Helsinki, 23 March 2017

Substance name: 1-[4-(1,1-dimethylethyl)phenyl]-3-(4-methoxyphenyl)propane-1,3-dione (BMDM)
EC number: 274-581-6
CAS number: 70356-09-1
Date of Latest submission(s) considered[1]: 15 July 2016
Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F)
Addressees: Registrant(s)[2] of 1-[4-(1,1-dimethylethyl)phenyl]-3-(4-methoxyphenyl)propane-1,3-dione (Registrant(s))

DECISION ON SUBSTANCE EVALUATION

1. Requested information

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

1) Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25 (OECD 309, "pelagic test") as further specified in Appendix I

If the test results for request 1 in surface water indicate that the registered substance does not meet the criterion for P[3], the following additional test is required:

2) Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24 (OECD 308) as further specified in Appendix I

The following test is required in parallel to request 1:

3) Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD 211)

The following test is only required, if (a) based on the test results from requests 1 and 3, the substance is P but not T, or (b) the substance is not T based on the test results from request 3 but it is P based on the test results from request 2:

4) Long-term toxicity testing on fish (Annex IX, 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD 210).

If based on the results from requests 1 (OECD 309) and 3 (OECD 211), the substance is both P and T you are required to provide an update by **2 January 2019** and no further

[1] This decision is based on the registration dossier(s) on the day until which the evaluating MSCA granted an extension for submitting dossier updates which it would take into consideration.

[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] When this decision refers to P, B or T, it means persistent, bioaccumulative or toxic in accordance with REACH Annex XIII

testing is required.

If based on the test results from requests 1 (OECD 309) and 3 (OECD 211), the substance is P but not T, you are required to provide an update containing in addition the information required in request 4 (OECD 210) by **2 January 2020** for information requests 1, 3 and 4.

If based on the test results from requests 1 (OECD 309) and 3 (OECD 211), the substance is not P but T, you are required to provide an update containing in addition the information required in request 2 (OECD 308) by **1 July 2019** for requirements 1, 2 and 3.

If the substance is not T based on the test results from request 3 (OECD 211) but P based on the test results from request 2 (OECD 308), you are required to provide an update containing in addition the information required in request 4 (OECD 210) by **30 June 2020** for requests 1, 2, 3 and 4.

In all cases, you shall 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.

The reasons of this decision and 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, including overview tables illustrating the testing strategy and deadlines. 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.

2. Who performs the testing

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

3. Appeal

You can appeal this decision to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has 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.

Appendix 1: Reasons

Based on the evaluation of all relevant information submitted on 1-[4-(1,1-dimethylethyl)phenyl]-3-(4-methoxyphenyl)propane-1,3-dione and other relevant available information, ECHA concludes that further information is required in order to enable the evaluating Member State Competent Authority (MSCA) to complete the evaluation of whether the substance constitutes a risk to the environment.

The evaluating MSCA will subsequently review the information submitted by you and evaluate if further information should be requested in order to clarify the PBT/vPvB concern for the environment.

The Concern(s) Identified

1-[4-(1,1-dimethylethyl)phenyl]-3-(4-methoxyphenyl)propane-1,3-dione (hereinafter called BMDM) is a potential PBT or vPvB substance which is produced in high volumes and constitutes one of the most widely used UV filters in cosmetic products worldwide. Due to its use in cosmetics, the substance enters the aquatic compartment via waste water or direct discharges. Several studies detected it in surface water (Poiger, T. et al. 2004; Remberger et al., 2011; Vila et al, 2016), in waste water treatment sludge (Rodil, R. et al. 2009; Tsui et al., 2014) and one in sediments (Kaiser, D. et al. 2012a and b). Concentrations found usually were in the ng per liter range, once in the µg per liter range (Vila et al, 2016). Tsui et al., 2014 report that elimination efficiency of BMDM varies depending on the treatment process used in waste water treatment plant but generally is moderate over the year. Chlorination and reverse osmosis are capable to remove it to > 99 % but other processes are less effective. Frequency of detection reported in literature varies between the authors. For example Poiger T. et al. 2004 detected the substance only once in surface water but Remberger et al., 2011 report to have detected it in 63 % of samples taken from effluent of waste water treatment plants. Due to its high adsorption potential (log Koc = 4.65), the main portion of BMDM will adsorb on sewage sludge of municipal wastewater treatment plants (WWTP), which will subsequently be applied on agricultural soils, thereby increasing the likelihood that terrestrial organisms will also be exposed to BMDM, particularly based on its suspected persistency. The monitoring data confirm that BMDM is found in both surface waters and wastewater treatment sludge which may be applied on agricultural soil. Thus, ECHA considers due to environmental emission pattern and the sorptive properties of the substance that surface water, soil and sediment as relevant compartments of concern as regards degradability. Due to the environmental exposure arising from the wide dispersive use of BMDM in cosmetics, a proper risk assessment including assessment of the suspected PBT properties is necessary. While the available information is sufficient to conclude on the B criterion, addition information on persistence and toxicity is required to conclude on the PBT concern.

Consideration of Registrants' general comments on the order of testing

In your comments to the draft decision, you agreed to conduct the requested toxicity

studies. However, you suggest performing these tests first to allow assessment of BMDM against the T criterion before further testing is performed. You provided information which in your eyes was sufficient to robustly conclude that the substance is 'not vB' and therefore no initial testing on persistence would be necessary and the focus on further testing should be to conclude on the potential PBT, not the potential vPvB status of BMDM. ECHA considers the testing required in this decision necessary to conclude on the PBT concern.

ECHA argues that the potential for persistence shall be clarified first as stated in the REACH Guidance and to conclude on the potential P status of the substance as currently no confident conclusion on the PBT status on BMDM is possible. Furthermore, the long-term toxicity tests are necessary to perform an environmental risk assessment for BMDM regardless of the REACH Annex XIII assessment of this substance.

Consequently, ECHA did not amend the intended order of testing and adheres to the necessity of parallel testing of persistence and long-term toxicity of BMDM taking into account results from persistency testing before further vertebrate testing has to be conducted.

Why new information is needed

Biodegradation

BMDM is a potential PBT substance. For assessing the P criterion according to Annex XIII of the REACH Regulation, information on biodegradation is required.

You provided two screening tests on biodegradation in the registration dossier(s). According to the test following test guideline ISO 11734, BMDM is not biodegradable under anaerobic conditions (0% degradation after 21 days). In an inherent biodegradability test according to test guideline OECD 302C, 4% degradation was observed after 28 days. According to guidance document R. 7b care must be taken when using DOC removal to ensure that elimination did not occur by adsorption or volatilization. These uncertainties are not relevant for the available test, because BOD was measured to assess the mineralization. Based on the results of the screening tests there is a concern that BMDM is at least persistent. As stated in the guidance document R. 11 PBT Assessment (ECHA, 2014) "Lack of degradation (<20% degradation) in an inherent biodegradability test equivalent to the OECD TG 302 series would provide sufficient information to confirm persistence without the need for further simulation testing." However, further testing is necessary to decide definitively whether or not the substance fulfils the P criterion.

Due to the insufficient data it is not possible to decide about the P-criterion according to REACH Annex XIII. Therefore, higher tier simulation tests on biodegradation behaviour of the substance are needed to draw a conclusion regarding the P criterion.

Based on the Chemical Safety Assessment and the life cycle description in the

registration dossier(s) direct emissions to the aquatic environment and direct emissions via wastewater treatment plants from cosmetic and personal care products of the substance are likely to occur and sediment is relevant based on adsorption potential and distribution modelling.

Request 1. Simulation test on ultimate degradation in surface water: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25 (OECD 309, "pelagic test")

As described above, the data provided by you are not sufficient to conclude on the P criterion.

The test system simulates mineralisation in surface water. It either uses surface water only (pelagic test), or surface water with addition of suspended solids or sediment as inoculum (suspended sediment test). It is the aim to test the substance in a test system with a small surface area for adsorption. Thus the pelagic version of the OECD 309 shall be performed.

Based on the above, the test system should be such that NER-formation is kept to a minimum. This is possible by choosing to perform the test in its pelagic version of OECD 309, i.e. without addition of sediment/suspended solids.

It is important that metabolites/ degradation products are identified /sufficiently characterized relative to the PBT properties. To this end the following conditions shall be fulfilled:

- The initial concentration of the substance in the test water should not exceed the water solubility. The registered substance shall be radiolabelled due to its low water solubility for an appropriate verification of the degradation kinetics and pathways. You shall provide justification for the location of the radiolabel on the molecule.
- The test shall be done as pelagic test without addition of sediment.
- Metabolites shall be identified and/or sufficiently quantified and characterized as regards their PBT properties (at a concentration of ≥ 0.1 % w/w unless it can be demonstrated that this is technically not possible).
- The test guideline OECD 309 stipulates a test duration of 60 days but also states that it may be extended to a maximum of 90 days. It further describes that the test duration may be prolonged to several months if the provisions of Annex 3 of the guideline are followed. Annex 3 describes the semi-continuous procedure which shall prevent deterioration of the system by keeping inoculum viable. However, this procedure includes replacement of water with freshly sampled water and may result in loss of a part of the substance. Hence, account of this should be made either in the procedure of the testing and/ or when evaluating the results of the study. In any case test water renewal shall be started at the latest possible time (e.g. after 60 days) and the number of subsequent repetitions of water removal shall be restricted to a minimum. It is necessary to closely check the test concentration just before and

after each test water renewal if this is employed. All procedures which could make interpretation more difficult or make such more difficult to extrapolate to the behaviour of the substance in environment should be avoided as far as possible.
- Sufficient measurements shall be performed to enhance the possibility of establishing a reliable kinetic modelling. The guideline OECD 309 stipulates that a minimum of 5 sampling points are required during the degradation phase. This refers to the test duration of 60 days, or 90 days if a semi-continuous procedure is used. A tight pattern of measurements at 1, 6, 12 and 24 hours and at day 7, 14, 28 and 56 and at the end of the test shall be made. If the test is longer than 60 days measurements should be made at regular intervals thereafter but for no longer than a month in agreement with the OECD 309 guideline, which states that more measurements can easily be done although it does not give a fixed time schedule.
- The REACH Guidance (cf. Table R.16-9) defines the average environmental temperature for the EU as 12°C and this is the reference temperature for the assessment of persistency in PBT/vPvB assessment. Therefore, you are requested to perform the kinetic part of the test at 12°C (293K). Test evaluation shall be comprehensive (cf. the procedures and approaches usually used for biocides/ pesticides).

To assess persistence it is necessary to differentiate between mere elimination and degradation processes (cf. REACH Guidance R 11.4.1.1). To this end for the registered substance detection and identification of metabolites shall be provided. This is also based on indications in available data.

Conclusion

Therefore, based on the substance evaluation and pursuant to Article 46(1) of the REACH Regulation, ECHA concludes that you are required to carry out the following study using the registered substance subject to this decision: **Simulating testing on ultimate degradation in surface water (test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25/OECD 309)**.

Assessment of alternative approaches and proportionality

The request for the OECD 309 test is suitable and necessary to obtain information that will allow to clarify whether BMDM is persistent according to REACH Annex XIII. More explicitly, there is no equally suitable alternative way available of obtaining this information. If the obtained data confirm the suspected PBT properties, it will allow authorities to consider further regulatory risk management in the form of SVHC identification and subsequent authorization or restriction of BMDM.

Request 2. Sediment simulation test: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24 (OECD 308)

Considerations on the test method and testing strategy

- The initial concentration of the substance in the test water should not exceed the water solubility. The registered substance shall be radiolabelled due to its low water solubility for an appropriate verification of the degradation kinetics and pathways. You shall provide justification for the location of the radiolabel on the molecule.
- Metabolites shall be identified and/or sufficiently quantified and characterized as regards their PBT properties (at a concentration of ≥ 0.1 % w/w unless it can be demonstrated that this is technically not possible).
- Test duration is preferred to be prolonged to 120 or even 180 days to facilitate comparison of data with the persistency trigger values. Experience[5] shows that an extension to 120 days or even longer is possible without reducing significance of data even though the test guideline states that test duration normally should not exceed 100 days.
- Measurements shall be done for modelling the degradation kinetics. The guideline OECD 308 stipulates that the number of sampling times should be at least six including zero time for a test duration of 100 days. This is insufficient for a difficult substance like the registered substance, which is expected to adsorb rapidly to sediment. The test regime shall be such that it is possible to follow the adsorption process over time. This is a necessary provision for a successful kinetic modelling when performing the data evaluation because it may be necessary to re-calculate the test concentration and to adequately identify the point in time to use as the starting point the calculation of the half-life. For being able to do this three samples shall be taken on the first day, after 1 hour, 6 and 12 hours; another sample shall be taken after 24 hours followed by sampling times at day 7, 14 and day 28. The following sampling times shall be nearly evenly distributed in a 4 weeks interval. Hence, depending of the total duration of the study, a total of at least 11 sampling time points for a test duration of 180 days shall be included in the study.
- The REACH Guidance (cf. Table R.16-9) defines the average environmental temperature for the EU as 12°C and this is the reference temperature for the assessment of persistency in PBT/vPvB assessment. Therefore, you are requested to perform the kinetic part of the test at 12°C (293K).
- Test evaluation shall be comprehensive (cf. those usually used for assessment of degradation of biocides/ pesticides). The following aspects are of special interest for test evaluation: Rate and course of kinetics of parent and metabolites in both the sediment and the water phase shall be evaluated. In respect to the water phase results they shall also be compared with the respective results of the OECD 309 study and considered in interpretation. Special consideration shall be given to:
  1) the kinetics in the water phase of both test systems and the differences found;
  2) the kinetics in the water phase compared to the course of non-extractable residues (NER) formation in the sediment phase of the OECD 308;
  3) the time at which metabolites emerge and their succession in the respective test system and
  4) comparison of the time at which metabolites emerge and their succession in both test systems.

[5] R&D projects 20667460/03 and 22801, UBA 2012 and 2013

- You are requested to justify scientifically that the extraction procedure /solvent chosen is appropriate in respect to the irreversibility of the binding of the substance/its metabolites to the sediment matrix when testing the degradation in these compartments. Strong extractions, such as Soxhlet-extraction with apolar solvents, should be used in order to conclude that the remaining part should be considered as NER.

Consideration of Registrants' comments on the testing for persistency

In your comments to the draft decision, you state that further information is needed regarding persistence if the substance met the REACH Annex XIII criteria on bioaccumulation and toxicity. Thus, you propose to only perform the suggested studies on persistence if this testing would still be deemed necessary after long-term toxicity testing on aquatic invertebrates (cf. information request 3) and after a potentially necessary additional bioaccumulation study (previous information request 1.5 which was removed following proposals for amendment). You furthermore suggest to only conduct the OECD 308 test and omit the OECD 309 test due to the anticipated partitioning of BMDM into the sediment compartment rather than surface water.

ECHA notes that, due to its main use as a UV filter in personal care products, BMDM directly enters the aquatic compartment via direct discharges or wastewater. Monitoring data confirms that BMDM is found in both surface waters and wastewater treatment sludge which may be applied on agricultural soil. Thus, ECHA considers all three compartments (water, sediment and soil) as relevant. ECHA adheres to the necessity of testing the persistency of BMDM initially in surface water via an OECD 309 test. This test makes a conclusion about the degradation rate of the substance possible and also serves to minimize the interpretation problems related to the likely NER formation of BMDM. Only in case this test does not allow the conclusion that the substance is persistent, a sediment simulation test (OECD 308) is required.

Consequently, ECHA did not amend the requested information on further persistency testing.

Consideration of proposals for amendment and Registrants' comments on them

A proposal was received by a Member State to use an alternative testing strategy for the simulation tests, including the request to conduct an OECD 307 study depending on the outcome of the OECD 308 study. In your comments to the proposal, you state that you do not consider the testing of soil as an additional compartment necessary in case the OECD 308 study shows that the substance is not persistent in sediment. ECHA does not consider requesting an OECD 307 study as proportional within the scope of the testing strategy and therefore rejected the proposal.

Another Member State proposed to make the requirement of the OECD 309 study conditional on the results of the toxicity tests. This proposal was rejected as ECHA

adheres to the need for parallel testing on toxicity and persistence to clarify the PBT concern and the additional concern of potential risk to the aquatic compartment.

Conclusion

Therefore, based on the substance evaluation and pursuant to Article 46(1) of the REACH Regulation, ECHA concludes that you are required to carry out the following study using the registered substance subject to this decision: Sediment simulating testing (Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/ OECD 308). This test is not required if the test results for request 1 in surface water indicate that the registered substance already meets the P criterion.

Assessment of alternative approaches and proportionality

The request for the OECD 308 test is suitable and necessary to obtain information that will allow to clarify whether BMDM is persistent according to REACH Annex XIII, if BMDM is not P according to the OECD 309 test performed first. More explicitly, there is no equally suitable alternative way available of obtaining this information. If the obtained data confirm the suspected PBT properties, it will allow authorities to consider further regulatory risk management in the form of SVHC identification and subsequent authorization or restriction of BMDM.

Ecotoxicity

BMDM is a potential PBT substance. For assessing the T-criterion according to Annex XIII of the REACH regulation, information on toxicity is required. ECHA notes that all aquatic long-term toxicity tests and toxicity tests on terrestrial organisms have been waived and hence an integrated assessment of toxicity is not possible. However, BMDM is produced in high volumes, enters the aquatic compartment as the most widely used UVA filter in cosmetics worldwide via waste water or direct discharges, and has been found in several surface waters (Poiger, T. et al. 2004; Remberger et al., 2011; Vila et al, 2016), in sediments (Kaiser, D. et al. 2012a and b), and in waste water treatment sludge (Rodil, R. et al. 2009; Tsui et al. 2014). Due to high adsorption potential (log Koc = 4.65) the main portion of BMDM will adsorb on sewage sludge of municipal WWTP, which will subsequently be applied on agricultural soils, thereby increasing the likelihood that terrestrial organisms will also be exposed, particularly based on suspected persistency. Being aware of the environmental exposure of BMDM from wide dispersive uses and the detection of the substance in the monitoring of several surface waters, a proper risk assessment is necessary. Due to the low water solubility of the substance, the risk assessment needs to be based on chronic toxicity data.

Request 3 Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD 211) and request 4 Long-term toxicity testing on fish (Annex IX, 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD 210)

As no data on long-term toxicity to aquatic organisms is available, more information is

needed to assess these endpoints and conclude on the risk assessment of BMDM.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0., November 2014), Chapter R7b, Figure R.7.8-4 page 57, if neither fish nor invertebrates are shown to be substantially more sensitive based on acute aquatic toxicity data, long-term studies are required on both.

The request for long-term toxicity testing on invertebrates and fish is suitable and necessary to obtain information that will allow to clarify whether there is a risk that BMDM is chronic toxic to aquatic species. More explicitly, between different available alternatives it is the least onerous way to obtain information. The possible alternative of applying QSAR for chronic toxicity does not generate the same information and is not targeted for BMDM as the current QSAR models for diketones (e.g. ECOSAR) are based on a dataset including only two substances. Hence QSAR application for chronic toxicity on invertebrates and fish would not provide sufficient certainty. The need for long-term aquatic toxicity testing is further justified by an additional concern of risk to the environment, based on the wide dispersive use of the substance, the high tonnage and monitoring data finding the substance in environmental media. Due to the low water solubility of BMDM the risk assessment has to be based on chronic toxicity data.

Regarding the long-term toxicity testing on fish, the Fish, early-life stage (FELS) toxicity test according to OECD 210 is the most sensitive of the standard fish tests as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth, and shall therefore be used (see ECHA G*uidance on information requirements and chemical safety assessment* (version 2.0., November 2014), Chapter R7b, Figure R.7.8-4 page 57). The test method OECD 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance R7b, version 1.2., November 2012, p. 26). For these reasons, the FELS toxicity test using the test method OECD 210 is appropriate and suitable.

For testing long-term toxicity to aquatic invertebrates the standard recommended test method EU C.20./OECD 211 is the most appropriate and suitable one.

<u>Considerations on the test method and testing strategy</u>

Due to the low solubility of the substance in water, the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, (OECD 2000) and ECHA Guidance, Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances shall be consulted for choosing the design of the requested long-term ecotoxicity tests and for calculation as well as expression of the results of the tests. Furthermore, a proper risk assessment is required because (1) BMDM has a very high tonnage between 1.000 and 10.000 tpa, (2) an environmental exposure of the substance is expected from wide dispersive uses and the detection of the substance in the monitoring of several surface waters, and (3) the substance’s low water solubility

requires a risk assessment to be based on chronic toxicity data. Hence, the OECD 211 invertebrate test shall be conducted in parallel with the OECD 309 simulation test (request 1.). Due to animal welfare reasons the OECD 210 FELS test (request 4) can be waived if the results of the Daphnia magna reproduction test (request 3) indicate that the substance meets the T criterion according to REACH Annex XIII. If the FELS test is not required to address the PBT concern, you shall consider the need for long-term fish toxicity testing for the environmental risk assessment by using the ITS in REACH guidance 7B (figure R7.8-4).

Consideration of Registrants' comments

In your comments to the draft decision, you agree to conduct the requested long-term aquatic toxicity studies with BMDM although you suggested to alter the sequence of requested testing, making the testing against the (v)P and (v)B criteria conditional on the outcome of the toxicity testing.

Consideration of proposals for amendment and Registrants' comments on them

Proposals were received by two Member States to make the requirement of a FELS test conditional on the outcome of the OECD 211 test. This proposal was welcomed by you in your comments and accepted by ECHA into the test strategy. The proposal of a Member State to make additional toxicity testing wholly conditional on the outcome of the persistence studies was rejected as ECHA regards the clarification of the additional concern of a potential risk to the aquatic compartment independent from the PBT concern.

Conclusion

Therefore, based on the substance evaluation and pursuant to Article 46(1) of the REACH Regulation, ECHA concludes that you are required to carry out the following study (request 3) using the registered substance subject to this decision:

- Daphnia magna reproduction test (test method: EU C.20./OECD 211);

The following test (request 4) can be waived if the results of the Daphnia magna reproduction test indicate that the substance meets the T criterion according to REACH Annex XIII: Fish, early-life stage (FELS) toxicity test (test method: OECD 210).

Once the results of the above long-term aquatic studies are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including a derivation of the aquatic PNECs.

References:

Title	Author	Publication/source details	Date
Determination of fourteen UV filters in bathing waters by headspace solid-phase microextraction and gas chromatography-tandem mass spectrometry	Vila et al (Marlene Vila, Maria Celeiro, Juan Pablo Lamas, Thierry Dagnac, Maria Llompart and Carmen Garcia-Jares)	Anal. Methods, 2016,8, 7069-7079 Article Online www.rsc.org, DOI: 10.1039/C6AY01787H	2016
Chapter R.11: PBT/vPvB assessment	ECHA	Guidance on Information Requirements and Chemical Safety Assessment, http://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf.	2014
Ecotoxicological effect characterisation of widely used organic UV filters	Kaiser et al (D. Kaiser, A. Sieratowicz, H. Zielke, M. Oetken, H. Hollert, J. Oehlmann)	Environmental Pollution, Volume 163; Pages 84-90, ISSN 0269-7491, http://dx.doi.org/10.1016/j.envpol.2011.12.014.	2012a
Occurrence of widely used organic UV filters in lake and river sediments	Kaiser et al (Dominic Kaiser, Olaf Wappelhorst, Matthias Oetken, and Jörg Oehlmann)	Environmental Chemistry 9(2) 139-147, January 2012, http://dx.doi.org/10.1071/EN11076	2012b
Seasonal occurrence, removal efficiencies and preliminary risk assessment of multiple classes of organic UV filters in wastewater treatment plants	Tsui et al (Mirabelle M.P. Tsui, H.W. Leung, Paul K.S. Lam, Margaret B. Murphy.)	Water Research, 53, 58-67 ISSN 0043-1354, http://dx.doi.org/10.1016/j.watres.2014.01.014	2014
Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures	OECD	ENV/JM/MONO(OECD 2000)6	2000
Occurrence of UV filter compounds from sunscreens in surface waters: regional mass balance in two Swiss lakes	Poiger, T. et al. (Thomas Poiger, Hans-Rudolf Buser , Marianne E. Balmer, Per-Anders Bergqvist, Markus D. Müller)	Chemosphere, Volume 55, Issue 7, May 2004, Pages 951-963,http://dx.doi.org/10.1016/j.chemosphere.2004.01.012.	2004
Results from the Swedish National Screening Programme 2009, Subreport 3: UV-filters	Remberger et al. (Mikael Remberger, Karl Lilja, Lennart Kaj, Tomas Viktor, Eva Brorström-Lundén, B1971, February 2011	IVL Swedish Environmental Research Institute Ltd, IVL Report B1971 https://www.diva-portal.org/smash/get/diva2:758141/FULLTEXT01.pdf	2011

Pressurised membrane-assisted liquid extraction of UV filters from sludge	Rodil, R. et al. 2009 (Rosario Rodil, Steffi Schrader, Monika Moeder)	Journal of Chromatography A, Volume 1216, Issue 51, 18 December 2009, Pages 8851-8858, ISSN 0021-9673, http://dx.doi.org/10.1016/j.chroma.2009.10.058	2009

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, wide dispersive use, exposure of environment, high (aggregated) tonnage, 1-[4-(1,1-dimethylethyl)phenyl]-3-(4-methoxyphenyl)propane-1,3-dione, CAS No 70356-09-1 (EC No 274-581-6) was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2015. The updated CoRAP was published on the ECHA website on 17 March 2015. The Competent Authority of Germany (hereafter called the evaluating MSCA) was appointed to carry out the evaluation.

Pursuant to 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.

In the course of the evaluation, the evaluating MSCA identified additional concerns regarding a potential risk to the aquatic environment, based on the wide dispersive use of the substance and monitoring data finding the substance in surface water.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 7 March 2016.

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

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 into account the comments from you, which were sent within the commenting period, and they are reflected in the Reasons (Appendix 1). The requested information was not changed in response to the submitted comments.

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

The evaluating MSCA notified the draft decision to the Competent Authorities of the other Member States and ECHA for proposals for amendment.

ECHA notified you of the draft decision and invited you to provide comments. Subsequently, the evaluating MSCA received proposals for amendment to the draft decision. As a result, the logical order of all information requirements in section "1. Requested Information" of the decision and specifically the requested sequence of the toxicity tests was amended, i.e. conditionality and the option to waive information request 4 depending on the outcome of information request 3 was implemented. The fish

bioaccumulation study according to OECD 305 using aqueous exposure was removed based on the PfA. The deadlines for the information requirements were accordingly reduced and adapted to account for the conditional routes of the amended testing strategy. ECHA invited you to comment on the proposed amendments. Any comments on the proposals for amendment were taken into account by the Member State Committee and are reflected in the Reasons (Appendix 1). The Member State Committee did not take into account any comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 52(2) and Article 51(5).

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

This decision does not preclude further information requests to clarify remaining concerns regarding the persistency, bioaccumulation or ecotoxicity properties of the substance.

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 fulfil otherwise 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/ies, the sample of the substance to be used shall have a composition that is within the specifications of the substance composition that are given by all Registrant(s). It is the responsibility of all the Registrant(s) to agree on the tested material to be subjected to the test(s) subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation.

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 is to 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 stud(y/ies) on behalf of all of them.

5. The following table summarises the tiered environmental testing strategy for the information requested in the decision:

Test requested	**Conditions when to perform test**
1 (OECD 309)	Unconditionally
2 (OECD 308)	If substance is not P according to request 1 (OECD 309)
3 (OECD 211)	Unconditionally
4 (OECD 210)	If substance is P according to request 1 (OECD 309) or 2 (OECD 308) and not T according to 3 (OECD 211)

Additionally, the dependency of the deadline for providing the information on the outcomes of the conducted tests is listed in the table below:

Conducted tests (and conclusion)	**Deadline for providing information on conducted tests (following decision date)**
1 (OECD 309) → **P** 3 (OECD 211) → **T**	21 months (for 1 and 3 only)
1 (OECD 309) → **P** 3 (OECD 211) → not T → 4 (OECD 210)	33 months (for 1, 3 and 4 only)
1 (OECD 309) → not P → 2 (OECD 308) 3 (OECD 211) → **T**	27 months (for 1, 2 and 3 only)
1(OECD 309) → not P → 2 (OECD 308) → **P** 3 (OECD 211) → not T → 4 (OECD 210)	39 months (for 1, 2, 3 and 4)

Appendix 4: List of registration numbers for the addressees of this decision. This appendix is confidential and not included in the public version of this decision.

EC number: 274-581-6
CAS number: 70356-09-1
Public name: 1-[4-(1,1-dimethylethyl)phenyl]-3-(4-methoxyphenyl)propane-1,3-dione

This decision is addressed to the Registrant(s) of the above substance with active registration pursuant to Article 6 of the REACH Regulation on the date on which the draft for the decision was first sent for comments. If Registrant(s) ceased manufacture upon receipt of the draft decision pursuant to Article 50(3) of the REACH Regulation, they did not become addressee(s) of the decision. A list of all the relevant registration numbers of the Registrant(s) that are addressees of the present decision is provided below.