

Helsinki, 8 August 2019

Addressee: [REDACTED]

Decision number: TPE-D-2114476275-42-01/F

Substance name: Fatty acids, C16-18 and C18-unsatd., branched and linear, butyl esters

EC number: 441-620-5

CAS number: NS

Registration number: [REDACTED]

Submission number: [REDACTED]

Submission date: 13/09/2018

Registered tonnage band: Over 1000

### **DECISION ON A TESTING PROPOSAL**

Based on Article 40 of Regulation ((EC) No 1907/2006) (the REACH Regulation), ECHA examined your testing proposal(s) and decided as follows.

Your testing proposal is accepted and you are requested to carry out:

- 1. Long-term toxicity on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Earthworm reproduction test, OECD TG 222) using the registered substance.**

You have to submit the requested information in an updated registration dossier by **15 May 2020**. You shall also 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.

### **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<sup>1</sup> by **Claudio Carlon**, Head of Unit, Hazard Assessment

<sup>1</sup> 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. Long-term toxicity to terrestrial invertebrates (Annex IX, section 9.4.1. and Annex X, Section 9.4.4.)**

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX and X, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX and X, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.).

The information on "long-term toxicity to invertebrates" 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 a long-term toxicity test on terrestrial invertebrates (OECD 222) with the following justification: *'The substance is not readily biodegradable, has a high log K<sub>oc</sub> and low water solubility. Thus, long term testing with soil macroorganism expect arthropods is considered appropriate instead of short term testing in accordance with Annex IX of Regulation (EC) No 1907/2006'*. ECHA considers that the proposed test is appropriate to fulfil the information requirement of Annex X, section 9.4.4. and at the same time that of Annex IX, Section 9.4.1.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are required to carry out the proposed study using the registered substance subject to the present decision: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (OECD 222).

## **Appendix 2: Procedural history**

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 13 September 2018.

This decision does not take into account any updates after **11 February 2019**, 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 took into account your comments and did not amend the requests.

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

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-65 written procedure and ECHA took the decision according to Article 51(6) 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 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.