Helsinki, 11 April 2018

Substance name: Phenol, 4-methyl-, reaction products with dicyclopentadiene and isobutylene
EC number: 271-867-2
CAS number: 68610-51-5
Date of latest submission(s) considered[1]: 24 November 2016
Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F)
Addressee(s): Registrant(s)[2] of Phenol, 4-methyl-, reaction products with dicyclopentadiene and isobutylene (Registrant(s))

DECISION ON SUBSTANCE EVALUATION

Based on Article 46(1) of the REACH Regulation (Regulation (EC) No 1907/2006), you are requested to submit the following information:

- **Bioaccumulation in fish; test method OECD 305: Bioaccumulation in Fish: Aqueous and Dietary Exposure with specific constituents of the registered substance using the dietary exposure route.** An equal mixture[3] of the representative constituents of the constituent groups considered as most likely to fulfil the criteria for PBT or vPvB as further specified in Appendix 1 shall be used as test material, and the chemical analyses and determination of BMF including estimation of tentative BCF values must be performed separately for each representative constituent present in the equal mixture.

You have to provide an update of the registration dossier(s) containing the requested information, including robust study summaries and, where relevant, an update of the chemical safety report by **18 January 2021**.

In addition to the robust study summary, you shall submit the full study report for the bioaccumulation study by the same deadline.

The deadline takes into account the time that you may need to agree on which of the registrant(s) will perform the required tests and time needed for preparation of the test

[1] This decision is based on the registration dossier(s) at the end of the 12-months evaluation period.

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

[3] You used the term "equal mixture" which ECHA interprets as a mixture containing similar percentages (w/w) of the constituent types to be studied, i.e. those most likely to meet the criteria for PBT/vBvP in Annex XIII of REACH on the basis of the screening assessment as explained in Appendix 1.

material.

The reasons of this decision and any further test specifications 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 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[4] by Leena Ylä-Mononen, Director of Evaluation

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

ECHA
EUROPEAN CHEMICALS AGENCY

Appendix 1: Reasons

Based on the evaluation of all relevant information submitted on phenol, 4-methyl-, reaction products with dicyclopentadiene and isobutylene (hereafter 'the registered substance') 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 risk to the environment.

In this Substance Evaluation decision, information is requested only for bioaccumulation regarding the concern on suspected PBT/vPvB properties. The evaluating MSCA will subsequently review the information submitted by you and evaluate if further information needs to be requested in a follow up decision to conclude the concern for suspected PBT/vPvB properties or the other identified concerns regarding wide dispersive use and exposure of the environment and sediment and soil toxicity.

On the PBT concern

In a combined OECD 301B and OECD 302B test (pre-exposed inoculum used) with the registered UVCB substance only 1 % degradation was observed after 28 days, and thus, the substance is neither readily nor inherently biodegradable. However, as the registered substance is a UVCB, the PBT assessment has to be done separately for individual constituents or constituent groups. Based on BIOWIN QSAR models the main constituent and most of the other possible constituents identified by you fulfil the screening criteria for P/vP. The constituents also screen B/vB as the measured and estimated log Kow values are above 4.5. The registered substance seems to fulfil the criteria for T in Annex XIII of REACH as it is classified as Repr. 2 by you. However, it is not possible to conclude on the toxicity of individual constituents based on this information. Based on the long-term aquatic toxicity tests on the UVCB substance, aquatic invertebrates seem to be the most sensitive organisms with reported 21 day NOELR of < 1 mg/L loading rate for reproduction of *Daphnia magna*. The predicted chronic toxicity values of the main constituent for fish and Daphnia are below 0.01 mg/L based on ECOSAR QSAR model.

Consequently, there is a concern that some of the constituents of the registered substance may have PBT/vPvB properties. This causes a potential risk for the environment as the substance has wide dispersive uses and there is potential for exposure of the environment.

Further information is requested to clarify the PBT concern.

What is the possible regulatory outcome

Where the new data, once obtained, confirms that the registered substance (or a relevant degradation product) meets the PBT or vPvB criteria, it will allow authorities to consider further regulatory risk management in the form of identification as a Substance of Very High Concern in accordance with REACH Article 57.

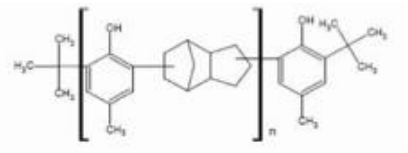
Test item selection

According to Annex XIII of REACH, the PBT assessment has to take account of all relevant constituents of the substance. ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB Assessment (Version 3.0, June 2017) describes relevant constituents as all constituents, impurities and additives present in the substance at levels equal or above 0.1 % (w/w). The registered substance

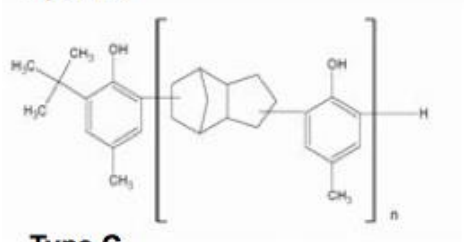
is a UVCB substance consisting of reaction products of p-cresol with dicyclopentadiene (DCPD) and isobutylene. The main constituent 2,2'-(octahydro-4,7-methano-1H-indenediyl)bis[6-tert-butyl-p-cresol] (EC No. 255-504-5) and one minor constituent, 2,6-di-tert-butyl-p-cresol (EC No. 204-881-4) of the registered substance are identified but the main part of the substance includes constituents at concentrations < 10 % w/w, which are unidentified but relevant for the PBT assessment. You have provided information on the possible structures of these unidentified constituents.

Based on that information ECHA considers that the possible constituents of the registered substance can be divided into at least seven different constituent groups, defined based on the end groups attached to the cresol-DCPD monomers. For the purposes of this decision, the different constituent groups are hereafter referred to as Type A, Type B, Type C etc. (see Figure 1). Each constituent group includes different isomers due to multiple possible positions of the phenol rings relative to the DCPD group. Furthermore, all constituent groups except one (Type G) include also different oligomers with varying number of cresol-DCPD monomers indicated with brackets and "n" in the molecular structures of figure 1 (n=1, n=2, etc.). Based on the available information, the most typical constituents are of Type A, which also includes the identified main constituent. Due to the UVCB nature of the registered substance, it is not clear whether constituents of all the other possible constituent groups are always present.

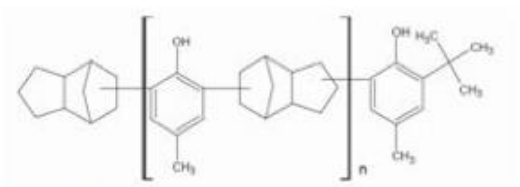
Type A



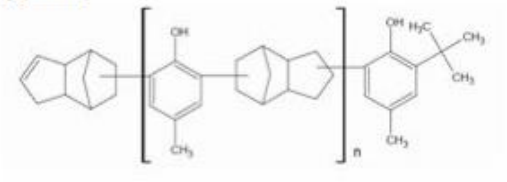
Type B



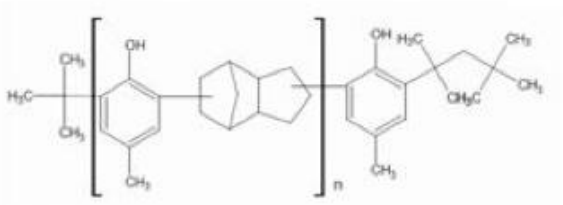
Type C



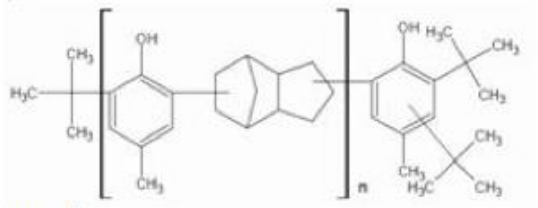
Type D



Type E



Type F



Type G

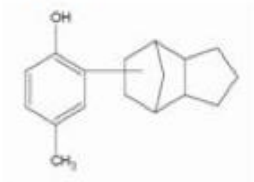


Figure 1. Possible structures present as constituents < 10 % w/w in the registered substance. The names Type A - Type G refer to the constituent groups. The markush bonds indicate that the phenol rings can attach to different positions of the DCPD group. The brackets indicate the cresol-DCPD monomer.

Since the registered substance may contain several different constituents, it is not feasible to determine the PBT properties of each constituent experimentally. Therefore, ECHA has used an approach that considers the identified main constituent of Type A (EC No. 255-504-5) and representative constituents of the other constituent groups included in Figure 1 individually in the PBT assessment assuming that the different isomers belonging to the same group are relatively similar with regard to their PBT properties and that the different oligomers of a group follow a predictable pattern. The identified minor constituent 2,6-di-tert-butyl-p-cresol (EC No. 204-881-4) is not considered further as the PBT assessment under the previous legislation concluded that this constituent is not PBT/vPvB[5].

A screening assessment on potential PBT properties was carried out for the main constituent, used as representative constituent for the Type A group, and for representative constituents of the other constituent groups included in Figure 1 based on the available information on the UVCB substance and QSAR predictions. The screening assessment was done for constituents with n=1 or n=2 (number of cresol-DCPD monomers indicated with brackets in the molecular structures in Figure 1) because the QSAR models predict that log Kow values increase and bioaccumulation potential decreases with increasing number of monomers, which could be explained by increasing molecular size and thus decreasing bioavailability. In addition, QSAR estimations were also done for representative constituents of Type B Type D with n=0. Constituent Type A with n=0 was not screened for PBT properties as this constituent type equals to the identified minor constituent 2,6-di-tert-butyl-p-cresol (EC No. 204-881-4) which, as already mentioned above, was concluded to be not PBT in an earlier PBT assessment. Based on the available information constituents of Type D with n=0 (i.e. butylated cresol-DCPD monomer) may be present in the UVCB substance whereas there is no analytical data available on the presence of constituents of Type B, C, E and F with n=0. However, theoretically this type of constituents are also possible, and hence, they were considered in the PBT assessment.

Based on EPISuite BIOWIN predictions, all constituents belonging to the groups Type A-Type F screen P/vP except for constituents of Type B with n=0. This constituent and constituents of Type G are borderline cases.

You have reported a log Kow of 7.93 measured based on the response for constituent(s) with n=1 in the slow-stirring method (OECD 123) using the whole UVCB substance as test item. However, it is not clear which constituent types with one cresol-DCPD monomer (n=1) were considered in the measurement, i.e. all different constituent types (Type A-F) with n=1 or only certain type of constituents, e.g. Type A n=1. As the constituents of Type A (which includes also the main constituent) are the most typical structures of the registered substance, ECHA considers that the measured log Kow could be most representative for that type of constituents. Therefore, for the main constituent, the QSAR models on other endpoints (e.g. bioaccumulation and ecotoxicity) are performed using as input both the measured log Kow of 7.93 and the predicted log Kow of 8.64 (KOWWIN). The predicted log Kow values of all constituents except one are above 5 based on EPISuite KOWWIN QSAR-model. The only exception is the Type B n=0 which has a predicted log Kow of 3.97 and therefore does not screen B. All other

[5] https://echa.europa.eu/documents/10162/1e278815-9f25-4d53-92cf-4efd48090c47

constituents are considered to screen B/vB. However, the predicted log Kow values of the more complex constituents, i.e. Types C - F with n≥1 and the constituents of Type A and B with n≥2, are above 10, which suggests that they may have lower potential for bioaccumulation.

The BCF values predicted by EPISuite BCFBAF model (using the regression method) for the main constituent are 2794 L/kg based on the measured log Kow of 7.93 and 1259 L/kg based on the predicted log Kow of 8.64. The predicted log Kow and BCF are 8.06 and 2421 L/kg, respectively, for the representative constituent of Type B n=1, and 5.30 and 1450 L/kg for the representative constituent of Type G. The representative constituents of Types C, D, E and F with n=0 have predicted log Kow values of 6.36, 6.14, 6.88 and 6.94, respectively, and predicted BCF values of 4350, 3138, 9680 and 10500 L/kg, respectively. For the remaining constituent types the model predicts low BCF values (< 200 or 100 L/kg). However, the predicted log Kow values of some of these constituents are outside the applicability range of the model.

The ECOSAR QSAR-model predicts chronic toxicity values of fish and Daphnia below 0.001 mg/L for the main constituent and the representative Type B constituent with n=1. The predicted chronic values for the representative constituents of Types C, D, E and F with n=0 are in the range of 0.002-0.007 mg/L for fish and 0.004-0.011 mg/L for Daphnia. This suggests that these constituents may meet the criteria for T in Annex XIII of REACH. For the representative constituent of Type G, the predicted chronic values for fish and Daphnia are 0.02 and 0.03 mg/L. The chronic values given by ECOSAR QSAR-model are geometric means of the predicted LOEC and NOEC, and hence, the predicted NOEC is lower than the given chronic value. Therefore, based on the QSAR predictions, this type of constituents may be borderline cases for T. The predicted log Kow values of other constituent types are outside the applicability range of the model (log Kow up to 8.0).

The PBT screening conclusions for different types of constituents are summarised in Table 1. The constituent types most likely to meet the criteria for PBT/vPvB in Annex XIII of REACH on the basis of the screening assessment are highlighted in grey. These include the constituents of Type A with one cresol-DCPD monomer (n=1, including the main constituent EC 255-504-5), Type B with one cresol-DCPD monomer (n=1) and Types C, D, E and F with n=0. The further testing to clarify the PBT concern is requested for these most relevant constituent types. However, it is noted that there is currently no information available on whether the possible constituent Types C, E and F with n=0 are present in the UVCB substance at a concentration relevant for the PBT assessment (i.e. ≥ 0.1 % (w/w)). If you as Registrant(s) can confirm that they are not present in the registered substance, testing is not required for them.

Table 1. QSAR Prediction of PBT properties of the different possible constituent groups of the registered substance (see Figure 1 for further information on the constituent groups).

Number of cresol-DCPD monomers indicated with brackets and *n* in Figure 1)	Constituent types						
	A	B	C	D	E	F	G
EC/CAS numbers	EC 255-504-5	No data on EC/CAS numbers					
n=0	EC 204-881-4 (not PBT/vPvB)	Border-line P Not B	Pot P Pot B Pot T				Not applicable
n=1	Pot P Pot B Pot T		Pot P Not B? T not possible to conclude				Borderline P Pot B? Borderline T
n=2	Pot P Not B? T not possible to conclude						Not applicable

General considerations on the testing strategy

The original testing strategy to addres the PBT concern included also study requests for water solubility, persistency and aquatic toxicity testing. Based on discussions at the Member State Committee on proposals for amendments (PfAs) related to the testing strategy the decision was changed to no longer require immediate testing for water solubility, persistency and aquatic toxicity.

Evaluating the outcome of the bioaccumulation study prior to providing further advice on the most appropriate test material for any subsequent testing was seen necessary. Therefore it was considered to request at this point of time only the bioaccumulation study. Once the results of the bioaccumulation study become available, the evaluating MSCA will consider the need for a second decision to clarify water solubility, persistency and aquatic toxicity.

Bioaccumulation in fish; test method OECD 305: Bioaccumulation in Fish: Aqueous and Dietary Exposure with specific constituents of the registered substance using the dietary exposure route

Why new information is needed

As explained above, there is a concern that some of the constituents of the registered substance may meet the criteria for PBT/vPvB in Annex XIII of REACH. Due to the complex nature of the substance, testing of all constituents is not feasible. Therefore, the evaluating MSCA has used a modelling approach to identify the constituent groups, which seem to be the most likely to meet the criteria for PBT/vPvB. The information requested for these constituents could then be read across to other constituents using a category approach.

There is no measured data on the bioaccumulation of the registered substance neither of its constituents. The EPISuite BCFBAF QSAR model suggests that the constituents of Type A and B with one cresol-DCPD monomer (n=1) as well as the constituents of Types C, D, E and F with n=0 may have BCF values above 2000. The same constituents are also predicted to be persistent and toxic to fish and aquatic invertebrates. The constituents of Type G (nonbutylated cresol-DCPD monomer) may also have a potential for bioaccumulation (predicted BCF 1450 and predicted log Kow 5.3), but they are borderline cases for P and T based on QSAR predictions. The other constituent groups have high predicted log Kow values (> 10) and low BCF values. Therefore, Type A and B with one cresol-DCPD monomer (n=1) as well as the constituents of Types C, D, E and F with n=0 are considered the worst-case constituents, and bioaccumulation testing is needed to allow a definitive conclusion on the B status of these six constituent groups. However, it is noted that there is currently no information available on whether the possible constituent Types C, E and F with n=0 are present in the UVCB substance at a concentration relevant for the PBT assessment (i.e. ≥ 0.1 % (v/v)). If you can confirm that they are not present in the registered substance at a concentration relevant for the PBT assessment, testing is not required for them.

Considerations on the test method and testing strategy

Normally, in order to avoid unnecessary vertebrate testing the assessment to clarify PBT concern starts with the confirmation of persistency followed by bioaccumulation testing. However, ECHA considers that for the substance subject to this decision, a reverted testing strategy starting with the bioaccumulation test is more feasible. The following aspects were considered in support of the testing order:

If testing was started with the persistency assessment, a mixture of the representative isomers of the constituent groups expected to have worst-case PBT properties should be tested in one simulation degradation study. A thorough investigation of the extraction procedures and analytical detection limits would be required. The result of this investigation might be that environmentally unrealistic high concentrations would need to be used for some of the constituents in the simulation study in order to ensure reliable results. Furthermore, when using a complex mixture as test item, only primary degradation of the constituents can be measured and only limited information can be obtained on the degradation products. In addition, as the water solubility of some of the constituents is expected to be very low, an OECD 309 test would probably not be feasible and thus a sediment or soil simulation study would need to be performed. This would make the interpretation of the results even more difficult as the formation of non-extractable residues (NER) is expected to be high.

Therefore, ECHA considers that in this case, where a complex UVCB is tested, starting the assessment with a bioaccumulation study is expected to give more reliable and useful results. This is because based on the results of the bioaccumulation study the number of constituents to be assessed in a persistency study potentially requested in a follow up decision may be reduced. A worst-case B/vB constituent may be identified in the bioaccumulation study.This leads to less technical constrains in chemical analyses in later persistency assessment. The reduction of the number of constituents potentially to be tested for persistency would avoid the need for a thorough investigation of the extraction procedures and analytical detection limits required since NERs are expected to be formed.

Regarding animal welfare considerations, ECHA considers that starting the assessment with a bioaccumulation study will not lead to unnecessary vertebrate testing. On the one hand, based on the QSAR predictions performed for individual constituents, most of the constituents of the substance are likely to fulfil the criteria for P/vP, and hence, a bioaccumulation study would probably be required in any case to clarify the PBT concern. Therefore, starting the assessment with the persistency study would likely not remove the need to perform vertebrate testing.

In conclusion, ECHA considers that in the case of the UVCB substance subject to this decision a reverted testing order for PBT assessment (i.e. first B and then P) is justified as it is likely to provide more reliable and useful results and because it is not expected to lead to vertebrate testing that could be avoided using the normal testing order. It is noted that this approach was also used in the PBT assessment of some other complex UVCB substances.

The bioaccumulation in fish study must be performed following the OECD TG 305 using the dietary exposure route. According to the ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB Assessment (Version 3.0, June 2017) the aqueous exposure route is always preferred, if technically feasible, as the obtained BCFs values can be directly compared with the Annex XIII criteria. However, according to the guidance and the OECD TG 305 the dietary exposure route may be more appropriate for substances with very low water solubility, if it is not possible to ensure aqueous exposure reliably and when testing mixtures. Due to the complexity of the substance and the expected high range of water solubility values of the constituents a dietary OECD 305 study is selected.

The bioaccumulation in fish study is requested using an equal mixture of the representative constituents of Types A and B with n=1 and Types C, D, E and F with n=0 (see Figure 1 above). The chemical analyses and determination of BMF values, estimation of tentative BCF values and other result parameters indicated in the OECD 305 TG must be made separately for each representative constituent of the equal mixture. In addition to this, based on the results of this study you are requested to conclude if the representative constituents fulfill the criteria for B/vB according to Annex XIII. Based on this, you are requested to provide your selection of the worst case constituent(s) to be used in any further persistency testing.

As no criteria (cut off value) are established in Annex XIII of REACH for the BMF values determined in the dietary test, ECHA notes that OECD TG 305 (dietary exposure) includes details on what parameters to report and how to calculate the BCF based on results from dietary exposure. In addition, Annex 8 of the OECD TG 305 and the Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (OECD, July 2017) include information on the estimation of the tentative BCFs from data obtained in

the dietary exposure study. Further information can be found in Section 4.1.2.3: Experimental dietary biomagnification in fish (experimental dietary BMF) of ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB Assessment (Version 3.0, June 2017). By applying these available techniques to estimate k1 (and thus a BCF), estimation of the bioaccumulation potential could be achieved. Therefore, ECHA concludes that comparison of the results of the requested dietary study with the BCF criteria set in Annex XIII of REACH should be possible.

You shall submit the full study report for the bioaccumulation study. Considering the complexity of the case as described above, access to all information available in the full study (i.a. implemented methods, raw data collected, interpretations and calculations, consideration of uncertainties) is needed. This will allow the evaluating MSCA to fully assess the provided information, including the statistic analysis and to efficiently clarify the concern for bioaccumulation.

Consideration of alternative approaches

The request for an OECD 305 test with dietary exposure is suitable and necessary to obtain information that will allow clarifying whether the constituents of the substance meet the criteria for bioaccumulation according to Annex XIII of REACH.

There is no equally suitable alternative way available of obtaining this information. ECHA notes that there is no experimental method available at this stage that would generate the necessary information and would avoid a test on vertebrate animals.

Consideration of registrants' comments on the draft decision and PfAs and of the PfAs

In your comments on the draft decision, you agreed to perform the bioaccumulation study but you argued that testing with the whole UVCB substance and making the chemical analyses separately for the worst-case constituents (as requested in the draft decision) is not going to be practical as it cannot be ensured that all the required constituents to be analysed are actually present within the UVCB mixture. You proposed to use as test material an equal mixture of the representative constituents of the constituent groups considered representing worst-case PBT/vPvB properties. According to you, this would ensure that more accurate results are obtained for these constituents.

ECHA agrees with your proposal on the test material as some of the constituents can be present at a low concentration in the UVCB substance, and hence, using an equal mixture of the representative constituents as test material is expected to make the chemical analyses and determination of separate BMF/BCF values more reliable and straightforward. The decision was modified accordingly.

In your comments on a PfA from a MSCA you indicated your wish to have a mutual discussion on the test item preparation. ECHA notes that communication with the evaluating MSCA is always possible.

Conclusion

Therefore, based on the substance evaluation and in accordance with Article 46(1) of the REACH Regulation, ECHA concludes that you are required to carry out the following study:

Bioaccumulation in Fish; test method OECD TG 305: Bioaccumulation in Fish: Aqueous and Dietary Exposure with specific constituents of the registered substance using the dietary exposure route.

An equal mixture of the representative constituents of Types A and B with n=1 and Types C, D, E and F with n=0 (see Figure 1 above) shall be used as test material, and the chemical analyses and determination of BMF values and estimation of tentative BCFs must be made separately for these representative constituents. However, it is noted that there is currently no information available on whether the possible constituent Types C, E and F with n=0 are present in the UVCB substance at a concentration relevant for the PBT assessment (i.e. ≥ 0.1 % (v/v)). If you can confirm that they are not present in the registered substance at a concentration relevant for the PBT assessment, testing is not required for them.

Deadline to submit the requested information

In the draft decision communicated to you, the time indicated to provide both the water solubility study (now removed) and the bioaccumulation study was 18 months from the date of adoption of the decision.

In your comments on the draft decision, you requested an extension of this timeline by 18 months. You sought to justify this request by claiming that it will take at least 18 months to be able to prepare and provide suitable test material for sampling due to the time needed for the determination of suitable analytical method and isolation of the required constituents as well as for sourcing of suitable laboratory / provider who can isolate the required constituents from commercial batches in sufficient amounts. Moreover, you justified the request to extend the timelines also based on the need to radiolabel the test material.

ECHA acknowledges that the determination of suitable analytical method and isolation of the required constituents from the registered UVCB substance may be challenging and time-consuming as the concentrations of some of the required constituents are expected to be low and several isomers can be present. In view of this the normally applied timelines may be insufficient. However, based on your comments on the draft decision, the constituents of Type G, which, based on your comments, seemed to be the most difficult to isolate, were left out from the testing requirements, as this type of constituents was not considered the most worst-case constituents in the PBT assessment. Therefore, the need for an additional time of 18 months to prepare the test material, as you proposed, may have been overestimated and ECHA considered additional 15 months sufficient.

In your comment on a PfA to include further constituents you requested additional three to 36 months in case this PfA would be accepted. As this PfA was accepted and further constituents were included, adding six additional months to the 15 months was considered appropriate.

Having regard of all the above, the deadline to provide the requested bioaccumulation study is therefore set to 33 months, which comprises nine months standard timeline for an OECD 305 test plus 21 months for test item preparation plus three months for the registrant(s) to agree who performs the test. ECHA notes that the newly set deadline also considers the fact that the water solubility request with a standard timeline of six months was removed.

Appendix 2: Procedural history

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to suspected PBT/vPvB properties, wide dispersive use and exposure of environment, phenol, 4-methyl-, reaction products with dicyclopentadiene and isobutylene CAS No 68610-51-5 (EC No 271-867-2) was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2016. The updated CoRAP was published on the ECHA website on 22 March 2016. The competent authority of Spain (hereafter called the evaluating MSCA) was appointed to carry out the evaluation.

In accordance with Article 45(4) of the REACH Regulation, the evaluating MSCA carried out the evaluation of the above substance based on the information in your registration(s) and other relevant and available information.

The evaluating MSCA considered that further information was required to clarify the following concerns: suspected PBT/vPvB properties, wide dispersive use and exposure of environment. Therefore, it prepared a draft decision under Article 46(1) of the REACH Regulation to request further information on suspected PBT/vPvB properties. It subsequently submitted the draft decision to ECHA on 22 March 2017.

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 deadlines were amended.

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 proposal(s) for amendment to the draft decision and modified the draft decision. They are reflected in the reasons (Appendix 1).

ECHA referred the draft decision, together with your comments, to the Member State Committee.

ECHA invited you to comment on the proposed amendment(s).

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

MSC agreement seeking stage

The Member State Committee reached a unanimous agreement on the draft decision during its MSC-58 meeting and ECHA took the decision according to Article 52(2) and 51(6) of the REACH Regulation.

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 requirement(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 testing is required for specific constituents of the registered substance and the requirements regarding the test material, as described in Appendix 1 in this decision, must be followed. It is the responsibility of all the registrant(s) to agree on the tested material to be subjected to the test and to document the necessary information on the composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluatingMSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation.

4. In relation to the experimental study 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 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

   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 study on behalf of all of them.