EUROPEAN CHEMICALS AGENCY

Helsinki, 7 December 2017

Addressee: [redacted]

Decision number: CCH-D-2114377287-37-01/F
Substance name: 2-[2-[2-[2-(1-methyl-2-prop-2-enoyloxy-ethoxy)ethoxymethyl]-2-[2-(2-prop-2-enoyloxypropoxy)ethoxymethyl]butoxy]ethoxy]propyl prop-2-enoate
EC number: 601-566-7
CAS number: 118800-30-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 24.04.2013
Registered tonnage band: 100 to 1000 tonnes per year

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **Name(s) in the IUPAC nomenclature or other international chemical name(s) (Annex VI, Section 2.1.1.) of the registered substance;**
   - **Chemical name, manufacturing process and EC and CAS entry which are consistent with each other and consistent with the composition reported in section 1.2 of the dossier**

2. **Composition of the substance (Annex VI, Section 2.3.)**
   - **Identity of the constituents**

3. **In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2, test method: OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2, test method: OECD TG 487) with the registered substance;**

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

5. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2; test method: EU B.31/OECD TG 414) in a first species (rats or rabbits), oral route with the registered substance;**

6. **Ready biodegradability (Annex VII, Section 9.2.1.1; test method: MITI test (I), OECD TG 301C) or**

   Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Closed bottle test, OECD TG 301D) or

   Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Manometric respirometry test, OECD TG 301F) or

   Ready biodegradability (Annex VII, Section 9.2.1.1; test method: Ready biodegradability – CO2 in sealed vessels (headspace test), OECD TG 310) with the registered substance;

7. **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 TG 309) at a temperature of 12 °C with the registered substance. The biodegradation of each constituent and relevant impurity present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed as further specified in Appendix 1, section 7. This can be done simultaneously during the same study;**

8. **Identification of the degradation products (Annex IX, Section 9.2.3.) using an appropriate and suitable test method;**

9. **Adsorption/desorption screening (Annex VIII, Section 9.3.1.; test method: Adsorption/desorption) using an appropriate test method with the registered substance;**

10. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305) with the registered substance. The bioaccumulation of each constituent and relevant impurity present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed as further specified in Appendix 1, section 10. This can be done simultaneously during the same study;**

11. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance;**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to IX and/or according to the general rules contained in Annex XI to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **16 December 2019**. You also have to update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2

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

Appendix 1: Reasons

You have applied read-across adaptations for several toxicological and ecotoxicological standard information requirements subject to the current decision. The proposed read-across is discussed in section 0 of this decision because it is based on similar justifications. The corresponding section 3 (in vitro cytogenicity study in mammalian cells or in vitro micronucleus study), section 4 (sub-chronic toxicity study, 90-day), section 5 (pre-natal developmental toxicity study) and section 6 (ready biodegradability) refer back to the conclusion of section 0 while analysing as well other information provided in the dossier and the need for further data to meet the relevant information requirements.

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".

Annex XI, 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 your justification for the proposed grouping approach and read-across hypothesis, together with ECHA's analysis concerning the justification in both a generic and an property-specific context.

0.1. Grouping of substances and read-across approach for toxicological information

In the registration, you have provided an analogue read-across rationale for human health hazard assessment, using the source substance ethoxylated trimethylolpropane triacrylate (TMPeoTA) (CAS no 28961-43-5). In that respect, you have provided the following studies on the source substance: three in vivo mammalian erythrocyte micronucleus tests, a carcinogenicity study, and a pre-natal developmental toxicity study.

These studies are provided in the dossier to adapt the information requirements for Section 8.4.2. of Annex VIII (in vitro cytogenicity study in mammalian cells or in vitro micronucleus study), Section 8.6.2. of Annex IX (sub-chronic toxicity study, 90-day), and Section 8.7.2. of Annex IX (pre-natal developmental toxicity study), respectively, by applying a read-across adaptation following REACH Annex XI, Section 1.5.

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

You provided the following, identical justification for all read-across studies:

"Propylidynetrimethanol, ethoxylated, esters with acrylic acid (CAS 28961-43-5) is structurally similar to Oxirane, methyl-, polymer with oxirane, ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1), 2 -propenoate (CAS 118800-30-9). Both molecules show no acute toxicity after oral or dermal exposure and did not induce gene mutations in bacteria or mammalian cells. In a developmental toxicity study using the read across substance Propylidynetrimethanol, ethoxylated, esters with acrylic acidat 1000mg/ kg b. w., poor general state and weight loss were observed in maternal animals, presumably as the result of local irritation of the gastrointestinal tract. Erosions in the stomach accompanied by weight loss within one week were also observed in a range finding test conducted with

Oxirane, methyl-, polymer with oxirane, ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1), 2 -propenoate using 600 and 1000mg/kg b. w.

The missing propoxy elements in CAS 28961-43-5 shorten the chain between the propylidynetrimethanol and the acrylic acid groups, leading to a lower molecular weight of app. 433g/mol and lower logPow of 2.89. It is reasonable to assume, that this also leads to a higher reactivity (i. e., an eye irritating and skin sensitizing potential, which is not observed for CAS118800 -30 -9), since the not ethoxylated Trimethylolpropane triacrylate (moleculare weight 296mg/mol, logPow 0.67) shows a further increased sensitizing potential in addition to eye and skin irritation, while also not being acutely toxic or mutagenic. Thus using data from 28961-43-5 is a reasonable worst case approach to cover the endpoints required for Oxirane, methyl-, polymer with oxirane, ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1), 2-propenoate."

ECHA understands that your proposed read-across is based on the hypothesis that the source substance propylidynetrimethanol, ethoxylated, esters with acrylic acid (CAS number 28961-43-5) is structurally similar to the registered substance (target substance), has a shorter chain leading to higher reactivity and hence toxicity, and therefore represents the worst-case. This hypothesis is the basis on which you predict the toxicological properties under consideration (*i.e.* in vivo micronucleus, carcinogenicity related also to sub-chronic toxicity, and pre-natal developmental toxicity studies).

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

With regard to the proposed predictions, ECHA has the following observations:

(i) The substance characterisation of the source studies needs to be sufficiently detailed in order to assess whether the attempted prediction is not compromised by the composition and/or impurities. In the ECHA practical guide "How to report on Read-Across" it is recommended to follow the Guidance on identification and naming of substances und REACH (version 2.1, May 2017) also for the source substances. This ensures that the identity of the source substance and its impurity profile allows an assessment of the suitability of the substances for read-across purposes.

ECHA observes that the source substance is merely identified by its chemical name and CAS number and no supporting information is available in the registration dossier of the target substance.

The impurity profile of the source substance cannot be assessed using the information provided in the registration dossier and, hence, ECHA cannot verify what chemical compounds are present. Therefore, as the structural similarity between the source substance and the target substance cannot be established, prediction of toxicological properties is not possible.

(ii) Structural similarity is a prerequisite for applying the grouping and read-across approach, but ECHA does not accept in general 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. 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.

The proposed read-across is based on vague descriptions of structural differences (see 0.1.1 above), their influence on absorption and bioavailability, and a superficial comparison of irritation, sensitisation, acute and mutagenic properties. You also argue that shorter chain length leads to higher reactivity and toxicity.

ECHA considers that (i) the limited information on toxicity provided in the dossier does not provide a reliable basis to predict the reactivity and toxicity of the registered substance for in vivo micronucleus, carcinogenicity and pre-natal developmental toxicity studies, and (ii) that the proposed mechanism does not account for toxicity through mechanisms which are not a result of the intrinsic reactivity of the substance, as explained in detail below.

You stated that the structural dissimilarities are linked to molecular weight, bioavailability, irritating and sensitising potential but you did not explain why these properties can be used to predict the properties under consideration. In particular, it is unclear why a comparison of irritation and sensitisation properties could support read-across of in vivo micronucleus, carcinogenicity and PNDT studies. You also did not explain why you regard the source as well as the target substances as being neither acutely toxic nor mutagenic. It is also unclear how the general statement that the substances are neither acutely toxic nor mutagenic supports the proposed read-across for in vivo micronucleus, carcinogenicity and PNDT studies.

Based on irritation and sensitisation, you explained that the source substance is considered "worst-case". However, it is unclear how a worst-case for irritation and sensitisation properties supports the assumption that the source substance is also worst-case for other properties of the registered substance - in vivo micronucleus, carcinogenicity and PNDT studies. Therefore, based on the information provided, ECHA cannot assess whether the assumption of the worst-case applies for the properties for which the read-across is proposed. For example, it is unclear how despite the identified differences between source and target substances (i.e. shorter chain length, lower molecular weight, assumed higher bioavailability, higher eye/skin irritation potential and higher skin sensitisation potential) the prediction that the registered substance does not induce cytogenetic damage, neoplastic lesions nor teratogenic effects could be made.
In view of the above, ECHA emphasises that from the provided read-across justification it cannot be concluded whether the source and target substances share a common underlying mechanism for the proposed read-across approach. ECHA considers that the requirement of Annex XI, 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.

(iii) Annex XI, Section 1.1.2 (2) and (3) and Annex XI, Section 1.5 require for non-GLP studies and studies used for read-across purposes that there is "adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test method referred to in Article 13(3)". Additionally, applying an adaptation of the information requirement in accordance with Annex IX, 8.6.2. (sub-chronic toxicity study, 90-day) column 2, second indent requires that "a reliable chronic toxicity study is available".

ECHA notes that as you classified the provided read-across carcinogenicity study as unreliable the conditions for adapting the information requirement of Annex IX,

8.6.2. (sub-chronic toxicity study, 90-day) are not met.

0.1.3. Conclusion

ECHA does not consider the read-across approach as proposed in the dossier to be a reliable basis to predict the relevant properties of the registered substance by interpolation for the reasons set out above. Thus, the proposed read-across approach does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and cannot be approved to adapt the standard information requirements for Section 8.4.2. of Annex VIII (in vitro cytogenicity study in mammalian cells or in vitro micronucleus study), Section 8.6.2. of Annex IX (sub-chronic toxicity study, 90-day), and Section 8.7.2. of Annex IX (pre-natal developmental toxicity study).

0.2. Grouping of substances and read-across approach for ecotoxicological information

In the registration, you have provided an analogue/category rationale for environmental hazard assessment. The provided rationale builds on the following category members:

- Propylidynetrimethanol, ethoxylated, propoxylated, esters with acrylic acid (> 1 <6.5 mol EO and >1 <6.5 mol PO) [TMP(PO)EOTA, CAS: 118800-30-9] (registered substance)
- Propylidynetrimethanol, ethoxylated, esters with acrylic acid, reaction products with 1-Butanamine, N-butyl- (> 1 <6.5 mol EO) [TMPEOTA-DBA, CAS: 195008-76-5]
- Propylidynetrimethanol, ethoxylated, propoxylated, esters with acrylic acid, reaction products with 1-Butanamine, N-butyl- (> 1 <6.5 mol EO) [TMP(PO)EOTA (DBA), CAS: 173011-06-8]

Within the rationale you have provided a read across study (OECD 301F, [redacted], 2007) using source substance CAS 173011-06-8. This study is provided in the dossier to adapt the information requirement for Section 9.2.1.1 of Annex VII (Ready biodegradability) by applying a read-across adaptation following REACH Annex XI, Section 1.5.

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

You provided the following read-across justification:

"The three products, identified by the CAS numbers 118800-30-9, 195008-76-5 and 173011-06-8, respectively, are subject to registration under Tier 2 of Regulation (EC) No 1907/2006 (REACH). No complete data set fulfilling the requirements of Annex IX of REACH is available for each of the submission items. However, the information available for the individual members is considered adequate to address the information needs for the entire group via read across.

CAS numbers 118800-30-9, 195008-76-5 and 173011-06-8, respectively, are grouped into a category based on their similar composition. Starting substance for all members of the group is [redacted] Subsequently, the material is [redacted] which gives CAS 118800-30-9 ([redacted]). In order to manufacture CAS 195008-76-5 (ethoxylated only) and 173011-06-8 (ethoxylated and propoxylated), the received multifunctional acrylate is further modified with [redacted] to yield the final products.

The variations in the manufacturing process ([redacted]) and the resulting, somewhat differing compositions are not expected to have significant impact on the potential environmental toxicity of the products. Rather, possible effects are supposed to be driven by the functional group of the category members, i.e. the acrylate group(s). This is confirmed by the available data on the aquatic toxicity of the products (see table 1):

Experimental studies on the acute toxicity to fish are available for CAS 118800-30-9 and 173011-06-8. These provide LC50 values of 3.8 mg/L and 4.4 mg/L, indicating a very similar effect on fish of both products. The comparable toxicity profile is further substantiated by results from acute studies on invertebrates, which show EC50 values above 100 mg/L for those two registration items. An additional study in algae (CAS 118800-30-9, EC50 = 27 mg/L)demonstrates that fish is the most sensitive species when exposed to these multifunctional acrylates. Only one study on the biodegradability of the group members is available. However, as the test item used (CAS 173011-06-8) contains the same chemical (sub-) structures as the other products of the category, the result of this study is considered suitable also for CAS 118800-30-9 and 195008-76-5, respectively. Taking the structural similarity as well as the available information stated above into account, it is highly likely that the environmental toxicity profiles of the members of the proposed group are very similar. Therefore, it is considered appropriate to fill data gaps within the category via read across to data from the other group members."

Table 1: Data matrix of the members of the proposed group

Name	Propylidynetrimethanol, ethoxylated, propoxylated, esters with acrylic acid (> 1 <6.5 mol EO and >1 <6.5 mol PO)	Propylidynetrimethanol, ethoxylated, esters with acrylic acid, reaction products with 1-Butanamine, N-butyl- (> 1 <6.5 mol EO)	Propylidynetrimethanol, ethoxylated, propoxylated, esters with acrylic acid, reaction products with 1-Butanamine, N-butyl- (> 1 <6.5 mol EO)
CAS	118800-30-9	195008-76-5	173011-06-8
Alkoxylation	EO, PO	EO	EO, PO
Amine-modified	no	yes	yes
Fish	**study**: LC50 (96h) = 3.8 mg/L	**RA**: LC50 (96h) = 3.8 mg/L	**study**: LC50 (96h) = 4.4 mg/L
Invertebrates	**study**: EC50 (48h) > 100 mg/L	**RA**: EC50 (48h) > 100 mg/L	**study**: EC50 (48h) > 100 mg/L
Algae	**study**: EC50 (72h) = 27 mg/L	**RA**: EC50 (72h) = 27 mg/L	**RA**: EC50 (72h) = 27 mg/L
Mircoorganisms	**RA**: EC20 (30 min) approx. 1000 mg/L	**RA**: EC20 (30 min) approx. 1000 mg/L	**study**: EC20 (30 min) approx. 1000 mg/L
Biodegradability	**RA**: OECD 301F, ready	**RA**: OECD 301F, ready	**study**: OECD 301F, ready

RA = readacross

ECHA understands that your proposed read across is based on the hypothesis that the composition of the category substances is similar and the variation resulting from the manufacturing process as [redacted] and the resulting, somewhat differing compositions are not expected to have significant impact on the potential environmental toxicity of the products.

This hypothesis is the basis on which you predict, using information on the source substance Propylidynetrimethanol, ethoxylated, propoxylated, esters with acrylic acid, reaction products with 1-Butanamine, N-butyl- (> 1 <6.5 mol EO) [TMP(PO)EOTA (DBA), CAS: 173011-06-8], the degradation properties of the registered substance (*i.e.* ready biodegradability).

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

With regard to the proposed predictions, ECHA has the following observations:

(i) The substance characterisation of the source studies needs to be sufficiently detailed in order to assess whether the attempted prediction is not compromised by the composition and/or impurities. In the ECHA practical guide "How to report on Read-Across" it is recommended to follow the Guidance on identification and naming of substances und REACH (version 2.1, May 2017) for all category members. This ensures that the identity of the source substance and its impurity profile allows an assessment of the suitability of the substances for read-across purposes.

ECHA notes that you have not provided detailed information on the identity of the grouped substances. In the registration dossier you have identified the substances in the category only by name and CAS number. For the source substance CAS 173011-06-8, only the purity is provided in the test material section for the biodegradability test. There are no typical concentrations or concentration ranges of the constituents provided for the target and the source substance to support the read-across.

Structural similarity is a prerequisite for applying the grouping and read-across approach, but ECHA does not accept in general that structural similarity per se is sufficient to enable the prediction of environmental hazard and fate properties of a substance, since structural similarity does not always lead to predictable or similar environmental hazard and fate properties.

The proposed read-across is based on descriptions of similar composition and available information on aquatic toxicity. However, three members of the group differ due to [redacted]. The registered substance is [redacted] The source substance (CAS 173011-06-8) with the information for ready biodegradation (OECD 301F) has been also [redacted] to yield the final products. You state that differing compositions are not expected to have significant impact on the potential environmental toxicity of the substances in the category and effects are to be driven by the functional group of the category members, i.e. the acrylate group(s). In particular you state that variation between the read across substances due to [redacted] would not have a significant impact on environmental toxicity. You support this statement with information on aquatic toxicity on registered substance and source substance. However, it is not clear if the comparison of aquatic toxicity is meant to support also the read-across on biodegradability and if so, how it would support the prediction of ready biodegradation. Further, you state that the result of the biodegradation study can be used for read-across because the source substance contains "*the same chemical (sub-) structures as the other products of the category*". However, 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. Moreover it has to be justified why the target substance would show at least the same biodegradability in order to qualify as ready biodegradable. The result for the source substance (CAS 173011-06-8) is with 60-70% degradation already close to the pass level and the read-across by itself introduces additional

uncertainty.

(ii) Annex XI, Section 1.5 require studies used for read-across purposes that "adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3)" and "reliable documentation of the applied method".

ECHA notes that you reported the provided read-across ready biodegradation study performed according to GLP (OECD TG 301F) as reliable with restrictions. ECHA points out that you have not reported the information essential for assessing if all the validity criteria set in the OECD TG 301 were met or not which prevents ECHA from concluding whether the study is valid or not.

0.2.3. Conclusion

ECHA does not consider the read-across approach as proposed in the dossier to be a reliable basis to predict the relevant property of the registered substance by interpolation for the reasons set out above. Thus, the proposed read-across approach does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and cannot be approved to adapt the standard information requirement for Section 9.2.1.1. of Annex VII (ready biodegradability).

1. Name or other identifier of the substance (Annex VI, Section 2.1.)

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

ECHA notes that you identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). Information required to be provided according to Annex VI section 2.1 of the REACH Regulation on the naming of UVCB substances such as the registered substance shall consist of two parts: (a) the chemical name and (b) a more detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 2.1, May 2017) - referred to as "the Guidance" thereinafter. Provided identifiers should be consistent and should allow unambiguous identification of the substance.

a) Chemical Name

The identifiers you have provided are not consistent and some of them do not support identification of your substance as a UVCB substance.

You have provided the IUPAC name [redacted] for your substance. This IUPAC name which you have assigned to your substance refers to a well-defined substance. The assigned name is not consistent with the other identifiers provided in your dossier as these all refer to a UVCB substance. You have provided structural formula which has variable number of repeating units which is not consistent with a well-defined substance. Furthermore the provided molecular formula and molecular weight range refer to a UVCB substance while the provided CAS entry refers to a polymeric substance. In addition the analytical information you have provided in section 1.4

supports the identification of your substance as a UVCB substance.

You are accordingly requested to revise the information provided in section 1.1 of your dossier and to ensure that the provided identifiers are consistent with each other and consistent with composition reported in IUCLID section 1.2. You should further ensure that the analytical information provided in IUCLID section 1.4 is sufficient and consistent with the identifiers you have provided. If your substance should be identified as UVCB substance then you are requested to revise the chemical name assigned to the registered substance. You are requested to ensure that the chemical name is representative of the specific substance which is the subject of this registration and that the name is consistent with the instructions given in the Guidance. If your substance should be identified as a well-defined substance you are requested to revise the identifiers accordingly and to provide analytical results which would support identification as a well-defined substance.

As for the reporting of the information in IUCLID, the chemical name or other identifiers which you have revised shall be specified in the relevant fields in IUCLID section 1.1.

b) Manufacturing process

You have given in IUCLID section 3.1 the following description of the manufacturing process for the registered substance: "[redacted]".

ECHA notes that the manufacturing process has not been provided to a sufficient level of detail for the identification of the registered substance.

You are accordingly requested to provide the missing information regarding your manufacturing process. The description of the manufacturing process should include information on the ratio of used starting materials and other reactants. Furthermore the description should include all necessary information about the applied process conditions. This information should include relevant operating parameters such as temperature and pressure as well as all other relevant operating parameters which may have influence to the produced substance.

As for the reporting of the information in IUCLID, the manufacturing process description shall be specified in the "Description" field in IUCLID section 1.1 and "Methods of manufacture of the substance" field in section 3.1, respectively.

c) EC and CAS entries

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2.1. of the REACH Regulation. The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore fundamental for substance identification. Adequate and consistent information needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have reported the CAS number 118800-30-9 as CAS information for the registered substance. The CAS name for this entry is "[redacted]".

The provided CAS information refers to a polymer and as such it is not consistent with the other identifiers which you have provided for identification of your substance. If you consider that your subtance does not meet the criteria for polymeric substance then the provided CAS information does not describe your substance.

Accordingly you are requested to delete the CAS number currently specified under the "CAS information" header of the reference substance in IUCLID section 1.1 and report a CAS number specifically corresponding to the registered substance (if available). If you so choose, you may specify the current CAS entry 118800-30-9 under the "Related CAS information" header in IUCLID section 1.1 for the registered substance.

If you consider that your substance meets the definition of polymer within the meaning of Article 3(5) of the REACH you are requested to reconsider your registration obligations under REACH.

In addition as the current list number is connected to CAS entry 118800-30-9 it does not correctly identify the registered substance and it will need to be revised. However, you are requested not to remove or modify the EC entry currently assigned to this registration when updating the dossier. As this registration is linked to this EC entry in REACH-IT, the IT system will not accept the updated dossier as an update when the EC entry has changed. Instead you are requested to include in the "Remarks field" of the reference substance the following: "The EC entry currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified in the present registration at this stage for technical reasons".

You should note that ECHA has established a process, subject to certain conditions, enabling registrants to adapt the EC identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

However, pending the resolution of all the incompliances highlighted in the present decision, the adaptation of the identifier can only be effective once ECHA is at least in a position to establish unambiguously the identity of the substance intended to be covered by this registration. Should the information you submit as a result of the present decision enable ECHA to identify the substance unambiguously, the process of adapting the identifier will be considered relevant. In that case, ECHA will inform you in due time as to when the identifier adaptation process shall be initiated.

In any case, you should note that the application of the process of adapting the identifier does not affect your obligation to fulfil the requirements specified in this decision.

Furthermore you are requested to ensure that representative identifiers are used throughout the dossier, and are consistent with the information on the composition in section 1.2 and the analytical data in section 1.4 of the IUCLID dossier.

Further technical details on how to report in IUCLID are available on the ECHA website: https://echa.europa.eu/manuals.

ECHA notes that in your comments you agreed to update section 1 of the IUCLID dossier concerning the above mentioned issues.

2. Composition of the substance (Annex VI, Section 2.3.)

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the cornerstone of all the REACH obligations.

As stated before, you have identified the registered substance as a UVCB substance. According to chapter 4.3 of the Guidance for UVCB substances such as the registered substance, the following applies:

I. All constituents present in the substance with a concentration of ≥ 10% shall be identified and reported individually;
II. All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually;
III. Unknown constituents shall be identified as far as possible by a generic description of their chemical nature. The identification of these other constituents must be provided in order to allow ECHA to establish the composition of the substance as manufactured and to use the compositional information as one identifier for the registered substance.
IV. For each constituent or group of constituents, the typical, minimum and maximum concentration levels shall be specified.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the registered substance and therefore its identity. More specifically, ECHA notes that constituents have not been reported individually in IUCLID section 1.2 of the dossier. Instead, one generic reference substance [redacted]) covering all constituents of the UVCB substance has been reported. A more detailed description of the composition of the analysed sample was reported in the attachment "[redacted]". However, no specific information on the typical concentrations and concentration ranges of the different constituents covered by the generic reference entry have been provided.

Therefore, ECHA notes that you have not reported and identified the individual constituents present in your substance to the level of detail required, as described above. As a result the provided information is insufficient to confirm the composition and identity of your subtance.
Pursuant to Article 41(1) and (3) of the REACH Regulation, you are accordingly requested to revise the information on the composition of the registered substance in order to establish a precise chemical representation of what the substance consists of. In particular you are requsted to:

I. Report separately the constituents referred to in the generic entry ("[redacted]"). Create for each constituent/group of constituent a repeatable block under the "Constituents" header in IUCLID section 1.2.
II. Identify and report individually all constituents with a concentration ≥10% (w/w).

III. Report the constituents/group of constituents with the typical, minimum and maximum concentration levels.

You should ensure that there is sufficient analytical information included in section 1.4 of the IUCLID dossier to identify and quantify the substance and to verify the information in IUCLID section 1.2.

Further technical details on how to report in IUCLID are available at: https://echa.europa.eu/manuals.

ECHA notes that in your comments you agreed to update section 1 of the IUCLID dossier concerning the above mentioned issues.

3. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(b) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

An "*In vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study" is a standard information requirement as laid down in Annex VIII, Section 8.4.2. 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.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records for three *in vivo* mammalian erythrocyte micronucleus tests according to OECD TG 474 with the analogue substance ethoxylated trimethylolpropane triacrylate (TMPeoTA) (CAS no 28961-43-5). However, as explained above in Appendix 1, section 0.1 of this decision, your adaptation of the information requirement cannot be accepted.

The information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In your comments on the draft decision, you agree "*that the provided read across justification is limited and needs to be improved*". However, you claim that"*sufficient data have been generated for many multifunctional acrylates to provide evidence that there is no concern for this chemical category regarding genotoxicity*." Hence, you are proposing a category approach based on "*Table 1: Results of mutagenicity assays for multifunctional acrylates*". However, ECHA considers that basic information, including name, structure, outcome of mutagenicity studies, of the six substances referred to in this category, is not sufficient for ECHA to be able to assess why the members of this category would be representative to read-across the in vitro mutagenicity data to the registered substance.

Finally, you also propose to "*perform an MNT assay in vivo instead of in vitro, since the high cytotoxicity and consequently positive in vitro results are also expected for the registered substance, which would need to be clarified in vivo, rendering a previous in vitro assay unnecessary*." ECHA considers that unless there is an already available in vitro genotoxicity test for the registered substance that has a positive result, there is no legal basis to perform an in vivo test, as the condition described in Annex VIII, section 8.4., column 2, is not met.

ECHA considers that the *in vitro* mammalian chromosome aberration test (test method OECD TG 473) and the *in vitro* micronucleus test (OECD TG 487) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.2. of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *In vitro* cytogenicity study in mammalian cells (test method: OECD TG 473) or *in vitro* mammalian cell micronucleus study (test method: OECD TG 487).

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(b) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

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

In the technical dossier you have provided a study record for a combined repeated dose toxicity study with the reproduction / developmental toxicity screening test according to OECD TG 422 using the registered substance. However, this study does not provide the information required by Annex IX, Section 8.6.2., in particular because the exposure duration is less than 90 days.

Furthermore, you have provided a read-across carcinogenicity study using the analogue substance ethoxylated trimethylolpropane triacrylate (TMPeoTA, CAS no 28961-43-5). According to column 2, second indent of Section 8.6.2., Annex IX, "*the sub-chronic toxicity study (90 days) does not need to be conducted if: [...] a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used [...]*". However, as explained above in Appendix 1, section 0.1 of this decision, the read-across cannot be accepted and the provided carcinogenicity study itself is unreliable. Therefore, the adaptation according to column 2, second indent of Section 8.6.2., Annex IX cannot be accepted, either.

You have also sought to adapt this information requirement by providing the following justification for the adaptation "*In a combined repeated dose / reproduction toxicity screening study, rats were exposed to the test substance at the maximum tolerated dose of 500mg/kg b.w. for up to 56 days. No signs of systemic toxicity were observed in these animals. No higher dose could be tested. Erosions in the stomach, and consequently poor general state and weight loss were observed in a range finding study at higher doses. No other effects are expected after exposure for 90 days. In addition, bioaccumulation of the test substance is not expected. In agreement with the principles of REACH to avoid unnecessary animal testing, a 90-day study is therefore considered scientifically unjustified.*" While you have not explicitly claimed an adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement according to Annex XI, 1.2. (weight of evidence). However, ECHA notes that your adaptation does not meet the general rules for adaptation of Annex XI, 1.2. Based on the findings in the provided OECD TG 422 study that "*no signs of systemic toxicity were observed in these animals*" and "*no higher dose could be tested*", you concluded that "*no*

other effects are expected after exposure for 90 days". You did not provide additional supporting information for your assumption. However, ECHA is of the opinion that the findings that "*no signs of systemic toxicity were observed*" and "*no higher doses could be tested*" do not support the assumption that no further effects are expected after a prolonged exposure duration of 90 days. It is generally known, that a prolonged exposure duration frequently results in qualitative and quantitative differences in the effects observed in toxicological studies. You have not provided additional evidence to support your assumption and, hence, ECHA can neither assume nor conclude that the registered substance exerts no other effects in a sub-chronic toxicity study (90-day). Furthermore, ECHA notes that your weight-of-evidence justification relies on the results of one study only. However, according Annex XI, 1.2., "several independent studies" are needed. Because your adaptation does not meet the general rules of Annex XI, 1.2. (weight of evidence) nor any of the specific rules for adaptation according to column 2 of Section 8.6.2., Annex IX, ECHA concludes that your adaptation of the information requirement cannot be accepted.

In your comments to the draft decision you propose to first conduct an OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test) with an analogue substance, TMPeoTA (CAS 28961-43-5), which you presume to be "*more reactive than the registered substance TMPeo/poTA (CAS 118800-30-9) due to slightly shorter chain lengths between the TMP and the acrylic groups.*". Thus, suggesting that it is possible to read-across from TMPeoTA as the worst case, and therefore suggest to perform the requested OECD 408 using TMPeoTA as the test substance. ECHA considers that performing an OECD 422 reproductive toxicity screening study with a read across substance is up to you, and that you may perform Annex VIII tests at any time.

However, ECHA notes that as explained above, the proposed read-across approach has been rejected. Hence the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA Guidance on information requirements and chemical safety assessment (version 6.0, July 2017) Chapter R.7a, section R.7.5.4.3 - is the most appropriate route of administration. More specifically, the substance is a liquid of very low vapour pressure. Uses with spray application are reported in the chemical safety report. However, the registered substance is not classified for skin/eye irritation. Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

According to the test method EU B.26./OECD TG 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, you are 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 TG 408) in rats.

5. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(b) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

A "pre-natal developmental toxicity study" (test method EU B.31./OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided a study record for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD TG 422). However, this study does not provide the information required by Annex IX, Section 8.7.2. This is because, contrary to Article 13(3) and Annex XI, Section 1.1.2. of the REACH Regulation, it does not cover key parameters of a pre-natal developmental toxicity study like examinations of foetuses for skeletal and visceral alterations. Therefore, your adaptation of the information requirement cannot be accepted.

You have also sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a pre-natal developmental toxicity study (OECD TG 414) with the analogue substance ethoxylated trimethylolpropane triacrylate (TMPeoTA, CAS no 28961-43-5). However, as explained above in Appendix 1, section 0.1 of this decision, your adaptation of the information requirement cannot be accepted.

In your comments you agree that "*the provided read across justification does not meet current requirements*". You also propose to perform a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test reproductive toxicity screening (OECD 422) in order to improve your read across justification. As noted already under section 4 it is up to you to perform such a study. However, as explained above, this study does not provide the information required by Annex IX, Section 8.7.2. Therefore, such a study would not be considered an adequate adaptation of this information requirement.

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

According to the test method EU B.31/OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are 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

TG 414) in a first species (rats or rabbits) by the oral route.

6. Ready biodegradability (Annex VII, Section 9.2.1.1.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Ready biodegradability", is a standard information requirement as laid down in Annex VII Section 9.2.1.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a Ready biodegradability: Manometric resppirometry Test (OECD TG 301 F) with the analogue substance Propylidynetrimethanol, ethoxylated, propoxylated, esters with acrylic acid, reaction products with 1-Butanamine, N-butyl- (> 1 <6.5 mol EO)[*TMP(PO)EOTA (DBA),* CAS no 173011-06-8].

However, as explained above in Appendix 1, section 0.2 of this decision, your adaptation of the information requirement cannot be accepted.

In your comments to the draft decision, you agreed with ECHA that the argumentation provided in the dossier – in its current form – is not adequately justified to meet the general rules for adaptation of Annex XI, Section 1.5.

In addition, you provided QSAR predictions (OASIS Catalogic v5.11.17 (CATALOGIC Kinetic 301F v.13.16 and VEGA´s in silico platform), with a representative structure in order to further elaborate on the biodegradation of the registered substance. However, the degree of biodegradation indicated by the model(s) is rather close to the pass levels set by the test guidelines of the OECD 301 test series. Therefore, you agree with ECHA's proposal to perform a study on "ready biodegradability" in order to support the conclusions drawn above by experimental data.

As explained above, the information provided on this endpoint does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information on this endpoint.

Regarding the test method, depending on the substance profile, you may conclude on ready biodegradability, by applying the most appropriate and suitable test guideline among those listed in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b (June 2017) and in the paragraph below. The test guidelines include the description of their applicability domain.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to perform one of the following tests with the registered substance subject to the present decision:

Ready biodegradability (Annex VII, 9.2.1.1.; test method: MITI test (I), OECD TG 301C).
or

Ready biodegradability (Annex VII, 9.2.1.1.; test method: Closed bottle test, OECD TG 301D).
or
Ready biodegradability (Annex VII, 9.2.1.1.; test method: Manometric respirometry test, OECD TG 301F).
or
Ready biodegradability (Annex VII, 9.2.1.1.; test method: Ready biodegradability – CO_2 in sealed vessels (headspace test), OECD TG 310).

7. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Simulation testing on ultimate degradation in surface water" is a standard information requirement as laid down in Annex IX, 9.2.1.2 of the REACH Regulation. Column 2 of Section 9.2.1.2 of Annex IX further indicates that the study does not need to be conducted if the substance is highly insoluble in water or if the substance is readily biodegradable. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of simulation testing on ultimate degradation in water in the dossier that would meet the information requirement of Annex IX, Section 9.2.1.2.

You have sought to adapt this information requirement according to Annex IX, Section 9.2.1.2., column 2. You provided the following justification for the adaptation; *According to column 2 of Annex VII of Regulation (EC) No 1907/2006, biodegradation in sediment does not need to be addressed when the submission substance is readily biodegradable.*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2.1.2., column 2 because, as explained in the section 6 in this decision, based on the information provided in the technical dossier there is currently no scientifically sound information that the registered substance is readily biodegradable.

In your comments, you first referred to the information provided under request 6, i.e. ready biodegradability. ECHA has addressed in the relevant section the reasons why the QSAR adaptations for ready biodegradability cannot be accepted.

In your comments to the draft decision, you provided supporting information from other substances of similar structure, i.e. a group of multifunctional acrylates. While you identify this as a grouping approach under general rules of Annex XI, section 1.5, effectively you provided a series of QSAR predictions for a number of selected analogues within that group. Therefore, ECHA considers this as an adaptation according to Annex XI, Section 1.3.

ECHA notes that the predictions provided for this group of acrylates are in most of the cases within the domain of the model. However, similarly to the ready biodegradability endpoint predictions, the analogues you selected have log Kow values ranging between 1 and 3. Therefore, the structures used for the predictions can neither be considered representative of the whole composition of the substance, nor a worst case. Hence, there is a residual

uncertainty regarding the components with log Kow above 3 which you identified in Section 4.7 of the technical dossier and thus your adaptation cannot be accepted.

ECHA notes that due to lack of information on the degradation of the substance you have not in your CSA or the technical dossier justified that there is no need to investigate further the degradation of the substance or its degradation products. ECHA considers that the information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

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

According to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017) Aerobic mineralisation in surface water – simulation biodegradation (test method EU C.25. / OECD TG 309) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.2.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions". The Guidance on information requirements and chemical safety assessment R.7b (version 4.0, June 2017) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-8 (version 3 February 2016) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the OECD TG 309. Therefore, the test should be performed at the temperature of 12°C.

In the OECD TG 309 Guideline two test options, the "pelagic test" and the "suspended sediment test", are described. ECHA considers that the "pelagic test" option should be followed as that is the recommended option for P assessment. The amount of suspended solids in the pelagic test should be representative of the level of suspended solids in EU surface water. The concentration of suspended solids in the surface water sample used should therefore be approximately 15 mg dw/L. Testing natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable. Furthermore, when reporting the non-extractable residues (NER) in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are 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 TG 309) at a temperature of 12 °C. The biodegradation of each constituent and relevant impurity present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.

Notes for your consideration

Before conducting the requested test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Sections R.7.9.4 and R.7.9.6 (version 4.0, June 2017) and Chapter R.11, Section R.11.4.1.1 (version 3.0, June 2017) on PBT assessment.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the test detailed above is available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

8. Identification of the degradation products (Annex IX, Section 9.2.3.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Column 2 of Section 9.2.3. of Annex IX further states that the study does not need to be conducted if the substance is readily biodegradable.

You have provided information on degradability of the read across substance and concluded the registered substance to be readily biodegradable. However, as explained above in Appendix 1, sections 0.2 and 6, your conclusion is not supported by the information provided and there is currently no scientifically sound information that the registered substance is readily biodegradable.

In your comments to the draft decision for this endpoint you have claimed that requested study is not needed as the information provided under requests 6 and 7 of your response demonstrated that multifunctional acrylates – including the registered substance – do sufficiently degrade in the environment and do not form persistent metabolites. However, as explained under requests 6 and 7, ECHA does not agree to your claims. Therefore ECHA considers your proposed adapation for the identification of the degradation products as not valid.

ECHA notes that you have not provided information on the identification, stability, behaviour, and quantity of the degradation products relative to the parent compound. Consequently there is data gap for identification of the degradation products.

Regarding appropriate and suitable test method(s), the method(s) will have to be substance specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition degradation half-life, log Kow and potential toxicity of the metabolite may be investigated.

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: Identification of the degradation products using an appropriate test method, as explained above in this section.

Notes for your consideration

Before conducting the above test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment Chapter R7b, Sections R.7.9.2.3 and R.7.9.4. (version 4.0, June 2017). In particular, Section R.7.9.4. states that when substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis.

The Registrant is advised to consult the REACH guidance on information requirements and chemical safety assessment in Chapter R.11.1.3. and Figure R. 11-1 on PBT assessment for the integrated testing strategy for persistency assessment taking into account the potential degradation products of the registered substance, and to update the CSR accordingly.

Moreover, pursuant to Annex I, section 4.1., the Registrant shall consider the information relevant for screening for P, B and T properties of the parent substance and the degradation products to decide whether further information needs to be generated for the PBT and vPvB assessment. Where only degradation of the parent substance is monitored, this does not address all concerns and further assessment of the degradation products may be required in order to complete the PBT/vPvB assessment. If testing in accordance with Annex IX or X of the REACH Regulation is deemed necessary, the Registrant is required to submit a testing proposal.

9. Adsorption/desorption screening (Annex VIII, Section 9.3.1)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Adsorption/desorption screening" is a standard information requirement as laid down in Annex VIII, Section 9.3.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record on adsorption/desorption in the dossier that would meet the information requirement of Annex VIII, Section 9.3.1.

You sought to adapt the information requirement by providing results obtained from the application of quantitative structure activity relationship models ((Q)SARs), namely SRC PCKOCWIN v2.00/EPI Win v4.10. According to Annex XI, Section 1.3. of the REACH Regulation the results of (Q)SARs may be used instead of testing when the following conditions are met:

- results are derived from a (Q)SAR model whose scientific validity has been established,
- the substance falls within the applicability domain of the (Q)SAR model,
- results are adequate for the purpose of classification and labelling and/or risk assessment, and
- adequate and reliable documentation of the applied model is provided.

You did not provide the adequate and reliable documentation of the applied models referred to under the fourth bullet point above. Without such documentation ECHA is not in a position to assess whether the other conditions outlined in the first three bullet points are

fulfilled. As you have not demonstrated that the conditions of the adaptation of Annex XI, Section 1.3. of the REACH Regulation are fulfilled, ECHA cannot accept the adaptation.

For the adaptation to be acceptable, you would have to provide the above mentioned documentation and you would have to demonstrate that the first three conditions for applying the proposed adaptation are fulfilled. The general form of the (Q)SAR Model Reporting Format (QMRF) and (Q)SAR Prediction Reporting Format (QPRF), are described in the ECHA Guidance on information requirements and chemical safety assessment Chapter R.6: (Q)SARs and grouping of chemicals (ECHA, May 2008). Under REACH, reporting formats can be submitted to ECHA as attached files in an IUCLID dossier.

As the conditions for adapting the information requirements in accordance with Annex XI, Section 1.3. of the REACH Regulation have not been fulfilled and no other information is available in the dossier for the endpoint in question, ECHA concludes that there is information gap and that it is necessary to provide information for the endpoint in order to bring the registration dossier into compliance with relevant information requirements.

Furthermore, based on log Kow > 4 of the major constituenst of the registered substance, there is potential for adsorption.
In your comments to the draft decision, you indicated your intention to conduct the test for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Adsorption/desorption screening (test method: Adsorption/desorption using an appropriate test method).

Guidance for determining appropriate test methods for the adsorption/desorption screening is available in the ECHA Guidance on information requirements and chemical safety assessment (version6.0, July 2017), Chapter R.7a, Section R.7.1.15.3.

10. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD 305).

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2.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.

You have not provided any study record on bioaccumulation in aquatic species in the dossier that would meet the information requirement of Annex IX Section 9.3.2.

You sought to adapt the information requirement by providing following results obtained from the application of quantitative structure activity relationship models ((Q)SARs);

- US EPA, T.E.S.T (v4.0.1) resulting predicted BAF of 7.33 ([redacted], 2013)
- BCFBAF v.3.01 of EPISuite v4.10 resulting calculated BCF value of 45.53 ([redacted], 2013).
- CATALOGIC v.5.11.2, BCF base-line model v2.05 ([redacted] 2012). Resulting BCF of

8.61 ([redacted] 2013; Dimitrov *et al.* 2005).

According to Annex XI, Section 1.3. of the REACH Regulation the results of (Q)SARs may be used instead of testing when the following conditions are met:

- results are derived from a (Q)SAR model whose scientific validity has been established,
- the substance falls within the applicability domain of the (Q)SAR model,
- results are adequate for the purpose of classification and labelling and/or risk assessment, and
- adequate and reliable documentation of the applied model is provided.

You did not provide the adequate and reliable documentation of the applied models referred to under the fourth bullet point above. Without such documentation ECHA is not in a position to assess whether the other conditions outlined in the first three bullet points are fulfilled. As you have not demonstrated that the conditions of the adaptation of Annex XI, Section 1.3. of the REACH Regulation are fulfilled, ECHA cannot accept the adaptation.

For the adaptation to be acceptable, you would have to provide the above mentioned documentation and you would have to demonstrate that the first three conditions for applying the proposed adaptation are fulfilled. The general form of the (Q)SAR Model Reporting Format (QMRF) and (Q)SAR Prediction Reporting Format (QPRF), are described in the ECHA Guidance on information requirements and chemical safety assessment Chapter R.6: (Q)SARs and grouping of chemicals (ECHA, May 2008). Under REACH, reporting formats can be submitted to ECHA as attached files in an IUCLID dossier.

Additionally ECHA notes that Column 2 of the Annex IX, Section 9.3.2.of the REACH Regulation states that if the substance has low potential for bioaccumulation (for instance a log Kow ≤ 3) the study needs not to be conducted. However, the reported log Kow -values for some components of the registered substance, are above log Kow > 3, which makes this adaptation possibility not relevant for the registered substance;
Start of the distribution: log Pow = -0.3 (extrapolated)
Main component 1: log Pow = 2.4 (7.1 area-%*)
Main component 2: log Pow = 4.1 (9.8 area-%*)
Main component 3: log Pow = 4.2 (24.0 area-%*)
Main component 4: log Pow = 4.7 (12.8 area-%*)
End of the distribution: log Paw = 5.6

In your comments to the draft decision, you provided the missing documentation (QMRFs and QPRFs), as well as new results from VEGA's *in silico* platform concluding overall that the bioaccumulation study is unnecessary.

However, as outlined also under request 6 above, the log Kow for the structure you used in the models is not representative of the values you have provided in the technical dossier for the registered substance. This evidence shows that the structure used for the predictions can neither be considered representative of the whole composition of the substance, nor a worst case. In particular, the predictions do not cover for the components with log Kow values above 3, which clealry indicates a potential for bioaccumulation. Furthermore, as also reported by some of the software you used, the reliability of the predictions is generally low (predictions are out of the domain of the VEGA and CATALOGIC models. Additional predictions provided in the dossier with BCFBAF are ran on an unknown structure. The same applies to the prediction generated with TEST). For these reasons ECHA considers your adaption as not acceptable.

As the conditions for adapting the information requirements in accordance with Annex XI, Section 1.3. of the REACH Regulation have not been fulfilled and no other information is available in the dossier for the endpoint in question ECHA concludes that the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA notes that due to lack of information on the fate of the substance you have not in your CSA or the technical dossier justified that there is no need to investigate further the bioaccumulation of the substance or its degradation products. As dsicussed above in section 7., ECHA considers that this information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 3.0, June 2017) bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2. ECHA Guidance defines further that results obtained from a test with aqueous exposure can be used directly for comparison with the B and vB criteria of Annex XIII of REACH Regulation and can be used for hazard classification and risk assessment. Comparing the results of a dietary study with the REACH Annex XIII B and vB criteria is more complex and has higher uncertainty. Therefore, the aqueous route of exposure is the preferred route and shall be used whenever technically feasible. If you decided to conduct the study using the dietary exposure route, you shall provide scientifically valid justification for your decision. You shall also attempt to estimate the corresponding BCF value from the dietary test data by using the approaches given in Annex 8 of the OECD 305 TG. In any case you shall report all data derived from the dietary test as listed in the OECD 305 TG.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Bioaccumulation in fish: aqueous or dietary bioaccumulation fish test (test method: OECD TG 305). The bioaccumulation of each constituent and relevant impurity present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study

Notes for your consideration

Before conducting the above test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11.4. and Figure R.11-4 on the PBT assessment for further information on the integrated testing strategy for the bioaccumulation assessment of the registered substance. You should revise the PBT assessment when information on bioaccumulation is available.

11. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Long-term toxicity testing on fish" is a standard information requirement as laid down in

Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a long-term toxicity on fish in the dossier that would meet the information requirement of Annex IX, Section 9.1.6.1 / 9.1.6.2 / 9.1.6.3.

Instead, you have sought to adapt this information requirement according to Annex IX, Section 9.1.6., Column 2. You provided the following justification for the adaptation: *"In Annex IX of Regulation (EC) No 1907/2006, it is laid down that chronic tests shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on fish. According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1272/2008 or is assessed to be a PBT or vPvB. The hazard assessment of the substance reveals neither a need to classify the substance as dangerous to the environment, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment. Therefore, and for reasons of animal welfare a chronic test on fish is not provided."*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., Column 2. In your adaptation you consider that the Chemical Safety Assessment (CSA) is not needed since the substance is not classified for environment nor is it considered a PBT/vPvB substance and therefore there is no need to conduct further chronic aquatic testing. However, as you have not submitted the environmental exposure assessment nor risk characterisation sections in the CSA, the argument that the long term test shall be proposed only if the CSA indicates the need cannot be used to adapt this information requirement and to show that there are no risks to the environment and that further aquatic testing would not be necessary.

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

Based on the information from the short term tests, there is evidence suggesting that the fish is likely to be at least a factor of 10 more sensitive than invertebrates (LC50 Fish = 3.8 mg/l, EC50 Daphnia > 100 mg/l, EC50 algae = 27 mg/l), therefore ECHA-S considers that fish is an appropriate species to be tested based on the integrated testing strategy (ECHA Guidance on information requirements and chemical safety assessment, Chapters R.7b (v 4.0, June 2017) Figure R.7.8—4 Decision scheme for the conclusion on chemical safety assessment (PNEC Derivation).

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) fish early-life stage (FELS) toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

However, the FELS toxicity test according to OECD TG 210 is more sensitive than the fish, short-term toxicity test on embryo and sac-fry stages (test method EU C.15 / OECD TG 212), or the fish, juvenile growth test (test method EU C.14. / OECD TG 215), as it covers several life stages of the fish from the newly fertilized egg, through hatch to early stages of growth (see ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June2017), *Chapter R7b, Figure R.7.8-4).*

Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of substances which are expected to cause effects over a longer exposure period, or which require a longer exposure period of time to reach steady state (ECHA *Guidance Chapter R7b,* version 4.0, June 2017).

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Notes for your consideration

Before conducting the test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapters R.4 (v.1.1, December 2011), R.5 (v.2.1, December 2011), R.6 (May 2008), R.7b (v 4.0, June 2017) and R.7c (v 3.0, June 2017). If you decide to adapt the testing requested according to the specific rules outlined in Annexes VI to X and/or according to general rules contained in Annex XI of the REACH Regulation, you are referred to the advice provided in practical guides on "How to use alternatives to animal testing to fulfil your information requirements for REACH registration".

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 4 November 2015.

On 19 April 2016, ECHA notified you of the draft decision with communication number CCH-D-2114313186-57-01/D and invited you to provide comments.

On 23 May 2016 ECHA received your comments on ECHA's draft decision.

After having received your comments on the draft decision of 19 April 2016, ECHA found that this draft decision included an error because the paragraphs on the deadline for submitting the required information and adaptation possibilities were missing. Therefore, the draft decision was corrected in this respect; *i.e.* page 2 of this corrected draft decision now includes the text on adaptation possibilities and the deadline. The draft decision dated 19 April 2016 is withdrawn and replaced by this draft decision.

On 10 November 2016, ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the request(s).

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

You did not provide any comments on the proposed amendment(s).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-56 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In carrying out the test(s) 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 test(s) 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 test(s) to be assessed.