Helsinki, 22 March 2018

Substance name: Ethyl 3,5-dichloro-4-hexadecyloxycarbonyloxybenzoate
EC number: 404-740-9
CAS number: 115895-09-5
Date of latest submission(s) considered[1]: 22/03/2017
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 Ethyl 3,5-dichloro-4-hexadecyloxycarbonyloxybenzoate] (Registrant(s))

DECISION ON SUBSTANCE EVALUATION

1. Requested information

Based on Article 46(1) of the REACH Regulation (Regulation (EC) No 1907/2006), you are requested to submit the following information on the registered substance Ethyl 3,5-dichloro-4-hexadecyloxycarbonyloxybenzoate, CAS 115895-09-5 (EC 404-740-9):

1. Enhanced ready biodegradation test (test method: enhancement of any of the four respirometric tests, OECD Test Guideline for Ready Biodegradability No. 301 B, C, D or F), as specified in Appendix 1.

   Alternatively, or if the enhanced ready biodegradation test is carried out but fails the pass level, the tests listed under request 2 below shall be performed on the registered substance Ethyl 3,5-dichloro-4-hexadecyloxycarbonyloxybenzoate, CAS 115895-09-5 (EC 404-740-9):

2.1. Water Solubility Test: EU A.6/OECD 105 using the column elution method.

and, depending on the outcome of the water solubility test, either option 2.2.1 or 2.2.2:

2.2.1. Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test: EU C.25 / OECD 309 at 12 °C in fresh water using radiolabelling. The amount of suspended solids in the pelagic test should be representative of the level of suspended solids in EU surface water. The concentration of suspended solids in the surface water sample used should therefore be approximately 15 mg dw/L. Testing natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable. This test shall be performed if monitoring is analytically feasible under the following conditions: the test item concentration in the water simulation test is lower or equal to the water solubility of the test item and the limit of quantification is equal to or less than 10 % of the applied concentration in the water simulation test (cf. paragraph 15 of OECD Guideline 309. This

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

test shall be used both to determine the half-life of the parent substance as well as to identify any transformation/degradation products;

or

2.2.2. Aerobic and Anaerobic Transformation in Soil Test: EU C.23/OECD 307 at 12°C using radiolabelling. This test shall be performed if both conditions explained in Appendix 1 for conducting the simulation biodegradation test in 2.2.1. cannot be fulfilled simultaneously. This test shall be used both to determine the half-life of the parent substance as well as to identify any transformation/degradation products.

Regarding request 1, you are given the option to perform the enhanced biodegradability test first, or perform directly the simulation tests. The water solubility test and a simulation test (request 2) shall be performed if the enhanced test failed or it is not performed, as further explained in Appendix 1.

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 **4 January 2021.** The full study report has to be submitted for the studies under request 1, 2.1 and 2.2.1/2.2.2. The deadline takes into account the sequence of testing and the time that you may need to agree on which of the registrant(s) will perform the required tests. The evaluating Member State Competent Authority (MSCA) requires to have access to the full study reports including all relevant details of the studies, ensuring that it can draw a clear conclusion regarding the scientific merits and the result of the studies.

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.

2. 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.

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[3] by Leena Ylä-Mononen, Director of Evaluation

[3] 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 Ethyl 3,5-dichloro-4-hexadecyloxycarbonyloxybenzoate 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.

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

The concern(s) identified

The overall concern evaluated in this substance evaluation is that both parent substance and some predicted hydrolysis products are suspected of having PBT/vPvB properties. According to the ECHA REACH Guidance Chapter R.11: PBT/vPvB assessment (ECHA, 2017), Ethyl 3,5-dichloro-4-hexadecyloxycarbonyloxybenzoate, CAS 115895-09-5 (EC 404-740-7) meets the screening criteria for P/vP[4] since it is not readily biodegradable. The substance screens as B/vB based on its measured Log Kow values of 4.7 and >9.29 in the registration dossiers. No conclusion can currently be made on fulfilment of the definitive or screening criteria for T as no long-term aquatic toxicity tests with fish or aquatic invertebrates are available.

A hydrolysis test on Ethyl 3,5-dichloro-4-hexadecyloxycarbonyloxybenzoate is available in the registration dossiers. The test indicates that this substance is expected to hydrolyse at pH 4 and 7, with a shortest half-life of 26 h at pH 4.0 and 25°C. The study did not provide any information on the identity of the hydrolysis products. One of the registrants provided a report to the evaluating MSCA (dated 28 November 2016) describing the use of a microbial metabolism simulator (OECD Toolbox) and EAWAG-BBD Pathway Prediction System to predict potential metabolites of Ethyl 3,5-dichloro-4-hexadecyloxycarbonyloxybenzoate and use of QSARs to screen their PBT properties. Based on this initial QSAR screening exercise, the report concludes that none of the potential metabolites would fulfil the PBT or vPvB criteria. However, ECHA considers that some of these potential metabolites could be PBT or vPvB.

Consideration of registrants' comments on the draft decision

One of the registrants provided comments on the draft decision, commenting that pelagic organisms are unlikely to be exposed to the registered substance via the water phase due to its low water solubility, high Log Kow and high Log Koc. Furthermore, they indicate that based on these physico-chemical properties the registered substance will be extensively removed during primary treatment in a sewage treatment plant limiting the amount that will be in contact with sewage sludge microorganisms and discharged to the

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

aqueous compartment.

The registrant also argued that the registered substance has no professional or consumer uses and is limited to use at industrial sites with negligible releases to the environment. Therefore, exposure to the aquatic, sediment and terrestrial compartments will be negligible.

In response to the comments arguing that the environmental exposure potential is low, it is important to consider that PBT assessment under the REACH Regulation is in the first place a hazard assessment aiming at the clarification of the PBT/vPvB properties of a substance and not at the assessment of risks posed by uses of the substance. The PBT/vPvB assessment addresses the long-term exposure to the environment. Experience with PBT/vPvB substances has shown that they give rise to specific concerns based on their potential to persist and accumulate in the environment leading to widespread distribution with potential to cause effects that are unpredictable in the long-term and are difficult to reverse. Furthermore, ECHA considers that some of the potential degradation/transformation products screen for PBT concern and their actual formation should be further investigated.

The registrant comments that exposure to the environment will be negligible. However, it is noted that their chemical safety report still predicts emissions to the environment.

Further, the request may lead to the identification of the substance as a SVHC and subsequently to restriction or authorisation requirements under REACH. Therefore, the request has a realistic possibility of leading to improved risk management measures.

The same registrant also provided comments arguing that the substance can be assumed to have a very limited potential for bioaccumulation in accordance with ECHA Guidance R11, 2017, since the Log Kow is >10 and an OECD 421 reproduction/developmental toxicity study did not result in any clinical signs of toxicity on reproduction parameters or offspring viability. ECHA notes that several values for Log Kow are reported in the registration dossiers. Measured Log Kow values of 4.70 ± 0.10 (20°C) and >9.29 are reported and a QSAR prediction is provided of 10.43. All values are considered to be reliable by the registrant. In addition, the registrant reports in section 2.3 of their registration dossier that "Considering the available data, the bioaccumulation criterion (B) cannot be excluded." Therefore, it cannot be concluded based on the information currently available whether the substance has a limited bioaccumulation potential. The substance screens as bioaccumulative based on its Log Kow. Furthermore, the PBT properties of the potential degradation/transformation products may need to be investigated further.

Tiered testing strategy

In accordance with ECHA REACH Guidance Chapter R.11: PBT/vPvB assessment (ECHA, 2017), ECHA considers that the P concern should first be clarified. Further testing to clarify the B and T concern may be requested in a future substance evaluation decision.

What is the possible regulatory outcome

Where the 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.

1. Enhanced biodegradation screening test

Before conducting any of the simulation test(s) requested in the decision, you are given the option to choose, as an initial step, to perform an enhancement to the ready biodegradation test.

Such enhancements of some of the standard conditions of the ready biodegradability screening tests address test duration, accessibility of test item for the microbial inoculum, test vessel size. Generation of data allows P assessment to be considered at the screening phase, without the immediate simulation level testing. Page 51 of ECHA Guidance, Chapter R11 (version 3.0, June 2017) states: "*Given the time, costs and in some cases practical difficulties associated with a simulation test, an enhanced ready biodegradation test design offers a cost effective intermediate screening test. If sufficient degradation is shown in such a test, i.e. the pass level is reached, the substance can be considered as "not P"".* Due to the little experience currently available on the use of these approaches for the P assessment, an enhanced biodegradation test could be considered on a case-by-case basis and it is justifiable when some biodegradation has been observed in a standard ready biodegradability test or it is supported by additional data (from QSARs or other structural analogues). In an OECD 301B study, the substance achieved 34% mineralisation after 42 days indicating significant ultimate biodegradation occurred. Considering the substance low water solubility and test item concentration during the study (10 mg/l), biodegradation may have been limited by low bioavailability. Repeating the study with enhanced modifications is considered appropriate and proportional to assess persistence in a step-wise approach.

If sufficient degradation is shown in such a test, i.e. the pass level is reached, the result is used to indicate that the substance will not persist in the environment and a further simulation test is considered not needed. In this regard, see also page 42 of Guidance R11: "*For example, a result of more than 60% ultimate biodegradability (ThOD, CO2 evolution) or 70% ultimate biodegradability (DOC removal) obtained during 28 days in an enhanced ready biodegradability test may be used to indicate that the criteria for P are not fulfilled"*. However, test substances that degrade in these enhanced biodegradation screening tests will not be considered as readily biodegradable.

According to the ECHA Guidance on Information Requirements and Chemical Safety Assessment (IR/CSA) Chapter R.7b: Endpoint specific guidance (Version 4.0 June 2017), sections R.7.9.4 and R.7.9.5, the approaches in enhanced biodegradation screening tests could include: test duration extension (up to 60 days), testing in larger vessels, increasing the accessible fraction of low water soluble substances by use of test systems with the test substance on silica particles.

Furthermore, due to the low water solubility and the high adsorption potential of the test substance, you shall decide on the appropriate test method among any of the four respirometric tests: OECD Test Guidelines No. 301 B, or C, or D, or F, as specified in the Appendix R. 7.9-3 of ECHA Guidance Chapter R.7b.

In case you decide to perform an enhanced ready test, ECHA requires adequate and exhaustive details on the test design and arguments justifying the choice of the enhancements test type. Therefore, pursuant to Article 46(1) of the REACH Regulation, you shall provide a full study report of the performed enhanced ready test.

In case the outcome of the enhanced test, as reported in the full study report, did not allow you to exclude unequivocally the persistence property (i.e. the enhanced ready test failed), water solubility testing followed by simulation testing shall be performed to clarify conclusively the concern, as required in the following.

Biodegradation simulation testing

2. 1 Water solubility test

Why new information is needed

The registration dossiers contain a water solubility test on the registered substance. The registrant(s) conclude from this test that the water solubility of the substance at 25°C is 0.078 mg/L. This value is higher than expected based on the experimentally derived log Koc for the substance of 8.4. In order to determine whether the persistence (P) criterion of Annex XIII of the REACH Regulation is fulfilled, further biodegradation simulation testing of the registered substance at a test temperature of 12°C is considered necessary (see request 2.2.1/2.2.2). A reliable water solubility test under environmental conditions comparable to the simulation testing, i.e. at 12°C, will provide essential information to decide whether a biodegradation simulation test in water at 12°C is analytically feasible or not. A reliable water solubility result will also help to decide the appropriate exposure route for future fish bioaccumulation testing, if needed at a later stage to clarify the B concern.

Considerations on the test method and testing strategy

The OECD 105 guideline recommends for low water soluble substances (< 10 mg/L) the column elution method. Given that the solubility is dependent on the temperature, it is recommended to perform this water solubility test at the same temperature as the simulation study, i.e. 12°C.

Consideration of registrants' comments on draft decision

One of the registrants provided comments on the draft decision, agreeing to perform the requested water solubility test.

Consideration of alternative approaches

The request for a water solubility test the registered substance is suitable and necessary to obtain information that will allow to decide on the most feasible degradation simulation test to perform to clarify the P concern. QSAR predictions of water solubility are not suitable/reliable because the registered substance is not within the applicability domain of the model. More explicitly, there is no equally suitable alternative way available of obtaining this information.

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 using the registered substance subject to this decision:

Water solubility test: EU A.6/OECD 105 using the column elution method, at a temperature of 12°C.

2.2.1/2.2.2 Simulation testing

Why new information is needed

Ethyl 3,5-dichloro-4-hexadecyloxycarbonyloxybenzoate, CAS 115895-09-5 (EC 404-740-7) shows 12-21% biodegradation in 28 days in a reliable ready biodegradability test available in the registration dossiers performed according to test guideline OECD 301B in 1989. The registered substance therefore screens as P/vP in accordance with ECHA REACH Guidance Chapter R.11: PBT/vPvB assessment (ECHA, 2017). The substance hydrolyses at pH 4 and 7, but the transformation products were not analyzed. There were some doubts about the reliability of the test as the concentration tested in the hydrolysis test appears to be above the measured water solubility, but the clear pH dependence of the hydrolysis suggests that hydrolysis of the substance is actually taking place.

In order to conclude the P assessment, the environmental half-life is needed together with identification of the degradation products. A simulation test allows a half-life to be measured and will allow identification of degradation products. It can be used to conclude on the P status of the registered substance and if degradation products are identified they can be further screened for their PBT properties.

Considerations on the test method and testing strategy

If, based on the outcome of the above requested water solubility test, you determine that it is analytically feasible to perform a simulation test in water, option 2.2.1 (aerobic

mineralization in surface water study) shall be performed. The following conditions need to be fulfilled: 1) the test item concentration in the water simulation test is lower or equal to the water solubility of the test item and 2) the limit of quantification is equal to or less than 10 % of the applied concentration in the water simulation test (cf. paragraph 15 of OECD Guideline 309). If both conditions cannot be fulfilled simultaneously, you shall perform a simulation test in soil, i.e. option 2.2.2.

In OECD TG 309, 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). The test shall be performed using natural surface water without the addition of suspended matter, as recommended in ECHA Guidance R11 (version 3.0, June 2017), page 55. The amount of suspended solids in the pelagic test should be representative of the level of suspended solids in EU surface water. The concentration of suspended solids in the surface water sample used should therefore be approximately 15 mg dw/L. Testing natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable.

If it is not technically feasible to perform the OECD TG 309 test, based on the criteria given above, an OECD TG 307 test shall be performed. Due to the low water solubility and high Log Koc (8.4), the substance can be expected to distribute to soil as well as water. Performing a study in soil will minimise any complications due to the low water solubility of the registered substance.

Irrespective of the test method performed, it is important that metabolites/degradation products are identified/sufficiently characterized relative to the PBT properties.

The REACH Guidance 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. Thus the selected study must be performed at 12°C.

To clarify the persistency (P) concern the evaluating MSCA decided during the evaluation period that as a first step modelling should be used to get more information about the degradation products and their PBT properties.

You submitted the outcome of a screening exercise on the potential microbial metabolites of Ethyl 3,5-dichloro-4-hexadecyloxycarbonyloxybenzoate. A total of 52 metabolites were identified by means of microbial metabolism simulator (OECD Toolbox) and EAWAG-BBD Pathway Prediction System. Subsequently all metabolites were screened with regard to its potential for P (persistence) using BIOWIN models as indicated in ECHA guidance R.11. Additionally, US EPA PBT profiler or if available experimental data was used. Overall, the report concluded that 13 metabolites have a potential for persistence and that only one metabolite may have a potential for bioaccumulation. This metabolite (metabolite 3) formed by hydrolysis of the benzoate ester bond is based on BIOWIN 3 predicted to be more persistent than the parent while based on the log Pow predicted by KOWWIN v1.68 to have a similar potential for bioaccumulation. The half-life for hydrolysis of metabolite 3 reported as predicted with Hydrowin is 34 days which is the same as that reported for the parent. The Meylan

Model (Meylan et al. 1999) for pH-sensitive substances was used to predict the BCF as the only model that automatically categorizes into non-ionic and ionic compounds and corrects in such circumstances the predicted BCF. The predictions using the Meylan model were well below the threshold for bioaccumulation for all metabolites except metabolite 3.

Regarding the persistence screening exercise several weaknesses were identified. Generally, even for screening assessments the applicability domain of the QSAR should have been checked. Metabolite 3 contains a linear 16-carbon chain which is recognized in BIOWIN 1-4 to a very limited extent (only a "linear C4 terminal chain [CCC-CH3]) whereas BIOWIN 5 and 6 recognize this part completely (a methyl group and 15 occasions of "-CH2- [linear]"). In addition, BIOWIN 5-6 recognize two occasions of "Aromatic-H" which is not included in BIOWIN 1-4. None of the BIOWIN models 1-6 recognize the ester fragments nor the carbonyl group between the aromatic ring and the linear carbon chain. Therefore, there is uncertainty in the predictions as several fragments are excluded from the prediction. The effect of these missing fragments on the degradability should be considered when using the predicted results (e.g., is the degradability likely to be underestimated or overestimated). The score in BIOWIN 3 is 1.75-2.25 which does not lead to conclude that P criterion is not fulfilled.

For the Hydrowin results no detailed information is available in the QSAR report provided (e.g., which parts of the molecule were recognized by the model or whether/which substitute fragments were used by the model). ECHA notes that EPI Suite (v4.00) HYDROWIN (v2.00) does not give a half-life prediction for Metabolite 3 at all but only gives the following result:

"Hydrolyzable Function detected: Carbonates

-C-O-C(=O)-O-C-"

Furthermore, the reference temperature for the hydrolysis model half-life is not mentioned in the QSAR report provided by the registrant(s). It is not clear if a conversion to 12°C is still needed.

Regarding the bioaccumulation screening exercise it is noted that for ionizing metabolites, the assessment used log D at neutral pH as screening parameter and a cut of value < 3. ECHA considers log D is not the best way to estimate the bioaccumulation potential of ionizing organic substances. Especially not for those ionizing organic substances, which are predominantly charged (> 90 % Armitage et al. 2016) under environmentally relevant pH conditions. Log D corresponds to Log Kow in dependence of pH. Using Log Kow for the screening of the bioaccumulation potential is based on the assumption that substances are bound to storage lipid. The sorption to membrane lipids or proteins is not considered (Escher and Schwarzenbach, 1996). The distribution of ionizing organic substances in organisms is strongly influenced by their charge. Due to their charge, ionizing organic substances may have a high potential to bind to membrane lipids and proteins. Therefore, Log D might only help to estimate the bioaccumulation

potential in dependence of pH for ionizing organic substances where the neutral as well as the charged form is environmentally relevant.

The primary hydrolysis metabolite that is identified as having the highest bioaccumulation potential still contains an ester bond which is recognized as abiotically or biotically degradable (see also ECHA guidance R.11, p72, ECHA, 2017). ECHA considers that a robust conclusion on the persistence of Ethyl 3,5-dichloro-4-hexadecyloxycarbonyloxybenzoate including its primary hydrolysis metabolite and other degradation products cannot be made based on existing information.

Simulation tests performed with sediment, soil or surface water with the addition of suspended sediment (Shrestha et al, 2016) possibly imply the formation of non-extractable residues (NER). These residues (of the parent substance and/or transformation products) are bound to the soil or to the sediment particles. NERs may potentially be re-mobilised as parent substance or transformation product unless they are irreversibly bound or incorporated into the biomass. When reporting the non-extractable residues (NER) in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

It is noted that the environmental distribution fugacity modelling ("Unit world model") indicates that the constituents of the registered substance are also significantly distributed to water, and that at steady state 11.6 % of relative mass fraction of the substance is predicted within the water compartment according to EPIWIN ver. 4.1, with equal emission to air, water and soil (relevant input parameters based on QSAR predictions by the EPIWIN program). With emission only to water (a more realistic emission profile for the registered substance) the relative mass fraction of the substance in the water compartment is predicted to be 64 % at steady state. Therefore, ECHA considers that surface water is an environmentally relevant compartment. Furthermore, experience has shown that from an analytical perspective, simulation tests in water are likely to be easier to conduct and interpret compared to simulation tests in soil. These considerations justify that the primary requested simulation test is a simulation transformation test in surface water (OECD TG 309), if technically feasible.

If the aquatic pelagic simulation test is demonstrated to be technically not feasible, a simulation test in soil is to be performed. Based on the relative mass distribution in Sewage Treatment Plants (biodegraded fraction / sludge adsorption /volatilization /emission to surface water) estimated within EPIWIN v. 4.1, by far the largest fraction of the substance will adsorb to sludge. According to the exposure scenarios provided in the CSR, the direct release to soil is not expected. The CSR states that indirect exposure of soil is only possible via air, but due to rapid indirect photodegradation by reaction with OH radicals indirect contamination of the soil compartment via the atmosphere is highly unlikely. However, a significant indirect exposure to soil via sludge application is not unlikely to occur given the high predicted concentrations in agricultural soil for two out of four exposure scenarios (ES1 and ES2) in the CSR. The predicted concentration in sediment is low for all four exposure scenarios.

Consideration of registrants' comments on draft decision

One of the registrants provided comments on the draft decision, agreeing to perform a degradation simulation test with the test guideline dependent on the outcome of the water solubility study.

Consideration of alternative approaches

To avoid unnecessary vertebrate testing the preference is to first try to clarify the persistence concern for the parent substance and to identify any degradation/transformation products. The OECD 309 or 307 test is suitable and necessary to obtain information that will allow to clarify this concern. More explicitly, there is no equally suitable alternative way available of obtaining this information.

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 using the registered substance subject to this decision:

Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test: EU C.25 / OECD 309 at 12°C in fresh water using radiolabelling and with the addition of suspended sediment in accordance with paragraph 20 of the OECD 309 test guideline. This test shall be performed if monitoring is analytically feasible under the following conditions: the test item concentration in the water simulation test is lower or equal to the water solubility of the test item and the limit of quantification is equal to or less than 10 % of the applied concentration in the water simulation test (cf. paragraph 15 of OECD Guideline 309);

or

Aerobic and Anaerobic Transformation in Soil Test: EU C.23/OECD 307 at 12°C using radiolabelling. This test shall be performed if both conditions for conducting the simulation biodegradation test in the above test (OECD 309) cannot be fulfilled simultaneously.

References

Armitage, J. M., Erickson, R. J., Luckenbach, T., Ng, C. A., Prosser, R. S., Arnot, J. A., Schirmer, K. and Nichols, J. W. (2016), Assessing the bioaccumulation potential of ionizable organic compounds: Current knowledge and research priorities. Environ Toxicol Chem. doi:10.1002/etc.3680

ECHA (2017): Guidance on information requirements and chemical safety assessment. Chapter R.11: PBT Assessment.

ECHA (2017). Guidance on information requirements and chemical safety assessment, Chapter R.7c: Endpoint specific guidance.

Escher, B. I. and R. P. Schwarzenbach (1996). "Partitioning of substituted phenols in liposome-water, biomembrane-water, and octanol-water systems." Environ Sci Technol 30(1): 260-270.

Gerloff-Elias, A., (2016), QSAR report, Identification and characterization of potential metabolites of Ethyl 3,5-dichloro-4-hexadecyloxycarbonyloxybenzoate (CAS no. 115895-09-5) with regard to PBT criteria using *in silico* methods. Dr.Knoell Consult GmbH, Germay.

Meylan W.M., Howard P.H., Boethling R.S. et al. (1999) Improved Method for Estimating Bioconcentration / Bioaccumulation Factor from Octanol/Water Partition Coefficient. Environ. Toxicol. Chem. 18(4): 664-672

Shrestha P, Junker T, Fenner K, Hahn S, Honti M, Bakkour R, Diaz C and Hennecke D (2016) Simulation Studies to Explore Biodegradation in Water-Sediment Systems: From OECD 308 to OECD 309. Environ Sci Technol 50:6856-64.

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 and exposure to the environment, ethyl 3,5-dichloro-4-hexadecyloxycarbonyloxybenzoate CAS No 115895-09-5 (EC No 404-740-9) 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 Slovenia (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 abovementioned concerns. Therefore, it prepared a draft decision under Article 46(1) of the REACH Regulation to request further information. It subsequently submitted the draft decision to ECHA on 16 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. ECHA received comments from one of the registrants and forwarded them to the evaluating MCSA without delay.

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

Subsequently, four Competent Authorities of the Member States and ECHA submitted comments and proposals for amendment to the draft decision. The evaluating MSCA reviewed the proposals for amendment received and where considered appropriate the draft decision was amended accordingly.

On 1 December 2017 ECHA notified you of the proposals for amendment to the draft decision and invited you pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

By 3 January 2018 ECHA did not receive any comments from you to the proposals for amendment to the draft decision.

MSC agreement seeking stage

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

EUROPEAN CHEMICALS AGENCY

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/ies, the sample of the substance to be used ('test material') has to 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 the 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 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 stud(y/ies) on behalf of all of them.