

Helsinki, 5 April 2019

Addressee: [REDACTED]

Decision number: TPE-D-2114466075-48-01/F  
Substance name: Humic acids, sodium salts  
EC number: 268-608-0  
CAS number: 68131-04-4  
Registration number: [REDACTED]  
Submission number: [REDACTED]  
Submission date: 19/04/2018  
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 testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) using the analogue substance Humic acids, potassium salts.**

You have to submit the requested information in an updated registration dossier by **13 January 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 Ofelia Bercaru, 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

### 1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

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

Long-term toxicity testing on aquatic invertebrates is a standard information requirement as laid down in Annex IX, Section 9.1.5. of the REACH Regulation.

You have submitted a testing proposal for testing the analogue substance Humic acids, potassium salts for long-term toxicity testing on aquatic invertebrates with the following justification: "*The information requirement will be filled by read-across principle from study proposed for structural analogue - Humic acids, potassium salts, which is proposed*". Therefore ECHA understands that you sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation.

In your study proposal, as well as in the supplemental read-across document and data matrix provided in IUCLID section 13, you further justify testing the analogue substance. You firstly claim that the registered and analogue substances are similar in molecular structure and that both substances are produced entirely in the same manner and using the same raw materials. The only difference is hydroxide solution used for neutralization of ground oxyhumolite (potassium for the analogue substance, sodium for the registered substance). You further argue that the substances have comparable results in available studies.

ECHA agrees that the existing information submitted in the IUCLID dossier supports your hypothesis. Therefore based on the information currently available, ECHA considers that your adaptation appear to meet the general rule for adaptation of Annex XI; Section 1.5.

While you do not specify the test guideline for performing this study, ECHA considers that the *Daphnia magna* reproduction test, EU C.20/OECD TG 211 study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH Regulation.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test using the analogue substance Humic acids, potassium salts: Long-term toxicity testing on aquatic invertebrates (test method: *Daphnia magna* reproduction test, EU C.20/OECD TG 211).

#### Notes for your consideration

Once results of the proposed test on long-term toxicity to aquatic invertebrates are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to investigate further the effects on aquatic organisms, you shall submit a testing proposal for a long-term toxicity test on fish in order to fulfil the standard information requirement of Annex IX, 9.1.6. If you come to the conclusion that no further investigation of effects on aquatic organisms is required, you shall update your technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.6.

## **Appendix 2: Procedural history**

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 5 June 2018.

This decision does not take into account any updates after **3 January 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 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 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. 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 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.

4. If the required tests are conducted with an analogue substance in the context of a read-across approach, the identity of the test material used to perform the test should be specified in line with the ECHA's Practical Guide on "[How to use alternatives to animal testing to fulfil your information requirements](#)" (chapter 4.4). This is required to show that the test material is representative of the analogue substance identified in the read-across approach and used to predict the properties of the registered substance.