Decision number: TPE-D-2114314157-57-01/F Helsinki, 09 March 2016

DECISION ON TESTING PROPOSAL(S) SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For 2,6,10,15,19,23-hexamethyltetracosane, EC No 203-825-6 (CAS No 111-01-3), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for 2,6,10,15,19,23-hexamethyltetracosane, EC No 203-825-6 (CAS No 111-01-3), submitted by [redacted] (Registrant).

- Simulation Test - Aerobic Sewage Treatment. A: Activated Sludge Units (OECD 303A)
- Bioconcentration: Flow-through Fish Test (OECD 305), with the registered substance on *Oncorhynchus mykiss*

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates after 8 April 2015, i.e. 30 calendar days after the end of the commenting period.

This decision does not imply that the information provided by the Registrant in his 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.

ECHA received the registration dossier containing the above-mentioned testing proposals for further examination pursuant to Article 40(1) on 28 November 2013.

ECHA held a third party consultation for the testing proposal on Bioconcentration test in fish from 14 August 2014 until 28 September 2014. ECHA did not receive information from third parties.

On 30 January 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 9 March 2015 the Registrant did not provide any comments on the draft decision to ECHA.

On 3 September 2015 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit

proposals for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, proposals for amendment to the draft decision were submitted.

On 9 October 2015 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 19 October 2015 ECHA referred the draft decision to the Member State Committee.

By 9 November 2015 the Registrant did not provide any comments on the proposal(s) for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 23 November 2015 in a written procedure launched on 12 November 2015.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

A. Tests required pursuant to Article 40(3)

The Registrant shall carry out the following proposed test pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

1. Degradation (Annex IX, 9.2., test method: Simulation Test - Aerobic Sewage Treatment -- A: Activated Sludge Units, OECD 303A).

The Registrant shall carry out the following additional test pursuant to Article 40(3)(c) and 13(4) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

2. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in Fish: Aqueous and Dietary Exposure, OECD 305, adopted on 2 October 2012).

While the originally proposed test for Bioconcentration: Flow-through Fish Test (OECD 305, adopted on 14 June 1996) proposed to be carried out using the registered substance is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

Note for consideration by the Registrant

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to IX 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 to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

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 the Member States.

B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **18 September 2017** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report. The timeline has been set to allow for sequential testing as appropriate.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals submitted by the Registrant for the registered substance.

A. Tests required pursuant to Article 40(3)

1. Degradation (Annex IX, 9.2.)

a) Examination of the testing proposal

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

As laid down in Annex IX, 9.2. of the REACH Regulation, further biotic degradation testing shall be proposed by the Registrant, if the chemical safety assessment indicated the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the chemical safety assessment and may include simulation testing in appropriate media.

Four screening studies for ready biodegradability are presented in the registration dossier. All of them are based on the OECD 301B guideline (CO2 evolution). The following results have been reported by the Registrant:

- 64.7% degradation after 28 days, failing the 10-day window (key study)
- 41% degradation after 28 days (key study)
- 55.9% degradation after 28 days (not GLP, supporting study)
- 77% degradation after 28 days, meeting the 10-day window (not GLP, supporting study)

Although the Registrant proposed to consider the substance to be readily biodegradable failing the 10-day window, he has also submitted a testing proposal for a simulation test for aerobic sewage treatment (OECD 303A). The Registrant did not provide justification for why he had proposed this test.

The substance has mainly wide-dispersive uses (e.g. it is used in cosmetics) and is expected to be found in sewage treatment plants (STP). The Registrant might be interested in getting more information on the actual behaviour of the substance in STPs.

Moreover, ECHA notes that no data is available on the toxicity of the substance on STP microorganisms (information requirement of Annex VIII 9.1.4.). ECHA guidance R7b indicates that results from an OECD 303A test may be acceptable to derive a PNEC for STP microorganisms, in particular for very adsorptive chemicals.

Finally, there are some indication in the public literature that microorganisms such as *Penicillum*, *Candida* and *Pseudomonas* do not readily metabolise squalane ([redacted]

Therefore ECHA believes that a simulation test using activated sludge units may help to clarify the actual biodegradability of squalane in STPs.

According to ECHA Guidance R7b the results from an OECD 303A study may be used to estimate substance removal in sewage treatment plants but cannot be used for assessing degradation in the aquatic environment (Annex IX, Section 9.2.1.2. of the REACH Regulation). However, ECHA considers that the proposed study conforms to Annex IX, Section 9.2. of the REACH Regulation.

b) Outcome

In conclusion, the Registrant shall carry out the OECD 303A test as proposed to improve the quantification of biodegradation in STPs. Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Simulation test – aerobic sewage treatment, activated sludge units (test method: OECD 303A) using the registered substance.

2. Bioaccumulation in aquatic species, preferably fish (Annex IX, 9.3.2.)

a) Examination of the testing proposal

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation.

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2. 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.

The Registrant has submitted a testing proposal for testing the registered substance according to the test method: Bioconcentration: Flow-through Fish Test (OECD 305, adopted on 14 June 1996), with the registered substance on species *Oncorhynchus mykiss*.

ECHA notes that the OECD 305 test method "Bioconcentration: Flow-through Fish Test" has now been superseded by the new OECD 305 test method "Bioaccumulation in Fish: Aqueous and Dietary Exposure" adopted on 2 October 2012 and available at: http://www.oecd-ilibrary.org/environment/test-no-305-bioaccumulation-in-fish-aqueous-and-dietary-exposure_9789264185296-en.

Therefore, the test method proposed by the Registrant is outdated and the Registrant shall perform the bioaccumulation testing in fish following the latest version of the OECD 305 Guideline: Aqueous and Dietary Exposure test, adopted on 2 October 2012.

The current OECD 305 Guideline incorporates a dietary accumulation test (305-III: Dietary Exposure Bioaccumulation Fish Test), which is recommended for highly hydrophobic substances to which potential environmental exposure may largely be via the diet. A log Kow of 5.49 and a water solubility limit of 2 mg/L at 20°C are reported in the dossier and hence the substance is hydrophobic. For the selection of the appropriate exposure route for the test, the Registrant is advised to consult the latest version of the OECD 305 Test Guideline and the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., November 2012), Chapter R7c, (Section R.7.10.3).

b) Outcome

Therefore, pursuant to Article 40(3)(c) and 40(3)(d) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance subject to the present decision: Bioaccumulation in Fish: Aqueous and Dietary Exposure, (OECD 305, adopted on 2 October 2012).

IV. Adequate identification of the composition of the tested material

The process of examination of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new studies meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for examination of the testing proposal. The Registrant must note, however, that this information, or the information submitted by other registrants of the same substance, has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the proposed tests, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants of the same substance to agree to the tests proposed (as applicable to their tonnage level) and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[2] by Claudio Carlon, Head of Unit, Evaluation, E2.

[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.