EUROPEAN CHEMICALS AGENCY

Helsinki, 19 September 2019

Addressee: [redacted]

Decision number: CCH-D-2114482153-52-01/F
Substance name: (Reaction product of 4-[2-(4-hydroxyphenyl)propan-2-yl]phenol, 2-(2-hydroxyethylamino)ethanol and formaldehyde), propoxylated
List number: 926-000-9
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 13/07/2018
Registered tonnage band: Over 1000

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. **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;**

2. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a second species (rabbit), oral route with the registered substance;**

3. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309) at a temperature of 12 °C either (a) with the registered substance or (b) on relevant constituents or fraction of constituents that are in a concentration at or above 0.1% (w/w);**

4. **Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method for the registered substance;**

5. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305) on the registered substance or relevant constituent(s) and/or on relevant degradation product(s);**

6. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with the registered substance;**

7. **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 have to submit the requested information of item (1) in an updated registration dossier by **28 September 2020**. You have to submit the requested information of item (2) in an updated registration dossier by **27 September 2021**. You have to submit the remaining requested information of items (3), (4), (5), (6) and (7) in an updated registration dossier by **26 September 2022**. You shall also update the chemical safety report, where relevant.

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.

This decision does not address the information requirement of the Extended one-generation reproductive toxicity study according to Annex X, Section 8.7.3. of the REACH Regulation.

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, has to 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, Hazard Assessment

[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

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

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

You have not provided any study record of a sub-chronic toxicity study (90 day) in the dossier that would meet the information requirement of Annex IX, Section 8.6.2.

a) Information provided

You have sought to adapt this information requirement according to Annex XI, Section 1. Hence, ECHA has evaluated your adaptation with respect to this provision.

You have provided the following justification for the adaptation: "*In accordance with section 1 of REACH Annex XI, a sub-chronic repeated dose toxicity study is not required. The substance is not classifiable as hazardous in respect to its repeated dose toxicity. A qualitative and quantitative evaluation of the toxicological properties of the substance indicates that while a study with longer exposure duration might produce information to refine the dose response relationship thereby enabling a more robust estimation of DNELs it would not generally change the hazard characterization. In view of the limited additional knowledge that data from a longer term exposure study would provide to improve the current risk and hazard characterization of the substance and the need to consider animal welfare, a sub-chronic repeated dose toxicity study has no priority.*"

While you have not explicitly claimed a specific adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement according to to Annex XI, Section 1.1.2. of the REACH Regulation, use of existing data. Hence, ECHA has evaluated your adaptation with respect to this adaptation.

To support your adaptation you have provided the following sources of information:

i. Popp L, 2013, reliability score 1, an oral gavage 28-day GLP compliant study in rat according to OECD TG 407 with the registered substance. Doses used were 0, 100, 500, 1000 mg/kg bw/day. At the 1000 mg/kg bw/day, liver weights were increased in females. In the thyroid gland, a minimal numerical increase of follicular cell hypertrophy was noticed in males at 1000 mg/kg bw. The NOAEL was set to 500 mg/kg bw/d for male (changes in thyroid gland) and 500 mg/kg bw/d for male/female (changes in erythrocytes, haemoglobin and hematocrit).

b) ECHA's evaluation and conclusion of the information provided

An adaptation pursuant to Annex XI, Section 1.1.2. use of existing data requires that data

shall be considered to be equivalent to data generated by the corresponding test methods referred to in Article 13(3) if the following conditions are met:
(1) adequacy for the purpose of classification and labelling and/or risk assessment;
(2) adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
(3) exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
(4) adequate and reliable documentation of the study is provided.

Your adaptation for use of existing data needs to address the specific conditions set out above for the registered substance with respect to a sub-chronic toxicity study (EU B.26/OECD TG 408). Relevant elements are in particular exposure route, duration and levels, two genders, sensitivity and depth of investigations to detect specific organ toxicity.

ECHA analysis of the sources of information that fails:

i. In the technical dossier you have provided a study record for a "repeated dose 28-day oral toxicity study" (test method: OECD TG 407). However, this study does not provide the information required by Annex IX, Section 8.6.2., because exposure duration is less than 90 days and the number of animals per dose group is significantly lower than in the 90 day sub-chronic toxicity study (OECD TG 408). Therefore, the sensitivity of a 28-day study is much lower than that of a 90-day study.

As indicated above, essential information on key elements, such as an adequate statistical power and exposure duration, is missing which does not allow ECHA to assess the potential hazard regarding to this particular endpoint.

Hence, the source of information you provided, does not allow to assume/conclude that the substance does not have a particular dangerous (hazardous) property with respect to the information requirement for Annex IX, Section 8.6.2.

Therefore, the general rules for adaptation laid down in Annex XI, Section 1.1.2. of the REACH Regulation are not met and your adaptation of the information requirement is rejected.

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.

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and/or 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, although the substance is a viscous liquid with a low vapour pressure and spraying applications are reported, according to the Chemical Safety Report risk management measures are in place to prevent exposure of humans via inhalation.
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.

In your comments on the draft decision, you asked ECHA to reconsider this study in the interests of animal welfare and proposed that if the study is still necessary to have staggered testing for the two mammalian toxicology studies. ECHA notes that there is an information gap and it is necessary to provide information for this information requirement as already explained in the decision. As regards the comment on staggered testing ECHA notes that the sub-chronic (90-day) study should be provided within the first deadline (12 months) given in this decision. As for the PNDT study, you may choose to perform this study following the 90-day study, as the deadline given in this decision to provide this study is 24 months.

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.

Notes for your considerations:

The Extended one-generation reproductive toxicity study (EOGRTS) according to Annex X, Section 8.7.3. is not part of this decision, because the results of the sub-chronic toxicity study (90-day) are considered crucial to inform on the study design of the EOGTRS. Therefore, the results of the sub-chronic toxicity study (90-day) should be used, among other relevant information, to decide on the study design of the EOGRTS.

ECHA may therefore launch a separate compliance check at a later stage addressing the EOGRTS information requirement.

Alternatively, you may also consider submitting a testing proposal for an Extended one-generation reproductive toxicity study together with the results of the requested sub-chronic toxicity study (90-day). The testing proposal should include a justification for its study design following ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a, Section R.7.6 (version 6.0, July 2017), taking into account the results of the sub-chronic toxicity study (90-day).

2. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species

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

Pre-natal developmental toxicity studies (test method EU B.31./OECD TG 414) on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

The technical dossier contains information on a pre-natal developmental toxicity study in rats by the oral route using the registered substance as test material. This study fulfils the standard information requirement for a pre-natal developmental toxicity study in a first

species (Annex IX, Section 8.7.2.).

However, there is no information provided for a pre-natal developmental toxicity study in a second species.

You have sought to adapt this information requirement according to column 2 of Annex IX, Section 8.7.2 and Annex XI, Section 1.2. You provided the following justification for the adaptation: "*According to column 2 of Annex IX section 8.7.2., the potential necessity to perform a prenatal developmental toxicity study on a second species should be based on the outcome of the first test and all available data. In the ECHA Guidance on Information Requirements: Chapter R7a: Endpoint Specific Guidance, Version 4.1, October 2015 (section R.7.6.2.3.2) the basis for decision on the second species is specified: 'A study on a second species might be necessary if the available data contain triggers for prenatal developmental toxicity. For example, performance of a prenatal developmental toxicity study in a second species may be justified if developmental effects that are not sufficient to meet classification criteria to Category 1B reproductive toxicant (but maybe sufficient to Category 2 reproductive toxicant) were observed in the prenatal developmental toxicity study with the first species. Further triggers may stem from non-animal approaches, structurally similar substances, mechanisms/modes of action or results from a screening study. However, if there are no triggers and no indication of prenatal developmental toxicity in the first prenatal developmental toxicity study, no study on a second species is necessary at REACH Annex IX level.' The following argumentation shows that there is no indication of prenatal developmental toxicity for the test material and no triggers can be identified. Thus, a developmental toxicity study on a second species is not needed for the assessment of the test material for this endpoint. In the developmental toxicity study (OECD TG 414), performed following the ECHA Decision on Testing Proposal of July 2015, mated female Wistar rats were treated once daily by gavage from Day 6 to 20 p.c. with the test material doses of 100, 300, and 1000 mg/kg bw/day in PEG 400. The control group received PEG 400 alone. On day 21 p.c. the animals were subjected to an examination post-mortem and external, thoracic and abdominal macroscopic findings were recorded. The fetuses were weighed, sexed and examined for external, visceral and skeletal malformations and developmental variations. No treatment-related effects on the fetal development were observed in all test material treatment groups. In detail, litter size, sex-ratio, fetal body weight, and fetal morphological examinations (external, visceral and skeletal) were not affected by the treatment. Accordingly, the developmental NOAEL in rats was established as being at least 1000 mg kg bw/day. In conclusion and in accordance with REACH Annex XI, section 1.2. there is proof to conclude that the test material is not a reproductive/ developmental toxicant and therefore further testing on vertebrate animals for that property shall be omitted. The available information on the reproductive/developmental toxicity potential of the test material is adequate for the purpose of classification and labeling and/or risk assessment*".

However, ECHA notes that since your substance is registered at more than 1000 tonnes per year, as a minimum, the information specified in column 1 of Annex X, Section 8.7.2 is required. Therefore your adapatation according to Annex IX, Section 8.7.2, is not applicable.

In addition, your adaptation does not meet either the criteria of the specific rule for adaptation of Annex X, Section 8.7, column 2, for the following reasons:
the registered substance is not a genotoxic carcinogen, or a germ cell mutagen, since it bears no corresponding classification. The substance is not classified as toxic for

reproduction category 1A or 1B. Furthermore following administration, there is systemic absorption as demonstrated by effects observed in the repeated dose toxicity studies and the adaptation requiring low toxicological activity, no systemic absorption, and no significant exposure is not met. Hence none of the criteria of the specific rules for adaptation of Annex X, Section 8.7, column 2 are met.

ECHA notes that you additionally mention Annex XI, Section 1.2., weight of evidence. Hence, ECHA has evaluated your adaptation with respect to this provision.

You have provided the following justification for the adaptation:*:"[...] proof that the test material is not a reproductive/developmental toxicant and available information on the reproductive/developmental toxicity potential of the test material is adequate for the purpose of classification and labeling and/or risk assessment.*"

An adaptation pursuant to Annex XI, Section 1.2. requires sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property with respect to the information requirement in question including an adequate and reliable documentation while the information from each single source alone is regarded insufficient to support this notion.

Your weight of evidence adaptation needs to address the specific dangerous (hazardous) properties of the registered substance with respect to a pre-natal developmental toxicity study (EU B.31/OECD TG 414). Relevant elements are in particular information on a second species, exposure route, duration and levels, sensitivity and depth of investigations to detect pre-natal developmental toxicity (including growth, survival, external, skeletal and visceral alterations) and maternal toxicity. Your adaptation lacks information from a second species (species differences).

Hence, the sources of information you provided, together with your justification for the adaptation, do not allow to assume/conclude on the dangerous (hazardous) property of the registered substance with respect to the information requirement for Annex X, Section 8.7.2.

Therefore, the general rules for adaptation laid down in Annex XI, Section 1.2. of the REACH Regulation are not met and your adaptation of the information requirement is rejected.

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.

The test in the first species was carried out by using a rodent species (rat). According to the test method EU B.31./OECD 414, the rabbit is the preferred non-rodent species. On the basis of this default assumption, ECHA considers that the test should be performed with rabbit as a second 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) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid with a low vapour pressure, ECHA concludes that testing should be performed by the oral route.

In your comments on the draft decision, you asked ECHA to reconsider this study in the interests of animal welfare and proposed that if the study is still necessary to have staggered testing for the two mammalian toxicology studies. ECHA notes that there is an information gap and it is necessary to provide information for this information requirement as already explained in the decision. As regards the comment on staggered testing ECHA notes that the sub-chronic (90-day) study should be provided within the first deadline (12 months) given in this decision. As for the PNDT study, you may choose to perform this study following the 90-day study, as the deadline given in this decision to provide this study is 24 months.

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 second species (rabbit) by the oral route.

Notes for your consideration

ECHA notes the registered substance is classified as Skin Irritant 2, Eye Damage 1, Skin Sensitiser 1B. According to Article 14(4) and Annex I, 0.6 of the REACH Regulation, when a substance fulfills the criteria for any of the hazard classes as set out in Annex I to Regulation (EC) No 1272/2008, the Chemical Safety Assessment shall include an exposure assessment, an exposure estimation and a risk characterisation. ECHA observes the quantitative exposure assessment is missing from your Chemical Safety Assessment. Additionally, ECHA underlines that the result of the toxicological studies requested with this decision shall be taken into account when revising the DNELs and the Chemical Safety Assessment.

Approach to PBT assessment of the substance

In your comments on the draft decision, you propose an alternative testing strategy to investigate the vPvB/PBT properties of the registered substance.

You propose the same approach as that which was set out in a substance evaluation decision (SEV-D-21144A5647-48-01/F) on 2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether (EC 926-564-6). You claim that this substance has similar properties, is also a polyether and therefore you suggest an analogous approach to investigate the PBT properties of your substance. However, we do not agree that this case is a suitable analogy because:

- Substance evaluation and dossier evaluation are distinct processes with different purposes. Substance evaluation investigates specific concerns for a given substance while dossier evaluation ensures that the standard information requirements as set out in Annexes VII-X of REACH are met via compliance check. As explained in this decision, there are incompliances for some of the standard information which needs to be addressed irrespective of the presence or absence of a PBT concern.
- Additionally, the cases are different in terms of the substances' bioaccumulation potential. In the substance evaluation case on EC 926-564-6, all the constituents have bioaccumulation potential, whereas in the case of this registered substance the range of logKow is -4.0 to 4.7, so only a proportion are above the threshold of concern for bioaccumulation. Therefore not all constituents of the registered

substance are relevant for the PBT/vPvB assessment.

You propose to waive the surface-water simulation test and identification of environmental degradants, and regard the substance as persistent, and to conduct only a fish bioaccumulation test on the whole registered substance to investigate the bioaccumulation potential, with analysis only of the constituents of the substance that are potentially bioaccumulative. Then if the substance is established as bioaccumulative or very bioaccumulative (B/vB), you argue that ECHA can follow up with a further compliance check with a view to deciding whether long-term aquatic organism studies are necessary to assess T. We do not agree to your proposed appoach, for the reasons given below in the sections 3 to 7.

Finally, you argue that ECHA's approach articulated in the decision is not proportionate. We consider that the studies in this amended decision are necessary to assess the PBT properties and for risk assessment of the substance for the reasons given in sections 3 to 7.

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

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

"Simulation testing on ultimate degradation in water" is a standard information requirement as laid down in Annex IX, section 9.2.1.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of simulation testing of the registered substance on ultimate degradation in water in the dossier.

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 IX, Section 9.2, column 2. You give the following justification for data waiving: '*The substance is not considered to be readily biodegradable as reflected by 9% degradation in 28 days (OECD 301F). Therefore, it is also not considered to be biodegradable in water and sediment if investigated in a simulation test which does, thus, not need to be conducted.*' However, ECHA notes that this forecast of non-biodegradability is not equivalent to a simulation test because the latter would give information on the rate of primary biodegradation, the rate of ultimate degradation and information on any persistent constituents of the registered substance and/or environmental transformation products.

According to Annex IX, Section 9.2.1.2, column 2 of the REACH Regulation, simulation testing on ultimate degradation in surface water does not need to be conducted if the substance is highly insoluble in water or is readily biodegradable. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable in an OECD 301F test (9% degradation in 28 days) and has a water solubility of 63mg/l (when measured at a loading rate of 100mg/l).

Furthermore, ECHA notes that you have not provided adequate justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to investigate further the degradation of the substance and its degradation products. As explained further below, 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.

The registered substance is a UVCB consisting of [redacted] Therefore the registered substance consists of constituents with widely differing physico-chemical properties. In particular, the study according to OECD 117 (Partition Coefficient, HPLC Method) resulted in 10 peaks in the chromatogram corresponding to constituents with log Kow values in the range -4 to 4.7. Hence there is a potential for bioaccumulation from the substance. Nevertheless, before undertaking a confirmatory fish bioaccumulation study, the persistence of the registered substance including all the constituents ≥ 0.1 % (w/w) should be examined first.

Therefore, your adaptation of the information requirement cannot be accepted.

In your comments on the draft decision, you repeat the argument from the registration dossier that the surface water simulation test can be waived because you regard the substance as persistent for the vPvB/PBT assessment. As we explain above, it is necessary to examine the rate of degradation and establish what are the ultimate degradation products. Furthermore, the simulation study is required to obtain a definitive conclusion on the persistency of the substance as explained in ECHA Guidance Chapter R.11. (version 3.0, June 2017).

In your comments on the draft decision, you also argue that it is not feasible for technical reasons to analyse constituents and degradation products down to 0.1%. You have not provided any specific justification to support your claim and to demonstrate the technical difficulties. ECHA notes also that in spite of any analytical challenges you may have to extract, identify and quantify the constituents of the registered substance and its transformation/degradation products, it is your responsibility to provide adequate information on the fate of the substance in the environment. Under Annex XIII, you must assess the PBT/vPvB properties of the relevant constituents of the your substance. Therefore, the persistence of each relevant constituent present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable must be assessed. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment. To assess which constituents to concentrate your assessment on you may first undertake further analysis of the composition of the substance and assessment of the physico-chemical properties of the constituents, such as estimating their logKow. The most relevant constituents to concentrate on would be those that meet the PBT/vPvB screening criteria. Finally, you have the option to use radiolabelled test material.

As explained above, the information provided 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 the 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 3.0 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 Test Guideline 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 from an Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD TG 309) at a temperature of 12°C either (a) with the registered substance or (b) with relevant constituents or fraction of constituents that are in a concentration at or above 0.1% (w/w).

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 are 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.

4. Identification of degradation products (Annex IX, 9.2.3.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same 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. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The biodegradation section in the technical dossier does not contain any information in relation to the identification of degradation products, nor an adaptation in accordance with column 2 of Annex IX, Sections 9.2 or 9.2.3. or with the general rules of Annex XI for this standard information requirement.

According to Annex IX, Section 9.2.3., column 2 of the REACH Regulation, identification of degradation products is not needed if the substance is readily biodegradable. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable as also discussed in section 3 above.

Furthermore, ECHA notes that you have not provided any justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to provide information on the degradation products. ECHA considers that this information is needed in relation to the PBT/vPvB assessment and risk assessment.

In your comments on the draft decision, you repeat an argument from the registration dossier that the identification of environmental degradants can be waived as you consider that, given the lack of degradation in the ready biodegradability study, the substance can be considered as persistent for the vPvB/PBT assessment and a simulation study is not needed. As explained above under section 3 ECHA considers it necessary to examine the rate of degradation and to establish what are the ultimate degradation products. Your assumption of persistence for the substance is yet to be confirmed and does not address the possibility that there may be environmental transformation products that are persistent.

You further comment that it is not feasible for technical reasons to analyse constituents and degradants down to 0.1%. We re-iterate the principles for providing information on identification of degradation products. You can choose to undertake a simulation test as a means of providing information on degradation products. Alternatively you can provide information on identification of environmental degradation products by other means, as explained in the paragraphs below. ECHA refers to its response to your comments in section 3. above with regards to technical feasibility. Furthermore, according to ECHA Guidance Chapter R.11 (version 3.0, June 2017) and OECD TG 309 relevant transformation/degradation products are those detected at 10 % of the applied concentration at any sampling time and those for which the concentration is continuously increasing during the study. Such degardation products should be identified and quantified, and as the next step assessed against the PBT/vPvB (screening) criteria set in Annex XIII of REACH.

As explained above, the information provided 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.

Regarding appropriate and suitable test method, the methods will have to be substance-specific. When analytically possible, identification, stability, behaviour, molar quantity of degradation products should be evaluated. In addition, degradation half-life, log Kow and potential toxicity of the degradation products may be investigated. You may obtain this information from the simulation test also requested in this decision, or by some other measure. You will need to provide a scientifically valid justification for the chosen method.

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: Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

5. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same 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 sought to adapt this information requirement according to Annex IX, Section 9.3.2., column 2. You provided the following justification for the adaptation. You argue that the substance has a low potential for bioaccumulation as reflected by the logKow of 1.4 expressed as the area weighted logKow of all the peaks from the chromatogram of the OECD 117 HPLC method. However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.3.2 because there were 10 peaks in the chromatogram corresponding to constituents with log Kow values in the range -4 to 4.7. Column 2 of Annex IX, Section 9.3.2 describes a low potential for bioaccumulation as being log Kow <3. Although you have shown that some of the constituents of the registered substance have a low potential for bioaccumulation, there are constituents in your substance with log Kow values > 3 which are potentially bioaccumulative and are relevant for PBT assessment.

If, based on the study requested under sections 3 or 4 of this decision, the substance, any of the constituents >0.1% (w/w) or degradation products is concluded to be persistent or very persistent, the bioaccumulation study needs to be conducted. You need to justify the relevance of the selected test material(s) for the bioaccumulation study as needed for the PBT/vPvB assessment.

Therefore, your adaptation of the information requirement cannot be accepted.

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 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 and in OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation, ENV/JM/MONO (2017)16. In any case you shall report all data derived from the dietary test as listed in the OECD 305 TG.

In your comments on the draft decision, you propose to waive the surface-water simulation test and the identification of transformation/degradation products, and instead only to conduct a fish bioaccumulation test on the whole registered substance, with analysis only of relevant constituents of the substance that are potentially bioaccumulative as specified by ECHA. As explained in the sections above, we reject your suggestion to waive the simulation tests and identification of degradants.

You further argue that if the simulation test shows any transformation/degradation products, they would have to be synthesised to provide samples for fish bioaccumulation studies, and in a worst case several bioaccumulation studies might have to be conducted on separate degradation products. Furthermore, you argue that it is not feasible for technical reasons to analyse constituents and degradants down to 0.1%. In response to the two issues you raise, firstly regarding technical feasibility ECHA refers you to its reply to your comments under section 3. Secondly, the decision allows for the possibility to investigate the bioaccumulation characteristics of the whole substance or relevant constituent(s) and/or degradant(s). To define the most relevant test material(s) for the bioaccumulation study you should follow the advice provided in ECHA Guidance Chapter R.11, section R.11.4.2.2 on different assessment approaches. Finally, as also noted above, you have the option to use radiolabelled test material.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived either (a) on the registered substance or (b) on relevant constituent(s) and/or (c) on relevant degradation product(s)

Bioaccumulation in fish: aqueous exposure bioconcentration fish test (test method: OECD TG 305-I) *or*
Bioaccumulation in fish: dietary exposure bioaccumulation fish test (test method: OECD TG 305-III) *or*
Bioaccumulation in fish: aqueous or dietary bioaccumulation fish test (test method: OECD TG 305)

The bioaccumulation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable should be assessed.

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. In particular, you are advised to first conclude whether the registered substance may fulfil the REACH Annex XIII criteria of being persistent or very persistent, and then to consult the PBT assessment for Weight-of-Evidence determination and integrated testing strategy for bioaccumulation assessment. You should revise the PBT assessment when information on bioaccumulation is available.

Approach to long-term aquatic organism toxicity testing

In your comments on the draft decision you raise several issues common to the long-term toxicity studies on Daphnia and fish:

a) You consider that the water accommodated fractions (WAFs) for the acute aquatic organism studies establish that there is no limit of water solubility up to a loading rate of 1000mg/l, but that at higher loading rate a lower proportion is dissolved. ECHA considers that this issue does not affect the need for the long-term studies for the reasons given below.
b) You contend that long-term effects of the poorly water soluble fraction will not be better assessed by long-term studies, because there was no acute toxicity at up to a loading rate of 1000mg/l. You elaborate this argument by pointing out that the concentration used in the long-term studies will be lower than was used in the acute studies. ECHA disagrees with this argument, because poorly water soluble substances (or in this case, the poorly-water soluble fraction of the substance) require longer time to reach steady-state conditions. Hence, the short-term tests may not give a true measure of toxicity for this type of substances and the long-term test is required.
c) You argue that if long-term testing is nevertheless to be conducted, testing in Daphnia is adequate, i.e. long-term testing in fish is not necessary, because the acute studies show no difference in sensitivity between fish and Daphnia. ECHA notes that according to the Integrated testing strategy (ITS) outlined in ECHA Guidance, Chapter R7b (Section R.7.8.5 including Figure R.7.8-4) a difference in sensititivity (indicated by a factor of 10 difference in LC50) can be used as an argument to waive one of the long term studies. However, firstly as explained above under point b) the registered substance has a poorly soluble fraction for which short-term data is not sufficient and secondly as no effects were observed in the short-term studies no species sensitivity difference can be demonstrated. Therefore, the Integrated testing strategy (ITS) outlined in ECHA Guidance, Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), is not applicable and the long-term studies on both invertebrates and fish are required.
d) You suggest tiered testing, beginning with the Daphnia test on animal welfare grounds. ECHA notes that although both long term studies are required for the

reasons explained below the 36-month time limit allows you to decide on the order of the studies.

e) You argue that the whole UVCB substance should be tested, not only the water soluble fraction, due to technical challenges and uncertainties in obtaining the sample of test material. ECHA accepts this and has amended the draft decision for testing of the whole registered substance.

f) You argue that long-term studies should only be requested for PBT assessment if there are (v)P(v)B constituents. ECHA reiterates that long-term studies are necessary for aquatic PNEC setting for environmental risk assessment.

6. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X 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 aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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 IX, Section 9.1, column 2. You provided the following justification for the adaptation : '*According to REACH regulation Annex IX, Column 2, long-term toxicity testing shall only be proposed by the registrant if the chemical safety assessments indicates the need for further investigation. However, acute toxicity was not determined up to 400 mg/L and, therefore, no long-term testing appears to be needed*'. However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1, column 2, because, as discussed below, you have not provided adequate justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to investigate further the long-term effects on aquatic organisms.

Therefore, your adaptation of the information requirement cannot be accepted.

The registered substance is a UVCB consisting of constituents with widely differing physico-chemical properties: in particular the study according to OECD 117 (Partition Coefficient, HPLC Method) resulted in 10 peaks in the chromatogram corresponding to constituents with log Kow values in the range -4 to 4.7. Therefore there will be a wide range of water solubilities of the constituents of the substance. There is evidence from the water solubility test using the flask shake method of OECD 120 that the substance consists of a poorly water soluble fraction and a moderately water soluble fraction. At a loading rate of 100mg/l, the water soluble fraction is measured at 63mg/l when measured by TOC analysis. At a loading rate 10 times higher, i.e. at 1,000mg/l, the water soluble fraction is measured by TOC at 566mg/l, i.e. approximately 9 times higher. These results suggest that in both cases about 45 to 50% by weight of the substance remains undissolved and all the remainder dissolves, so that the concentration measured in solution is determined by the amount of water soluble fraction available in the loading mixture, i.e. not limited by water solubility.

The acute Daphnia toxicity test (OECD 202) was conducted in a series of WAFs derived from loading rates of 100, 200 and 400 mg/l. Analysis by HPLC of these WAFs after the exposure period showed dissolved material in the range 36 to 96 mg/l, which is consistent with the finding from the water solubility test given the difference in extraction conditions (notably Daphnia media instead of pure water). No acute effects in Daphnia were shown at a loading rate of up to 400mg/l. Therefore it can be concluded that the moderately water soluble fraction of the registered substance is of low acute toxicity to Daphnia. It can also be concluded that there is no acute toxicity to Daphnia at the limit of water solubility of the poorly water soluble fraction under the conditions of that test.

However, the long-term toxicity to Daphnia of the poorly water soluble faction of the registered substance has not been established given that available short term tests do not provide information on the toxicity of the poorly soluble fraction. The long-term effects to aquatic organisms is pertinent for PBT assessment of the persistent and bioaccumulative constituents and degradation products, if any, that are identified as an outcome of the studies requested under sections (3), (4) and (5). Furthermore, a long-term study on aquatic organisms is needed to establish an aquatic PNEC for risk characterisation.

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 ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) *Daphnia magna* reproduction test (test method EU C.20. / OECD TG 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information on the registered substance: Daphnia magna reproduction test (test method: EU C.20./OECD TG 211).

Notes for your consideration

Once results of the test on long-term toxicity to aquatic invertebrates are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation.

Following your comments on the draft decision: ECHA notes that due to lack of effects in short-term studies it is not possible to determine the sensitivity of species. Therefore, the Integrated testing strategy (ITS) outlined in ECHA Guidance on information requirements and chemical safety assessment (version 3.0, February 2016), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), is not applicable in this case and the long-term studies on both invertebrates and fish are requested to be conducted. As the registered substance has a poorly soluble fraction, long-term studies are required.

Due to the properties of the material to be tested, you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing

of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

In addition, regarding the use of the Water Accommodated Fraction (WAF) approach, please note that the WAF approach is problematic when used with a test substance containing several constituents, as in the case of the registered substance. In such cases the toxicity cannot be allocated to specific constituents directly and interpretation of the results in the risk assessment requires careful consideration taking into account differences in fate of the constituents in the environment. When constituents of varying solubility are present there can be partitioning effects which limit dissolution in the water. These effects should be minimised and appropriate loadings selected accordingly to allow an appropriate determination of the toxicity of the different constituents. In that respect, it is critical that a robust chemical analysis is carried out to identify those constituents present in the water to which the test organisms are exposed. Additionally, chemical analysis to demonstrate attainment of equilibrium in WAF preparation and stability during the conduct of the test is required. Methods capable of identifying gross changes in the composition of WAFs with time are required such as ultra-violet spectroscopy or total peak area have been used successfully for this purpose. The method used to prepare the WAF should be fully described in the test report and evidence of its compositional stability over time should be provided.

7. 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 more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X 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 sought to adapt this information requirement according to Annex IX, Section 9.1, column 2. You provided the following justification for the adaptation: '*According to REACH regulation Annex IX, Column 2, long-term toxicity testing shall only be proposed by the registrant if the chemical safety assessments indicates the need for further investigation. However, acute toxicity was not determined up to 400 mg/L and, therefore, no long-term testing appears to be needed*'. However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1, column 2, because, as discussed below, you have not provided adequate justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to investigate further the long-term effects on aquatic organisms.

Therefore, your adaptation of the information requirement cannot be accepted.

The registered substance is a UVCB consisting of constituents with widely differing physico-chemical properties: in particular the study according to OECD 117 (Partition Coefficient, HPLC Method) resulted in 10 peaks in the chromatogram corresponding to constituents with

log Kow values in the range -4 to 4.7. Therefore there will be a wide range of water solubilities of the constituents of the substance. There is evidence from the water solubility test using the flask shake method of OECD 120 that the substance consists of a poorly water soluble fraction and a moderately water soluble fraction. At a loading rate of 100mg/l, the water soluble fraction is measured at 63mg/l when measured by TOC analysis. At a loading rate 10 times higher, i.e. at 1,000mg/l, the water soluble fraction is measured by TOC at 566mg/l, i.e. approximately 9 times higher. These results suggest that in both cases about 45 to 50% by weight of the substance remains undissolved and all the remainder dissolves, so that the concentration measured in solution is determined by the amount of water soluble fraction available in the loading mixture, i.e. not limited by water solubility.

The acute fish toxicity test (OECD 203) was conducted in a series of WAFs derived from loading rates of 100, 200 and 400 mg/l. Analysis by HPLC of these WAFs after the exposure period showed dissolved material in the range 29 to 84 mg/l, which is consistent with the finding from the water solubility test given the difference in extraction conditions (notably fish media instead of pure water). No acute effects in fish were shown at a loading rate of up to 400mg/l. Therefore it can be concluded that the moderately water soluble faction of the registered substance is of low acute toxicity to fish. It can also be concluded that there is no acute toxicity to fish at the limit of water solubility of the poorly water soluble fraction under the conditions of that test.

However, the long-term toxicity to fish of the poorly water soluble faction of the registered substance has not been established given that available short term tests do not provide information on the toxicity of the poorly soluble fraction. The long-term effects to aquatic organisms is pertinent for PBT assessment of the persistent and bioaccumulative constituents and degradation products, if any, that are identified as an outcome of the studies requested under sections (3), (4) and (5). Furthermore, a long-term study on aquatic organisms on the the registered substance is in any case needed to establish an aquatic PNEC for risk characterisation.

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 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) can be performed 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, June 2017), Chapter R7b, Section R.7.8.4.1.

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 on the registered substance: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Notes for your consideration

Following your comments on the draft decision: ECHA notes that due to lack of effects in short-term studies it is not possible to determine the sensitivity of species. Therefore, the Integrated testing strategy (ITS) outlined in ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), is not applicable in this case and the long-term studies on both invertebrates and fish are requested to be conducted. As the registered substance has a poorly soluble fraction, long-term studies are required.

Once results of the requested tests are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation.

Due to the properities of the material to be tested you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

In addition, regarding the use of the Water Accommodated Fraction (WAF) approach, please note that the WAF approach is problematic when used with a test substance containing several constituents, as in this case. In such cases the toxicity cannot be allocated to specific constituents directly and interpretation of the results in the risk assessment requires careful consideration taking into account differences in fate of the constituents in the environment. When constituents of varying solubility are present there can be partitioning effects which limit dissolution in the water. These effects should be minimised and appropriate loadings selected accordingly to allow an appropriate determination of the toxicity of the different constituents. In that respect, it is critical that a robust chemical analysis is carried out to identify those constituents present in the water to which the test organisms are exposed. Additionally, chemical analysis to demonstrate attainment of equilibrium in WAF preparation and stability during the conduct of the test is required. Methods capable of identifying gross changes in the composition of WAFs with time are required such as ultra-violet spectroscopy or total peak area have been used successfully for this purpose. The method used to prepare the WAF should be fully described in the test report and evidence of its compositional stability over time should be provided.

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 08 November 2017.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and amended the request(s).

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

As no amendments were proposed, ECHA took the decision according to Article 51(3) 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 requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In carrying out the tests 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 or imported. If the registration of the substance covers different grades, the sample used for the new tests must be suitable to assess these.

   Furthermore, there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.