Decision number: TPE-D-0000003072-86-05/F Helsinki, 25 July 2013

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

For Octadecanoic acid, branched and linear, CAS No. 68201-37-6 (EC No. 269-214-1), 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)(e) thereof for Octadecanoic acid, branched and linear, CAS No. 68201-37-6 (EC No. 269-214-1), by [redacted] (Registrant).

- Earthworm, Acute Toxicity Test (OECD 207), proposed to be carried out with the analogue substance Fatty acids, C16-18 and C18-unsatd., branched and linear, CAS No. 68955-98-6 (EC No. 273-295-9)

- Daphnia magna Reproduction Test (OECD 211), proposed to be carried out with the analogue substance Fatty acids, C16-18 and C18-unsatd., branched and linear, CAS No. 68955-98-6 (EC No. 273-295-9)

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 18 January 2013, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

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.

On 2 April 2012 pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals set out by the Registrant in the registration dossier for the substance mentioned above.

On 21 November 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 27 Nobember 2012 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

ECHA considered the Registrant's comments received.

On 18 January 2013 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 21 February 2013 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and decided not to amend the draft decision.

On 4 March 2013 ECHA referred the draft decision to the Member State Committee. The Registrant provided comments on the proposals for amendment on 22 March 2013. The Member State Committee took the comments of the Registrant into account and modified the draft decision.

After discussion in the Member State Committee meeting on 24-25 April 2013, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 24 April 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

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 analogue substance Fatty acids, C16-18 and C18-unsatd., branched and linear, CAS No. 68955-98-6 (EC No. 273-295-9):

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).

The Registrant shall carry out the following additional test pursuant to Article 40(3)(c) of the REACH Regulation using the indicated test method and the analogue substance Fatty acids, C16-18 and C18-unsatd., branched and linear, CAS No. 68955-98-6 (EC No. 273-295-9):

2. Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222);

while the originally proposed test for a Short-term toxicity to terrestrial invertebrates (test method: Toxicity for earthworms, EU C.8/OECD 207) proposed to be carried out using the analogue substance CAS No. 68955-98-6 (EC No. 273-295-9) is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

The Registrant is obliged to ensure and to demonstrate, in accordance with the specific requirements outlined in Sections III and IV below, that the test material is suitable to identify relevant hazards for the substance subject to present decision and that testing of such material does not result in an underestimation of the hazards.

Once results of the proposed test on long-term toxicity to aquatic invertebrates and of the

requested toxicity test on terrestrial invertebrates are available, the Registrant 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, the Registrant shall consider submitting 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. He shall equally consider whether there is a need to investigate further the effects on terrestrial organisms in order to fulfil the information requirements of Section 9.4. of Annexes IX and X. If the Registrant concludes that further investigation of effects on terrestrial organisms is required, he shall submit testing proposals for each additional terrestrial toxicity test. If the Registrant concludes that no further investigation of long-term toxicity on fish or on effects on terrestrial organisms is required, he shall update his technical dossier by clearly stating the reasons for adapting the information requirement of Annex IX, Sections 9.1.6, 9.4. and Annex X, Section 9.4. of the REACH Regulation respectively for sections to which no information has been provided

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **25 April 2014** an update of the registration dossier containing the information required by this decision.

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 on the analogue substance Fatty acids, C16-18 and C18-unsatd., branched and linear (CAS No. 68955-98-6, EC No. 273-295-9), the submitted read-across and (sub-)category justification document(s) and the data matrices therein.

In relation to the testing proposals subject to the present decision, the Registrant has proposed to use a read-across and grouping approach, in accordance with Annex XI, 1.5 of the REACH Regulation, and to perform the tests on the analogue substance Fatty acids, C16-18 and C18-unsatd., branched and linear, CAS No. 68955-98-6 (EC No. 273-295-9). To the extent that all proposed testing relies upon an identical read-across hypothesis, ECHA has considered first the scientific validity of the proposed read-across and grouping approach (Section 0, below), before assessing the testing proposed (Sections 1 and 2, below).

0. Grouping of substances and read-across approach

Article 13(1) of the REACH Regulation allows that information on intrinsic properties of substances may be generated whenever possible by means other than tests, including information from structurally related substances (grouping or read-across), "*provided that the conditions set out in Annex XI are met*". According to the Registrant, there is a category of *Dimerised fatty acids and its Derivatives*, with two sub-categories (sub-category 1: "predominantly monomers" and sub-category 2 "predominantly oligomers (dimers, trimers)") based on environmental fate properties and that read-across is possible within this category. The substance subject to the present decision has been placed in sub-category 1.

The evaluation by ECHA of testing proposals submitted by registrants aims at ensuring that generation of information is tailored to real information needs. More specifically, Section 1.5 of Annex XI of the REACH Regulation sets out the conditions to be met by alternative methods so that equivalent results to the prescribed test may be obtained. To this end, it is necessary to consider whether programmes of testing proposed by registrants are

appropriate to fulfil the relevant information requirements and to guarantee the identification of health and environmental hazards of substances. In that respect, the REACH Regulation aims at promoting wherever possible the use of alternative means, as long as equivalent results to the prescribed test are provided on health and environmental hazards.

The Registrant has proposed to test Fatty acids, C16-18 and C18-unsatd., branched and linear, CAS No. 68955-98-6 (EC No. 273-295-9) on the basis that this substance can be regarded as a representative worst case test substance for the proposed sub-category 1 "predominantly monomers" of Dimerised fatty acids and its derivatives. The Registrant has indicated that in the proposed read-across and grouping approach for the Dimerised fatty acids and its derivatives all substances covered show similarity in regard to their composition containing common or closely related constituents.

ECHA notes that in the registration dossier the Registrant has provided a category definition, a justification for the category and the required respective documentation. The category justification contains a similarity assessment detailing the common origin and associated similar structure characteristics with typical molecular structures of the category members. The similarity of the source and target substances has been assessed and the decision process for the selection of the source substance has been detailed and documented. The category and read-across based classification has been explained based on available data. The Registrant has provided a detailed overview of ecotoxicological, environmental fate and toxicological data and addressed metabolic pathways and toxicokinetics. With regards to environmental fate and ecotoxicology endpoints the category has been further divided into two sub-categories based on physichochemical properties and environmental fate. The category hypothesis and scientific basis for the read-across given by the Registrant is the absence of (environmental) toxicity for all category members which the Registrant seeks to confirm by the testing proposed.

ECHA considers that the category hypothesis as currently documented is plausible. The target and source substances have been appropriately selected and their similarity with regards to chemical structures, environmental fate, and ecotoxicology and physicohemical properties has been satisfactorily presented. The obvious datagaps for the category members with regards to environmental endpoints may be covered with the testing addressed in this decision. However, ECHA notes that for the assessment of the relevance of the studies requested for the category justification in relation to the substance subject to present decision there must be adequate information on the identity of the sample tested and the substance registered (Octadecanoic acid, branched and linear). In particular, given the intrinsic compositional variability of the registered substances of the sub-category and the intended read-across, information as specified below has to be provided:

a) The identity and concentration of all known constituents and structural elements (aromatic and aliphatic rings, degree of unsaturation, branching, molecular size and carbon chain length distribution). Constituents, which have a common functionality or belong to the same class, shall be grouped as far as possible. In particular constituents or groups of constituents with hazards must be reported separately together with their concentration values;

b) An explanation based on factual evidence present in the dossier of why the composition of the sample tested represents a worst case scenario for the applicability domain of the sub-category and how it relates to the substance subject to this decision. More specifically, the data supporting the notion that in general constituents bearing double bond functionalities pose a higher risk than saturated carboxylic acids must be present in the dossier in form of robust study summaries

in IUCLID endpoint study records.

Despite the need to provide this further information and explanation, ECHA considers that the justification given and the documentation provided demonstrates to a sufficient level the plausibility of the read-across approach. I.e. the requirements of Annex XI, Section 1.5 in conjunction with Article 13(1) and Annexes IX/X, third introductory paragraph, of the REACH Regulation may be met. However, a final conclusion on the validity of the suggested approach to adapt the standard information requirement will only be possible when it has been demonstrated and further documented on the basis of test results from the experimental studies proposed by the Registrant and required by the present decision that the conditions set out in Annex XI, Section 1.5 are met for these specific endpoints.

ECHA emphasises that it is the Registrant's responsibility to amend and substantiate the read-across and category justification according to Annex XI, 1.5. and to use all relevant available data.

Following the update of the dossier based on the present decision, ECHA will determine whether the documentation provided is ultimately sufficient to satisfactorily address the ecotoxicological information requirements of Annexes IX and X for the substance subject to this decision as proposed by the Registrant. If, upon further consideration, the proposed approach does not satisfy the conditions set out in Annex XI, 1.5. including the adequacy of the results for the purpose of classification and labelling and/or risk assessment, ECHA reserves the right to request the information necessary to fulfil the information requirements.

1. Long-term toxicity testing on aquatic invertebrates

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

According to column 1 of Section 9.1.5. of Annex IX of the REACH Regulation, long-term toxicity testing on invertebrates is required to fulfil the standard information requirements. 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 provided the following justification for conducting the proposed test: "There is no long-term test on aquatic invertebrates available for the sub-category 1 members Dimerised Fatty Acids and its derivatives. Since all substances within this category are readily biodegradable, it is foreseen that they will not pose a risk to aquatic invertebrates on the long-term. However, due to the poor water solubility of the test substance and as long-term toxicity to aquatic organisms is a mandatory endpoint in accordance to Regulation (EC) No 1907/2006, Annex IX 9.1 Aquatic toxicity, we propose to test the long-term toxicity on invertebrates in order to confirm that no toxicity to aquatic organisms occurs." Furthermore the Registrant indicates: "as there was no sign that fish are more sensitive than aquatic invertebrates in the short term tests, we expect that a long-term test with fish will not generate different results than a long-term study on aquatic invertebrates, therefore as part of an integrated testing strategy a long-term study on fish is not required unless otherwise triggered."

ECHA notes that the Registrant has considered that long-term test with fish as laid down in Annex IX Section 9.1.6 of the REACH Regulation is not required in addition to the long-term toxicity testing on invertebrates proposed. According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1, August 2008), Chapter R7b,

Figure R.7.8-4 page 53, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both.

According to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, a testing proposal for a long-term fish study needs to be submitted.

Based on data submitted in the registration dossier for the substance subject to the present decision, the ready biodegradation claim of sub-category 1 substances is questionable. This inconsistency does not affect the evaluation or the acceptance of the aquatic long-term testing proposed. However, the issue of ready biodegradation of sub-category 1 substances is further discussed under Section 2 below.

When designing the tests, the Registrant shall take account of the low water solubility of the substance and shall follow the recommendations given in the EU C.20/OECD 211 Guideline and the OECD Guidance document No. 23 on aquatic toxicity testing of difficult substance and mixtures (ENV/JM/MONO(2000)6) when performing the test and interpreting the results.

As pointed out above in Section 0, ECHA considers the proposal for testing the analogue substance Fatty acids, C16-18 and C18-unsatd., branched and linear, to meet this endpoint requirement plausible. Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, the Registrant is required to carry out the proposed study: Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211) using the analogue substance Fatty acids, C16-18 and C18-unsatd., branched and linear CAS No. 68955-98-6 (EC No. 273-295-9).

2. Long-term toxicity on terrestrial invertebrates

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

Long-term toxicity to terrestrial invertebrates is a standard information requirement as laid down in Annex X, Section 9.4.4. 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 generate the data for this endpoint.

The Registrant provided the following justification for conducting the proposed earthworm acute toxicity test: "Due to the fact that the sub-category 1 members of the Dimerised Fatty Acids and its derivatives have the general estimated logkow >4 and logKoc > 4 < 5 (worst case), i.e. adsorption to organic carbon in soils is expected, and considering that a direct exposure of the soil compartment cannot be ruled out, data on terrestrial toxicity is required for the chemical safety assessment." Furthermore, the Registrant has given the following as further justification for proposing the acute earthworm test instead of the long-term one required at this tonnage level under Annex X of the REACH Regulation: "A long-term test is considered not be relevant as the results of the chemical safety assessment according to Annex I did not indicate the need to investigate further effects of the substance on terrestrial organisms. All sub-category 1 members have been shown to be readily biodegradable and therefore do not have a potential for persistence and thus indirect chronic exposure. Additionally no toxicity was observed in the standard acute toxicity tests

to aquatic organisms on the three trophic levels (fish, Daphnia, algae). Furthermore, a long-term toxicity test to aquatic invertebrates is also planned for Fatty acids, C16-18 and C18-unsaturated, branched and linear, "Monomer acid", CAS No. 68955-98-6 in order to further confirm that no chronic toxicological effects occur to aquatic organisms within the water solubility of the members of this sub-category."

ECHA considers this justification for short-term testing not appropriate. The registration for the substance subject to the present decision belongs to a tonnage band where Long-term toxicity to terrestrial invertebrates is a standard information requirement as laid down in Annex X, Section 9.4.4. of the REACH Regulation. Furthermore, ECHA notes that both the registered substance and the analogue substance proposed for testing have a high potential to adsorb to soil and are substances of unknown or variable composition, complex reaction products or biological materials (UVCB) of low water solubilities. As anticipated by the Registrant, the long-term aquatic invertebrate study proposed may bring added value to the Registrants hypothesis of no (eco)toxicity. However, testing for the terrestrial effects of these category substances has been deemed necessary by the Registrant. ECHA notes further that the absence of acute aquatic toxicity is not a reliable indicator for potential effects on soil organisms due to the low water solubility and consequent low exposure in aquatic toxicity tests (ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., August 2008), Chapter R7c, page 121)). In addition, as noted above under Section 1. the Registrant's claim of ready biodegradation for sub-category 1 as a whole is questionable. In a biodegradation study reported in the scientific dossier of the substance subject to present decision only 47 % degradation was observed in 28 days. According to ECHA Guidance on information requirements and chemical safety assessment (version 1.1., August 2008), Chapter R7b, page 177 a minimum of 60 % biodegradation would need to be obtained within 28 days for a substance to be considered readily biodegradable. Therefore, as this registration is subject to the information requirement as laid down in Annex X, Section 9.4.4. and the substance registered meets the conditions set in Column 2 of Annex IX, Section 9.4.1. of the REACH Regulation, ECHA has rejected the Registrant's proposal for acute earthworm testing as non-compliant.

As pointed out above in Section 0, ECHA considers the proposal for testing the analogue substance Fatty acids, C16-18 and C18-unsatd., branched and linear, to meet this endpoint requirement plausible. Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the additional study: Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4.; test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei), OECD 222) using the analogue substance Fatty acids, C16-18 and C18-unsatd., branched and linear CAS No. 68955-98-6 (EC No. 273-295-9).

The originally proposed test OECD Guideline 207 is rejected in accordance with Article 40(3)(d) of the REACH Regulation.

ECHA notes that one Member State Competent Authority (MSCA) submitted the proposal for amendment (PfA) to insert in section II point 1 of the draft decision the following: "Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2); test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei) OECD 222, or Enchytraeid reproduction test OECD 220, or Collembolan reproduction test in soil OECD 232)". The Registrant in his subsequent comments agreed with the MSCA PfA "to extend the methods mentioned in Section II for testing for long term toxicity to terrestrial toxicity."

However, the Registrant in his initial testing proposal (OECD 207) provided the following justifications for the choice of species: "Testing of the toxicity on earthworm evaluates the exposure to the test substance via soil pore water, surface contact as well as by ingestion of soil particles (...) As an earthworm tests allows uptake via all possible routes, via surface

contact, soil particle ingestion and the porewater, Fatty Acids, C16-18 and C-18, Unsaturated, Branched and Linear was determined as the most bio-available substance of the 3 subcategory members." ECHA agrees that earthworm test would cover all exposure routes and would thus be the most relevant taxonomic group for testing also for the requested long-term toxicity test to terrestrial invertebrates.

Since no further information was provided by the MSCA in the PfA or the Registrant in his subsequent comments to why the alternative species in OECD 220 or OECD 323 tests would be more or equally sensitive than the requested species in OECD 222 test, Section II point 2 of the decision was not amended.

IV. Adequate identification of the composition of the tested material

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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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Geert Dancet
Executive Director