EUROPEAN CHEMICALS AGENCY

Helsinki, 25 October 2017

Addressee: [redacted]

Decision number: CCH-D-2114375744-39-01/F
Substance name: *A mixture of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; [...]*
EC number: 401-680-5
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 04.03.2014
Registered tonnage band: 100-1000T

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance;**

2. **Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method, as explained in Appendix 1, section 2, with the registered substance;**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **3 August 2020**. You also have to update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations 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 suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by Kevin Pollard, Head of Unit, Evaluation E1.

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

EUROPEAN CHEMICALS AGENCY

Appendix 1: Reasons

1. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.1.6., column 2. You provided the following justification for the adaptation: *"In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing to fish shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on fish. According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB. A long-term toxicity test on daphnids is available and did not reveal any effect. The hazard assessment of test substance reveals neither a need to classify the substance as dangerous to the environment, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment. For these reasons, and for reasons of animal welfare, a long-term toxicity test in fish is not provided."*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., column 2.

More specifically, you indicate that the registered substance has a harmonised classification of Aquatic chronic 2. You claim further that this classification was not valid, however, ECHA notes that you have not provided compliant information on aquatic toxicity that would confirm your statement. While the harmonised classification as Aquatic Chronic 2 is still applicable, the Risk Assessment Committee has on 4 December 2015 issued an opinion "that the harmonised classification of Aquatic Chronic 2 should be changed to Aquatic chronic 4. The codification of this proposed amendment to the CLP Regulation is still pending. At any rate, the registered substance shall be considered potentially hazardous for the environment.

You argue further that a chemical safety assessment would be required to indicate the need to investigate further effects to aquatic organisms. However, ECHA notes that you have not conducted an exposure and risk assessment for the aquatic environment to demonstrate the safe use despite an existing classification for this environmental sphere. Your conclusion that no further testing is required cannot be verified therefore.
According to REACH Annex VIII, Section 9.1.3., the long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6) shall be considered if the substance is poorly water soluble. Poorly soluble substances require longer time to be significantly taken up by the test organisms and so steady state conditions are likely not to be reached within the duration of a short-term test.

Short-term tests may thus not give a true measure of toxicity for poorly soluble substances and toxicity may actually not even occur at the water solubility limit of the substance if the test duration is too short.

The long-term toxicity testing in *Daphnia* with the registered substance did not reveal any effects up to the water solubility limit. However, due to lack of effects seen in short-term studies it is not possible to determine a difference in the sensitivity of species and thus to draw conclusions on environmental risks for aquatic organisms testing for long term effects in fish is required.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) fish early-life stage (FELS) toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

However, the FELS toxicity test according to OECD TG 210 is more sensitive than the fish, short-term toxicity test on embryo and sac-fry stages (test method EU C.15 / OECD TG 212), or the fish, juvenile growth test (test method EU C.14. / OECD TG 215), as it covers several life stages of the fish from the newly fertilized egg, through hatch to early stages of growth (see ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), *Chapter R7b, Figure R.7.8-4).*

Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of substances which are expected to cause effects over a longer exposure period, or which require a longer exposure period of time to reach steady state (ECHA *Guidance Chapter R7b,* version 4.0, June 2017).

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you have highlighted that no effects were observed up to the water solubility limit of the substance for algae, *Daphnia* (short-term and long-term), and fish (short-term). You have also pointed out that no effects were observed on fish during the duration of the bioaccumulation tests (28-29 days), even when conducted at concentration above the water solubility limit of the substance. You have concluded that no long-term toxicity test on fish are necessary. ECHA however notes that juvenile or mature fish are used in bioaccumulation tests whereas early life stage fish are tested for the OECD 210 test guideline.

Early life stage fish are deemed more sensitive than juvenile or adult fish. ECHA considers that the information currently available is insufficient to rule out effects on early life stages of fish.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Notes for your consideration

Due to the low solubility of the substance in water you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

2. Identification of degradation products (Annex IX, Section 9.2.3.)

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The technical dossier does not contain an adaptation in accordance with column 2 of Annex IX, Sections 9.2 or 9.2.3. or with the general rules of Annex XI for this standard information requirement.

According to Annex IX, Section 9.2.3., column 2 of the REACH Regulation, identification of degradation products is not needed if the substance is readily biodegradable. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable in OECD 301B test, degradation 13-19% in 28 days (IUCLID Section 5.2.).

Furthermore, ECHA notes that you have not presented any further justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to provide information on the degradation products. ECHA considers that this information is needed in relation to the PBT/vPvB assessment.

Pursuant to Annex XIII of the REACH Regulation "*the identification* [of PBT and vPvB substances] *shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products*". ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11.4.1. further specifies that "*constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation*. [...] *Similar arguments apply to relevant transformation/degradation products.*
The PBT/vPvB assessment should normally be carried out for each relevant transformation or degradation product". ECHA notes that your CSA does not contain any information on whether the degradation products could be PBT/vPvB or not.

Information on degradation products shall also be taken into account for the exposure assessment (Annex I 5.2.4. of the REACH Regulation) and for the hazard assessment (e.g. column 2 of Annex X 9.4 and Annex X 9.5.1 of the REACH Regulation). Finally, information on degradation products is required for the preparation of Section 12 of the safety datasheet (Annex II of the REACH Regulation).

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

Regarding appropriate and suitable test methods, they will have to be substance-specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition, degradation half-life, log Kow and potential toxicity of the metabolite may be investigated. You will need to provide a scientifically valid justification for the chosen method. You are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R.7b., Section R.7.9.4. for more information.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you have claimed that testing the registered substance is technically not feasible since an it is an UVCB (substance of Unknown or Variable composition, Complex reaction products or Biological materials) and an appropriate analytical method to identify the possible degradation products does not exist.

As part of your comments, you have used model Oasis CATALOGIC to predict the metabolites for several representative constituents. Based on these predictions, you have concluded that the constituents with branched chains would not degrade and that the experimental identification of degradation products for those constituents would thus not be practicable. You concluded that a representative constituent with a linear chain should preferably be tested.

However, you have also claimed that it is technically not possible to synthesise one specific constituent in a controlled manner and proposed instead to perform an OECD 308 test with substance 2-(Benzotriazol-2-yl)-4-dodecylphenol (CAS 3142-42-5), but which is not part of the registered substance.

ECHA takes note of your testing strategy and explanations, but notes that you did not assess whether the metabolites you have predicted could be PBT/vPvB.

ECHA agrees with you that the phenolic benzotriazole core of the registered substance should be regarded as recalcitrant. ECHA also agrees that the linear side chains are likely to be degraded by β-oxidation processes whereas the branched chains are expected to be more stable. ECHA notes that the OECD 308 test you have proposed to perform with the read-across substance 2-(Benzotriazol-2-yl)-4-dodecylphenol (CAS 3142-42-5) could be used to verify that hypothesis, but would not be enough for the PBT/vPvB assessment of the registered substance. Pursuant to Annex XIII of the REACH Regulation, the PBT/vPvB properties of every relevant constituent and degradation products of the registered substance need to be assessed. Even if the constituents with a linear chain are the most abundant, ECHA considers that other constituents and their degradation products are also relevant and that their PBT/vPvB properties need to be assessed.

In particular, ECHA notes that other substances of the hydroxyphenyl-benzotriazole class with branched chains have been identified as vP/vB and consequently as Substances of Very High Concern (SVHC), *e.g.* UV-320 (EC 223-346-6) and UV-328 (EC 247-384-8).

Based on its own calculations, ECHA further notes that most of the metabolites you have identified are predicted to be not readily biodegradable and therefore potentially persistent or very persistent. In addition, they have predicted log Kow values that exceed 4.5, and therefore meet the screening criterion for high bioaccumulation. ECHA acknowledges that actual bioconcentration from water may not be significant for very hydrophobic substances (e.g. log Kow >6) but notes that bioaccumulation via the diet may still be.

In conclusion, ECHA considers that the information gathered so far on the predicted metabolites needs to be included in your registration dossier and you shall further assess their PBT/vPvB properties pursuant to Annex XIII of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision:

Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

3. Deadline to submit the requested information in this decision

In the draft decision communicated to you, the time indicated to provide the requested information was 18 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 33 months. You justified this request by providing statements from the testing laboratories indicating availabilities and timelines for processing the requested tests. Therefore, ECHA has granted the request and set the deadline to 33 months.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 2 December 2016.

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

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

ECHA took into account your comments and amended the deadline.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

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

3. In carrying out the tests required by the present decision, it is important to ensure that the particular sample of substance tested is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported. If the registration of the substance covers different grades, the sample used for the new tests must be suitable to assess these.

   Furthermore, there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.