~~Confidential~~

Helsinki, 05 November 2021

Addressees
Registrant(s) as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
15/01/2014

Registered substance subject to this decision ("the Substance")
Substance name: 2-[2-(3-butoxypropyl)-1,1-dioxo-1,2,4-benzothiadiazin-3-yl]-5'-tert-butyl-2-(5,5-dimethyl-2,4-dioxo-1,3-oxazolidin-3-yl)-2'-[(2-ethylhexyl)thio]acetanilide
EC number: 448-060-0
CAS number: 727678-39-9

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 ***12 February 2025***.

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

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

1. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211)

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)

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

1. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.; test method: OECD TG 473) or In vitro micronucleus study (Annex VIII, Section 8.4.2.; test method: OECD TG 487)

2. If negative results are obtained in test performed for the information requirement of Annex VIII, Section 8.4.2. then: In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490)

3. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats

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

5. 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.

6. 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.

7. 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.

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

9. Bioaccumulation in aquatic species (triggered by Annex I, sections 0.6.1. and 4.; Annex XIII, Section 2.1.; test method: OECD TG 305, aqueous exposure)

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

- Appendices entitled "Reasons to request information required under Annexes VII and 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 and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes".

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 VII of REACH

1. Long-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.). Long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

You have provided an OECD TG 202 study but no information on long-term toxicity on aquatic invertebrates for the Substance.

We have assessed this information and identified the following issue:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does 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).

In the provided OECD TG 105 (2003), the saturation concentration of the Substance in water was below the response of the lowest calibration standard used in the analytical method (*i.e.* 0.04 mg/L). Furthermore, a dilution factor of 1:1 was applied to the test samples, meaning that water solubility is below 0.08 mg/L (i.e. double of the lowest calibration standard).

Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

Study design

The Substance is difficult to test due to the low water solubility (below 0.08 mg/L) and adsorptive properties (log Koc above 5.63). OECD TG 211 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 211. 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.

For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (ECHA Guidance, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among

others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

2. Growth inhibition study aquatic plants

Growth inhibition study aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

You have provided the following information:
- [redacted] 2004, OECD TG 201 (Alga, Growth Inhibition Test) conducted with the Substance.

We have assessed this information and identified the following issues:

To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

Reporting of the results
- the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;
- adequate information on the analytical method (including sampling frequency, performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided;

Additional requirements applicable to difficult to test substances
- If the test material is poorly water soluble, evidence must be provided that the test solution preparation allowed achieving the maximum dissolved concentration under test conditions;
- A justification for, or validation of, the separation technique is provided, especially if filtration is used, as it can cause losses due to adsorption onto the filter matrix;

Validity criteria
- exponential growth in the control cultures is observed over the entire duration of the test;
- the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;
  the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Pseudokirchneriella subcapitata*

Your registration dossier provides an OECD TG 201 showing the following:

Reporting of the results
- you have not reported the analytic data nor specified the sampling frequency applied to determine the mean concentration of the test material;
- tabulated data on the algal biomass determined daily for each treatment group and control are not reported;

Additional requirements applicable to difficult to test substances
- you report that the test solution (100 mg/L nominal) was prepared, stirred for 30 minutes and filtered through a rough paper filter;
- you have claimed that short stirring was used due to expected low stability of the

Substance however you have not provided further justification for the methods used to prepare the test solutions.

Validity criteria

- you have not specified if the validity criteria were met.

Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results. More, specifically:

- *Reporting of the results and validity criteria*: you have reported that the average exposure concentration was equal to the limit of detection of the analytic method used (LOD=0.02 mg/L) and you have not reported the measured concentrations. Therefore, it is not possible to assess the reliability of the effect concentration determined. Moreover, as you have not provided tabulated data on the growth of control cultures, it is not possible to verify that the validity criteria are met.

- *Additional requirements applicable to difficult to test substances*: the Substance is difficult to test due to poor water solubility and adsorptive properties and there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, you have not justified nor demonstrated that the method applied in test media preparation allowed achieving maximum dissolved concentrations, including the use of filter as a separation method.

Therefore, the requirements of OECD TG 201 are not met. On this basis, the information requirement is not fulfilled.

Study design

OECD TG 201 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A, Section 1.

Appendix B: Reasons to request information required under Annex VIII of REACH

1. In vitro cytogenicity study in mammalian cells or In vitro micronucleus study

An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is an information requirement under Annex VIII to REACH (Section 8.4.2.).

You have provided a key study in your dossier:

- [redacted] 2004 , *In vitro* mammalian chromosome aberration test conducted with the Substance.

We have assessed this information and identified the following issue(s):

To fulfil the information requirement, the study has to be equivalent to the information from an *in vitro* chromosomal aberration test or an *in vitro* micronucleus test, conducted in mammalian cells in accordance with OECD TG 473 or OECD TG 487, respectively[2]. The key parameter(s) of these test guidelines include:

a) The maximum concentration tested must induce 55±5% of cytotoxicity compared to the negative control, or the precipitation of the tested substance. If no precipitate or limiting cytotoxicity is observed, the highest test concentration must correspond to 10 mM, 2 mg/mL or 2 µl/mL, whichever is the lowest.
b) At least 300 well-spread metaphases must be scored per concentration.

The reported data for the study you have provided did not include:

a) a maximum tested concentration of 10 mM, 2 mg/mL or 2 µl/mL, or that induced 55±5% of cytotoxicity compared to the negative control, or the precipitation of the tested substance.
b) the scoring of at least 300 metaphases per concentration.

The information provided does not cover key parameter(s) required by OECD TG 473. Therefore, the information requirement is not fulfilled.

2. In vitro gene mutation study in mammalian cells

An *in vitro* gene mutation study in mammalian cells is an information requirement under Annex VIII to REACH (Section 8.4.3.) in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

Triggering of the study

Your dossier contains (i) a negative result for *In vitro* gene mutation study in bacteria, and (ii) inadequate data for the *in vitro* cytogenicity test (*In vitro* cytogenicity study in mammalian cells or *In vitro* micronucleus study).

The *in vitro* cytogenicity study in mammalian cells ([redacted] 2004) provided in the dossier is rejected for the reasons provided in Appendix B, Section 1.

The result of the request for information in Appendix B, Section 1 will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

Assessment of information provided

[2] Guidance on IRs and CSA, Table R.7.7–2, p.557

You have provided a key study in your dossier:

- [redacted] 2013, *In vitro* mammalian cell gene mutation test conducted with the Substance.

We have assessed this information and identified the following issue(s):

To fulfil the information requirement, the *in vitro* gene mutation study on mammalian cells has to meet the requirements of OECD TG 476 or OECD TG 490[3]. The key parameter(s) of these test guidelines include:

a) The maximum concentration tested must induce 80-90% of cytotoxicity compared to the negative control, or the precipitation of the tested substance. If no precipitate or limiting cytotoxicity is observed, the highest test concentration must correspond to 10 mM, 2 mg/mL or 2 µl/mL, whichever is the lowest.

The reported data for the study you have provided do not include:

a) a maximum tested concentration of 10 mM, 2 mg/mL or 2 µl/mL, or that it induced 80-90% of cytotoxicity compared to the negative control, or the precipitation of the tested substance.

The information provided does not cover key parameter(s) required by OECD TG 476. Therefore, the information requirement is not fulfilled.

Consequently, you are required to provide information for this endpoint, if the *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study provides a negative result.

Study design

To fulfil the information requirement for the Substance, either the *in vitro* mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) or the thymidine kinase gene (OECD TG 490) are considered suitable.

3. Screening for reproductive/developmental toxicity

A Screening for reproductive/developmental toxicity study (test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) is a standard information requirement under Annex VIII to REACH (Section 8.7.1.), if there is no evidence from analogue substances, QSAR or *in vitro* methods that the Substance may be a developmental toxicant. There is no information available in your dossier indicating that your Substance may be a developmental toxicant.

According to the first paragraph, third indent, the study does not need to be conducted if relevant human exposure can be excluded in accordance with Annex XI, Section 3.

You have provided an adaption in Section 7.8.1 of your dossier, and you conclude that "*No significant exposure is expected throughout all relevant exposure scenarios*"

As stated in Annex XI, Section 3, testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annexes IX and X may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report (CSR), by providing an adequate and scientifically-supported justification based on a thorough and rigorous exposure assessment in accordance with Section 5 of Annex I and by communicating the specific conditions of use through the supply chain. Any one of the following criteria 3.2.(a),(b) or (c) shall be met. In particular:

[3] Guidance on IRs and CSA, Table R.7.7–2, p.557

- 3.2 (a) the manufacturer or importer demonstrates and documents that all of the following conditions are fulfilled,
  - i. the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5.;
  - ii. a suitable DNEL or a PNEC can be derived from results of available test data for the Substance taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes; and
    - i. the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC.

- 3.2 (c) where the substance is incorporated in an article in which it is permanently embedded in a matrix or otherwise rigorously contained by technical means, it is demonstrated and documented that all of the following conditions i) to (iii) are fulfilled, where the first condition is
  - i. the substance is not released during its life cycle.
  - ii. the likelihood that workers or the general public or the environment are exposed to the substance under normal or reasonably foreseeable conditions of use is negligible; and
  - iii. the substance is handled according to the conditions set out in Article 18(4)(a) to (f) during all manufacturing and production stages including the waste management of the substance during these stages.

ECHA assessed this information according to the requirements of Annex XI, Section 3 of the REACH Regulation and identified the following issues:

The first criterion 3.2(a) requires three elements, i, ii, and iii to be met:

i. "*absence of or no significant exposure in all scenarios of the manufacture and all identified uses*". ECHA notes firstly that exposure to the Substance cannot be excluded as demonstrated by the exposure estimations in your CSR. Secondly, ECHA notes that the exposure assessment in your CSR cannot be reliably used to determine that the exposure is not significant. The justification for omitting this test must be based on a 'thorough and rigorous' exposure assessment in accordance with section 5 of Annex I.

   In the information that you provided, the exposure assessment is based solely on modelling. ECETOC TRA v.3 has been used for estimating inhalation and dermal exposure. ECETOC TRA v.3 is a first-tier exposure modelling tool. Rigorous and thorough exposure assessment that would justify *no or no significant exposure* cannot be achieved by solely using a tier 1 exposure modelling tool, which is generally conservative, but also very uncertain. To demonstrate absence of or no significant exposure measured data or higher tier exposure modelling should be used.

   According to Guidance on IRs and CSA, Section R.14.6.1, "*Uncertainty of the exposure estimate needs to be considered to ensure that the conditions of use are sufficiently covered by the exposure estimate. Depending on the level of uncertainty around the various factors contributing to the exposure estimate and resulting RCR, it is recommended to refine (re-iterate) the exposure by alternative means, to reduce the uncertainty. This may include for example modelled exposure from higher tier models, sensitivity considerations regarding input data in models, and by inclusion of or*

resorting to (additional) measurement data in a weight of evidence approach to increase reliability of the outcome and to guarantee safe use."

ii. the DNEL which is used in risk characterisation is derived from a short-term repeated dose toxicity study (28-days; [redacted] 2004) with a NOAEL of 1000 mg/kg/day, no adversity but treatment related effects on haematology and some organ weights idnetified. You have used Assessment Factors according to ECHA Guidance for duration of exposure, interspecies differences and intra-species differences and an assessment factor of 2 for remaining uncertainties due to data waiving for toxicity to reproduction. ECHA does not consider that a short-term repeated dose toxicity study (28-days) is a valid starting point for deriving a DNEL for reproductive toxicity since this study does not investigate reproductive toxicity (e.g. functional fertility) nor developmental toxicity. Adding an additional assessment factor does not mitigate this issue. Your DNEL is not appropriate for the information requirement to be omitted or for risk assessment purposes.

iii. When comparing your exposure estimates with their respective DNELs, ECHA does not consider these RCRs to be well below one. For example, exposure scenario 2 for workers "*Automatic inversion of powder from pot to mixing tank, mixing with other chemicals, gelatine and water in a fully closed system (PROC 8b)*" demonstrated an RCR of [redacted] when comparing the exposure estimate with the DNEL.

ECHA notes that according to your CSR this exposure scenario is a fully closed system, though you have estimated exposures as high as [redacted] mg/m^3. This is not indicative of a fully closed system. You should consider re-iterating your exposure estimations to establish a more realistic exposure estimate for each of your exposure scenarios. You should also consider modelling exposure with higher tier models and/or providing representative workplace measurement data. This may reduce the uncertainty of your attempt to demonstrate that exposures are well below the DNEL.

ECHA notes that in section 10 of your CSR, page 69, you conclude "*The results of the modelled data show that the formulation steps of UY-330 can be considered as safe, since the available RCRs are < 1.*" Whilst an RCR <1 demonstrates safe use for a substance where the toxicological endpoints are fulfilled, this is not sufficient for omitting testing in accordance with Annex 8.7. For the omission of testing, the exposure assessment needs to show that exposures are always well below the derived DNEL. The assessment needs to take into account the increased uncertainty resulting from the omission of the information requirement.

On this basis, the justification for waiving a standard requirement cannot be accepted.

For the third criterion 3.2(c) you state that the Substance is maintained in the matrix of the article, but you have not provided evidence that demonstrates that the Substance is not released from the article throughout its life cycle.

According to Guidance on IRs and CSA, Section R.5.1.5.3.3, accepted justification would include elements such as:

- Proof that no emissions from the article occur, including disposal and recovery of article waste.
- Proof that the amounts of substance released from the article are contained by technical means or directly destroyed (e.g. during thermal treatment of waste). If the substance is embedded in the matrix of the article: a description of the stability of the

article matrix and the bonds between the substance and the matrix during the different life cycle stages of the article.

- Proof that the substance remains fully immobile inside the article and does not migrate to the surface and out of it (e.g. due to the inherent physicochemical properties of the substance, or a special coating of the article).

ECHA concludes that no or no significant human exposure cannot be justified since there is article service life reported and no acceptable justification such as the elements listed above to confirm that there are no releases from articles during the uses or during the disposal and waste stage.

Based on the above, your adaptation is rejected, and the information requirement is not fulfilled.

Information on study design

A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats with oral[4] administration of the Substance.

4. Long-term toxicity testing on fish

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 on fish for the Substance.

We have assessed this information and identified the following issue:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does 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).

As already explained under Appendix A, Section 1, the Substance is poorly water soluble and information on long-term toxicity on 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.).

OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A, Section 1.

5. Simulation testing on ultimate degradation in surface water

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).

[4] Guidance on IRs and CSA, Section R.7.6.2.3.2.

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 an OECD TG 301 B), and
- 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).
- it meets the T criteria set in Annex XIII: NOEC or EC10 < 0.01 mg/L

Your registration dossier provides the following:

- The Substance is not readily biodegradable (9% degradation after 29 days in OECD TG 301 B) and no further information on degradability was reported;
- The Substance has a high potential to partition to lipid storage (Log K_{ow} of 8.8 based on OECD TG 117).

Furthermore, the information in your dossier is currently incomplete and therefore:

- it is not possible to conclude on the bioaccumulation potential of the Substance (see Appendix B, Section9 of this decision), andit is not possible to conclude on the toxicity of the Substance (see Appendix A, Sections 1 and 2 and Appendix B, Section 4 of this decision).

The information above indicates that the Substance is a potential PBT/vPvB substance.

Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

Study design

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.

You must perform the 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.).

6. Soil simulation testing

and

7. 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:

- it is potentially persistent or very persistent (P/vP) as:
  - it is not readily biodegradable (*i.e.* <60% degradation in an OECD TG 301 B), and
- 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).
- it meets the T criteria set in Annex XIII: NOEC or EC10 < 0.01 mg/L

Your registration dossier provides the following:

- The Substance is not readily biodegradable (9% degradation after 29 days in OECD TG 301 B) and no further information on degradability was reported;
- The Substance has a high potential to partition to lipid storage (Log K_{ow} of 8.8 based on OECD TG 117).

Furthermore, the information in your dossier is currently incomplete and therefore:

- it is not possible to conclude on the bioaccumulation potential of the Substance (see Appendix B, Section 9 of this decision), and
- it is not possible to conclude on the toxicity of the Substance (see Appendix A, Sections 1 and 2 and Appendix B, Section 4 of this decision).

As already mentioned in Appendix B, Section 5, the information above indicates that the Substance is a potential PBT/vPvB substance. The Substance has low water solubility (below 0.08 mg/L), high partition coefficient (log Kow of 8.8) and high adsorption coefficient (log Koc_{soil} above 5.63), indicating high potential to adsorb to soil and sediment.

Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, soil and sediment represent relevant environmental compartments.

Study design

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.

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).

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 307.

In accordance with the specifications of OECD TG 307 and 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 307 and OECD TG 308; ECHA Guidance R.11.4.1.).

8. 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 Appendix B, Sections 5 to 7, the Substance is a potential PBT/vPvB substance. Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

You have not provided information on the identity of transformation/degradation products for the Substance. On this basis, the information requirement is not fulfilled.

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 B, Sections 5 to 7 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 study according to OECD TG 309 (Appendix B, Section 5) must be conducted at 12°C and at a test concentration < 100 µg/L. Whereas, the requested studies according to OECD TG 307 and 308 (Appendix B, Sections 6 and 7) 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, *e.g.* 20°C for OECD TG 309) and at higher application rate (*i.e.* > 100 µg/L for OECD TG 309 or 10 times for OECD TG 307 and 308).

9. Bioaccumulation in aquatic species

Bioaccumulation in aquatic species is required for the purpose of PBT/vPvB assessment (Annex I, Sections 0.6.1 and 4 to REACH).

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species (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 an OECD 301 B), and
- 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);
- it meets the T criteria set in Annex XIII: NOEC or EC10 < 0.01 mg/L

Your registration dossier provides the following:

- The Substance is not readily biodegradable (9% degradation after 29 days in OECD TG 301 B) and no further information on degradability was reported;
- The Substance has a high potential to partition to lipid storage (Log K_{ow} of >6.2 based on OECD TG 117 and 8.8 based on Rekker calculation method);

Furthermore, the information in your dossier is currently incomplete and therefore:

- it is not possible to conclude on the persistence of the Substance (see Appendix B, Sections 5 to 7 of this decision), and
- it is not possible to conclude on the toxicity of the Substance see Appendix A, Sectiona 1 and 2 and Appendix B, Section 4 of this decision).

As mentioned above, the substance is not ready biodegradable therefore, it is not possible to conclude on persistence (P/vP).
Regarding bioaccumulation potential (B/vB) the substance has high log Kow, therefore lipid particioning cannot be excluded.
Furthermore, not enough data yet exists on (eco)toxicity to conclude on this property.

In addition you have provided various types of information regarding bioaccumulation potential of the Substance. In this context, ECHA understand that you have sought to adapt this standard information requirement according to Annex XI, Section 1.2. of REACH (weight

of evidence). In support of your adaptation, you have provided the following sources of information:

i. Two QSAR predictions claimed as key studies:
   a. Bieberstein, U., 2013, BCFBAF v3.01 (EPISuite v4.10), regression based estimation
   b. Bieberstein, U., 2013, BCFBAF v3.01 (EPISuite v4.10), Arnot Gobas model

ii. A statement under IUCLID section 5.3.1 endpoint summary stating the following: *"(…) The available experimental mammalian data and QSAR predictions considered for the toxicokinetics statement in IUCLID section 7.1 indicate that UY-330 has a low bioaccumulation potential in mammals and that the fraction absorbed via the oral and dermal route will be rapidly metabolized and excreted. Furthermore, no systemic effects were observed both during the acute and subacute studies performed with rats, indicating that the substance has limited oral bioavailability ([redacted] 2003 and [redacted] 2004). The lack of irreversible adverse effects in the 28-day oral repeated dose toxicity study ([redacted], 2004) indicates that the substance will be metabolized and/or excreted rapidly. Even considering the extrapolation from mammals to fish physiology, the experimental data show that the substance is chronically non-toxic and provides strong evidence of the unlikelihood of the substance being very Bioaccumulative (vB). (…) Moreover, the PBT assessment guidance states that at log Kow values above 6, a decreasing relationship between log Kow and bioaccumulation potential is observed. One of the reasons that might explain this pattern is the reduced uptake of highly hydrophobic substances due to increasing molecular size. According to this same Guidance, if a substance has a molecular weight higher than 700 g/mol (as UY-330), this is an indicator showing that the BCF value will be below 5000 L/kg. (…)"*

We have assessed this information and identified the following issue(s):

Annex XI, Section 1.2 states that there may be sufficient weight of evidence weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the (dangerous) property investigated by the required study.

Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence adaptation.

While you have listed various hazard-related aspects (i.e. reason on bioaccumulation, metabolism and excretion and chronic toxicity potential) to justify you adaptation, you have not included a justification with an assessment, integration and weighing of the individual sources of information for relevance, reliability, coverage, consistency and results, and subsequently decided whether they together provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Irrespective of the above mentioned deficiencies on the documentation, which in itself could lead to the rejection of the adaptation, ECHA has assessed the provided sources of information and identified the following issues:

To fulfil the information requirement of bioaccumulation, a study must provide information on at least one of the following key parameters, obtained from an aquatic species and measured in whole body of the test organisms:

1. the uptake rate constant (k_1) and loss rate constants including the depuration rate constant (k_2),
2. the steady-state bioconcentration factor (BCF_{SS}),
3. the kinetic bioconcentration factor (BCF_K),
4. the dietary biomagnification factor (BMF).

Neither of the sources of information listed under i. and ii. provide information on key parameters (1), (3) or (4) above.

Concerning key parameter (2) the steady-state bioconcentration factor (BCF_{SS}):

The sources of information listed under i. may provide relevant information on steady-state bioconcentration factor (BCF_{SS}).

The information listed under ii. does not provide information on key investigations. Therefore the source information ii cannot be considered as relevant information on steady-state bioconcentration factor (BCF_{SS}). Furthermore, the justification provided does not support your conclusion that the substance is not very bioaccumulative (vB). According to ECHA guidance R.11, an inverse relation between log Kow and bioaccumultion is only seen for substances with molecular weight above 700 and log Kow above 10. The registered substance is claimed to have log Kow of 8.8, based on Rekker calculation method, therefore reduced B/vB potential is not foreseen. In addition, as stated above (see Sections B.1-3), concluive toxicological information is not available to support your claim regarding chronic toxicity an metabolism/excretion potential. Therefore the source of information ii is also not considered relevant to conclude on the B/vB properties of the Substance.

On this basis, the information listed under ii. is not considered relevant to conclude on the B/vB properties of the Substance.

Reliability of sources of information listed under i. is significantly affected by the following deficiencies:

According to ECHA's Practical guide "How to use and report (Q)SARs", section 3.4, a QSAR Model Reporting Format (QMRF)[5] and a QSAR Prediction Reporting Format (QPRF)[6] are required to establish the scientific validity of the model, to verify that the Substance falls within the applicability domain of the model, and to assess the adequacy of the prediction for the purposes of classification and labelling.

In support of your adaptation you have provided in your dossier a range of BCF values which were calculated using two QSAR models:

a. BCFBAF regression based estimation indicating a BCF value of 442.1 L/kg;
b. BCFBAF Arnot-Gobas model indicating a range of BCF 109.2- 5.004e+06 L/kg for different trophic levels

[5] ECHA Guidance R.6, Section R.6.1.9
[6] ECHA Guidance R.6, Section R.6.1.10

1. For both models (a. and b.), you have not provided documentation of the prediction (QPRF) therefore, you have not established whether the Substance falls within the applicability domain of the model and whether the model is reliable for the prediction of this property.

2. *The prediction does not cover all constituents of the Substance.*

Under ECHA Guidance R.6.1.7.3. a prediction is adequate for the purpose of classification and labelling and/or risk assessment if the following condition is met:

- different constituents of the same substance are predicted individually.

Your registration dossier provides the following information:

- In Section 1.1 of your technical dossier, you define the Substance as multi-constituent
- In Section 1.2, you indicate the following constituents in the composition of your Substance:

[redacted]For the assessment, you provided predictions for the following structure: [redacted]

As you have used only one structure, representing the constituents, for the prediction while the Substance is composed of other two impurities therefore, you have not covered all constituents of the Substance.

Therefore, you have not demonstrated that the prediction is adequate for the purpose of classification and labelling and/or risk assessment.

3.*The prediction is not adequate due to low reliability*

Under ECHA Guidance R.6.1.3.4 a prediction is adequate for the purpose of classification and labelling and/or risk assessment when the model is applicable to the chemical of interest with the necessary level of reliability. ECHA Guidance R.6.1.5.3. specifies that, among others, the following condition must be met:

- the model predicts well substances that are similar to the substance of interest.

Your registration dossier provides the following information:

- two predictions (1.a and 1.2) claiming that 'The substance fits in the applicability domain of the model. The prediction is valid and can be used for classification and risk assessment.'

ECHA was able to investigate the predictions using VEGA software and the sotware highlighted the following key shortcomings:

- for i.a and i.b, no similar compounds with known experimental value in the training set have been found;
- accuracy of prediction for similar molecules found in the training set is not adequate for i.a and is not optimal for i.b.

The predictions for the Substance used as input are not reliable because no similar substances are available in the training set to allow reliable prediction of this property (BCF_{SS}).

Therefore, you have not demonstrated that the prediction for the Substance is adequate for the purpose of classification and labelling and/or risk assessment.

Taken together, even if the sources of information (i.a) and (i.b) may provide information on one of the key parameters necessary to be investigated for this information requirement (the steady-state bioconcentration factor (BCF_{SS})), their reliability is affected significantly.

Accordingly, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular property foreseen to be under the corresponding endpoints. Therefore, your adaptation is rejected.

Therefore, the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species.

Study design

Bioaccumulation in fish: aqueous and dietary exposure (Method EU C.13 / OECD TG 305) is the preferred test to investigate bioaccumulation (ECHA Guidance R.7.10.3.1.). Exposure via the aqueous route (OECD TG 305-I) must be conducted unless it can be demonstrated that:

- a stable and fully dissolved concentration of the test substance in water cannot be maintained within ± 20% of the mean measured value, and/or
- the highest achievable concentration is less than an order of magnitude above the limit of quantification (LoQ) of a sensitive analytical method.

This test set-up is preferred as it allows for a direct comparison with the B and vB criteria of Annex XIII of REACH.

You may only conduct the study using the dietary exposure route (OECD 305-III) if you justify and document that testing through aquatic exposure is not technically possible as indicated above. You must then estimate the corresponding BCF value from the dietary test data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO(2017)16).

Appendix C: 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[7].

B. Test material

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 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 all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[8].

[7] https://echa.europa.eu/practical-guides
[8] https://echa.europa.eu/manuals

Appendix D: 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 E: Procedure

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

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

The compliance check was initiated on 30 October 2020.

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

ECHA did not receive any comments within the commenting period.

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 F: List of references - ECHA Guidance[9] 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)[10]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[11]

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[12]

[9] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[10] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[11] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[12] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

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

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 G: 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]

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.