Helsinki, 15 December 2020

Addressees

Registrants of Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol listed in the last Appendix of this decision (registrant(s)[1])

Decision/annotation number

Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F)

Registered substance subject to this decision, hereafter 'the Substance'

Substance name: Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol (OAPP)
EC number: 700-960-7
CAS number: -

DECISION ON SUBSTANCE EVALUATION

Based on Article 46(3) of Regulation (EC) No 1907/2006 (REACH), ECHA requests you to submit the following information on the Substance and constituents of the Substance, as specified under the individual requests below:

Environment:

Request 1: Aerobic mineralisation in surface water – simulation biodegradation test (OECD TG 309) on the constituent 1,1,3-trimethyl-3-phenylindan (CAS 3910-35-8), as specified in Appendix 1:

- The test has to be performed at a temperature of 12°C.
- You must minimise any losses of the test substance due to volatilisation.
- You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids.
- Non-extractable residues (NER) must be quantified and the reporting of results must include a scientific justification of the used extraction procedures and

[1] The terms registrant(s), dossier(s) or registration(s) are used throughout the decision, irrespective of the number of registrants addressed by the decision.

solvents.

- The constituent shall be radiolabelled due to its low water solubility and the consequentially low concentration of the substance in the test.

Should it prove technically unfeasible to perform the water degradation test, a sediment simulation degradation test will be needed instead (*Aerobic and anaerobic transformation in aquatic sediment systems - OECD TG 308)*.

The OECD TG 308 must be performed, as specified in Appendix 1:

- The test has to be performed at a temperature of 12°C.
- You must minimise any losses of the test substance due to volatilisation.
- Non-extractable residues (NER) must be quantified and the reporting of results must include a scientific justification of the used extraction procedures and solvents.
- The constituent shall be radiolabelled.
- Sterile water-sediment controls must be included in the test to determine to what extent the test substance decrease is due to biotransformation or to potential abiotic losses.

Request 2: Identification and clarification of composition and structure of C9 trimers present in the Substance, as specified in Appendix 1

Deadline to submit the requested information

You have to provide an update of the registration dossier(s) containing the requested information, including robust study summaries and an update of the chemical safety report by the deadline(s) indicated below.

Request 1 and 2: The information required shall be generated and provided **by 20 September 2022,** as explained in Appendix 1.

In addition to the robust study summaries, you shall submit the full study report for request 1 by the same deadline, by attaching it to the relevant endpoint studies record in IUCLID.

Appendix 1: Section 4. provides further details of how the deadlines were derived.

Appendices

The reasons of this decision and any further test specifications of the requirements are set out in Appendix 1. The procedural history is described in Appendix 2. Further information, observations and technical guidance as appropriate are provided in Appendix 3. Appendix 4 contains a list of registration numbers for the addressees of this decision. This appendix is confidential and not included in the public version of this decision.

Who performs the testing?

Based on Article 53 of the REACH Regulation, you are requested to inform ECHA who will carry out the study/ies on behalf of all registrant(s) within 90 days. Instructions on how to do this are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has a suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals

Authorised[2] by Christel Schilliger-Musset, Director of Hazard Assessment

[2] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

Based on the evaluation of all relevant information submitted on Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol and other relevant available information, ECHA concludes that further information is required to enable the evaluating Member State competent authority (MSCA) to complete the evaluation of whether the Substance constitutes a potential risk to the environment.

The evaluating MSCA will subsequently review the information submitted by you and evaluate if further information should be requested in another decision to clarify the concern, according to Article 46(3) of REACH.

1. The potential risk – environment

The identification of a potential risk is based on a combination of exposure and hazard information.

According to information in the registration dossier, the Substance is used in formulation of rubber, in coatings, in adhesives and in inks. The type of use includes industrial, professional and consumer use, e.g. [redacted] Significant exposure to the environment cannot be excluded.

Based on the requested information and information from the published literature, as detailed below, there is a concern that the Substance may be a potential PBT or vPvB substance as defined in Annex XIII to REACH.

Based on this exposure and hazard information, there is a potential risk for the environment. As the available information is not sufficient to conclude on the potential PBT/vPvB properties, further information is needed, as explained below.

2. The possible risk management measures – environment

There are currently no EU-wide regulatory risk management measures in place for the Substance. If the obtained data from the Requests are sufficient to confirm the suspected PBT/vPvB properties as defined in REACH Annex XIII, the evaluating MSCA will assess the need for further regulatory risk management in the form of identification as a substance of very high concern (SVHC) under Article 57 of REACH and subsequent authorisation or

restriction of the Substance.
While the current decision does not address the concern for endocrine disrupting (ED) properties in the environment, it should be noted that the Substance could possibly be identified as a substance of very high concern because of its ED properties in the environment under Article 57(f) of REACH. However, this remains to be confirmed. The identification of the Substance as PBT/vPvB would lead to an immediate requirement for minimisation of exposure and emissions to humans and the environment according to Section 6.5, Annex I to REACH. This requirement does not automatically apply to substances identified under Article 57(f) (e.g. due to their ED properties). Therefore, there would be an additional benefit of possible PBT/vPvB identification and identification as SVHC under Article 57 (d) or (e) in addition to possible SVHC identification under Article 57 (f).

3. Explanation of the testing strategy – environment

In respect to the vPvB/PBT properties, a 'reverse PBT testing strategy' was applied for the Substance with bioaccumulation testing (tier 1) requested before persistency testing (tier 2). The information requested in this decision partly represents the beginning of tier 2 to clarify the concerns for persistency.

Based on results from the bioaccumulation and persistency testing, a third tier of the PBT testing strategy may be triggered. If constituents of the Substance are concluded to meet the criteria for P- and B- of Annex XIII to REACH, these constituents may need to be evaluated with regard to the criteria for toxicity.

REQUEST 1 (simulation biodegradation test (OECD TG 309)): The concern(s) identified

Under the last introductory paragraph of Annex XIII to REACH, the identification of PBT/vPvB properties of a substance must also take account of those properties of relevant constituents of the substance.

Based on the results of the OECD TG 305 dietary study performed on the Substance, ECHA considers the dimer fraction of the Substance to fulfil the 'B'-criterion of BCF>2000 and the trimer fraction of the Substance to fulfil the 'B' and 'vB'-criterion of BCF>5000, as set out in Annex XIII to REACH. According to ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB assessment, June 2017, Section R.11.4.1, a constituent should normally be considered relevant for the PBT/vPvB

assessment when present in a concentration of ≥ 0.1% (w/w). For the PBT assessment of this substance, the evaluating MSCA considers that the dimer and trimer fractions are both relevant due to their concentrations. The dimers and trimers therefore need to be evaluated for P properties.

Why new information is needed

Only a few experimental data exists for the Substance and its constituents addressing persistency. No simulation tests are available for the Substance.

A ready biodegradability test with the Substance was conducted according to OECD TG 310. After 28 days the test item attained 4 % degradation. Based on these results the Substance is not readily biodegradable and therefore fulfils the screening criterion for persistence.

A ready biodegradability test equivalent to OECD TG 301 C has been carried out with the dimer of C9 constituent 1,1'-(1,1-dimethyl-3-methylene-1,3-propanediyl)bisbenzene (CAS 6362-80-7). After 28 days the test item showed 0 % degradation as measured by oxygen consumption and 4 % degradation as measured by HPLC analysis. The test substance was therefore not readily biodegradable (NITE 2002). In the registration dossier for CAS 6362-80-7, a modified MITI (II) test (302C) reports 18% degradation based on oxygen consumption after 14 days and 64% after 28 days. Compound specific analysis showed primary degradation of 82% after 28 daysin deionised water.

Based on the gathered information, the constituent 1,1'-(1,1-dimethyl-3-methylene-1,3-propanediyl)bisbenzene in the dimer fraction could be P as the MITI (II) test does not reach 70% mineralisation in 14 days and no information is available on the lag phase.

Table R.11-4 of the ECHA Guidance R11 on PBT assessment (ECHA, 2017a), states that a substance is potentially P or vP if Biowin 2 or 6 predictions are below 0.5 and Biowin 3 is below 2.25. Table 1 summarises the Biowin results for 1,1'-(1,1-dimethyl-3-methylene-1,3-propanediyl)bisbenzene. The PBT guidance indicates that cases where the Biowin 2 and 6 criteria are fulfilled, but Biowin 3 is between 2.25 and 2.75 are borderline cases that warrant more data to conclude on persistence. Based on the result of the MITI (II) test and the Biowin scores, the constituent 1,1'-(1,1-dimethyl-3-methylene-1,3-propanediyl)bisbenzene may be regarded as a borderline case.

However, according to Biowin it is not likely to be the most persistent dimer as the dimer constituent 1,1,3-trimethyl-3-phenylindan has lower Biowin 2 and 3 scores.

ECHA therefore requests simulation biodegradation testing on 1,1,3-trimethyl-3-phenylindan to clarify whether this dimer constituent fulfils the P criterion in surface water.

Table 1 Biowin results for constituents 1,1'-(1,1-dimethyl-3-methylene-1,3-propanediyl)bisbenzene and 1,1,3-trimethyl-3-phenylindan calculated by the evaluating MSCA. Biowin 2, 3 and 6 mentioned in the PBT guidance (ECHA, 2017a) are in bold.

	1,1'-(1,1-dimethyl-3-methylene-1,3-propanediyl)bisbenzene (CAS 6362-80-7)		**1,1,3-trimethyl-3-phenylindan (CAS 3910-35-8)**	
Biowin	**Prediction**	**Result**	**Prediction**	**Result**
Biowin 1	Biodegrades fast	0.7030	Does not biodegrade fast	0.3953
Biowin 2	**Biodegrades fast**	**0.8216**	**Does not biodegrade fast**	**0.1197**
Biowin 3	**Weeks-months**	**2.5087**	**Weeks-months**	**2.2746**
Biowin 4	Days-Weeks	3.3631	Weeks	3.2047
Biowin 5	Not readily degradable	0.2214	Not readily degradable	0.2391
Biowin 6	**Not readily degradable**	**0.1023**	**Not readily degradable**	**0.1068**
Biowin 7	Does not biodegrade fast	0.2963	Does not biodegrade fast	0.8318

Considerations on the test method

Testing in water is considered appropriate since the predicted water solubility for 1,1,3-trimethyl-3-phenylindan (CAS 3910-35-8) (WATERNT v1.01: 0.0339 mg/l; WSKOWWIN v1.42: 0.2525 mg/L) (EPI Suite v4.11) indicates that it would be technically possible. ECHA Guidance R11 explains that the aquatic compartment is considered to be a relevant environmental compartment for persistence assessment because the criteria for B/vB and T are mainly based on tests performed in this compartment. In addition, the water compartment receives a significant amount of emissions and once entering water, a substance may reside there for a very long time and be spread over long distances before it reaches other environmental compartments.

You must perform the test, by following the pelagic test option in OECD TG 309 with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (ECHA Guidance R.11.4.1.1.3.).

The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Table R.16-8, ECHA, 2016) and is in line with the applicable test conditions of the OECD TG 309.

As specified in ECHA Guidance R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test substance concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Therefore, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded parent. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website[3].

The test shall be performed on 1,1,3-trimethyl-3-phenylindan (CAS 3910-35-8) selected as a worst-case representative of the C2 dimers as it is predicted to be the most stable based on QSAR results. The constituent shall be radiolabelled due to its low water solubility

[3] https://echa.europa.eu/documents/10162/13632/bg_note_addressing_non-extractable_residues.pdf/e88d4fc6-a125-efb4-8278-d58b31a5d342

and the consequentially low concentration of the substance in the test. You shall provide justification for the location of the radiolabel on the molecule.

The test must be conducted in closed bottles to minimise any losses of the test substance due to volatilisation. The predicted Henry's law constant for the constituent is 7.25 10^{-4} atm·m^3/mol (HenryWIN v3.20 in EPI Suite 4.11) and according to OECD TG 309 "*Using closed flasks with a headspace, it is possible to test slightly volatile substances (with Henry's law constants <100 Pa · m^3 /mol or <10^{-3} atm · m^3/mol) without losses from the test system*."

ECHA notes that communication with the eMSCA is possible in case you wish to have a mutual discussion on the technical feasibility of performing the OEDC TG 309.

Should it prove technically unfeasible to perform the water degradation test, a sediment simulation degradation test will be needed instead (*Aerobic and anaerobic transformation in aquatic sediment systems - OECD TG 308)*.

Similarly for the OECD TG 309 test, the OECD TG 308 must be performed, as specified:

- The test has to be performed at a temperature of 12°C.
- You must minimise any losses of the test substance due to volatilisation.
- Non-extractable residues (NER) must be quantified and the reporting of results must include a scientific justification of the used extraction procedures and solvents.
- The constituent (CAS 3910-35-8) shall be radiolabelled.

Furthermore, sterile water-sediment controls must be included in the OECD TG 308 test to determine to what extent the test substance decrease is due to biotransformation or to potential abiotic losses (e.g. volatilisation, formation of non-extractable residues (NER)).

ECHA notes that it is important to ensure that test conditions in the sterile controls and the active test bottles are as identical as possible. A precondition for conclusion on degradation is that other removal processes are not assessed as degradation. With this aim it is necessary to compare processes observed in sterile controls with those observed in the active test bottles under comparable test conditions.

Therefore, other test specifications of the sterile control bottles, such as the headspace volume, sampling times, analytical measurements as well as any potential causes of disturbance (such as aeration events) that might affect the distribution of the test

substance or that could cause leakage, must be the same as in the active water-sediment test bottles, to ensure comparability.

OECD TG 308 does not include instructions for a sterile control. However, OECD TG 309 gives guidance on the preparation of sterile water controls as well as sterile controls containing water with sediment added in large amounts. Furthermore, ECHA notes that the OECD TG 308 test (ECHA, 2018) for decamethylcyclopentasiloxane (EC 208-764-9), as well as other published water-sediment degradation simulation studies (e.g. Liu et al. 2013; Shrestha et al. 2016, 2020) included sterile controls and can provide guidance on the preparation of sterile controls. In these studies the sterilisation was done either by the addition of sodium azide, autoclaving or both. In addition, in another publication (Otte et al. 2018) different methods for sterilisation of marine sediment were compared.

The selection of the sterilisation method and time to perform the sterilisation in the sterile water-sediment controls, e.g. before or after the acclimation period specified in the paragraph 31 of OECD TG 308, may have an effect on the sediment properties. Based on Otte et al. (2018), thermal sterilisation, gamma radiation and chemical sterilisation have all advantages and disadvantages. Considering the importance of the integrity of the sediment phase to produce meaningful results for comparison to unsterilised conditions, ECHA recommends to use methods that have the least impact on the mineral phases and the geochemistry of the sediment. OECD TG 309 indicates that the sorption characteristics of the sediment may be altered by autoclaving. According to Otte et al. (2018) autoclaving and gamma radiation lead to a large increase in dissolved organic carbon and have impacts on the mineral phase, while chemical sterilisation seems to be the method that would likely have the least impact on the geochemistry of the sediment phase. However, it should be noted that chemical sterilisation may also affect some sediment properties, e.g. triggering changes in pH.

In conclusion, you must explain and justify the methods and procedure used for establishing the sterile controls in the study report, and determine the efficiency of the sterilisation by measurements of microbial biomass. OECD TG 308 indicates that the microbial biomass of both water and sediment must be measured at post-handling, test start and test end, and mentions methods for that. Finally, ECHA notes that communication with the eMSCA is possible in case you wish to have a mutual discussion on the preparation of the sterile controls.

You shall submit the full study report for Request 1. A complete rationale of test design and interpretation of results and access to all information available in the full study report (implemented method, raw data collected, interpretations and calculations, consideration of uncertainties, argumentation, etc.) are needed. This will allow the evaluating MSCA to fully assess all the provided information, including the statistical analysis, and to efficiently clarify the concern for Persistency.

The requested simulation test OECD TG 309 (or OECD TG 308 if OECD 309 is not technically feasible) is a standard information requirement at Annex IX, Section 9.2.1.2/9.2.1.4 of REACH. It could therefore be subject to a compliance check under Article 41 of REACH. However, the requested study is to be performed on a constituent of the Substance. In addition, the need to use non-standard parameters was discussed during decision making. Since the information request is based on a potential risk that the Substance poses, the request is necessary under the current substance evaluation.

Alternative approaches and proportionality of the request

The request for simulation testing is suitable and necessary to obtain information that will allow to clarify whether there is a potential risk for PBT/vPvB.

Alternatively, enhanced ready biodegradation testing could be requested as was described in the original draft decision. However, the available data does not indicate that an enhanced ready test is expected to clarify the persistency concern. Therefore a proposal for amendment was received, proposing to instead request simulation testing. According to ECHA PBT guidance (ECHA, 2017a) screening level testing (e.g. enhanced ready biodegradation) can be used to remove a concern for persistency but may not allow a firm conclusion on P or vP. As less stable constituents in the Substance have failed to demonstrate sufficient biodegradation to remove the concern for persistency, the chosen worst-case constituent is unlikely to show more biodegradation, which would be needed to remove the need for simulation testing. Requesting an enhanced ready test would therefore likely lead to unnecessary delay as well as use of resources, as simulation testing is likely to be needed to clarify the concern.

In your comments on the proposal for amendment, you disagree with the request for simulation testing on CAS 3910-35-8 and prefer to conduct an enhanced ready biodegradation test. In your view, an enhanced ready biodegradation test on CAS 3910-35-8 would allow to conclude whether it is P or not P. You argue that a

simulation test can be used to clarify a vP concern, however as the dimer is not vB such clarification is not needed and it is sufficient to clarify whether or not CAS 3910-35-8 meets the P criterion.

ECHA disagrees with your comments as the point of the requested simulation test indeed is to clarify whether the dimer constituent fulfils the P criterion. Performing simulation testing is the most direct way of producing data that can be compared to this criterion. As described above, the enhanced ready biodegradation is in contrast unlikely to clarify the concern.

REQUEST 2 (C9 trimer composition): The concern(s) identified

As mentioned above, the eMSCA considers the trimers to fulfil the B and vB criteria and therefore it should be evaluated whether this fraction also fulfil the PBT and vPvB criteria.

Why new information is needed

Identification and clarification of the composition and structure of C9 trimers are needed in order to enable evaluation of the persistency of the group of constituents. Currently, structures and composition of this fraction are only hypothetical based on likely reaction products.

Based on this information, a simulation degradation study may be requested to clarify whether the trimer fraction fulfil the P and/or vP criteria. The information requested is therefore vital to enable and pinpoint further testing decisions, if any.

Considerations on the test method

Analytical examination and verification of the composition and structure of the trimers of C9 are needed as much as technically feasible. Such information could be obtained through nuclear magnetic resonance spectroscopy, GC-MS or other analytical techniques capable of separating and identifying the constituents in the trimer fraction.

Alternative approaches and proportionality of the request

Trimers could be assessed P based on a read across approach if the dimer fraction potentially is evaluated to be P as well. However, as the trimer fraction is considered vB and the dimer fraction is unlikely to be vP, read across from this fraction will not be adequate to clarify the vPvB concern for the trimers. In your comments on the draft

decision you agree with the suggested approach and the request to identify and clarify the composition and the structure of C9 trimers.

4. Consideration of the time needed to perform the requested studies

The deadline[s] for provision of the requested data take[s] into account the time required for developing an analytical method, conduct of the study according to the test guideline, preparation of the study report and reporting in IUCLID.

For Request 1, ECHA considers that 18 months is usually sufficient time for conduct and reporting of an OECD TG 309 study. This is the standard deadline used by ECHA for a single simulation test. For Request 2, ECHA considers that 6 months is sufficient time for clarifying the composition and reporting. It is assumed that Requests 1 and 2 can be performed in parallel and a deadline of 18 months is therefore allocated for all requests of the present decision.

5. References

ECHA 2016 Guidance on information requirements and Chemical Safety Assessment, Chapter R.16 - Environmental exposure assessment (version 3.0, February 2016).

ECHA 2017a. Guidance on information requirements and chemical safety assessment, Chapter R.11 – PBT/vPvB assessment (version 3.0, June 2017).

ECHA 2017b. Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017).

ECHA 2018. Member State Committee support document for identification of dodecamethylcyclohexasiloxane (D6) as a substance of very high concern because of its PBT and vPvB properties (Article 57 D&E) adopted on 13 June 2018. https://echa.europa.eu/documents/10162/a9682f4b-fc3e-cd99-3db9-b0f9f383c3c5

Liu YS, Ying GG, Shareef A, Kookana RS 2013. Degradation of six selected ultraviolet filters in aquifer materials under various redox conditions. Groundwater Monitoring & Remediation, 33(4):79-88.

NITE (National Institute of Technology and Evaluation, Japan), 2002.

Readily biodegradation test with 1,1’-(1,1-dimethyl-3-methylene-1,3-Propanediyl)bisbenzene (CAS RN 6362-80-7) from existing chemicals survey conducted by the Japanese Government. Study Report (in Japanese).

Otte J, Blackwell N, Soos V, Rughöft S, Maisch M, Kappler A, Kleindienst S, Schmidt C, 2018. Sterilization impacts on marine sediment---Are we able to inactivate microorganisms in environmental samples?, FEMS Microbiology Ecology, 94(12): 10.1093/femsec/fiy189. doi:10.1093/femsec/fiy189

Shrestha, P., Junker, T., Fenner, K., Hahn, S., Honti, M., Bakkour, R., Diaz, C., Hennecke, D. (2016). Simulation Studies to Explore Biodegradation in Water–Sediment Systems: From OECD 308 to OECD 309. Environ. Sci. Technol. 50 (13): 6856-6864.

Shrestha, P., Meisterjahn, B., Hughes, C.B., Mayer, P., Birch, H., Hennecke, D. (2020): Biodegradation testing of volatile hydrophobic chemicals in water-sediment systems – Experimental developments and challenges. Chemosphere, 238 (January 2020).

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after 25 June 2020.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to Suspected PBT and Potential endocrine disruptor, Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol EC No 700-960-7 was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2012. The CoRAP was published on the ECHA website on 29 February 2012. The competent authority of Denmark (hereafter called the evaluating MSCA) was appointed to carry out the evaluation.

In accordance with Article 46(1) of the REACH Regulation, a substance evaluation decision was issued on 24 February 2014 requesting further information. You submitted all the requested information on 28 February 2018. The evaluating MSCA carried out the evaluation of the information in your updated registration(s) and other relevant and available information.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns: Environmental ED effects and PBT/vPvB. Therefore, it prepared a draft decision under Article 46(3) of the REACH Regulation to request further information. It subsequently submitted the draft decision to ECHA on 26 February 2019.

The decision making followed the procedure of Articles 50 and 52 of the REACH Regulation as described below.

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

Registrant(s)' commenting phase

ECHA received comments from you and forwarded them to the evaluating MSCA without delay.

The evaluating MSCA took the comments from you, which were sent within the commenting period, into account and they are reflected in the reasons (Appendix 1). The request(s) and the deadline were amended.

You agreed to the requests needed to clarify the PBT/vPvB concern with a modification to the requested enhanced ready biodegradation test. Since the draft decision you have updated your dossier to include a read across to a positive FSDT study (OECD TG 234) for the phenolic fraction and therefore the ED concern is considered clarified.

Proposals for amendment by other MSCAs and ECHA and referral to the Member State Committee

The evaluating MSCA notified the draft decision to the competent authorities of the other Member States and ECHA for proposal(s) for amendment.

Subsequently, the evaluating MSCA received proposals for amendment to the draft decision and modified the draft decision.

ECHA invited you to comment on the proposed amendments.

Your comments on the proposed amendments were taken into account by the Member State Committee.

Based on the received proposals for amendment, the requested enhanced ready biodegradation test was replaced with a simulation biodegradation test.

MSC agreement seeking stage

The Member State Committee reached a unanimous agreement in its MSC-72 written procedure and ECHA took the decision according to Article 52(2) and Article 51(6) of REACH.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided by you in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on your dossier(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

2. Failure to comply with the request(s) in this decision, or to otherwise fulfil the information request (s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the required experimental study/ies, the test materials for each study are as specified in Section 1.

4. In relation to the experimental stud(y/ies) the legal text foresees the sharing of information and costs between registrant(s) (Article 53 of the REACH Regulation). You are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who will carry out the study on behalf of the other registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at: https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx?CaseNumber=DEC-SEV-700-960-7-1-1
   Further advice can be found at http://echa.europa.eu/regulations/reach/registration/data-sharing. If ECHA is not informed of such agreement within 90 days, it will designate one of the registrants to perform the stud(y/ies) on behalf of all of them.