EUROPEAN CHEMICALS AGENCY

Helsinki, 11 September 2020

Addressees
Registrants of Sulfochlorin.Paraff.Low Sulpho listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
08/03/2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Paraffin waxes and Hydrocarbon waxes C14-17, chloro, sulfochlorinated, low sulphonated, saponified
List number: 939-273-4
CAS number: NS

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***17 December 2021***.

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. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method OECD TG 301B/C/D/F or OECD TG 310) on relevant constituent(s) from various fractions of the Substance.

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

1. Revised PBT and vPvB assessment (Article 14 (3)(d) in conjunction with Annex I, Section 4 and Annex XIII).

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

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

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 Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- 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;

- the information specified in Annexes VII to X to REACH, for registration at more than 1000 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".

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.

Appendix A: Reasons to request information required under Annex VII of REACH

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

Ready biodegradability is a standard information requirement at Annex VII of REACH.

You have provided in your dossier results of the key study performed according to OECD TG 301F on the whole Substance.

Tests on substances must be conducted in accordance with the applicable OECD test guidelines or other recognised international test methods (Article 13(3) of REACH). For ready biodegradability testing OECD test guideline [301 and 310] are appropriate.

As indicated under section for *Ready biodegradability tests* in the Revised Introduction to the OECD Guidelines for Testing of Chemicals, Section 3 - Part 1: Principles and strategies related to the testing of degradation of organic chemicals[2], "*Although these tests are intended for pure chemicals, it is sometimes relevant to examine the ready biodegradability of mixtures of structurally similar chemicals*". It further recommends that *"a case by case evaluation should take place on whether a biodegradability test on such a complex mixture would give valuable information regarding the biodegradability of the mixture as such (i.e. regarding the degradability of all the constituents) or whether instead an investigation of the degradability of carefully selected individual components of the mixture is required. (...) Tests for ready biodegradability are not generally applicable for complex mixtures containing different types of chemicals.*"

The Substance is organic UVCB substance which is considered as a complex mixture of various constituents. In the composition of the substance reported in the registration dossier there is a number of constituents from different fractions (e.g. saturated sulfochlorinated paraffins, saturated sulfoparaffins, unsaturated sulfochlorinated paraffins, unsaturated chlorinated paraffins, saturated and unsaturated paraffins) that are expected to have different properties, in particular, in terms of solubility, emulsifying properties, log Kow, bioaccumulation, ecotoxicity and biodegradability. Specifically biodegradability potential of constituents of the Substance might be affected, at least, by the carbon chain length, branching, chlorine content, presence of multi-bonds (unsaturated constituents) and possible impact of sulphonation. Thus, the ready biodegradability of each constituent of the Substance cannot be concluded on the basis of results of the key study performed on the whole Substance.

Therefore, the provided study is not sufficient to conclude on the ready biodegradability of each constituent of the Substance and does not fulfil the information requirement.

According to ECHA Guidance R.11 for the purpose of the PBT/vPvB assessment "Known constituents" approach "*can be applied when a substance is 'a priori' known to contain specific constituents at relevant concentrations, these constituents are suspected based on available information to represent the worst case of the (v)P, (v)B and T properties of all constituents of the substance, and these specific constituents can be isolated or separately manufactured or otherwise acquired for the purpose of testing.*" As the Substance consists of constituents from different fractions that are expected to have different properties, ECHA considers that information on ready biodegredability "*of carefully selected individual components*" might be relevant for the PBT/vPvB assessment of the Substance. These individual components selected for the testing should be reasonably the most persistent constituent(s) from each fraction of the Substance. The selection of the most persistent constituent(s) must be justified and reported in the registration dossier. The selection shall consider, at least, the carbon

[2] http://www.oecd.org/chemicalsafety/testing/34898616.pdf

chain length, branching, chlorine content, presence of multi-bonds (unsaturated constituents) and possible impact of sulphonation of the constituents.

In your comments to the draft decision, you note that the Substance, based on complexity of the starting material (UVCB itself) and manufacturing process, is very complex UVCB. So, it is quite unlikely to define "a priori" which specific constituent can represent a worst case and at which relevant concentration and you cannot isolate some of them in a quantity useful to perform any test. Thus, you conclude that the "known constituent approach" is not practically applicable to the Substance.

Furthermore, you note that it seems that in the decision it is also proposed to use 'block' (or 'fraction') approach for the PBT/vPvB assessment of the Substance. You explain that the composition, as presented in section 1.2 of the dossier, has not been derived by physically separating the different fractions, but it has been a theoretical elaboration from analytical parameters, identification of starting materials and process. In practice, you were able to separate the Substance into two portions: one of lipophilic and one of hydrophilic constituents. Then, each fraction has been separately analysed and the extreme complexity of the Substance with very many constituents was detected. In each fraction the degradation, bioaccumulation and toxicity properties cannot be predicted as following a regular predictable pattern, therefore the 'fraction' approach cannot completely represent the behaviour of the Substance. Thus, you suggest that neither a "known constituents approach" nor a "fraction approach" may be practically applicable for the Substance.

Moreover, you argue that the test performed on the whole Substance is more representative for the biodegradation property under investigation. In fact, it has to be considered that the emulsifying molecules act as surfactant towards the hydrophobic molecules with the following consequences:

- Bring them into the water compartment, improving their bioavailability towards microorganisms
- Lowering their own surface tension and improving as a consequence their dispersion into the water solution and the available surface with better availability for the microbial attack and degradation.

Such concept of improving biodegradability of hydrophobic substances of hydrocarbon origin with the use of surfactants and dispersants has been widely applied during the bioremediation as a supplemental clean-up technology in the biggest oil spill events. Taking into account the above considerations, this UVCB Substance, which is a fine stable emulsion, must be considered as a whole, where hydrophobic molecules are perfectly emulsified and water dispersed and therefore, the behaviour toward biodegradation has been well described in the performed biodegradability test and even better and more correctly described than using other approaches.

You further note that the ready biodegradability study reported in the dossier is deemed valid, conclusive and thus suitable for assessment without restrictions. You refer to various documents, the CLP Regulation, ECHA Guidance R.7b and OECD Revised Introduction to the OECD Guidelines for Testing of Chemicals. Section 3. Part 1: Principles and Strategies Related to the Testing of Degradation of Organic Chemicals where it is discussed that for ready biodegradability tests 60% (when based on oxygen demand or carbon dioxide evolution measurements) or 70% (when based on dissolved organic carbon measurements) removal reached in a 10-day window within the 28-day period of the test practically represents complete ultimate degradation of the test substance and that such tests might be relevant to examine the ready biodegradability of mixtures of structurally similar chemicals and that for substances with structurally similar constituents (chemicals) or mixtures of homologous

compounds 10-day window should not be applied to interpret the results of the test. You sumarise that the reported study shows rapid, ready and ultimate biodegradation of the whole Substance.

Also you note that it seems reasonable to think that some concern is raised by the potentially relevant amount of chlorinated paraffins in the Substance. You refer to the updated dossier of medium-chain chlorinated paraffins (MCCPs) published on the ECHA website and note that in the studies where bioavailability of MCCPs was increased it was demonstrated that MCCPs up to 50% chlorination by weight are readily biodegradable while MCCPs of the 50-60% chlorination by weight are inherently biodegradable. One important conclusion from this work is that MCCPs cannot degrade into short-chain chlorinated paraffins as the chain-shortening reaction will involve oxidation of the molecule to a fatty acid. Thus, concern for MCCPs is strictly related to the chlorine content in the molecule (more than 40-50 %). You note that from the analytical identification of different batches of the starting material to obtain the Substance, it is evident that the total chlorine percentage is set between [redacted] which will also result in a less chlorine percentage in the final product, due to the saponification reaction and beta-elimination of hydrogen chloride.

Finally, you note that in the reported study the "steady state" has not been reached yet and the biodegradation process can continue further. To better assess the potential for a complete degradation of the Substance, excluding any concern for persistency, a test (preferably according to OECD 301B) can be performed, up to 60-90 days. In this respect you ask for the possibility to postpone the indicated deadline to submit the updated dossier from 9 months to 18 months.

In response to your comment on the difficulty to define the the worst case constituent(s), you should note that the worst-case constituent(s) are to be predicted in regard of the property under consideration (e.g. ready biodegradability). Intrinsic property is not dependent on the quantity/concentration of the constituent in the fraction or substance. Instead, the selection of the most (suspected) persistent constituent must consider, as noted above, at least, the carbon chain length, branching, chlorine content, presence of multi-bonds (unsaturated constituents) and possible impact of sulphonation of the constituents.

As provided in ECHA Guidance R.11 (p. 109), you can first screen the known constituents of the Substance. Hereby assessment approaches applied to pure (i.e. mono-constituent) substances can be applied (e.g. using experimental data, read across, QSARs). Testing, if necessary, is done by using individual constituents (or their surrogates) as test items. Furthermore, it is correct that one fraction cannot completely represent the behaviour of the Substance (unless this is a fraction of constituents which are to such extent similar that their degradation property can be predicted to follow a regular predictable pattern and it can be justified that such fraction represents the worst-case degradation property comparing to constituents from other fractions of the Substance) and that ready biodegradability tests with pass levels of 60-70% of removal reached within the 28-day period are relevant to examine the ready biodegradability of only mixtures of structurally similar chemicals. Therefore, in regard of ready biodegradability the Substance should be profiled by dividing it in the fractions of structurally similar (homologous) constituents and identifying the most (suspected) persistent constituent(s) in each of these fractions. Only relevant constituents, as explained in ECHA Guidance R.11, should be considered for the profiling.

As already acknowledged above, the Substance is considered as a complex mixture of various constituents. However, based on the information provided in the registration dossier the Substance consists of constituents from chemically different fractions (e.g. saturated sulfochlorinated paraffins, saturated sulfoparaffins, unsaturated sulfochlorinated paraffins, unsaturated chlorinated paraffins, saturated and unsaturated paraffins) that are expected to

have different properties. Once representative worst-case constituent(s) from each fraction of the Substance are selected, such constituent(s) should be synthesised or isolated for the testing. Such isolated or synthesised test material may include a pure suspected worst-case constituent or alternatively, a number of homologous structurally similar constituents with maximised concentration of a worst-case constituent or alternatively, constituents which are to such extent similar that their degradation property can be predicted to follow a regular predictable pattern.

It is not clear from your comments why the separation of the Substance is limited to two fractions (hydrophilic and lipophilic) only and further separation and isolation or synthesis of constituent(s) of interest is not possible. E.g. further separation could be achieved through the use of different extraction solvents, other extraction techniques and/or chromatographic techniques (e.g. gel permeation chromatography, adsorption chromatography, HPLC chromatography testing different stationary and/or mobile phases).

As explained above, ready biodegradability of each constituent of the Substance cannot be concluded on the basis of results of the key study performed on the whole Substance. According to OECD TG 301 for substances poorly soluble in water, an emulsifier which gives a stable dispersion of the chemical may be used. It should not be toxic to bacteria and must not be biodegraded or cause foaming under test conditions. The same criteria apply to solvents as to the emulsifiers. Thus, for testing of poorly soluble in water constituent(s) of the Substance emulsifiers and solvents can be used to enhance bioavailabiity of such constituent(s), but degradation of emulsifier (in terms of parameter followed in the test, e.g. consumption of oxygen or evolution of carbon dioxide) should be separated from degradation of the constituent(s).

There are many constituents that are structurally different from linear saturated MCCPs (which are addressed in the substance evaluation report at https://echa.europa.eu/documents/10162/a72b228a-e417-5b53-b2b9-3b45c8e6eec5) present in the composition of the Substance. Furthermore, even in the substance evaluation report for MCCPs it is noted that chlorine content is a key factor in degradation behaviour regardless of carbon chain length, the actual influence of carbon chain length is unknown. Thus, ready biodegradability of all, not only MCCPs, constituents (e.g. unsaturated and/or branched chlorinated paraffins etc.) of the Substance needs to be addressed taking into account various structural differences of the constituents present in the composition of the Substance.

For all these reasons, relevant constituent(s) from various fractions of the Substance have to be tested. As explained above, the test material may include a pure suspected worst-case constituent or alternatively, a number of homologous structurally similar constituents with maximised concentration of worst-case constituent or alternatively, constituents which are to such extent similar that their degradation property can be predicted to follow a regular predictable pattern. You may start the testing with the worst-case constituent(s) of the Substance. If the test result shows that constituent(s) to be readily biodegradable, you may consider justifying that all other constituents of the Substance could also be readily biodegradable.

The request for extention of deadline is addressed in the Appendix E below.

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

1. **Revised PBT and vPvB assessment (Article 14 (3)(d) in conjunction with Annex I, Section 4 and Annex XIII)**

According to Article 14 (3) of the REACH Regulation a chemical safety assessment of a substance shall include persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment. Annex I, Section 4 of the REACH Regulation notes that the objective of the PBT and vPvB assessment shall be to determine if the substance fulfils the criteria given in Annex XIII and if so, to characterise the potential emissions of the substance. Pursuant to Annex XIII of the REACH Regulation the identification of the PBT and vPvB substances shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products.

ECHA Guidance R.11 explains that the term "constituent" refers to the main constituents, impurities and additives of substances of well-defined composition and constituents of UVCB substances. Furthermore, in this Guidance document it is noted that the registrant should make efforts for carrying out a PBT/vPvB assessment for all constituents, impurities and additives present in concentrations $\geq$ 0.1% (w/w). Similar arguments apply to relevant transformation/degradation products. The PBT/vPvB assessment should normally be carried out for each relevant transformation or degradation product.

You have reported results of PBT/vPvB assessment in the document attached in section 2.3 of your dossier. For the PBT/vPvB assessment you use combination of two approaches "Whole substance approach" with use of the experimental data on the whole Substance (used for persistence and toxicity assessment) and on source substance (EC 269-145-7) (used for persistence assessment) and "Fraction profiling" based on estimations of various properties by QSAR models (used for bioaccumulation and persistence assessment). As a result of your assessment you have concluded that substance is neither P or vP, nor B, nor T.

ECHA notes the following shortcomings with regards to your PBT/vPvB assessment:

Applicability of the "Whole substance approach"

According to the ECHA Guidance R.11 under the "Whole substance approach" "*The substance is considered to be one chemical substance for the purpose of the assessment and testing. This is possible, if all the constituents therein can be justified to be very similar with regard to the PBT-properties relevant for the assessment based on information on, e.g. manufacturing method, raw materials and/or chemical composition/analyses.*"

As noted in the Appendix A, section 1 above, ECHA observes that in the composition of the substance reported in the registration dossier there is a number of constituents from different fractions that are expected to have different properties. More specifically, biodegradability, bioaccumulation and aquatic toxicity of constituents of the Substance might be affected by structural differences of constituents between and within fractions.

Therefore, ECHA considers that it cannot be concluded on the persistence and aquatic toxicity of each constituent of the Substance on the basis of results of studies performed on the whole Substance.

Use of information generated with the source substance

Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies).[3]

In the PBT/vPvB assessment document you refer to the ready biodegradability study conducted with another substance other than your Substance. You have not provided documentation as to why this information is relevant for your Substance.

In the absence of such documentation, ECHA cannot verify that the properties (in this case biodegradability) of your Substance can be predicted from the data on the source substance.

Use of information generated with QSAR models

Annex XI, Section 1.3. states that results obtained from valid QSAR models may be used instead of testing when the cumulative conditions are met, in particular adequate and reliable documentation of the applied method is provided.

According to ECHA's Practical guide "How to use and report (Q)SARs", section 3.4, a QSAR Model Reporting Format (QMRF) and a QSAR Prediction Reporting Format (QPRF) 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 the PBT/vPvB assessment document you refer to the use of QSAR models for persistence and bioaccumulation assessment.

You have not provided any documentation for the QSAR predictions. In particular, you have not included a QMRF and/or a QPRF in your technical dossier. Therefore, ECHA cannot establish whether the model is scientifically valid, whether the Substance or constituents of it for which QSAR estimations were carried out fall within the applicability domain of the model, and whether the results are adequate for PBT/vPvB assessment as well as for classification and labelling and/or risk assessment.

Prediction of bioaccumulation potential for the surface-active substances

To predict bioaccumulation potential for a substance on the basis of the octanol-water partitioning coefficient (Kow) the Kow should be a valid descriptor of the bioaccumulation of such substance and reliable information should be provided for Kow.

ECHA notes that log Kow is not considered a valid descriptor of the bioaccumulation potential and measured BCF values are preferred for surface-active substances (ECHA Guidance R.7c, Appendix R.7.10-3).

In the document summarising results of the PBT/vPvB assessment provided in the IUCLID dossier you note that "*The screening criteria will be based, in first instance, on the Log Kow and BCF values*".

The surface tension of the Substance reported in the dossier is 34.0 mN/m at 20 °C. This means that the Substance reduces surface tension of water which is app. 72 mN/m at 20 °C. This indicates that some of the constituents of the Substance are surface-active and therefore, partition to lipids may not be the sole driver of bioaccumulation for these

[3] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.6.1

constituents. Accordingly, Log Kow is not a valid descriptor of the bioaccumulation potential for these surface-active constituents of the Substance.

Thus, based on the above listed shortcomings ECHA considers that information used for the PBT/vPvB assessment of the Substance, including relevant constituents is not adequate.

In your comments to the draft decision, you agree to revise PBT and vPvB assessment. Furthermore, you note that will provide necessary documentation for the data generated with the source substance and generated by application of QSARs taking into account applicability domain of applied QSARs.

Summarising, you consider the "whole substance" approach as the most appropriate for evaluating persistency, bioaccumulation and toxicity of the assessed substance.

Moreover, you propose to perform a new test on biodegradation to evaluate the complete curve of degradation and ask for the possibility to postpone the indicated deadline to submit the updated dossier from 9 months to 18 months.

As already explained above, in the composition of the Substance reported in the registration dossier there are a number of constituents from different fractions (saturated sulfochlorinated paraffins, saturated sulfoparaffins, unsaturated sulfochlorinated paraffins, unsaturated chlorinated paraffins, saturated and unsaturated paraffins) that are expected to have different properties, in particular, in terms of solubility, emulsifying properties, log Kow, bioaccumulation, ecotoxicityand biodegradability. Thus, it cannot be concluded on the ready biodegradability (for persistence assessment) and aquatic toxicity of each constituent of the Substance on the basis of results of studies performed on the whole Substance. However, e.g. simulation degradation studies and bioaccumulation study in fish on the whole Substance might be relevant for persistence and bioaccumulation assessment respectively, e.g. if constituent-specific analytical monitoring of relevant constituents of the Substance is feasible and is conducted in the study.

The request for extention of deadline is addressed in the Appendix E below.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation you are requested to provide a revised PBT and vPvB assessment of relevant constituents and degradation products.

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[4].

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 identify all the constituents as far as possible as well as their concentration (OECD GLP (ENV/MC/CHEM(98)16) and EU Tests Methods Regulation (EU) 440/2008 (Note, Annex). Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.
   - The reported composition must also include 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[5].

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

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

A. 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 synthetize 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 22 May 2019.

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

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

ECHA took into account your comments and amended the deadline.

Registrant requested prolongation of timeline

The timeline indicated in the draft decision to provide the information requested is 9 months from the date of adoption of the decision.

In your comments on the draft decision, you requested an extension of the timeline to 18 months. You justified your request stating that you wanted to select the whole substance approach and to extend the duration of the test up to 60-90 days to better assess the potential for a complete degradation of the Substance.

As explained in ECHA Guidances R.11 and R.7b, positive results from the enhanced readily biodegradability tests may be used together with other supporting information to conclude that a substance is not P/vP. Among other conditions which should be followed for the enhanced tests it is noted that the test duration should never been extended beyond 60 days. However, as already noted above, constituents from different fractions are expected to have different properties, including biodegradability and that ready biodegradability of each constituent of the Substance cannot be concluded on the basis of results of the study performed on the whole Substance. Therefore, deadline is extended by 3 months, if for any of constituent(s) ready biodegradability test would need to be enhanced from standard 28 days to 60 days duration.

Therefore, ECHA has only partially granted the request and set the deadline to 12 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.

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Appendix F: List of references - ECHA Guidance[6] 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)[7]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[7]

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[8]

[6] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[7] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[8] 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]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[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.