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Decision number: CCH-D-2114343376-48-01/F Helsinki, 19 October 2016

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

For tert-butyl acrylate, CAS No 1663-39-4 (EC No 216-768-7), 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 tert-butyl acrylate, CAS No 1663-39-4 (EC No 216-768-7), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of [redacted] per year. This decision does not take into account any updates after the deadline for updating (15 March 2015) communicated to the Registrant by ECHA on 6 February 2015.

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 25 February 2014.

On 15 May 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

On 18 June 2014 ECHA received comments from the Registrant on the draft decision, concerning the information requirements of Annex I, Sections 1.4.1., 3.3; Annex I, Section 5.1.1. in conjunction with Annex II, Sections 0.1.2. and 8.2.2.2(b); Annex VIII, Sections 8.4.2. and 8.4.3.; Annex IX, Section 8.7.2.; and Annex X, Section 8.7.3.

On 25 November 2014 the Registrant updated his registration dossier with the submission number [redacted].

The compliance check requirement to submit information of a two-generation reproductive toxicity study (EU B.35, OECD TG 416) or an extended one-generation reproductive toxicity study (EU B.56, OECD TG 443) has been removed from this draft decision due to the legislative amendments to the REACH Regulation regarding Annex X, Section 8.7.3. In light of this, ECHA Secretariat did not consider further the Registrant's comments and update(s) concerning the information requirement of Annex X, Section 8.7.3. ECHA may, in accordance with Article 41 of the REACH Regulation, initiate a further compliance check of the registration dossier with respect to this information requirement.

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However, ECHA Secretariat did consider further the Registrant's comments and update(s) concerning the information requirements of Annex I, Sections 1.4.1., 3.3; Annex I, Section 5.1.1. in conjunction with Annex II, Sections 0.1.2. and 8.2.2.2(b); Annex VIII, Sections 8.4.2. and 8.4.3.; and Annex IX, Section 8.7.2.

Section II of the draft decision was amended and the Statement of Reasons (Section III) was changed accordingly.

On 21 July 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 proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

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

Pursuant to Articles 41(1), 41(3), 10(a)(vi) and/or (vii), 12(1)(e), 13 and Annexes VIII, IX, X of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

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

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

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

1. Revised Predicted No-Effect Concentration (PNEC) for soil as specified below under III.B.3.(Annex I, Section 3.3.).

C. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit the information required by this decision in the form of an updated registration to ECHA by **26 October 2017**. 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.

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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 [redacted] per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

The decision of ECHA is based on the examination of the Registrant's comments and the updated registration submitted for the tert-butyl acrylate, CAS No 1663-39-4 (EC No 216-768-7); hereafter referred to as 'target substance'. In his comments on the draft decision and in the updated registration, the Registrant has provided a justification for his read-across approach which were not present in the initial dossier examined by ECHA. The Registrant is using a grouping of substances and read-across approach to adopt the standard information requirement for Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.).

ECHA has considered first the scientific validity of the proposed read-across and grouping approach in the section below, and thereafter addressed the information requests.

0. Grouping of substances and read-across approach

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated by means other than tests. Such other means include the use of information from structurally related substances (grouping of substances and read-across), "provided that the conditions set out in Annex XI are met".

ECHA based its decision on the evaluation of your registration dossier that contains for the endpoints (Annex IX, Section 8.7.2.) adaptation arguments in form of a grouping and read-across approach under Annex XI, Section 1.5. of the REACH Regulation. Annex XI, Section 1.5. requires a structural similarity among the substances within a group or category such that relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation. The following analysis presents the Registrant's justification for the proposed grouping approach and read-across hypothesis, together with ECHA's analysis concerning the justification in both a generic and and property-specific context.

0.1 Description of the grouping and read-across approach proposed by the Registrant

In his comments and the up-dated registration dossier the Registrant has grouped the target substance with other substances for the purpose of read-across in a category named "*Acrylic acid and esters category*".

i. The Registrant states that "*The Acrylic Acid and Esters category is defined as a structurally related group of substances including acrylic acid (CAS No. 79-10-7), methyl acrylate (CAS No. 96-33-3), ethyl acrylate (CAS No. 140-88-5), n-butyl acylate (CAS No. 141-32-2), i-butyl acrylate (CAS No. 106-63-8), t-butyl acrylate (CAS No. 1663-39-4), and ethyl hexyl acrylate (CAS No. 103-11-7). All of these chemicals have a common Structure-Activity-Relationship (SAR) to serve as the technical basis for the category.*"

ii. The Registrant further states thate the category members consists of molecules based on acrylic acid, and includes esters of the acid of increasing chain length, and that the category is based on the following REACH criteria:

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a. the sharing of a common functional group (all are esters of acrylic acid),
b. common chemical classes,
c. an incremental change in chain length across the category, and
d. common breakdown products for related acids and esters.

iii. According to the Registrant: *"Because these substances exhibit similarity in their physicochemical properties and toxicological properties in mammals, and because the acrylate esters have been shown to be metabolized in the mammalian body in minutes to acrylic acid and the corresponding alcohol, they can be considered to constitute a chemical category. Data gaps for mammalian toxicity can be addressed by read-across between category members."*

ECHA understands this as the hypothesis under which the Registrant makes predictions for the properties listed above.

0.2 Support of the grouping and read-across approach

The Registrant has provided elements of a read-across justification as part of the comments on the draft decision and as two separate attachments in the updated dossier:

- A read-across justification attached in IUCLID section 13;
- A IUCLID category object, containing a 'Category definition' and 'Category rationale', together with a document "Acrylate Category Justification revised 02.06.2014" attached in the IUCLID category element.

With regard to pre-natal developmental toxicity the following studies have been provided in IUCLID:

- Experimental result on the target substance, Reliability 1 (reliable without restriction), GLP, [redacted], rats, combined inhalation Sub-chronic toxixity study with the Reproduction/Developmental Toxicity Screening Test (similar to to OECD TG 413/422, time of exposure in mailes 10 weeks premating + 3 weeks mating and postmating, exposure in females 10 weeks premating though gestation to postnatal day 4);
- Read-across from analogue substance, Reliability 2 (reliable with restrictions), non-GLP, [redacted], non-guideline inhalation study in rats (other guideline similar to OECD 414 *"Guidelines for reproduction studies for safety evaluation of drugs for human use, FDA, Jan. 1966 and Guidance on reproduction studies from the Association of the British Pharmaceutical Industry, 1975"*), Test material: n-Butyl acrylate[1];
- Read-across from analogue substance, Reliability 2 (reliable with restrictions), non-GLP, Saillenfait 1999, non-guideline inhalation study in rats (Similar to OECD 414, *"well-documented publication"*, *"Groups of 20-29 bred female rats (17-25 pregnant) were exposed to the compound 6h/day on days 6 through 20 of gestation. Control animals were exposed concurrently to filtered room air."*), Test material: n-Butyl acrylate[1];
- Read-across from analogue substance, Reliability 2 (reliable with restrictions), non-GLP, Rohm & Haas 1979, non-guideline inhalation study in rats (similar to OECD 414, *"Groups of bred female mice were administered with the test compound through oral gavage route on days 5 through 20 of gestation. Control animals received concurrently the vehicle."*, Test material: n-Butyl acrylate;
- Read-across from analogue substance, Reliability 1, GLP, [redacted], Rabbits, inhalation, Prenatal Developmental Toxicity Study (OECD 414), Test material: methyl acrylate, CAS 96-33-311[1];
- Read-across from analogue substance, Reliability 2 (reliable with restrictions), non-GLP, [redacted], non-guideline inhalation study in rats (similar to OECD 414,

[1] Study record labelled as "deleted" from the IUCLID dossier.

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"*well-documented publication*"; "*Groups of 20-29 bred female rats (17-25 pregnant) were exposed to the compound 6h/day on days 6 through 20 of gestation by inhalation. Control animals were exposed concurrently to filtered room air.*"); Test material ethyl acrylate[1];

- Read-across from analogue substance, Reliability 2 (reliable with restrictions), non-GLP; Saillenfait 1999, non-guideline inhalation study in rats (similar to OECD 414, "well-documented publication", "Groups of 20-29 bred female rats (17-25 pregnant) were exposed to the compound 6h/day on days 6 through 20 of gestation by inhalation. Control animals were exposed concurrently to filtered room air."); Test material 2-Ethylhexyl acrylate[1]; and
- Read-across from analogue substance, Reliability 2 (reliable with restrictions); non-GLP; IATG 1981; non-guideline inhalation study in rats (similar to OECD 414, "Pregnant Sprague-Dawley rats (33 per group) were exposed to 0, 50, or 150 ppm (corresponding to 0, 0.21, 0.62 mg/L)* of ethyl acrylate for 6 hr/day during Days 6 through 15 of gestation (the period of major organogenesis)."); Test material Ethyl acrylate[1].

The following toxicokinetic information has been provided: Experimental results on the target substance; Reliability 2 (reliable with restrictions); GLP; 2001; non-guideline; Study entitled: "[redacted]"; Principle of the test: The isomers of butyl acrylate were tested for relative rates of hydrolysis by a mammalian esterase (Porcine hepatic esterase). The Registrant concluded that: "*n-Butyl acrylate and isobutyl acrylate showed rapid hydrolyis under identical conditions in the same study (> 50% after 5 min in the 0.2 mM treatment)*", and in contrast, "*T-butyl acrylate did not appear to be substrate for this mammalian esterase, since little or no enzyme-catalyzed hydrolysis was detected under the reaction conditions.*"

0.3 ECHA analysis of the grouping and read-across approach in light of the requirements of Annex XI, Section 1.5.

Based on the read-across approach and supporting information provided, ECHA understands that the prediction is based on a category approach which uses the other members of the category as source substances to predict the properties of the target substance.

According to ECHA's understanding the Registrant suggests that predictions of the properties of the target substance is possible because

1. all substances within the category are stucturally similar, *i.e.* they are all esters of acrylic acid;
2. "*these substances exhibit similarity in their physicochemical properties and toxicological properties in mammals*";
3. "*the acrylate esters have been shown to be metabolized in the mammalian body in minutes to acrylic acid and the corresponding alcohol*".

In the following, ECHA examines the Registrant's arguments.

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(1) Structural (dis)similarities and their impact on prediction

Structural similarity is a prerequisite for applying the grouping and read-across approach, but ECHA does not accept in general or this specific case that structural similarity per se is sufficient to enable the prediction of human health properties of a substance, since structural similarity does not always lead to predictable or similar human health properties. It has to be justified why such prediction is possible in view of the identified structural differences and the provided evidence has to support such explanation. In particular, the structural similarities must be linked to a scientific explanation of how and why a prediction is possible.

Furthermore, ECHA notes that the Registrant has clearly identified the structural similarites between the substances, but he has not not addressed the structural differences, such as branching and different chain length of the parent compounds, and the impact of these differences on the predictions of toxicokinetic and toxicological properties of the target substance.

The provided explanation is therefore not sufficient to establish a scientifically credible link between the structural similarity and the prediction.

(2) Similar physicochemical and toxicological properties

Annex XI, Section 1.5. provides that "substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as result of structural similarity may be considered as a group or 'category' of substances". One prerequisite for a prediction based on read-across therefore is that the substances involved are structurally similar and are likely to have similar properties. One important aspect in this regard is the analysis of the data matrix to compare the properties of source and target substances and to establish whether indeed they are similar or follow a regular pattern.

For the substances included in the "Acrylic acid and esters category" the Registrant states that "*these substances exhibit similarity in their physicochemical properties and toxicological properties in mammals"; a*nd that the physico-chemical parameters/properties of target and source substances are similar. The Registrant makes the same argument by stating that there is a "*common Structure-Activity-Relationship (SAR)*". The Registrant has proposed that the similar physico-chemical properties of the target and source substances support the read-across between the substances.

ECHA observes that the physico-chemical properties of target and source substances are in the same/similar range. However, ECHA considers that the fact that physico-chemical parameters are in the same range may support a similar toxicokinetic and toxicity profile, but cannot be used alone to justify a prediction of properties related to human health. This is because substances may have similar physicochemical properties, but different toxicological properties. It has to be justified why such prediction is possible in view of the identified structural differences and the provided evidence has to support such explanation. In particular, the structural similarities must be linked to a scientific explanation of how and why a prediction is possible.

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The Registrant has also proposed that it is possible to predict the properties of the registered substance as a result of similarity in toxicological properties in the grouping. While similarity (or a regular pattern) in toxicological properties is a prerequisite for applying the grouping and read-across approach, ECHA does not accept in general or this specific case that similarity in toxicological properties per se is sufficient to enable the prediction of human health properties of a substance, since similarity in toxicological properties does not always lead to predictable or similar human health properties, either for the same endpoint or for different endpoints. Hence, further elements are needed such as a well-founded hypothesis of (bio)transformation to a common compound(s), or that different compounds have the same type of effect(s), to allow a prediction of human health properties that does not underestimate risks. (Note that the Registrant's hypothesis of common hydrolysis product is addressed separately below). ECHA considers that the requirement of Annex XI, Section 1.5, that human health effects may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach), has not been met.

(3) Rapid metabolism to acrylic acid and the corresponding alcohol

The Registrant claims that "*the acrylate esters have been shown to be metabolized in the mammalian body in minutes to acrylic acid and the corresponding alcohol*". ECHA considers that if there is only ever systemic exposure to the common breakdown product and the corresponding alcohol, then it would be possible to read-across from other acrylates for systemic effects. However, it is necessary to establish in some way that there is only ever systemic exposure to the common breakdown product and the corresponding alcohol.

With regard to metabolism the Registrant has provided the following infromation:
"*With regard to acrylate ester metabolism in mammals, studies have been conducted in order to evaluate the possibility that acrylate esters are hydrolyzed to acrylic acid and an alcohol in vivo and in vitro, and to determine the extent to which acrylic acid and the acrylate esters bind glutathione (GSH) in vitro (Miller et al., 1979). The acrylate esters were found to disappear rapidly in rat whole blood in vitro; the $t_{½}$ was 3.6, 4.6, and 7.1 minutes for disappearance of methyl, ethyl, and butyl acrylate, respectively.*"

"*Recent investigations on the in vitro metabolism of acrylates and methacrylates showed a fast esterase cleavage within the first 10 incubation minutes, with a parallel increase of acrylic acid after incubation with S9 fraction of rat liver for methyl-, ethyl-, n-butyl-, iso-butyl, 2-ethylhexyl- acrylate and a much ([redacted]). The $t1_{/2}$ was 0.84 min for butyl acrylate, 1.4 min for ethyl acrylate and about 3 min (due to a technical error determined on the acrylic acid formation) for MA. In plasma the disappearance was by factor or 10 slower.*"

The Registrant claims furthermore that "*the acrylate esters have been shown to be metabolized in the mammalian body in minutes to acrylic acid and the corresponding alcohol*". However, for the target substance the available data provided in the Basic Toxicokinetics section in the registration dossier contradicts this statement, stating "*T-butyl acrylate did not appear to be substrate for this mammalian esterase, since little or no enzyme-catalyzed hydrolysis was detected under the reaction conditions.*" In addition, ECHA notes that there is a more recent version of the [redacted] report on the *in vitro* metabolism of acrylates and methacrylates available than the one cited in the category justification document. According to this report, the target (registered) substance did not hydrolyse whereas most of the other acrylates did ([redacted]).

ECHA concludes that the available information on hydrolysis of the target substance contradicts the Registants read-across hypothesis that the target substance is "metabolized

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in the mammalian body in minutes to acrylic acid and the corresponding alcohol"." The available information demonstrates that the target substance is not likely to hydrolyse within minutes, in contradistinction to the source substances. Therefore, the Registrant's hypothesis of rapid hydrolysis to acrylic acid and corresponding alcohol is falsified, and the exposure of the systemic circulation to parent substance cannot be excluded. There is no other viable basis proposed to predict the properties of the (parent) registered substance. Consequently, this argument also is not an adequate basis for predicting the properties of target substance from the data of the source substances.

0.4 Conclusion on the read-across approach

The adaptation of the standard information requirements for the endpoint and Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in the technical dossier is based on the proposed read-across approach examined above. ECHA does not consider the read-across justification to be a reliable basis to predict the properties of the registered substance for the reasons set out above. Thus, the adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5 and is rejected.

1. 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 any study record of a pre-natal developmental toxicity study on the registered substance in the dossier that would meet the information requirement of Annex IX, Section 8.7.2.

In the technical dossier the Registrant has provided a study record for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD 422) conducted on the registered substance.

However, ECHA notes that the "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD 422) 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. Moreover, the results show induction of embryo/foetal deaths at maternally toxic dose level but malformations (gross, visceral and skeletal) are not examined in this study. In addition, the inhalation route is not adequate to be used for this substance because the nasal irritation limits the dose level selection and does not allow hazard identification for classification and labelling including the possibility to evaluate the relationship of systemic effects with effects on developmental toxicity.

In his comments on the draft decision and the subsequent update, the Registrant has provided a justification read-across and grouping adaptation. ECHA has assessed the new information and concluded this adaptation does not meet the general rules for adaptation of Annex XI, 1.5. for the reasons set out above (Section III.A.0.).

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Consequently there is an information gap and it is necessary to provide information for this endpoint.

In his comments to the draft decision the Registrant argues inhalation route as the only relevant route of exposure in the workplace. However, ECHA considers that the purpose of testing for pre-natal developmental toxicity testing is to identify a potential reproductive hazard and the test method, such as OECD TG 414, indicates that the oral route is the preferred route. The reason is to maximise systemic exposure. In case of irritating/corrosive substances the maximum concentrations which can be administered via inhalation and subsequently the systemic exposure is limited by the local effects on the respiratory tract. ECHA therefore considers the default oral route as most appropriate route also in the case of tert-butyl acrylate.

According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used. Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rats or rabbits by the oral route.

Notes for consideration by the Registrant

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

The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 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 fulfill 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.

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

1) Revised Predicted No-Effect Concentration for soil (Annex I, 3.3.)

Pursuant to Annex I, section 3.3. of the REACH Regulation, based on the available information, the PNEC for each environmental sphere shall be established. If it is not possible to derive each PNEC, then this shall be clearly stated and fully justified.

ECHA observes that the Registrant derived the PNEC for the soil compartment on the basis of results of the only available toxicity study with soil microorganisms conducted with the analogue substance, methyl acrylate.

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ECHA underlines that the Registrant failed to provide any read-across justification to support this approach for toxicity to soil organisms in the original dossier, in the comments on the draft decision and in the updated dossier. Therefore, adequate and reliable documentation pursuant to Annex XI, Section 1.5 of the REACH Regulation was not provided, except for a claim of structural similarity between the registered substance and the analogous substance, methyl acrylate, and results of toxicity studies with aquatic organisms for various acrylates.

In the comments on the draft decision and the updated dossier, ECHA observes a revised PNEC soil based on the analogue substance, methyl acrylate. However, as stated above, sufficiently adequate and reliable documentation pursuant to Annex XI, Section 1.5 of the REACH Regulation was not provided.

Also, ECHA notes that the Guidance on information requirements and chemical safety assessment, Chapter R.10 (p. 41) (ECHA, 2008) states that: "*If results from short-term tests with a producer, a consumer and/or decomposer are available, the result is divided by a factor of 1000 to calculate the* $PNEC_{soil}$. *If only one terrestrial test result is available (earthworms or plants), the risk assessment should be performed both of this test result and on the basis of the outcome of the aquatic toxicity data to provide an indicator of the risk.*"

This indicates that the use (in chemical safety assessment) of the PNEC for soil based only on the result of the toxicity test with soil microorganisms (decomposer) with assessment factor of 1000 is not sufficient to claim safe use of a substance. ECHA therefore concludes that the PNEC for soil cannot be derived solely on the basis of the toxicity test with soil microorganisms on the analogues substance, methyl acrylate, by applying an assessment factor of 1000. Moreover, ECHA notes that the Integrated testing strategy (ITS) for effects on terrestrial organisms as summarised in the Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 1.1, November 2012) shall be followed by the Registrant in performing the risk assessment of the soil compartment. The information available in the updated registration dossier provide indication that the registered substance is neither highly adsorptive, nor highly persistent, neither very toxic to aquatic organism and therefore, based on Table R.7.11-2 contained in the above mentioned Guidance, a screening assessment for the soil compartment shall be performed.
In such a case, the risk characterisation can be based on the PNEC for soil derived by applying the Equilibrium Partitioning Method (EPM). Moreover, in such a situation testing on soil organisms would not be necessary in the initial step of risk assessment.

Therefore, ECHA concludes that the derivation of the PNEC for soil, on the basis of available toxicity data with soil microorganisms conducted on an analogue substance, is not acceptable. Moreover, based on the information available in the updated registration dossier, ECHA concludes that the PNEC has not been derived according to the relevant provision of the REACH Regulation and to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.10: Characterisation of dose [concentration]-response for environment (May 2008).

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Therefore, pursuant to Article 41(1)(c) and 41(3) of the REACH Regulation the Registrant shall establish the PNEC for soil using the EPM method, as described in Section R.10.6. of the Guidance on information requirements and chemical safety assessment, Chapter R.10. The derived PNEC for soil shall be further used in the CSA as described in the ITS for effects on terrestrial organisms in Figure R.7.11-3 Scheme B and Table R.7.11-2 of the above mentioned Guidance, Chapter R.7c. The IUCLID registration dossier and chemical safety report shall be amended accordingly.

C. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 36 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also contained a two-generation reproductive toxicity study or an extended one-generation reproductive toxicity study (Annex X, 8.7.3.). As this is no longer part of the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 12 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

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://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[2] by Hannu Braunschweiler, Head of Unit, Evaluation E1

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