EUROPEAN CHEMICALS AGENCY

Helsinki, 20 August 2020

Addressees
Registrants of Desmodur RFE listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
09/01/2015

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Tris(p-isocyanatophenyl) thiophosphate
EC number: 223-981-9
CAS number: 4151-51-3

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

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 ***27 November 2023***.

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. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method OECD 421/422) in rats, oral route ;

2. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.; test method EU C.7./OECD TG 111) ;

3. Simulation testing on ultimate degradation in surface water at a temperature of 12 °C also requested at B.3. below (triggered by Annex VIII, Section 9.2., column 2);

4. Soil simulation testing at a temperature of 12 °C also requested at B.4. below (triggered by Annex VIII, Section 9.2., column 2);

5. Sediment simulation testing at a temperature of 12 °C also requested at B.5. below (triggered by Annex VIII, Section 9.2., column 2);

6. Identification of degradation products using an appropriate test method also requested at B.6. below (triggered by Annex VIII, Section 9.2., column 2).

B. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) in rats ;

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route ;

3. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method EU C.25./OECD TG 309) at a temperature of 12 °C;

4. Soil simulation testing (Annex IX, Section 9.2.1.3.; test method EU C.23./OECD TG 307) at a temperature of 12 °C;

5. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method EU C.24./OECD TG 308) at a temperature of 12 °C;

6. Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method.

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

- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required under Annexes VII to IX 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;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;

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

For certain endpoints, ECHA requests the same study from registrants at different tonnages. In such cases, only the reasoning why the information is required at lower tonnages is provided in the corresponding Appendices. For the tonnage where the study is a standard information requirement, the full reasoning for the request including study design is given. Only one study is to be conducted; the registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants under Article 53 of REACH.

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.

Approved[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.

EUROPEAN CHEMICALS AGENCY

Appendix on Reasons common to several requests

(i) Assessment of adaptations under Annex XI

Annex XI, Section 1.1.2., Existing data

Screening for reproductive/developmental toxicity and sub-chronic toxicity are standard information requirements in Annex VIII and IX to the REACH Regulation.

You have adapted the standard information requirement according to Annex XI, Section 1.1.2., Existing data, of REACH.

The adaptation rule in Annex XI, Section 1.1.2 enables registrants to claim that the data from experiments not carried out according to GLP or the test methods referred to in Article 13(3) can be considered equivalent to data generated by those test methods where a number of cumulative conditions are met.

In your dossier, you submitted an adaptation referring to Annex XI, Section 1.1.2. In this regard, you have submitted the following three studies:
i) an acute inhalation toxicity study in the rat - OECD TG 403 (2011a);
ii) analysis of bronchoalveolar lavage following acute inhalation toxicity study in the rat – similar to OECD TG 403 (2011b) and;
iii) 28 day repeated dose inhalation toxicity study in the rat - OECD TG 412 (2012).

These studies have been carried out according to GLP and the test methods referred to in Article 13(3). Therefore, Annex XI, section 1.1.2 cannot be used for adapting this information requirement.

Therefore your adaptation under Annex XI, section 1.1.2 is rejected.

Annex XI, Section 1.2., Weight of evidence

Screening for reproductive/developmental toxicity, sub-chronic toxicity and prenatal developmental toxicity in one species are standard information requirements in Annex VIII and IX to the REACH Regulation.

You have adapted the standard information requirement according to Annex XI, Section 1.2. Weight of evidence of REACH.

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

i. Acute inhalation toxicity study in the rat - OECD TG 403 (2011a).
ii. Analysis of bronchoalveolar lavage following acute inhalation toxicity study in the rat – similar to OECD TG 403 (2011b).
iii. 28 day repeated dose inhalation toxicity study in the rat - OECD TG 412 (2012).
iv. Several scientific publications from the open literature where the relevance of histopathological data from repeated dose toxicity studies is discussed with respect to reproductive toxicity evaluation. These studies seem not to have been performed with the Substance.

Based on the presented sources of information, you argue that the available data gives sufficient information to conlude on reproductive/developmental toxicity, sub-chronic toxicity

and prenatal developmental toxicity because:

a) based on the results of the subacute inhalation study with tris(p-isocyanatophenyl) thiophosphate there is no indication of a reproductive toxicity potential,
b) neither gross pathological nor histopathological changes of the male and female reproductive organs have been reported,
c) histopathological examinations of rodent's reproductive tissues in repeated dose toxicity studies are of high value and high sensitivity for evaluation of reproductive toxicity in males and females,
d) effects seen after repeated dose exposure via inhalation are focused on the port of entry and reveal a pattern characteristic for a particle-overload-like phenomenon,
e) it is not assumed that a longer treatment duration would substantially change the hazard assessment of the substance.

Annex XI, Section 1.2 states that there may be sufficient weight of evidence (WoE) 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.4.4, a weight of evidence adaptation involves an assessment of the relative values/weights of 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 of the information for the given regulatory information requirement. Subsequently, relevance, reliability, 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/hazardous) 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 approach.

While you have listed various risk-related aspects (a-e) to justify your adaptation, you have not included a justification with an assessment and balancing of the individual sources of information for relevance, reliability, 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.

The sources of information provide sufficient weight of evidence to conclude that the information requirements for OECD TG 421/422, OECD TG 408, and OECD TG 414 are fulfilled for the properties screening for reproductive/developmental toxicity, sub-chronic toxicity and prenatal developmental toxicity if by weighing the evidence, e.g. the following aspects are covered: Information on sexual function and fertility (mating, fertility, gestation, parturition and lactation) including histopathology of gonads and accessory sex organs for reproductive/developmental toxicity (OECD TG 421/422), exposure duration is 90 days for sub-chronic toxicity (OECD TG 408) assessed in 10 animals/sex/dose group and for prenatal developmental toxicity (OECD TG 414), that structural gross, visceral and skeletal malformations and variations are investigated.

ECHA has assessed to what extent the sources of information submitted enables a conclusion on these properties as investigated in the information requirement(s) proposed to be adapted and identified the following deficiencies:

Reproductive/developmental toxicity, sub-chronic toxicity

One source of information (iii, OECD TG 412) provides information on repeated dose toxicity, including investigation of histopathology of gonads and accessory sex organs. This information is partly relevant for the (dangerous) properties investigated, sexual function and fertility (in OECD TG 421/422), and sub-chronic toxicity (in OECD TG 408).

Annex XI, Section 1.2 states that there may be sufficient weight of evidence "from several independent sources of information".

You have only provided one partly relevant source of information.

Therefore your adaptation is rejected and the information requirements reproductive/developmental toxicity and sub-chronic toxicity are not fulfilled.

Pre-natal developmental toxicity

None of the information sources, alone or together, provide any information on structural gross, visceral and skeletal malformations and variations.

Your weight of evidence adaptation does not include any relevant sources of information to conclude on the property pre-natal developmental toxicity. Therefore your adaptation is rejected and information requirement is not fulfilled.

Appendix A: Reasons for the requests to comply with Annex VIII of REACH

1. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

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, 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.

You have adapted this information requirement under Annex IX, Section 8.7, Column 2, first paragraph, third indent (low toxicity).

In addition, you have submitted adaptations of this information requirement according to Annex XI, Section 1.1.2 (use of existing data) and Annex XI, Section 1.2 (weight of evidence).

We have assessed this information and identified the following issues:

A. According to Annex VIII, Section 8.7.1., Column 2, first paragraph, the study does not to be conducted if one of the following conditions is fullfilled:
— the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented, or
— the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented, or
— relevant human exposure can be excluded in accordance with Annex XI section 3, or
— a pre-natal developmental toxicity study (Annex IX, 8.7.2) or, either an Extended One-Generation Reproductive Toxicity Study (B.56, OECD TG 443) (Annex IX, section 8.7.3) or a two-generation study (B.35, OECD TG 416), is available.

As noted above, you have submitted an adaptation for this information requirement under Annex IX, Section 8.7.1., Column 2, first paragraph, third indent. In this regard, you have submitted the following three studies:
i) an acute inhalation toxicity study in the rat - OECD TG 403 (2011a);
ii) analysis of bronchoalveolar lavage following acute inhalation toxicity study in the rat – similar to OECD TG 403 (2011b) and;
iii) 28 day repeated dose inhalation toxicity study in the rat - OECD TG 412 (2012).

Based on this information you claim that there is no indication of systemic availablilty or systemic toxicity of your substance.

ECHA notes that the provided justification in your adaptation for this information requirement does not fulfil any of the conditions of Annex VIII, Section 8.7.1., Column 2, first paragraph.

Therefore your adaptation is rejected.

B. As noted above, in your dossier, you submitted an adaptation for this information requirement referring to Annex XI, Section 1.1.2. However, as explained in the Appendix on Reasons common to several requests, your adaptation is rejected.

C. As noted above, in your dossier, you submitted an adaptation for this information requirement referring to Annex XI, Section 1.2. However, as explained in the Appendix on Reasons common to several requests, your adaptation is rejected.

In your comments you further explained that you will perform the OECD TG 414 study and that it is your intention to adapt the information required for this endpoint according to Annex VIII, Section 8.7.1., Column 2. ECHA confirms that adaptations of the standard information are possible under the specific rules set out in Column 2 of the Annexes to REACH, but observes that there is at present no information available that could be assessed by it.

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[2] administration of the Substance.

2. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.)

Hydrolysis as a function of pH is a standard information requirement under Annex VIII to REACH.

You have provided an adaptation referring to Column 2 of Annex VIII, Section 9.2.2.1 and a second adaptation referring to Annex XI, Section 1.5. with the hydrolysis study (according to OECD TG 111) conducted with the source substance (EC No 247-840-6).

We have assessed your adaptations and identified the following issues:

A. Adaptation based on column 2 of Annex VIII, Section 9.2.2.1.

Hydrolysis as a function of pH does not need to be conducted if the substance is highly insoluble in water or is readily biodegradable (Annex VIII, Section 9.2.2.1., column 2).

In your dossier you provide the following adaptation statement:
"*In accordance with column 2 of REACH Annex VIII, a study does not need to be conducted as the substance is highly insoluble in water. Rapid hydrolysis (as for isocyanates in general) is considered for the substance. The hydrolysis products are mainly insoluble oligomeric and polymeric ureas. Theoretically the corresponding amine can be regarded which however is not formed in significant concentrations.*"

The screening information provided in your dossier indicates that the Substance is not readily biodegradable (58.2 % in 28 days in OECD TG 301F).

In your dossier you also noted that for the test item preparation in the water solubility test the Substance was "*stirred on a magnetic stirrer for 24 hours at 20 °C in a temperature-controlled water bath*". Due to the ability of isocyanates to undergo hydrolysis, it could be considered that the test item in the water solubility test was partly or fully composed of hydrolysis product(s) and not of the (parent) Substance.

Consequently, there is currently no adequate data supporting the claim that the Substance is highly insoluble and the reference to high insolubility of the Substance in water is not acceptable.

Therefore your adaptation is rejected and the information requirement is not fulfilled.

B. Adaptation according to Annex XI, Section 1.5

[2] ECHA Guidance R.7a, Section R.7.6.2.3.2.

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled to apply grouping and read-across. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (read-across approach).

A read-across hypothesis needs to be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. This hypothesis should be based on recognition of the structural similarities and differences between the substances[3]. It should explain why the differences in the chemical structures should not influence the toxicological/ecotoxicological/fate properties or should do so in a regular pattern.

Your read-across hypothesis is that the structural similarity between the source substance in the submitted hydrolysis study and your Substance is a sufficient basis for predicting the properties of your Substance.

While structural similarity is a prerequisite for applying the grouping and read-across approach, it does not necessarily lead to predictable or similar ecotoxicological/fate properties. Proposed read-across should be supported by the information allowing to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance. You have not provided a well-founded hypothesis supported by any other information to establish a reliable prediction for a fate property, based on recognition of the structural similarities and differences between the source substance and your Substance.

Therefore, the provided adaptation is rejected.

As a result of the above, the information requirement is not fulfilled.

In your comments on the draft decision you noted that you agree on the need for further information on the hydrolysis behaviour of the substance. However, you noted that for analysis of hydrolysis of the Substance following modifications of the OECD TG 111 might be useful:

a) Higher percentages (>1%) of a modifier might be necessary to obtain a concentration of the Substance in water which allows a monitoring of the degradation products.
b) It might be necessary to perform hydrolysis study with the Substance not totally dissolved at the start of the test. This modification would increase the concentration of the test substance and might be useful to characterize solid hydrolysis products.

In regard of the first proposed adaptation OECD TG 111 recommends that in case a higher concentration of water miscible solvents is considered to be applied (e.g. in the case of poorly soluble test substances), this could only be allowed when it can be shown that the solvent has no effect on the hydrolysis (i.e. kinetic of hydrolysis and identity of products formed) of the test substances.

In regard of the second proposed adaptation OECD TG 111 notes that most hydrolysis reactions follow apparent first order reaction rates and, therefore, half-lives are independent

[3] Guidance on information requirements and chemical safety assessment, Chapter R.6: QSARs and grouping of chemicals.

of the concentration. This usually permits the application of laboratory results determined at 10^{-2} to 10^{-3} M to environmental conditions ($\leq 10^{-6}$ M).

Therefore, if hydrolysis (it's kinetics and identity of products formed) is dependant of the concentration of the Substance this should be investigated.

Thus, any adaptations to the OECD TG 111 as well as interpretation of the results and it's use for the chemical safety assessment (CSA) should be explained and justified in the chemical safety report (CSR).

3. Simulation testing on ultimate degradation in surface water also requested at B.3. below (triggered by Annex VIII, Section 9.2., column 2)

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).

Annex I requires that the CSA includes the PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) assessments (Section 4), exposure assessement (Section 5) and risk characterisation (Section 6).

The CSA must take account of relevant and adequate information on degradation/biodegradation of a substance in the environment, including information on the kinetics of degradation in various environmental compartments and identity of products formed as outcome of such degradation processes. Information on the degradability of substances may be used for hazard assessment (e.g. for classification and labelling), exposure assessment, risk characterisation and persistence assessments.

There is no adequate information in the dossier provided on the degradation kinetics/products formed in the surface water under environmentaly relevant conditions and concentrations (to note that these might differ from the kinetic determined and products formed in the hydrolysis study).

The concentration ranges and conditions applied in various standard (bio)degradation tests differ, e.g. test concentrations change from relatively high concentrations in ready biodegradability and hydrolysis tests to relatively low (more environmentally relevant test concentrations) in the simulation tests. Thus, it is important to investigate in various compartments and under conditions applied in various simulation tests requested under Appendix B, sections 3-6: the degradation kinetics and degradation products formed.

The examination of the information provided by you on the degradation simulation in surface water and your comments on the draft decision are addressed in Appendix B, Section 3.

4. Soil simulation testing also requested at B.4. below (triggered by Annex VIII, Section 9.2., column 2)

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).

Annex I requires that the CSA includes the PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) assessments (Section 4), exposure assessement (Section 5) and risk characterisation (Section 6).

The CSA must take account of relevant and adequate information on degradation/biodegradation of a substance in the environment, including information on the kinetics of degradation in various environmental compartments and identity of products formed as outcome of such degradation processes. Information on the degradability of substances may be used for hazard assessment (e.g. for classification and labelling), exposure assessment, risk characterisation and persistence assessments.

There is no adequate information in the dossier provided on the degradation kinetics/products formed in the soil under environmentaly relevant conditions and concentrations (to note that these might differ from the kinetic determined and products formed in the hydrolysis study).

As noted in Section A.3.above, it is important to investigate in various compartments and under conditions applied in various simulation tests requested under Appendix B, sections 3-6: the degradation kinetics and degradation products formed.

The examination of the information provided by you on the degradation simulation in soil and your comments on the draft decision are addressed in Appendix B, Section 4.

5. Sediment simulation testing also requested at B.5 below (triggered by Annex VIII, Section 9.2., column 2)

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).

Annex I requires that the CSA includes the PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) assessments (Section 4), exposure assessement (Section 5) and risk characterisation (Section 6).

The CSA must take account of relevant and adequate information on degradation/biodegradation of a substance in the environment, including information on the kinetics of degradation in various environmental compartments and identity of products formed as outcome of such degradation processes. Information on the degradability of substances may be used for hazard assessment (e.g. for classification and labelling), exposure assessment, risk characterisation and persistence assessments.

There is no adequate information in the dossier provided on the degradation kinetics/products formed in the sediment under environmentaly relevant conditions and concentrations (to note that these might differ from the kinetic determined and products formed in the hydrolysis study).

As noted in Section A.3.above, it is important to investigate in various compartments and under conditions applied in various simulation tests requested under Appendix B, sections 3-6: the degradation kinetics and degradation products formed.

The examination of the information provided by you on the degradation simulation in sediment and your comments on the draft decision are addressed in Appendix B, Section 5.

6. Identification of degradation products also requested at B.6. below (triggered by Annex VIII, Section 9.2., column 2)

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).

Annex I requires that the CSA includes the PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) assessments (Section 4), exposure assessement (Section 5) and risk characterisation (Section 6).

The CSA must take account of relevant and adequate information on degradation/biodegradation of a substance in the environment, including information on the kinetics of degradation in various environmental compartments and identity of products formed as outcome of such degradation processes. Information on the degradability of substances may be used for hazard assessment (e.g. for classification and labelling), exposure assessment, risk characterisation and persistence assessments.

There is no adequate information in the dossier provided on the degradation products formed in the surface water/soil/sediment under environmentaly relevant conditions and concentrations (to note that these might differ from the products formed in the hydrolysis study).

As noted in Section A.3. above, it is important to investigate in various compartments and under conditions applied in various simulation tests requested under Appendix B, sections 3-6: the degradation kinetics and degradation products formed.

The examination of the information provided by you on the identity of degradation products and your comments on the draft decision are addressed in Appendix B, Section 6.

Appendix B: Reasons for the requests to comply with Annex IX of REACH

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

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement under Annex IX, Section 8.6.2., Column 2, first paragraph, fourth indent.

In addition, you have submitted an adaptation of this information requirement according to Annex XI, Section 1.1.2. Use of existing data.

ECHA has further examined your adaptation under the requirements of Annex XI, Section 1.2.

We have assessed this information and identified the following issues.

A. As provided in Annex IX, Section 8.6.2, Column 2, first paragraph, fourth indent you may adapt the information requirement, provided you fulfil the following criterion:

- the Substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit test', particularly if it is coupled with limited human exposure.

As noted above, in your dossier, you submitted an adaptation referring to Annex IX, Section 8.6.2, Column 2, first paragraph, fourth indent. In this regard, you have provided the following information in your dossier:

i. Acute inhalation toxicity study in the rat - OECD TG 403 (2011a).
ii. Analysis of bronchoalveolar lavage following acute inhalation toxicity study in the rat – similar to OECD TG 403 (2011b).
iii. 28 day repeated dose inhalation toxicity study in the rat - OECD TG 412 (2012).

Based on this information you argue that there is no substantial evidence of systemic absorption after inhalation.

However, you have not demonstrated that the Substance is unreactive, not inhalable and that there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit test'. On the contrary, you indicated in your dossier that "*rapid hydrolysis (as for isocyanates in general) is considered for the substance*". Because the substance hydrolyses, it is chemically reactive. You also reported industrial and professional spraying as uses in your Chemical Safety Report, which indicate that human exposure to the Substance by the inhalation route is possible. You further indicated that "*the hydrolysis products are mainly insoluble, inert oligomeric and polymeric ureas and thus not bioavailable. Theoretically the corresponding amine can be regarded which however is not formed in significant concentrations.*". You did not provide any toxicokinetic data to support your claims and to exclude systemic absorption after inhalation.

Therefore, your adaptation under Annex IX, Section 8.6.2, Column 2, first paragraph, fourth indent is rejected.

B. As noted above, in your dossier, you submitted an adaptation for this information requirement referring to Annex XI, Section 1.1.2. However, as explained in the Appendix on Reasons common to several requests, your adaptation is rejected.

C. As noted above, ECHA has examined your adaptation for this information requirement under the requirements of Annex XI, Section 1.2. However, as explained in the Appendix on Reasons common to several requests, your adaptation is rejected.

Information on the design of the study to be performed (route/ species/ strain)
Following the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity. The sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance, because, although the information you provided indicates that human exposure to the Substance by the inhalation route is likely, the exposure concentrations reported in the chemical safety report for the inhalation route are low (maximum 0.036 mg/m^3) compared to the toxicity profile of the substance.

In your comments on the draft decicion you agree to perform this test.

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

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX to REACH.

You have adapted the standard information requirement according to Annex XI, Section 1.2. Weight of evidence of REACH. However, as explained in the Appendix on Reasons common to several requests, your adaptation is rejected.

Information on study design
A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[4] administration of the Substance.

In your comments on the draft decision you agree to perform this test.

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

Simulation testing on ultimate degradation in surface water is a standard information requirement at Annex IX to REACH.

You have sought to adapt this information requirement by stating that "*According to REACH Annex XI, a simulation test to investigate biodegradation in water and sediment is scientifically unjustified. A simulation test should provide data on biodegradation under specified environmentally relevant conditions. The slow degradation (58.2 % degradation after 28 days) in a study according to OECD Guideline 301 F (Ready Biodegradability: Manometric Respirometry Test) provides sufficient information to confirm the slow degradation in the environment without the need for a further simulation test. No additional information would be obtained through that test*".

In your adaptation you make reference to Annex XI of REACH. However, your justification does not appear to fall under any of the adaptation possibilities set out therein. It is ECHA's understanding that you rather sought to adapt this information requirement on the basis of Column 2, Annex IX, Section 9.2.

[4] ECHA Guidance R.7a, Section R.7.6.2.3.2.

We have assessed this information and identified the following issues.

Further biotic degradation testing must be considered if the chemical safety assessment indicates the need to investigate further the degradation of the substance and its degradation products (Annex IX, Section 9.2., Column 2).

The CSA must take account of relevant and adequate information on degradation/biodegradation of a substance in the environment, including information on the kinetics of degradation in various environmental compartments and identity of products formed as outcome of such degradation processes. Information on the degradability of substances may be used for hazard assessment (e.g. for classification and labelling), exposure assessment, risk characterisation and persistence assessments. This may be useful for prioritising testing requirements to those environmental compartments that are the most relevant. Consideration should be given to whether the substance being assessed can be degraded to give stable and/or toxic degradation products. Where such degradation can occur, the assessment should give due consideration to the properties (including toxic effects and bioaccumulation potential) of the products that might arise (ECHA Guidance R.7b).

In addition, rapid hydrolysis rate cannot alone lead to concluding that a substance is not persistent , e.g. the degradation half-lives obtained in a hydrolysis test cannot on their own be compared to the persistence criteria of Annex XIII (ECHA Guidance R.11).

The concentration ranges, test mediums and conditions applied in various standard (bio)degradation tests differ, e.g. test concentrations change from relatively high concentrations in ready biodegradability and hydrolysis tests to relatively low (more environmentally relevant) test concentrations in the simulation tests.

You have indicated in the dossier that "*Rapid hydrolysis (as for isocyanates in general) is considered for the substance. The hydrolysis products are mainly insoluble oligomeric and polymeric ureas. Theoretically the corresponding amine can be regarded which however is not formed in significant concentrations.*"

In your comments on the draft decision you further noted that abiotic degradation (hydrolysis) is expected to be the predominant degradation pathway in the environment for the substance. Based on the general knowledge on aromatic isocyanates, you suggest that the substance would hydrolyse into oligomeric and polymeric ureas which are insoluble in water and therefore, not biodegradable. Due to the molecular weight and size, you consider that these hydrolysis products are not bioavailable and biodegradation of these molecules in surface water, soil or sediment is unlikely. Furthermore, you noted that bioaccumulation potential of primary predicted degradation products of the substance is very low due to the molecular size and due to the low values of bioconcentration factor predicted by QSAR modelling. Thus, as the B (vB) property of hydrolysis products can be excluded, the performance of a study is not justified and the determination of the P(vP) property would not yield additional scientific knowledge. Summarising, you noted that depending on the results of the hydrolysis experiments you will consider to provide either an adaptation statement or to perform a simulation study.

ECHA Guidance Chapter R.11 notes that additional evidence is also needed to examine whether the fate properties of the substance would cause attenuation of the hydrolysis rate in sediment or soil, or whether DOC would similarly affect the rate in aquatic media such as river or sea water. Additional studies, e.g. examining the influence of dissolved organic carbon / adsorption processes on hydrolysis rates, may be necessary for this. The degradation half-lives obtained in a hydrolysis test cannot be compared to the persistence criteria of Annex

XIII. In principle, degradation simulation studies performed in appropriate environmental media and at environmentally realistic conditions are the only tests that can provide a definitive degradation half-life that can be compared directly to the persistence criteria as defined in REACH Annex XIII. Such tests allow both biotic and abiotic degradation processes to operate. The simulation tests as described in OECD TGs 307, 308 and 309 address the fate and behaviour of a substance as it may be expected in the environment including information about partitioning in the test system, primary or complete degradation, adsorption behaviour and route(s) of degradation (degradation products).

Information in the dossier and in your comments on the draft decision indicates possible complex behaviour of the Substance in the environment which might be dependant on the compartment where substance is present, concentration of the Substance present there and specific environmental conditions. Therefore, in order to understand behaviour of the Substance in environment and to carry out adequate CSA, it is important to investigate the kinetics of degradation of the Substance (i.e. of the specific isocyanate) and identity of products formed as outcome of such degradation processes in various environmental compartments (test mediums), under various test conditions and test consentrations.

Currently there is no adequate information available in the dossier on the kinetics of degradation of the Substance in various environmental compartments under environmentaly relevant conditions and concentrations and on the identity of products formed as outcome of such degradation processes (to note that these might differ from the kinetic determined and products formed in the hydrolysis study). Furthermore, you have not provided adequate justification in your chemical safety report (CSR) or in the technical dossier for why there is no need to investigate further the degradation of the Substance and its degradation products.

Consequently, proper CSA of the Substance, including classification, risk assessment and PBT assessment, is not possible. Thus, it is important to investigate in various compartments and under conditions applied in various simulation tests requested under Appendix B, sections 3-5: the degradation kinetics and degradation products formed.

Therefore, your adaptation is not acceptable and does not fulfil the information requirement.

Study design

OECD test guideline 309 is an appropriate method for studying degradation in surface water. Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. Therefore:

- You must perform the OECD TG 309 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).

- You must perform the test at the temperature of 12 °C, the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8). Performing the tests at this temperature is in line with the applicable test conditions of the OECD TG 307 and TG 308 and TG 309.

Non-extractable residues (NER) needs to be quantified in all simulation studies. 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 Chapter R.11).

4. Soil simulation testing (Annex IX, Section 9.2.1.3.)

Soil simulation testing is a standard information requirement at Annex IX of REACH for substances with a high potential for adsorption to soil. The Substance has high partition coefficient (log Kow app. 8) and high adsorption coefficient (log Koc >5), indicating high potential for adsorption.

You have provided an adaptation referring to Column 2 of Annex IX, Section 9.2.1.3 *"as a direct or indirect exposure of the soil compartment can be excluded".*

We have assessed this information and identified the following issues:

Simulation testing on soil does not need to be conducted if direct or indirect exposure of soil is unlikely (Annex IX, Section 9.2.1.3, Column 2).

In your dossier you provide the following adapatation statement:

"According to column 2 of REACH Annex IX, a simulation test to investigate the degradation of the substance in soil does not need to be conducted as a direct or indirect exposure of the soil compartment can be excluded. A direct exposure of soil can be excluded as the substance is not applied on soil. Furthermore, all relevant surfaces are sealed to prevent any exposure. Substances may indirectly enter the soil compartment via atmospheric deposition or the application of sewage sludge. Atmospheric deposition can be considered to be negligible as any waste air is incinerated in a thermal combustion unit, is filtered or is washed in an extraction column if significant amounts of waste air are to be expected. Application of sewage sludge is not relevant since the chemical safety assessment determined that no emission to waste water occurs. Concluding, the indirect exposure of the terrestrial compartment can be excluded."

The absence of environmental exposure has not been demonstrated. There are industrial and professional uses of the Substance are identified and assessed in the CSR which is provided by the lead registrant on behalf of the members of the joint submission. The Substance is used by professional users in spraying, brushing applications in indoor and outdoor settings. ECHA notes the following:

- some risk management measures described in the CSR for the professional use outdoor cannot be considered as technically achievable for such type of the use, e.g. for the soil : *"All relevant surfaces in the facility are sealed or measures are taken to prevent the substance from getting into contact with soil."* or for air *"air is incinerated in a thermal combustion unit, is filtered or is washed in an extraction column if significant amounts of waste air are to be expected."*; and

- it is not sufficiently explained (only general reference to implementation of local waste regulations is given) how waste with the substance (e.g. from articles or generated by removal of the substance deposited from air to the sealing surfaces) is treated to prevent any environmental releases;

- possible leaching, washing out from the matrixes/articles into/onto which substance is applied is not considered in the CSR.

Thus, potential environmental exposure (especially of soil) cannot be ruled out.

In your comments on the draft decision you noted that even it could be expected that hydrolysis in soil might occur somehow slower than in a pure water test due to the fact that less water is available, the hydrolysis reaction would be still rapid and therefore hydrolysis is expected to be the predominant degradation process. Based on the general knowledge on aromatic isocyanates, you suggest that the substance would hydrolyse into oligomeric and polymeric ureas which are insoluble in water and therefore, not biodegradable. Due to the molecular weight and size, you consider that these hydrolysis products are not bioavailable and biodegradation of these molecules in surface water, soil or sediment is unlikely. Furthermore, you noted that bioaccumulation potential of primary predicted degradation products of the substance is very low due to the molecular size and due to the low values of bioconcentration factor predicted by QSAR modelling. Thus, as the B (vB) property of hydrolysis products can be excluded, the performance of a study is not justified and the determination of the P(vP) property would not yield additional scientific knowledge. Summarising, you noted that depending on the results of the hydrolysis experiments you will consider to provide either an adaptation statement or to perform a simulation study.

As explained under Appendix B, section 3 above, it is important to investigate in various compartments and under conditions applied in various simulation tests requested under Appendix B, sections 3-5: the degradation kinetics and degradation products formed.

Therefore, your adaptation is not acceptable and does not fulfil the information requirement.

Study design

OECD TG 307 is appropriate method for studying the degradation in sediment and soil. The requested simulation tests shall be performed under relevant conditions (12 °C) and non-extractable residues (NER) must be quantified, for the reasons explained above in section B.3. The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable, shall be assessed. This can be done simultaneously during the same study. Alternatively, you shall provide a justification for why you consider these as not relevant for the PBT/vPvB assessment.

5. Sediment simulation testing (Annex IX, Section 9.2.1.4.)

Sediment simulation testing is a standard information requirement at Annex IX of REACH for substances with a high potential for adsorption to sediment. The Substance has high partition coefficient (log Kow app. 8) and high adsorption coefficient (log Koc >5), indicating high adsorption potential.

You have sought to adapt this information requirement by stating that "*According to REACH Annex XI, a simulation test to investigate biodegradation in water and sediment is scientifically unjustified. A simulation test should provide data on biodegradation under specified environmentally relevant conditions. The slow degradation (58.2 % degradation after 28 days) in a study according to OECD Guideline 301 F (Ready Biodegradability: Manometric Respirometry Test) provides sufficient information to confirm the slow degradation in the environment without the need for a further simulation test. No additional information would be obtained through that test".*

In your adaptation you make reference to Annex XI of REACH. However, your justification does not appear to fall under any of the adaptation possibilities set out therein. It is ECHA's understanding that you rather sought to adapt this information requirement on the basis of Column 2, Annex IX, Section 9.2.

In your comments on the draft decision you noted that when injecting the substance to a water-sediment system via the water phase, the key reaction would also be the hydrolysis and the hydrolysis reaction is expected to be the predominant degradation process. Based on the general knowledge on aromatic isocyanates, you suggest that the substance would hydrolyse into oligomeric and polymeric ureas which are insoluble in water and therefore, not biodegradable. Due to the molecular weight and size, you consider that these hydrolysis products are not bioavailable and biodegradation of these molecules in surface water, soil or sediment is unlikely. Furthermore, you noted that bioaccumulation potential of primary predicted degradation products of the substance is very low due to the molecular size and due to the low values of bioconcentration factor predicted by QSAR modelling. Thus, as the B (vB) property of hydrolysis products can be excluded, the performance of a study is not justified and the determination of the P(vP) property would not yield additional scientific knowledge. Summarising, you noted that depending on the results of the hydrolysis experiments you will consider to provide either an adaptation statement or to perform a simulation study.

We have assessed this information and identified the folloiwng issues:

Further biotic degradation testing must be considered if the chemical safety assessmnet indicates the need to inverstigate further the degradation of the substance and its degradation products (Annex IX, Section 9.2., Column 2).

The CSA must take account of relevant and adequate information on degradation/biodegradation of a substance in the environment, including information on the kinetics of degradation in various environmental compartments and identity of products formed as outcome of such degradation processes. Information on the degradability of substances may be used for hazard assessment (e.g. for classification and labelling), exposure assessment, risk characterisation and persistence assessments. This may be useful for prioritising testing requirements to those environmental compartments that are the most relevant. Consideration should be given to whether the substance being assessed can be degraded to give stable and/or toxic degradation products. Where such degradation can occur, the assessment should give due consideration to the properties (including toxic effects and bioaccumulation potential) of the products that might arise (ECHA Guidance R.7b).

Rapid hydrolysis rate cannot alone lead to concluding that a substance is not persistent , e.g. the degradation half-lives obtained in a hydrolysis test cannot on their own be compared to the persistence criteria of Annex XIII (ECHA Guidance R.11).

As explained above in Appendix B, section 3, the concentration ranges, test mediums and conditions applied in various standard (bio)degradation tests differ. Currently there is no adequate information available in the dossier on the kinetics of degradation of the Substance in various environmental compartments under environmentaly relevant conditions and concentrations and on the identity of products formed as outcome of such degradation processes (to note that these might differ from the kinetic determined and products formed in the hydrolysis study). Furthermore, you have not provided adequate justification in your CSR or in the technical dossier for why there is no need to investigate further the degradation of the Substance and its degradation products. Such information important and needed in order to understand behaviour of the Substance in environment and to carry out adequate CSA for the Substance.

Thus, proper CSA of the Substance, including classification, risk assessment and PBT assessment, is not possible. Thus, it is important to investigate in various compartments and

under conditions applied in various simulation tests requested under Appendix B, sections 3-5: the degradation kinetics and degradation products formed.

Therefore, your adaptation is not acceptable and does not fulfil the information requirement.

Study design

OECD TG 308 is appropriate method for studying the degradation in sediment and soil. The requested simulation tests shall be performed under relevant conditions (12 °C) and non-extractable residues (NER) must be quantified, for the reasons explained above in section B.3. The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable, shall be assessed. This can be done simultaneously during the same study. Alternatively, you shall provide a justification for why you consider these as not relevant for the PBT/vPvB assessment.

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

Identification of the degradation products is a standard information requirement at Annex IX of REACH.

In your dossier, you have noted the formation of a possible hydrolysis products.

We have assessed this information and identified the folloiwng issue.

Identification of degradation products does not need to be conducted if the substance is readily biodegradable (Annex IX, Section 9.2.3, Column 2).

Identity and relevance and of degradation products must be included in the risk assessment (Annex I) and PBT assessment (Annex XIII).

In your dossier you provide following information: "*The hydrolysis products are mainly insoluble oligomeric and polymeric ureas. Theoretically the corresponding amine can be regarded which however is not formed in significant concentrations.*"

As noted under Appendix A, Section 1, there is no adequate information on the hydrolysis of the Substance to substantiate the claim about rapid hydrolysis of it as well as about the identity of the hydrolysis products.

Based on the information available in the dossier the Substance is not readily biodegradable. The available result for the ready biodegradability test indicates that some biodegradation could occur (58.2% degradation based on oxygen consumption were measured after 28 days in the test performed according to EU method C.4-D). Therefore some biotic degradation products could be formed. However, you have not identified any potential biotic degradation products.

In your comments on the draft decision you noted that you agree to provide more information on the degradation products of the substance. You plan to perform a hydrolysis study that includes information on the kinetics of degradation and identification of products formed as outcome of such degradation process.

As explained above in Appendix B, section 3, the concentration ranges, test mediums and conditions applied in various standard (bio)degradation tests differ. Thus, it is important to

investigate in various compartments and under conditions applied in various simulation tests requested under Appendix B, sections 3-5: the degradation kinetics and degradation products formed.

Therefore, the information provided does not fulfil the information requirement.

Study design

Regarding appropriate and suitable test method, the methods 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 Kow and potential toxicity of the transformation/degradation may be investigated. You may obtain this information from the hydrolysis and simulation degradation studies also requested in this decision or by some other measure, considering that the degradation kinetics/products formed in the surface water/soil/sediment under environmentaly relevant conditions and concentrations, might differ from the kinetic determined and products formed in the hydrolysis study. If the any other method than the requested hydrolysis and simulation degradation tests is used for identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

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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[5].

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 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 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[6].

[5] https://echa.europa.eu/practical-guides
[6] 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

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.

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 11 March 2019.

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

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

ECHA took into account your comments, and amended the deadline for the following reasons.

The timeline indicated in the initial draft decision to provide the information requested was 30 months from the date of adoption of the decision.

In your comments on the draft decision, you requested an extension of the timeline to 36 months. You justified your request stating that the Substance is marketed and handled as solution in [redacted]. Due to the hazardous effect of [redacted] the limit dose for your Substance may not be reachable in sub-chronic and pre-natal developmental toxicity studies. You have identified two methods to limit the content of [redacted] in your test material – either by reducing the content of [redacted] to the extent possible, or removing it completely and solve/suspend the neat tris(p-isocyanatophenyl) thiophosphate in a suitable vehicle such as [redacted].

An extention of the timeline would allow time to deal with the technical and analytical efforts in finding a suitable test material in an appropriate quantity for the tests. The test material would also need to be tested for stability and homogeneity before being used in the studies.

You propose to discuss the issue with your test material further with ECHA. We note, however, that preparation of a suitable test material as well as justifying the doses used in the requested studies are the responsibility of the Registrant and will only be evaluated after the submission of your updated registration dossier at the set deadline of this decision.

ECHA has granted the request and set the deadline to 36 months.

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[7] 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)[8]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[8]

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[9]

[7] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[8] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[9] 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: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fufilled
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.