~~Confidential~~

Helsinki, 27 August 2021

Addressees
Registrant(s) of JS_EC 701-349-8 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
26/06/2020

Registered substance subject to this decision ("the Substance")
Substance name: N-(2-{[C16-18 (even numbered) alkanoyl]amino}ethyl)-N-(2-hydroxyethyl)[C16-18 (even numbered) alkylamide]
EC number: 701-349-8
CAS number: NS

Decision number: [Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)]

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***3 June 2024***.

Requested information must be generated using the Substance unless otherwise specified.

A. Information required from all the Registrants subject to Annex VIII of REACH

1. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., column 2; test method: OECD TG 210)

2. Simulation testing on ultimate degradation in surface water (triggered by Annex VIII, Section 9.2.; test method: EU C.25./OECD TG 309) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

3. Soil simulation testing (triggered by Annex VIII, Section 9.2.; test method: EU C.23./OECD TG 307) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

4. Sediment simulation testing (triggered by Annex VIII, Section 9.2.; test method: EU C.24./OECD TG 308) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided

5. Identification of degradation products (triggered by Annex VIII, Section 9.2; test method: using an appropriate test method).

Reasons for the request(s) are explained in the following appendix:

- Appendix entitled "Reasons to request information required under Annexes VII to VIII of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

The studies relating to biodegradation are necessary for the PBT assessment. To determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which the tests are performed and other conditions described in Appendix C entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". As described in Appendix C you are advised to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP. Bioaccumulation testing may be addressed in a separate decision once the information from the simulation studies and identification of degradation products has been provided as described in Appendix D entitled "Procedure".

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Christel Schilliger-Musset, Director of 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 A: Reasons to request information required under Annex VIII of REACH

1. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., column 2)

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.). Long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

You have provided an OECD TG 203 study but no information on long-term toxicity to fish for the Substance.

We have assessed this information and identified the following issue[s]:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests do not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7.8.5).

Under Section 4.8 of your technical dossier, you have provided information on water solubility that does not fulfil the information requirement (Annex VII, Section 7.7.). The OECD TG 105 was not followed appropriately.

- According to the OECD TG 105 shake flask test 3 replicate vessels should be used and the concentrations measured in at least the two last vessels should not differ by more than 15%. You did not use 3 replicate vessels and you did not confirm that the difference between replicates was 15% or less.
- OECD TG 105 recommends that a substance-specific analytical method should be used. You did not use a substance-specific analytical method only the non-specific measurement of dissolved carbon.
- There were outlier values in the test results due to contamination issues. Contamination issues indicate that GLP Practices were not followed and the results are considered unreliable.

There are critical methodological deficiencies affecting the reliability of the water solubility test results.

However, despite the incompliant water solubility test, we note that in an algal growth inhibition study conducted according to OECD TG 202, the saturation concentration of the Substance was determined to be 0.72 mg/L. In addition, in a short-term toxicity to fish test conducted according to OECD TG 203, the saturation concentration of the Substance was determined to be <0.072mg/L, i.e. below the limit of quantification (LOQ) of the analytical method (0.072 mg/L) in that test.

Based on the latter information ECHA concludes that the Substance must be regarded as poorly water soluble in relevant aqueous medium. Therefore, information on long-term toxicity to fish must be provided.

Study design

To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

The Substance is difficult to test due to the low water solubility (<1mg/L) and adsorptive properties (as indicated by log Kow >6 & Log Koc >6). OECD TG 210 specifies that, for difficult

to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 210. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.

In the comments to the draft decision, you agree to perform the requested study.

2. **Simulation testing on ultimate degradation in surface water; and**
3. **Soil simulation testing; and**
4. **Sediment simulation testing**

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4.). This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as:
  - it is not readily biodegradable (*i.e.* <60% degradation in OECD 301B)
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - it has a high potential to partition to lipid storage (*e.g.* log K_{ow} > 4.5);

Your registration dossier provides the following:

- The Substance is not readily biodegradable (0% degradation after 28 days in OECD TG 301B provided in IUCLID section 5.2.1);
- The Substance has a high potential to partition to lipid storage (Log K_{ow} of >6.5 based on EU Method A.8 provided in IUCLID section 4.7);

Your dossier does not contain any further information on P/vP assessment beyond testing for ready biodegradability. You have provided no definitive information to assess whether the Substance, or its relevant constituents or degradation products, would meet the PBT/vP/vB criteria.

In your PBT assessment you state '*No conclusion can be reached based on available information. In accordance with ECHA Guidance on PBT assessment (Table R11-4) the test substance is considered as potentially P or vP based on available screening information (OECD 301B, Best, 2017).*' With regards to B/vB you conclude that the Substance should not be considered B or vB based on predicted BCF values using a QSAR (BCFBAF v3.01, Arnot-Gobas BCF & BAF Methods).

ECHA notes the following shortcomings in your conclusions on non-B/vB:

a) BCF Estimations

Annex XI, Section 1.3. specifies that the following conditions must be fulfilled whenever a (Q)SAR approach is used:

1. the prediction needs to be derived from a scientifically valid model,
2. the substance must fall within the applicability domain of the model,
3. results need to be adequate for the purpose of risk assessment or classification and labelling, and
4. adequate and reliable documentation of the method must be provided.

In regards to point "2." above, ECHA Guidance R.6.1.5.3. states that a prediction is within the applicability domain of the model when, among others, the substance and the structures selected for the prediction fall within descriptor, structural, mechanistic and metabolic domain.

With regard to these conditions, we have identified the following issue(s):

The applicability domain of the BCFBAF model (BCFBAF v3.01, Arnot-Gobas BCF & BAF Methods) you used is defined as follows:

- Min Log Kow: -1.37, and Max Log Kow: 11.26;
- For fragment -CH2- [linear], the maximum number of occurrences in the training set of the model is 28 (provided by the model developer);
- There should be suitable structural analogues to the Substance within the training set.

The Substance constituents have the following properties related to the estimation of applicability domain:

- Log Kow for constituents 5, 6 and 7 are 12.24, 12.73, 13.32, respectively;
- Structural fragment -CH2- [linear] is 30 to 36 for constituents 1 to 7, respectively;
- You state that there are no suitable structural analogues in the training set for most the constituents of the Substance.

Having regard of the above, the selected structure(s) used as input for the prediction are outside the applicability domain of the model because

- Constituents 5 – 7 are outside Log Kow domain;
- For fragment -CH2- [linear], the maximum number of occurrences in the training set of the model is 28. Therefore this threshold was exceeded for constituents 1 to 7, with fragments -CH2-[linear] occurring 30 and 36 time, respectively;
- Because the structures are outside of the logKow and fragment domains, we agree that the training set of the BCFBAF model does not have structurally similar substances to most of the constituents.

Therefore, you have not demonstrated that the Substance falls within the applicability domain of the model.

b) Potential degradation products are not considered

In the context of the PBT/vPvB assessment (Annex I, Section 4) and the risk assessment (Annex I, Section 6) of the Substance, the CSA must address relevant transformation/degradation products (Annex XIII, 5th paragraph; ECHA Guidance R.11.4.1.).

Your PBT assessment does not consider potential degradation products of the Substance, and whether the degradation products would be persistent or very persistent (P/vP) and bioaccumulative or very bioaccumulative (B/vB).

The PBT properties of the Substance, its constituent and relevant transformation/degradation products cannot be assessed with the information provided.

Without this information, no conclusion on vPvB and PBT properties of the Substance and its potential degradation products can be made.

In conclusion, the PBT properties of the Substance, its constituents and relevant degradation/transformation products, cannot be assessed with the information provided. The information above indicates that the Substance is a potential PBT/vPvB substance.

The Substance has low water solubility (<1 mg/L), high partition coefficient (log Kow: >6) and high adsorption coefficient (log Koc: >6), indicating high potential to adsorb to soil and sediment. Based on the adsorptive properties of the substance, soil and sediment represent relevant environmental compartments. Surface water is a relevant compartment based on available water solubility data (water solubility > 1µg/L) and the potential for releases to the aquatic compartment in pulp and paper effluents.

Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Simulation tests on ultimate degradation in surface water (OECD TG 309), soil (OECD TG 307), and sediment (OECD TG 308) are therefore required.

In your comments on the draft decision you agree that further testing on persistence is required to determine if the Substance, or its relevant constituents or degradation products, would meet the PBT/vPvB criteria. However, you propose that the study for ultimate degradation in surface water '*is removed from the draft decision, or at the very least should be considered last in the testing strategy […] and only conducted if absolutely necessary*' because you consider that the low water solubility of the Substance presents analytical method sensitivity challenges. In addition, you request clarification on the sequence for simulation testing. You propose to conduct the sediment study first, and only conduct the additional soil study if the sediment study shows the substance not to be persistent.

Omitting the surface water simulation study based on technical feasibility:

Annex XI Section 2 allows for testing for a specific endpoint to be omitted if it is technically not possible to conduct the study as a consequence of the properties of the substance. ECHA Guidance R.11.4.1.1.1 states that the OECD TG 309 is the preferred test to start persistency assessment and if another test is selected for further testing, this should be justified, based on the following:

- Aquatic testing is not technically feasible i.e. it can be demonstrated that it has been impossible, with allocation of reasonable efforts, to develop suitable analytical methods and other test procedures to accomplish testing in surface water so that reliable results can be generated. Appropriate analytical methods should have a suitable sensitivity and be able to detect relevant changes in concentration (including that of metabolites). Generally, when water solubility of a substance is very low (typically below 1 µg/L), testing on sediment (OECD TG 308) and/or soil (OECD TG 307) may be needed instead of a pelagic test (OECD TG 309);

You have not provided an adaptation under Annex XI Section 2 to omit the surface water simulation study. You claim in your comments on the draft decision that the surface water simulation test is not needed because:

- it is not feasible based on low solubility of this substance (< 1 mg/L) causing challenges in analytical method sensitivity as indicated by aquatic toxicity tests;

We have assessed your comments and note the following issues:

- Based on the information in the dossier the water solubility of the Substance is likely <1 mg/L but it is not proven to be <1 µg/L, which in general indicates infeasibility to conduct the surface water simulation study. You have not demonstrated in your comments that it has been impossible to develop suitable analytical methods and other test procedures to accomplish testing in surface water so that reliable results can be generated.

The data in your registration dossier therefore do not justify omittance of the surface water study (OECD TG 309) based on the information provided in the comments.

Sequence of testing:
As specified in Appendix C of the draft decision you may decide on the sequence of simulation degradation testing considering the intrinsic properties of the Substance, and its identified uses and release patterns.

Regarding surface water simulation study, the aquatic compartment is considered to be a relevant environmental compartment by default because it receives significant amount of emissions directly or indirectly, and transports/distributes the substance through e.g. deposition and run-off. This is the case unless, based on the fate and release(s) of the substance, it is considered that the water compartment is not a relevant environmental compartment at all.

You propose in your comments on the draft decision to start persistency testing with sediment simulation study. You furthermore claim that the surface water simulation test is not a relevant environmental compartment of concern due to the adsorptive properties of the Substance (log Kow >6 & log Koc>6) and therefore propose to perform the surface water simulation last (if at all).

You may choose to conduct the sediment study first, with appropriate documented justifications based on intrinsic properties, uses, releases, and the compartment considered most likely to provide a worse-case assessment of persistence. The surface water compartment is relevant for this Substance due to releases in pulp and paper effluents and you have not demonstrated based on the fate and release(s) of the Substance that the water compartment is not a relevant environmental compartment at all.

Omitting further simulation studies based on conclusion on "P"

In ECHA Guidance R.11 it is stated that appropriate data need to be available to conclude the P/vP-assessment with a conclusion "not P/vP" on all three (five) compartments: water (marine water), sediment (marine sediment) and soil. If a conclusion "P" or "vP" is reached for one compartment, no further testing or assessment of persistence of other environmental compartments is normally necessary (ECHA Guidance R.11.4.1.1.1).
In your comments on the draft decision, you propose that if the Substance is persistent based on the result of the OECD TG 308, no further testing would be warranted.

If the Substance, or any of its degradation products, is found to be 'P' in a previous simulation test this cannot be used to justify omitting the remaining simulation test(s). Given that no conclusion can be made on B and T properties for the Substance as explained under Appendix A.1-A.5, the sequence of simulation testing could only stop if the Substance, or any of its degradation products, is confirmed to be 'vP'.

Study design

Test material for the simulation studies:

In your comments on the draft decision you propose that the simulation studies required be conducted on a single constituent of the Substance, acting as a surrogate for the entire substance. You identify that the best candidate for testing would be constituent [redacted]. You justify this choice based on the fact that all constituents are [redacted] and thus share close structural similarity. You justify proposing the [redacted] (constituent 7) for testing based on: (i) It is the largest molecule of the constituents and would logically have the slowest rate of degradation, but comparable routes of degradation to the other compounds and, (ii) It is one of the two major constituents of the UVCB compound, with typical values almost identical to that of the other main constituent (constituent 5).

As stated in Appendix C of this decision, and further elaborated in ECHA Guidance R. 11.4.2.2.2, a substance can be divided conceptually into fractions or blocks containing constituents which are very similar with regard to the properties to be assessed. Within a 'block' read-across criteria can be applied among the constituents. A prerequisite for application of this approach in persistence testing is that the P/vP-properties are assumed to be the same in the fraction or to follow a regular – predictable - pattern. The assessment report should justify why the constituents in the blocks can be considered to be sufficiently similar for the purpose of the PBT/vPvB assessment.

In this case, use of the block approach for selection of the test material for simulation studies can be justified based on the structural similarities of the components. You should provide a clear justification for the approach used and ensure to fully justify and document your choice of testing material in the study reports. Note that any read-across adaptation under Annex XI, section 1.5 requires adequate and reliable documentation, which ECHA would assess in the follow-up dossier evaluation.

Simulation degradation studies must include two types of investigations (ECHA Guidance R.7.9.4.1.):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

Further details on the study designs are provided below for simulation tests on ultimate degradation in surface water (OECD TG 309), soil (OECD TG 307), and sediment (OECD TG 308), respectively.

Surface Water (OECD TG 309)

You must perform the surface water test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (ECHA Guidance R.11.4.1.1.3.).

The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

As specified in ECHA Guidance R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test substance concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Therefore, non-extractable residues (NER) must be quantified. The

reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; ECHA Guidance R.11.4.1.).

Soil Simulation Study (OECD TG 307)

In accordance with the specifications of OECD TG 307, you must perform the test using at least four soils representing a range of relevant soils (*i.e.* varying in their organic content, pH, clay content and microbial biomass).

The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 307.

In accordance with the specifications of OECD TG 307, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (ECHA Guidance R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 307; ECHA Guidance R.11.4.1.).

Sediment Simulation Study (OECD TG 308)

In accordance with the specifications of OECD TG 308, you must perform the test using two sediments. One sediment should have a high organic carbon content (2.5-7.5%) and a fine texture, the other sediment should have a low organic carbon content (0.5-2.5%) and a coarse texture. If the Substance may also reach marine waters, at least one of the water-sediment systems should be of marine origin.

The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 308.

In accordance with the specifications of OECD TG 308, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (ECHA Guidance R.7.9.4.1.). By default, total NER is

regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 308; ECHA Guidance R.11.4.1.).

5. Identification of degradation products

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

As already explained under Section A.2 to A.4, the Substance is a potential PBT/vPvB substance. Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

In the context of the PBT/vPvB assessment (Annex I, Section 4) of the Substance, the CSA must address relevant transformation/degradation products (Annex XIII, 5th paragraph).

You have provided no information on the identity of transformation/degradation products for the Substance. This information is required for the purpose of the PBT/vPvB assessment (Annex I, Section 4) of the Substance.

Therefore, this information requirement is not met.

Study design

Regarding the selection of appropriate and suitable test method(s), the method(s) will have to be substance-specific. Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You may obtain this information from the degradation studies requested in Appendix A.2, 3, 4 or by some other measure. If any other method is used for the identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

To determine the degradation rate of the Substance, the requested studies according to OECD TG 309/308/307 must be conducted at 12°C and at test material application rates reflecting realistic assumptions. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline) and at higher application rate (*e.g.* 10 times).

You note in your comments on the draft decision that identification of degradation products is implicitly covered in the relevant simulation studies that will be conducted, covering those detected at ≥ 10 % of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose. This is consistent with ECHA Guidance R.11.4.1.1.3.

Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

1. Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

2. Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[2].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

   The Test Material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

[2] https://echa.europa.eu/practical-guides
[3] https://echa.europa.eu/manuals

Appendix C: General recommendations when conducting and reporting new tests for REACH purposes

A. Strategy for the PBT/vPvB assessment

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. You must assess the PBT properties of each relevant constituent of the Substance present in concentrations at or above 0.1% (w/w) and of all relevant transformation/degradation products. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

You are advised to consult ECHA Guidance R.7b (Section R.7.9.), R.7c (Section R.7.10) and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

In particular, you are advised to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation. When determining the sequence of simulation degradation testing you are advised to consider the intrinsic properties of the Substance, its identified uses and release patterns as these could significantly influence the environmental fate of the Substance. You must revise your PBT assessment when the new information is available.

B. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

Appendix D: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present. The information requirement for Bioaccumulation testing (Annex I, Section 4; Annex XIII, Section 2.1) is not addressed in this decision. This may be addressed in a separate decision once the information from the simulation studies and identification of degradation products requested in the present decision is provided; due to the fact that the relevant constituents and degradation products need to be identified in order to decide the test material for Bioaccumulation study (Annex XIII 5th paragraph).

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 22 July 2020.

ECHA notified you of the draft decision and invited you to provide comments. ECHA took into account the comments and did not amend the requests.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix E: List of references - ECHA Guidance[4] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[5]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[5]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[6]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[6] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix F: Addressees of this decision and their corresponding information requirements

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.