Helsinki, 3 May 2016

Addressee: [redacted]

Decision number: CCH-D-2114329334-54-01/F
Substance name: 2-hydroxy-2-methylpropiophenone
EC number: 231-272-0
CAS number: 7473-98-5
Registration number: [redacted]
Submission number: [redacted]
Submission date: 19.08.2015
Tonnage band: 1000 tonnes or more per year

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. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a second species (rabbits), oral route with the registered substance;**

2. **Robust study summary for [redacted] Biodegradation in water; screening tests (Annex VII, Section 9.2.1.1 in conjunction with Annex 1, Section 3.1.5).**

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 of the REACH Regulation. In order 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 are required to submit the requested information in an updated registration dossier by **10 August 2017**. You shall also 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. 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, 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[1] by Ofelia Bercaru, Head of Unit, Evaluation E3

[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.

Appendix 1: Reasons

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

Pre-natal developmental toxicity studies (test method EU B.31./OECD TG 414) on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

The technical dossier contains information on a pre-natal developmental toxicity study in rats by the oral route using the registered substance as test material.

You attempted to fulfil this information requirement with an adaptation.

You provided the following justification for the adaptation: "*The need for testing for developmental toxicity in rabbits will be assessed once the first results of the extended one-generation-study have become available. At the moment, there is insufficient data to decide if waiving criteria can be applied or not. No rise of concern for developmental toxicity arises from the teratogenicity study in rats.*"
ECHA considers that you may be seeking to adapt this information requirement according to Annex X, Section 8.7., column 2, paragraph 2 and wait for the results of the reproductive toxicity study to see if they indicate a need to classify the substance to toxic to reproduction category. However, ECHA notes that your adaptation would not meet the specific rules for adaptation of Annex X, Section 8.7., column 2, paragraph 2, because classification as '*toxic for reproduction category 1A or 1B: May damage fertility (H360F)*' is a waiving criterion for further testing on toxicity for fertility. However, even if it is fulfilled, testing for developmental toxicity must still be considered.

You further justify your adaptation with an argument that no concern arises from the first prenatal developmental toxicity study. This is not a valid reason to adapt this information requirement under Annex X, Section 8.7, column 2 or Annex XI to the REACH Regulation.

Therefore, your adaptation of the information requirement is rejected.

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.

The test in the first species was carried out by using a rodent species rats. According to the test method EU B.31/OECD 414, the rabbit is the preferred non-rodent species. On the basis of this default assumption, ECHA considers that the test should be performed with rabbits as a second species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA Guidance on information requirements and chemical safety assessment (version 4.1, October 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

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: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a second species rabbits by the oral route.

In your comments you requested for an extension of the period for updating the dossier in order to perform at least one additional dose-range-finding study. Considering these circumstances ECHA agrees that a three month extension of the previously considered twelve months deadline is appropriate. The deadline for provision of the requested information is therefore set to 15 months from the notification of this decision.

2. Robust study summary for [redacted] Biodegradation in water; screening tests (Annex VII, Section 9.2.1.1. in conjunction with Annex 1, Section 3.1.5)

Pursuant to Articles 10(a)(vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

Pursuant to Articles 10(a)(vii) of the REACH Regulation, the information set out in Annex VII to XI must be provided in the form of robust study summary, if required under Annex I. Article 3(28) defines a robust study summary as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the Practical Guide 3: 'How to report robust study summaries'.

A Ready biodegradability study is a standard information requirement as laid down in Annex VII, Section 9.2.1.1. 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. Furthermore, pursuant to Article 10 (a)(vii) and Annex I, Section 3.1.5. if there are several studies addressing the same effect, then, the study or studies giving rise to the highest concern shall be used to draw the conclusion and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust summaries will be required of all key data used in the hazard assessment.

You have provided a study record for a biodegradation in water: screening test [redacted] to meet the standard information requirement of Annex VII, Section 9.2.1.1.

However, ECHA notes that, contrary to Article 3 (28) of the REACH Regulation the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and its use for hazard assessment. In particular, the following elements are missing:

a. Results: data in tabular form; any observed inhibition or toxicity; any observed abiotic degradation;
b. Specific chemical analytical data, if available;
c. Analytical data on intermediates, if available;
d. The graph of percentage degradation against time for the test and reference substances to include lag phase, degradation phase, the 10-d window and slope percentage removal at plateau, at end of test, and/or after 10-d window.
e. Discussion of results
f. Detailed information on the validity criteria spesified in OECD TG 301B.

Therefore, you need to provide a complete robust study summary with the above missing elements for this study.

ECHA acknowledges from your comments on the draft decision that further information will be included in the robust study summary for [redacted], Biodegradation in water; screening tests ([redacted]) in a registration update. Please note in this regard that 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 information in the updated dossier will be evaluated at the follow up phase of the process.

Hence, 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.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information: Robust study summary for [redacted] Biodegradation in water; screening tests ([redacted]

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 23 November 2015.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation:

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

ECHA took into account your comments and amended the deadline for provision of the information requested by this decision.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) 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. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2019.

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

3. 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.

4. In carrying out the test(s) 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 test(s) must be suitable to assess these. Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.