EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114308425-56-01/F Helsinki, 17 September 2015

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

For Fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyl ether and triethylenetetramine, CAS No 186321-96-0 (EC No 606-078-8), 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 Fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyl ether and triethylenetetramine, CAS No 186321-96-0 (EC No 606-078-8), submitted by [redacted] (Registrant).

- Toxicity for earthworms, (OECD 207);
- 90-day oral toxicity study (OECD 408), oral route;
- Developmental toxicity / teratogenicity study (OECD 414).

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 the deadline for updating (12 March 2015) communicated to the Registrant by ECHA on 3 February 2015

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 May 2013.

ECHA held a third party consultation for the testing proposals from 4 April 2014 until 19 May 2014. ECHA did not receive information from third parties.

On 13 November 2014 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 16 December 2014 ECHA received comments from the Registrant agreeing to ECHA's draft decision. The ECHA Secretariat considered the Registrant's comments.
On basis of this information, the decision was not amended.
On 23 July 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.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Testing required

A. Tests required pursuant to Article 40(3)

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

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26/OECD 408) in rats;

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in rats or rabbits, oral route;

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

3. Effects on terrestrial organisms:
   a) Long-term toxicity to terrestrial invertebrates (Annex IX, Section 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);
   b) Long-term toxicity testing on plants (Annex IX, Section 9.4.3., column 2); test method: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030);
   c) Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216).

while the originally proposed test for a Toxicity for earthworms, (test method: OECD 207) is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

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 **25 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.

Note for consideration by the Registrant:

The Registrant 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 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 requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, willl result in a notification to the Enforcement Authorities of the Member States.

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. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2)

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

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, Section 8.6.2. 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 a sub-chronic toxicity study (90 day) via the oral route (EU B.26/OECD 408) with the following justification: '*The fatty acids, C18-unsatd., dimers, oligomeric reaction products with tall-oil fatty acids and triethylenetetramine is a precursor of Fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyl ether and triethylenetetramine, having a lower molecular weight compared to the crosslinked reaction product, and therefore considered more bioavailable. This substance has been investigated in an OECD 422 study resulting in a NOAEL of 1000 mg/kg bw/d, indicative of limited bioavailability. Thus, although it may therefore be seen as worst case surrogate, it lacks certain functional groups and this is why a 90-day oral dosed repeated dose toxicity study is proposed to investigate long term toxicity of fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyl ether and triethylenetetramine.*'

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 8.6.2. of the REACH Regulation.

The Registrant proposed testing by the oral route. In light of the physico-chemical properties of the substance (liquid with low vapour pressure) and the information provided on the uses and human exposure (no uses with spray application), ECHA considers that testing by the oral route is most appropriate.

The Registrant did not specify the species to be used for testing. According to the test method EU B.26/OECD 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the proposed study with the registered substance subject to the present decision: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26/OECD 408).

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

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

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. 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 a pre-natal developmental toxicity study according to EU B.31/OECD 414 with the following justification: '*The effects of Fatty acids, C18-unsatd., dimers, oligomeric reaction products with tall-oil fatty acids and triethylenetetramine, a component and starting material of fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyly ether and triethylenetetramine, on fertility and on developmental parameters has been investigated in a combined repeated dose/reproductive screening toxicity study conducted according to OECD Test Guideline 422 ([redacted]). No developmental effects, effects on reproductive parameters or treatment-related signs of systemic toxicity were observed in the study. Based on this study, The No-Observed-Adverse-Effect-Level (NOAEL) for the effects of the substance on fertility in male and in female rats and for developmental toxicity was considered to be 1000 mg/kg bw/day (i.e. the highest dose tested).*

A pre-natal developmental toxicity study using fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyl ether and triethylenetetramine in the rat (OECD Test Guideline 414) is proposed in order to further evaluate the developmental (and reproductive) hazard potential of the substance.'

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

The Registrant did not specify the species to be used for testing. He did not specify the route for testing. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the proposed study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in rats or rabbits, oral route (test method: EU B.31/OECD 414).

3. Effects on terrestrial organisms (Annex IX, Section 9.4)

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.

The Registrant must address the standard information requirements set out in Annex IX, section 9.4., for different taxonomic groups: effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), and

short-term toxicity testing on plants (Annex IX, section 9.4.3.). Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The information on the endpoint 'effects on terrestrial organisms' is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements.

a) Terrestrial Invertebrates (Annex IX, Section 9.4.1.)

The Registrant proposed a short-term toxicity test on terrestrial invertebrates (OECD 207), with the following justification: *The substance fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyl ether and triethylenetetramine is not readily biodegradable and slightly soluble. Thus, indirect exposure via aqueous release cannot be fully excluded and sediment might be exposed to the substance. Hence, an acute toxicity study according to OECD 207 with earthworms is proposed to assess toxicity to sediment and soil organisms.*

This test is in principle suitable to address the standard information requirement of Annex IX, section 9.4.1.

However, according to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. ECHA notes that, according to the evidence presented within the Registration dossier, the substance is very toxic to aquatic organisms (EC/LC_{50} <1 for algae and daphnia) and is likely to be very persistent (the default setting for not readily biodegradable substances, when no DT_{50} in soil available) and therefore meets the column 2 adaptation criteria of Annex IX, section 9.4. concerning the use of long-term testing instead of short-term.

Furthermore, based upon the available aquatic toxicity information and the physico-chemical properties of the substance, and in relation to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012), ECHA considers that the substance would fall into soil hazard category 4. Table R.7.11-2 of the abovementioned Guidance states that for soil hazard category 4 substances, a screening assessment based on EPM is not recommended since the intrinsic properties of the substance indicate a high hazard potential to soil organisms and long-term toxicity tests should be conducted according to the standard information requirements of Annex X, choosing the lowest value obtained for derivation of PNEC soil.

ECHA further notes that the abovementioned Guidance only foresees scenarios whereby long-term toxicity studies are used to undertake PNEC derivation and risk assessment of soil hazard category 4 substances. Presently it is not possible to determine whether results obtained from the proposed short-term test would confirm that the above is applicable. No argument has been provided in the dossier as to why, despite the persistence of the substance, long-term testing is not appropriate. Therefore ECHA concludes that considering the properties of the substance only a long-term toxicity test on invertebrates (and not the short-term) will provide the necessary useful information.

The earthworm reproduction test (OECD 222), Enchytraeid reproduction test (OECD 220), and Collembolan reproduction test (OECD 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term

toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out one of the following additional studies using the registered substance subject to the present decision: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (OECD 222), or Enchytraeid reproduction test (OECD 220), or Collembolan reproduction test in soil (OECD 232), while the originally proposed test for a Toxicity for earthworms (OECD 207) is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

b) Terrestrial Plants (Annex IX, Section 9.4.3.)

The proposed test on terrestrial invertebrates, under subsection (a) above, is not sufficient by itself to address the standard information requirements of Annex IX, section 9.4.3. ECHA notes that the registration dossier does not contain data for this endpoint.

The Registrant proposed to adapt this standard information requirement with the following justification: '*No significant exposure of the soil or terrestrial compartment is expected. Furthermore In the chemical safety assessment performed in connection with Annex I no risk was identified. Consequently, in accordance with Column 2 of REACH Annex X, the study does not need to be conducted as all identified uses of the substance are assessed as safe for the environment.*'

The submitted adaptation argument is conflicting with the testing proposal assessed under subsection (a) above, as ECHA considers that by submitting testing proposal on terrestrial invertebrates the Registrant recognises the need to assess toxicity of the substance to soil organisms. Furthermore, ECHA notes that the exposure of soil cannot be ruled out, as there are direct and indirect (via aplication of Sewage Treatment Plant's sludge on agricaltural soil) releases of the substance to soil reported in the Chemical Safety Report (CSR). Therefore, ECHA concludes that the soil exposure by the registered substance is likely and the testing of toxicity to soil plants cannot be omitted using 'no soil exposure' argument.

As noted under subsection (a) above, ECHA considers that the substance would fall into soil hazard category 4 and for such substances a screening assessment for soil based on EPM is not recommended. Consequently, it is not possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), mentioned in Column 2 of Annex IX, section 9.4. Consequently there is an information gap and it is necessary to provide information for the standard information requirement of Annex IX, Section 9.4.3.

ECHA considers based on the substance properties as discussed under subsection (a) above, that the substance is likely to be very persistent in soil. Persistence of the substance indicates the need for long-term testing to be performed (Column 2 of Section 9.4. of Annex IX). At this tonnage level, according to column 2 the registrant shall consider long-term testing. No argument has been provided in the dossier as to why, despite the persistence of the substance, long-term testing is not appropriate.
Therefore ECHA concludes that considering the properties of the substance only a long-term toxicity test on plants (and not the short-term) will provide the necessary useful information. Furthermore, ECHA *Guidance on information requirements and chemical safety assessment* Chapter R10, section R.10.6.2., (version May 2008) allows the potential application of a lower assessment factor (AF) if information on additional long-term terrestrial toxicity test of two trophic levels were available. In contrast, the Guidance does

not allow for a lower AF to be applied if information on a short-term study were to become available in addition to the long-term invertebrate study.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum and testing shall be conducted, as a minimum with two monocotyledonous species and four dicotyledonous species. The Registrant should consider if testing on additional species is required to cover the information requirement.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following additional study using the registered substance subject to the present decision: Long-term toxicity testing on plants according to test method: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030).

c) Soil microorganisms (Annex IX, section 9.4.2.)

The hazard to soil microbial communities is a standard information requirement under Annex IX, section 9.4.2. of the REACH Regulation. ECHA notes that the registration dossier does not contain data for this endpoint and that the proposed test on terrestrial invertebrates,under subsection (a) above, is not sufficient to address this standard information requirement.

The Registrant proposed to adapt this standard information requirement with the following justification: *'No significant exposure of the soil or terrestrial compartment is expected. Furthermore In the chemical safety assessment performed in connection with Annex I no risk was identified. Consequently, in accordance with Column 2 of REACH Annex X, the study does not need to be conducted as all identified uses of the substance are assessed as safe for the environment.'*

As noted under subsection (b) above, ECHA concludes that the soil exposure by the registered substance is likely and the testing of toxicity to soil microorganisms cannot be omitted using 'no soil exposure' argument. Furthermore, it is not possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM.

ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test (test method: EU C.21 or OECD 216).

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following additional study using the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216).

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 has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

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

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[1] by Claudio Carlon, Head of Unit, Evaluation

[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.