EUROPEAN CHEMICALS AGENCY

Helsinki, 21 July 2017

Addressee: [redacted]

Decision number: TPE-D-2114366682-42-01/F
Substance name: 2,4,6-trimethylphenol
EC number: 208-419-2
CAS number: 527-60-6
Registration number: [redacted]
Submission number: [redacted]
Submission date: 30/09/2016
Registered tonnage band: 100-1000

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation ((EC) No 1907/2006) (the REACH Regulation), ECHA examined your testing proposal and decided as follows[1].
You are requested to perform:

1. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309) at a temperature of 20°C including the identification of the degradation products (Annex IX, Section 9.2.3.) using 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 an adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **28 January 2019**. You also have to update the chemical safety report, where relevant.

The reasons for 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.

[1] No testing must be started or performed at this moment. A decision only becomes legally effective and binding for you after a decision has been adopted according to Article 51 of the REACH Regulation. ECHA will take the decision either after the date it has become clear that Member State competent authorities have not made any proposals to amend to the draft decision or, where proposals to amend it have been made, after the date the Member State Committee reached a unanimous agreement on the draft decision.

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[2] by Kevin Pollard, Head of Unit, Evaluation, E1

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

Appendix 1: Reasons

The decision of ECHA is based on the examination of the testing proposals submitted by you.

1. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)**

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"Simulation testing on ultimate degradation in surface water" is a standard information requirement as laid down in Annex IX, Section 9.2.1.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for testing the registered substance in a Simulation biodegradation study in surface water (OECD TG 309 / EU C.25) with the following justification: "*Testing proposal on the basis of the screening test on biodegradation in water results as not readily biodegradable*". ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.2.1.2. of the REACH Regulation.

Furthermore, ECHA notes that according to Section 9.2.3 in Annex IX of the REACH Regulation identification of degradation products is a standard information requirement. The biodegradation section in the technical dossier does not contain any information in relation to the identification of degradation products, nor 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. Consequently there is an information gap and it is necessary to provide information for this information requirement. The identification of degradation products should therefore be included in the requested degradation simulation test. It is also noted that the OECD TG 309 Test Guideline features the formation and identification of the degradation products.

Annex XIII of the REACH Regulation indicates that identification of PBT/vPvB substances shall also take account of the PBT/vPvB properties of relevant constituents of a substance and relevant transformation and/or degradation products.

The information currently available in the technical dossier and the Chemical Safety Assessment (CSA) is not sufficient to conclude on the biodegradation potential and consequently the persistence of the registered substance or its degradation products in water and thus, it is necessary to generate additional information for this endpoint.

In the testing proposal you have not specified the temperature at which the test shall be performed. ECHA considers that the main interest of the proposed testing lies on the identification of the degradation products. Therefore, a test temperature of 20°C is more appropriate because it results in a faster degradation rate.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study using the registered substance subject to the present decision:

Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25/OECD TG 309) at a temperature of 20°C including the identification of the degradation products (Annex IX, Section 9.2.3.).

Notes for your consideration

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the test detailed above is available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.11.1.3. and Figure R. 11-1 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 30 September 2016.

This decision does not take into account any updates after **24 May 2017**, 30 calendar days after the end of the commenting period.

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 did not receive any comments by the end of the commenting period.

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 decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the 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 the Member States.

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.