EUROPEAN CHEMICALS AGENCY

Helsinki, 18 July 2017

Addressee
[redacted]

Decision number: CCH-D-2114366657-35-01/F
Substance name: citronellyl acetate
EC number: 205-775-0
CAS number: 150-84-5
Registration number: [redacted]
Submission number: [redacted]
Submission date: 15/04/2016
Registered tonnage band: 100-1000

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. **Robust study summary (RSS) for key study, "The Biodegradability of Perfume Ingredients in the Sealed Vessel Test", Ready biodegradability (Annex VII, Section 9.2.1.1 in conjunction with Annex I, Section 3.1.5)**

2. **Robust study summary (RSS) for supporting study, "Pruefung der vollstaendigen biologischen Abbaubarkeit von Citronellylacetat in einem Respirometer ueber die Messung des biologischen Sauerstoffverbrauchs", Ready biodegradability (Annex VII, Section 9.2.1.1 in conjunction with Annex I, 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 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 **25 January 2018**. You also have to update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

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 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.

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Appendix 1: Reasons

1. **Robust study summary (RSS) for key study, "The Biodegradability of Perfume Ingredients in the Sealed Vessel Test", Ready biodegradability (Annex VII, Section 9.2.1.1 in conjunction with Annex I, Section 3.1.5)**

2. **Robust study summary (RSS) for supporting study, "Pruefung der vollstaendigen biologischen Abbaubarkeit von Citronellylacetat in einem Respirometer ueber die Messung des biologischen Sauerstoffverbrauchs", Ready biodegradability (Annex VII, Section 9.2.1.1 in conjunction with Annex I, Section 3.1.5)**

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.

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 ECHA Practical Guide 3: 'How to report robust study summaries'.

"Ready biodegradability" 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 study summaries will be required of all key data used in the hazard assessment.

In the technical dossier you have provided the following study records to fulfil the standard information requirement of Annex VII, Section 9.2.1.1.:

- Key study, reliability 2, "The Biodegradability of Perfume Ingredients in the Sealed Vessel Test", non GLP, test method: OECD Guideline 301 B (Ready Biodegradability: CO2 Evolution Test) with the registered substance
- Supporting study, reliability 1, "Pruefung der vollstaendigen biologischen Abbaubarkeit von Citronellylacetat in einem Respirometer ueber die Messung des biologischen Sauerstoffverbrauchs", GLP, test method: OECD Guideline 301 F (Ready Biodegradability: Manometric Respirometry Test)

ECHA notes that you have not provided sufficient information in the technical dossier to allow verification of reliability of these studies, neither have you populated the "Validity criteria fulfilled" in the relevant IUCLID fields under these endpoint study records.
Firstly, the OECD TG 301 (1992) recommends that for 301 B CO2 EVOLUTION TEST method (used in key study), the test substance should be non-volatile, while insoluble and volatile substances may be assessed using 301 F MANOMETRIC RESPIROMETRY TEST (used in supporting study) but provided that precautions are taken. ECHA notes that you have

reported a Henry's law constant of 236 Pa m³/mol in the technical dossier of the registered substance, indicating potential volatilisation of the test material. You have not justified why the results of the tests would be still reliable despite the limitations in applicability of the OECD TG 301B and 301F to volatile substances.

Secondly, according to general validity criteria described in OECD TG 301 (1992), paragraph 24, a test is valid when (1) the difference in removal of the test chemical between the replicate values at the plateau is less than 20%, at the end of the test or at the end of the 10-d window, as appropriate, and (2) if the percentage degradation of the reference compound has reached the pass levels by day 14. If either of these conditions is not met, the test should be repeated. ECHA notes that you have neither provided results on the replicate samples separately (both key and supporting studies) nor on the reference material (the key study). Therefore it is not possible to evaluate whether the validity criteria of these studies have been fulfilled.

Furthermore regarding the key study, the OECD TG 301 (1992), paragraph 31 of section 301 B CO2 EVOLUTION TEST, requires that (1) the inorganic carbon (IC) content of the test substance suspension in the mineral medium at the beginning of the test must be less than 5% of the TC, and (2) the total C02 evolution in the inoculum blank at the end of the test should not normally exceed 40 mg/l medium. If values greater than 70 mg CO2/l are obtained, the data and experimental technique should be examined critically. ECHA notes that you have not reported the IC and total organic carbon, or their ratio, at the beginning of the test, neither the total C02 evolution in the inoculum blank at the end of the test. Therefore it is not possible to evaluate whether the validity criteria have been fulfilled.

Regarding the supporting study, the OECD TG 301 (1992), paragraph 22 of section 301 F MANOMETRIC RESPIROMETRY TEST, requires that the oxygen uptake of the inoculum blank is normally 20-30 mg 02/l and should not be greater than 60 mg/l in 28 days. Values higher than 60 mg/l require critical examination of the data and experimental technique. ECHA notes that you have not reported the oxygen uptake of the inoculum blank. Therefore it is not possible to evaluate whether the validity criteria have been fulfilled.

Considering all abovementioned deficiencies in reporting, ECHA cannot verify whether the validity criteria have been fulfilled for these studies.

In addition, ECHA notes that, contrary to Article 3 (28) of the REACH Regulation the documentation of these studies is insufficient and does not allow an independent assessment of the adequacy of the studies, their results and use for hazard/risk assessment. In particular, the following elements are not reported:
a. Specific chemical analytical data, if available;
b. 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;
c. Discussion of results and explanation of the deviations;
d. Detailed information on the validity criteria specified in OECD TG 301 (1992) as outlined above in detail for 301 B CO2 EVOLUTION TEST method (used in key study) and 301 F MANOMETRIC RESPIROMETRY TEST (used in supporting study);
e. Information on how the volatility of the registered substance was taken into account in the test design, calculations and expression of the result of the tests and whether you consider OECD TG 301 B and OECD TG 301 F applicable.

In order to allow an independent assessment of the studies submitted, pursuant to Article 41(1) and (3) of the REACH Regulation you are requested to provide complete robust study summaries with the above missing elements for the key and supporting studies.

Notes for your consideration:

The outcome of the ready biodegradability test(s) was used to adapt the information requirements for simulation testing in surface water, soil and sediment (Annex IX Sections 9.2.1.2, 9.2.1.3 and 9.2.1.4). These adaptations are thus dependent on the validity of the ready biodegradability test(s). However, as currently the validity of the ready biodegradability test(s) cannot be established, you may have to repeat the ready biodegradability test and/or re-assess these other information requirements in light of the requested complete robust study summaries. To do so, you may wish to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11 on PBT/vPvB assessment, in particular Section R.11.4.1.1. on Persistence assessment and Figure R. 11-3 describing Integrated testing strategy for persistency assessment.

Furthermore, in light of the requested complete robust study summaries for the ready biodegradability test(s), based on this information on degradation you may need to revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, and as a result you may further consider the need for generating information on other interlinked information requirements.

Deadline to submit the requested information in this decision

In the draft decision communicated to you, the time indicated to provide robust study summaries for both the key and supporting studies for biodegradation and to submit the robust study summaries to ECHA in a dossier update was 3 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of this timeline in order to obtain the available key study from the study owner. ECHA is aware that data access to studies can be a prolonged matter. Based on the registrant's comments on the draft decsion, ECHA has granted the request and set the deadline for providing the robust study summaries for both the key and supporting studies for biodegradation and to submit the robust study summaries to ECHA in a dossier update to 6 months from the date of adoption of the decision.

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 07 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 relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests 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 by each registrant.

If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally 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.