LEV modifier is not appropriate for the dermal exposure assessment of the registered substance. ECHA believes that the use of gloves, if applied in all cases where dermal exposure may be expected, would form a better basis for the risk assessment.

As explained above, the information provided on the dermal exposure estimates 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. Consequently it is necessary to

[1] Targeted Risk Assessment (TRA) Tool, European Centre for Ecotoxicology and Toxicology of Chemicals, http://www.ecetoc.org/tra

revise the dermal exposure estimates.

In his comments, the Registrant agreed to review the DNELs and to revise the exposure assessment for the dermal route.

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: revised exposure assessment for the dermal route and re-assessment of related risks. The Registrant shall ensure that the calculated risk characterisation ratios will still be below 1, in order to demonstrate the safe use of the registered substance.

2. Documentation for the recommended personal protective equipment, i.e. gloves to be worn when handling the substance or mixture (Annex I, Section 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 for hand protection is missing both from the CSR and from the information on safe use within the IUCLID dossier.

In the CSR, the Registrant indicated that *"chemically resistant gloves (tested to type EN374)"* should be used in combination with *"basic employee training"* or *"specific training"*, depending on the situation.

In IUCLID Section 11, he has reported the following for 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.

In his comments, the Registrant agreed to take into account the request for a more detailed

level of information on personal protective equipment.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested 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.

It is recognised that several exposure scenarios for the registered substance will result in exposure to a mixture of chemicals and the appropriate advice on the specific glove requirements for these undefined situations will be within the safety data sheets relating to product formulations. The selection of gloves will be determined by the most relevant components of those mixtures and this information is not required within the CSR or Section 11 of IUCLID.

3. Risk characterisation for local dermal effects (Annex I, Section 1.4.1., Annex I, Section 6.5.)

Annex I, 1.0.1 and Annex I, 1.4.1 of the REACH Regulation require the Registrant to establish DNELs for the registered substance for each relevant human population and for different routes of exposure.

For those human effects for which it is not possible to determine a DNEL, Annex I, 6.5 of the REACH Regulation indicates that a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario shall be carried out.
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 [2] provides further details and specifically provides default factors which should be applied to derive DNELs in the absence of substance specific information.

ECHA notes that the CSR provided by the Registrant does not contain DNELs for local dermal effects (acute and long-term) and that no qualitative assessment has been carried out.

Serious local dermal effects (necrosis) were observed in the subchronic 90-day dermal toxicity study in rats, performed by [redacted] while the exposure scenarios presented in the CSR indicate that dermal exposure is possible. Pursuant to Annex I, 6 of the REACH Regulation the Registrant shall demonstrate that those local dermal effects are avoided when implementing the exposure scenarios.

In his comments, the Registrant agreed to revise the exposure assessment and the risk characterisation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to perform a risk characterisation for local dermal effects. The Registrant is given

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

two options: the Registrant shall either derive a DNEL according to ECHA Guidance on information requirements and chemical safety assessment, R.8 (version 2.1, November 2012) as explained above, or the Registrant shall perform a qualitative assessment of dermal effects.

4. Revised exposure assessment and risk characterisation for the inhalation route (Annex I, Sections 5. and 6.)

Annex I, Section 5.2.4, of the REACH Regulation requires the Registrant to perform an estimation of the exposure levels for all human populations (workers, consumer and humans liable to exposure via the environment) for which exposure to the substance is known or reasonably foreseeable. Each relevant route of exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure) shall be addressed. In addition, Annex I, Section 5.2.5 of the REACH Regulation indicates that appropriate models can be used for the estimation of exposure levels.

Annex I, Section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario and to consider the human population (exposed as workers, consumers or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonable foreseeable, under the assumption that the risk management measures described in the exposure scenarios in Section 5 of Annex I of the REACH Regulation have been implemented.

Further, Annex I, Section 6.5. of the REACH Regulation states that "*for those human effects and those environmental spheres for which it was not possible to determine a DNEL or a PNEC, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenarios shall be carried out.*"

ECHA notes that the Registrant has not assessed quantitatively the inhalation exposure with the following justification: "*On the basis of physico-chemical properties (relatively low vapour pressure), it was concluded that exposure via inhalation will be less relevant compared to dermal exposure. Based on working experience with the substance, it can be concluded that the major route of exposure will be dermal. Therefore, no exposure assessment was performed for inhalation. In addition, the substance is mainly used in closed systems and local exhaust ventilation is present to control vapours or mists. Whenever exposure might occur, NIOSH-certified (or equivalent) organic vapour/particulate respirator needs to be used.*"

However, ECHA notes that the Registrant is, and was, able to derive DNELs for inhalation exposure and therefore a quantitative exposure assessment and risk characterisation is required for assessing the inhalation exposure to the registered substance. In addition, inhalation exposure cannot be disregarded considering the vapour pressure provided in the registration dossier (i.e. 682 Pa at 20 C). In particular PROC 7 is included in exposure scenario 3 (ES3: industrial processing aid) in the registration dossier suggesting that exposure to the registered substance as aerosol is also possible. In fact, the Registrant himself is recommending risk management measures to control the inhalation exposure to the registered substance. This shows the Registrant also recognises inhalation exposure is possible and therefore, it should be properly assessed to show that the risks via that route of exposure are indeed controlled and the identified risk management measures are adequate.

In addition, ECHA notes that the Registrant has considered dermal exposure to be the most relevant route of exposure but, also that at the same time he has stated that dermal

absorption will be very limited considering the high water solubility (i.e. 562 g/L) and the low logKow (i.e. -1.13) of the substance. Thus, the physicochemical properties of the substance suggest that the actual systemic exposure to the registered substance via the dermal route would be limited and therefore that dermal exposure is likely not the most relevant route of exposure contrary to what has been claimed by the Registrant.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide an adequate quantitative exposure assessment and risk characterisation of the inhalation route for all the uses described for the registered substance and revise the risk characterisation accordingly.

Note for consideration by the Registrant:
If the Registrant uses a model to estimate the exposure to the registered substance, it should be used within its applicability domain. In this regard, the model used by the Registrant in the current registration dossier (i.e. ECETOC TRA) is not suitable to estimate exposure to aerosols. In addition, the Registrant is expected to use the latest version available for the models he may use.

5. Revised environmental exposure assessment (Annex I, Section 5)

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 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.

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. Pursuant to Annex I, section 5.1.1. of the REACH Regulation, exposure scenarios (ES) shall include, where relevant, a description of operational conditions (OCs) and of risk management measures (RMMs). As indicated in Annex I, section 5.2.2. of the REACH Regulation, emission estimation shall be performed under the assumption that the risk management measures and operational conditions described in the exposure scenario have been implemented. These RMMs and OCs should be included in the exposure scenarios 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), operational conditions "*consist of a set of actions, tools, parameters such as amount of substance, process temperature and pH, duration and frequency of release, type of use (e.g. indoor or outdoor), containment of process (open or closed), continuous or batch process (leading to an intermittent release), capacity of surroundings, etc. having, as a side effect, an impact on the release and the exposure*". Risk management measures "*consist of technologies and procedures aimed at either reducing the releases and/or preventing a release pathway. Examples of risk management measures intended to reduce release are filters, scrubbers, biological or physico-chemical wastewater treatment plants etc.*" Both OCs and RMMs have an impact on the type and amount of release and the resulting exposure.

The release factors associated with Environmental Release Categories (ERCs) cited in ECHA's guidance R.16 can be used for a first tier assessment of the emissions. However, better information may be available that could then be used instead. In particular, release

factors can be refined by taking into account RMMs and OCs. In this case, it is important to explicitly link such RMMs and OCs to the release factors and communicate them properly to the downstream users in the exposure scenarios. Sector specific environmental release categories (spERCs) developed by industrial sector organisations can be used in place of the default ERCs of ECHA's guidance R.16. However, spERCs have to be linked to the applied RMMs and OCs driving the release estimation and that shall be described in the exposure scenarios.

The Registrant has provided 4 exposure scenarios in the CSR:
- ES1: reactant/intermediate. This applies to the substance used as curing agent.
- ES2: formulation. This applies to the formulation of solvent-based coatings and specialities.
- ES3: industrial processing aid. This applies to the industrial use of the substance in solvent-based coatings and specialities and in the use as hardener (helps curing and homogenising) for an epoxy-resin used in the manufacture of wind mill blades.
- ES4: professional uses. These uses apply to the professional uses and service life of solvent-based coatings and specialities at construction sites.

ECHA has identified the following deficiencies:

a. The scope of exposure scenario ES3 is unclear

Five environmental release categories are mentioned for exposure scenario ES3, i.e.: ERC 5, ERC 6b, ERC 7, ERC 12a, ERC 12b. These five ERCs cover very different (and incompatible) use conditions with very different release profiles and rates:

- ERC 5 (Industrial inclusion into or onto a matrix) should be applied for chemicals that are processed with the specific goal of being included (physically or chemically bound) into or onto a matrix.

- ERC 6b (Industrial use of reactive processing aids) should be applied for chemicals reacting on use.

- ERC 7 (Industrial use of substances in closed-systems) should be applied for chemicals used in closed equipment (e.g. liquids in hydraulic systems, cooling liquids in refrigerators, lubricants in engines, dielectric fluids in electric transformers, oil in heat exchangers).
- ERC 12a (Industrial processing of articles with abrasive techniques – low release) is relevant for chemicals included into or onto articles and materials and which are released (intended or not) from the matrix as a result of processing by workers. The expected release is supposed to remain low for this ERC (e.g. for processes such as cutting, machining or coarse grinding of polymers in engineering industries).

- ERC 12b (Industrial processing of articles with abrasive techniques – high release) is relevant for chemicals included into or onto articles and materials and which are released (intended or not) from the matrix as a result of processing by workers. The removal of material is intended and high amounts of dust may be expected (e.g. during sanding operations or paint stripping by shot-blasting).

For scenario ES3, the Registrant refers to use of the substance as a hardener for an epoxy-resin used for the production of wind mill blades. For such a use, ECHA understands that the substance would be intended to be consumed (it would react with the epoxy-resin).

However, ES3 scenario also mentions use in "*solvent-based coatings and specialities*". It is not clear whether this covers the same use (hardener for an epoxy-resin, in the form of coatings or specialities, which would mean that the substance is eventually consumed) or whether this is a totally different use that would then have to be described in a separate exposure scenario. In particular, the service life of the substance should be clearly defined and it should be made clear whether the substance is released during its service-life and if yes to what extent.

b. Insufficient justification for the release factors used for exposure scenario ES3

For exposure scenario ES3, the release factors used by the Registrant for exposure to the air is 0.01% and is derived from use of the substance as curing agent (i.e. hardener) or for its use in injection moulding as described in the OECD Emission Scenario Document on Plastics Additives[3]. Because the description of exposure scenario ES3 is insufficient, it is not possible to judge whether the scenarios developed by OECD can apply for exposure scenario ES3 and whether the release factor to the air assumed by the Registrant is sensible.

For water the release factor is set to zero, but no adequate justification is provided (see issue III.B.5.c below).

For soil, it is not clear what release factor has been applied. By default, one could assume that it is based on default release factors recommended in REACH Guidance R.16, but this is not explained in the CSR. Since 5 ERCs are cited for ES3, it is anyway not clear what ERC would have actually been applied for deriving the release factor to soil.

c. Insufficient justification for claiming absence of releases to wastewater for ES1, ES2 and ES3

For all industrial uses (ES1, ES2 and ES3), emissions to waste water have been set to zero by the Registrant with the justification that "*all precautions are taken to prevent that the substance ends up in the wastewater system*".

However, what these precautions actually are is not specified. Risk management measures to be taken for achieving zero release for each of the processes covered by these 3 scenarios are not described.

d. The exposure assessment for ES4 is not transparent

ES4 applies to professional uses of the substance; however the exact scope of this scenario is not clear.

Four environmental release categories are mentioned for this scenario, i.e.: ERC 8c, ERC 8f, ERC 10a, ERC 11a. These four ERCs cover very different (and incompatible) use conditions with very different release profiles and rates:

- ERC 8c (Wide dispersive indoor use resulting in inclusion into or onto a matrix) is relevant for chemicals that are used indoor by professionals/general public and which are physically or chemically bound into or onto a matrix.

- ERC 8f (Wide dispersive outdoor use resulting in inclusion into or onto a matrix) is relevant for chemicals that are used outdoor by professionals/general public and which are physically or chemically bound into or onto a matrix.

[3] Emission Scenario Document on Plastics Additives, ENV/JM/MONO(2004)8

- ERC 10a (Wide dispersive outdoor use of long-life articles and materials with low release) is relevant for chemicals included into or onto articles and materials during their service life in outdoor uses.

- ERC 11a (Wide dispersive indoor use of long-life articles and materials with low release) is relevant for chemicals included into or onto articles and materials during their service life from indoor uses

For each of these four ERC, the Registrant has used distinct release factors and calculated distinct PECs. Therefore ES4 should preferably have been split into four different exposure scenarios.

For uses corresponding to ERC 10a and ERC 11a the Registrant has not explained what release factors he has applied.

For uses corresponding to ERC 8c the Registrant has applied release factors specified in EFCC SpERC 8C.1a.v1 (from the European Federation for Construction Chemicals) and which are 0, 0.01 and 0 for air, water and soil respectively. By comparison, default release factors recommended by guidance R.16. for ERC 8c are 0.15, 0.01 and 0 for air, water and soil respectively. EFCC SpERC 8C.1a.v1 is designed for wide dispersive indoor use of non-volatile substances in construction chemicals.

For uses corresponding to ERC 8f the Registrant has declared that he has applied release factors of 0, 0.01 and 0.037 for air, water and soil respectively. By comparison, default release factors recommended by guidance R.16. for ERC 8f are 0.15, 0.01 and 0.005 for air, water and soil respectively. As justification for the release factors he has used, the Registrant makes reference to EFCC SpERC 8F.1a.v1. However the current version of the EFFC SpERC was last revised in October 2012, i.e. after the CSR has been finalised, and recommends the following release factors for EFCC SpERC 8F.1a.v1.: 0, 0.01 and 0 for air, water and soil respectively. Therefore the reference to EFCC SpERC 8F.1a.v1. provided by the Registrant is not valid anymore to explain the release factors he has actually applied.

The values for the release factors recommended by the EFCC SpERC 8F.1a.v1. are anyway not acceptable as such since the assumptions and methods used by the SpERC developer for deriving release factors are not sufficiently described in the available documentation. In particular the corresponding operating conditions and risk management measures are not provided in the SpERC documentation.

e. Outcome

In his comments, the Registrant agreed to revise the environmental exposure assessment taking into account the issues raised in the draft decision.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to revise the environmental exposure assessment for the registered substance as explained above. In particular, the Registrant shall ensure that:

- the revised exposure assessment covers all the uses of the substance,
- distinct uses are covered by distinct exposure scenarios,
- the value of the release factors applied and the reasoning for deriving them are presented and justified,
- when using release factors other than the default recommended values (including also release rate of 0), the assumptions and methods for deriving them are adequately documented (i.e. operating conditions and risk management measures).

C. Information in the technical dossier related to the manufacture and use(s) of the substance

Pursuant to Article 10(a)(iii) of the REACH Regulation the technical dossier shall contain information on the manufacture and use(s) of the substance as specified in Annex VI, Section 3 of the REACH Regulation.

1. A revised life cycle description considering the inclusion of consumer uses (Annex VI, sections 3.5, 3.6 and 3.7).

Article 10(a)(iii), together with Annex VI, sections 3.5., 3.6. and 3.7. of the REACH Regulation require the Registrant to provide a description of the life-cycle of the substance by describing all the registrant's identified uses, providing information on waste and identifying the uses advised against and why these uses are advised against respectively.

The Registrant has not claimed any consumer use in the life-cycle of the substance and, consequently, no exposure assessment has been provided for the general population. The Registrant states that "*consumer use is not applicable*" and "*currently, no consumer use is considered in this chemical safety assessment*".

According to the information provided in exposure scenario ES4, the substance is used in solvent-based coatings and specialities in construction sites. This exposure scenario only covers professional use and service life.

However it is not clear how the substance is actually used in these solvent-based coatings and specialities in constructions sites. In the absence of further information, one cannot rule out that the general population will ultimately be exposed to the substance contained in these coatings and specialities in constructions sites. For example, the exposure scenario does not explain whether the substance is used in construction sites for residential buildings or whether indoor exposure of the general population is possible. Exposure assessment and risk characterisation for the general population during the service life of these coatings/specialities have not been addressed.

Furthermore, ECHA notes that the Registrant has not advised against the consumer use of the registered substance in the technical dossier. Thus, consumer uses have not been prevented and it is not clear that consumer exposure can be disregarded.

In his comments, the Registrant agreed to review the life cycle of the substance and to revise the exposure and risk assessment accordingly, if relevant.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to clarify the life-cycle description of the substance considering the inclusion of consumer uses, if relevant. Pursuant to Annex I Section 5 of the REACH Regulation, if consumer uses are identified in the life-cycle of the substance, then the Registrant shall generate exposure scenario(s), exposure estimations and risk characterisation accordingly.

IV. Adequate identification of the composition of the tested material

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

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

V. Information on right to appeal

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

Authorised[5] by Ofelia Bercaru, Head of Unit, Evaluation E3

[5] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.