ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114299842-34-01/F Helsinki, 24 April 2015

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For Fatty acids, tall-oil, compds. with N-[3-(dimethylamino)propyl]tall-oil amides, CAS No 92128-22-8 (EC No 295-714-4), 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 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for Fatty acids, tall-oil, compds. with N-[3-(dimethylamino)propyl]tall-oil amides, CAS No 92128-22-8 (EC No 295-714-4), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Sections 9.4 of Annexes IX and X of the REACH Regulation relating to terrestrial toxicity. ECHA stresses that it has not checked the information provided by the Registrant for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration 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 submitted after 5 March 2015, 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.

The compliance check was initiated on 5 May 2014.

On 10 July 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. That draft decision was based on submission number [redacted].

On 15 August 2014 ECHA received comments from the Registrant on the draft decision. On 14 October 2014 the Registrant updated his registration dossier with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update.
The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 5 March 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. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a) (vii), 12(1)(e), 13 and Annexes IX and X of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. Long-term toxicity testing on terrestrial invertebrates (Annex X, 9.4.4.; 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);

2. Long-term toxicity testing on plants (Annex X, 9.4.6.; test method: Terrestrial Plant Test: Seedling Emergence and Seedling Growth, 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); and

3. Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD 216).

Pursuant to Articles 41(1), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, once the results of the above long-term terrestrial studies are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including an updated derivation of the terrestrial PNEC.

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 sound 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, will result in a notification to the Authorities of the Member States for enforcement.

B. Deadline for submitting the required information

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **1 February 2016**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

Pursuant to Articles 10(a)(vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more

per year shall contain as a minimum the information specified in Annexes VII, VIII, IX, and X of the REACH Regulation.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, Section 9.4., of the REACH Regulation. Adequate information on effects on soil micro-organisms (Annex IX, section 9.4.2.), 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.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

1. Terrestrial Invertebrates (Annex IX, 9.4.1. and Annex X, 9.4.4.)

Toxicity to terrestrial invertebrates is a standard information requirement under Annex IX, 9.4.1. and Annex X, 9.4.4. of the REACH Regulation. The registration dossier does not contain data for these endpoints. Instead, the Registrant had proposed to adapt short- and long-term toxicity testing on effects on terrestrial invertebrates using the following justification:

"According to column 2 of REACH Annex X, a toxicity test to terrestrial organisms shall be proposed if the outcome of the CSA indicates a need on further testing. No direct toxicity data for terrestrial compartment are available for the determination of PNECsoil for Fatty acids, tall-oil, compounds with N-[3-(dimethylamio)propyl]tall-oil amides. According to the Annex IX data requirements stipulated in Regulation (EC) No 1907/2006, these tests are not required where the risk assessment based on the equilibrium partitioning method does not indicate a concern for the relevant compartment. Using the equilibrium partitioning method (TGD on risk assessment, part II, Chapter 3, section 3.6.2.1, p 117) a PNECsoil of 307.7 mg kg-1 (wet weight) is obtained. Having a PECsoil/PNECsoil ratio < 1 for all exposure scenarios, there is no need to perform a toxicity test for terrestrial compartment as the risk towards terrestrial organisms is sufficiently controlled based on the already available information."

In his proposed adaptation the Registrant claims that there is no need to investigate the effects on terrestrial organisms further. He justifies this conclusion by explaining that by using the equilibrium partitioning method (EPM) he has derived RCRs below 1.

The Registrant seems to consider that with the EPM alone registrants could waive all five standard information requirements for effects on terrestrial organisms. However, the provision in Column 2 of Annex IX, 9.4. does not state that the EPM alone is sufficient to justify the adaptation of the standard information requirements. The second subparagraph of that Column 2 provision needs to be read in its entirety. Its aim is to establish whether there is a possibility to waive some of the standard information requirements stemming from Column 1 of Annex IX, 9.4. In order for an adaptation of the Column 1 provisions to be justified, registrants would have to demonstrate by means of the CSR that the conditions of an adaptation possibility in Column 2 or Annex XI are fulfilled. In establishing this, in some cases, registrants may use the EPM. Upon such a basis, registrants can then depending on the case establish whether provision of information regarding some taxonomic group(s) could be waived.

In this context registrants have to take into account the other relevant provisions in Column 2 of Annex IX. The last sub-paragraph of that provision states that when a substance has a high potential to adsorb to soil or is highly persistent, even for registrations at a tonnage level between 100 up to 1000 tonnes long-term testing shall be considered instead of short-term testing. For registrations at a tonnage level of 1000 tonnes this is a standard information requirement.

In this specific case, based on the information available in the dossier on physio-chemical properties and on aquatic toxicity 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* (November 2012), ECHA considers that there are indications for high adsorption of the substance in soil and also indications that the substance is very toxic to aquatic organisms. More specifically, ECHA notes that the technical dossier contains a study on the determination of the adsorption coefficient considered reliable by the Registrant (Klimisch score 1 or 2), in which the log Koc is reported to be 8.2-8.5. The Registrant also concludes under this endpoint that "*the estimated log Koc-values 8.2 -8.5 indicate a very strong adsorption potential to soil and sediment*", and the substance is classified as very toxic to aquatic life.

In accordance with section R.7.11.6 of ECHA Guidance Chapter R.7c, the EPM-method is not applicable for substances that are very toxic to aquatic organisms and highly adsorptive in soil. Consequently there is an information gap and it is necessary to provide information for short- and long-term toxicity on terrestrial invertebrates.

Based on the indication for high adsorption in soil, ECHA notes that even if the substance was only registered at a tonnage of 100 to 1000 tonnes, long-term testing instead of short-term testing should have been considered.

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. Each of these tests is suitable to also address the information requirement of Annex IX, section 9.4.1., as specified above. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

In his updated dossier (submission number: [redacted]) the Registrant has changed the justification to: "In accordance with the REACH Regulation, Annex X, section 9.4, column 2 studies on terrestrial organisms do not need to be conducted as direct and indirect exposure to the soil compartment is unlikely. There is only minor emission to the environment from industrial manufacture of the substance and only to the water compartment.
A study on inherent biodegradation, which reflects treatment conditions close to those of an industrial STP, reported of 97 % degradation. Thus, on the one hand it is very likely that under these specific waste water treatment conditions most of the substance is degraded before release of the waste water to the receiving water. Furthermore, due to the low vapour pressure emission from water to soil is unlikely. On the other hand, there is no application of sewage sludge from the industrial STP to agricultural soil.
In conclusion, there is only minor emission to the water compartment and direct or indirect emission of the substance to the soil compartment is unlikely."

In his comments to the draft decision, the Registrant further explained that:
"The consumer use of articles containing the substance comprises the use of articles which are [redacted]. The substance is bound [redacted]. Therefore, emission to air as well as indirect emission to soil via air is unlikely. The current consumer exposure scenario describes an unrealistic worst case emission to air which will be corrected with a release factor for emission to air of zero.
In conclusion, in the updated CSR the release factor for emission to water from manufacture will be corrected based on the measured concentration in STP effluent and is expected to be zero or at least negligible. Furthermore, the supposed emission to air from the consumer use, which could indirectly result in emission to soil, will be revised and set to zero."

ECHA agrees with the Registrant that exposure to soil might be not significant for exposure scenarios ES1 (Manufacture) and ES4 (Consumer uses). As manufacturer of the substance, the Registrant has clearly good knowledge of the risk management measures implemented in his plant. As for consumer uses, the substance is apparently only used as incorporated in very specific articles in which it is permanently embedded in a matrix.

But in the exposure scenarios (ESs) 2 (Formulation) and 3 (Use of preparations containing the substance), the Registrant claims total absence of emissions to water, soil and air all together. This is however not demonstrated nor justified in the CSR. These two scenarios, unfortunatelly, the Registrant does not discuss in his comments to the DD.

In the exposure scenarios for workers for ES2 and ES3, it is true that some processes are described as closed (e.g. PROC 1, 2, 3) but potential for exposure in the workplace exists for other processes (e.g. during transfer of the substance, equipment maintenance/cleaning operations). If the substance is emitted at the workplace then it may end-up in wastewater, solid wastes (for which specific legislation exists) and/or in the atmosphere. Without further information, it is not possible to rule-out that some of the substance will end-up in wastewater. The Registrant needs to demonstrate that there is no release to wastewater, e.g. during cleaning and maintenance operations (which seem not to be addressed for these two exposure scenarios).

Furthermore, the registrant claims, without justification, efficiency of 100% for municipal STP for scenarios ES2 and ES3. ECHA concludes that such high efficiency of substance removal in municipal STP is not justified by the Registrant. Furthermore, it is not explained whether removal from wastewater could be caused by degradation of the substance or partly by the adsorption of the substance to sludge. In ECHA's view posibility of adsorption of the substance to sludge is not ruled out by the Registrant, moreover ECHA considers that due to high adsorption potential of the substance (log Koc of 8.5) it will, at least partly, adsorb to sludge at municipal STP. Furthermore, ECHA notes that the application of sludge to the soil from unknown municipal STPs can not be excluded. Therefore if there are releases to wastewater for ES2 and ES3, then some of the substance will end-up in the municipal STP sludge and finally in agricultural soils.

Thus, ECHA concludes that at least indirect exposure to soil via application of sludge from STPs cannot be excluded for ES2 and ES3 and the adaptation provided by the Registrant is not justified.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (test method: OECD 222), or Enchytraeid reproduction test (test method: OECD 220), or Collembolan reproduction test in soil (test method: OECD 232).

2. Toxicity testing on terrestrial plants (Annex IX, 9.4.3. and Annex X, 9.4.6.)

Toxicity to terrestrial plants is a standard information requirement under Annex IX, 9.4.3. and Annex X, 9.4.6. of the REACH Regulation. The registration dossier does not contain data for these endpoints. Instead, the Registrant has proposed to adapt short- and long-term toxicity testing on effects on terrestrial plants using the following justification:

"*According to column 2 of REACH Annex X, a toxicity test to terrestrial organisms shall be proposed if the outcome of the CSA indicates a need on further testing. No direct toxicity data for terrestrial compartment are available for the determination of PNECsoil for Fatty*

acids, tall-oil, compounds with N-[3-(dimethylamio)propyl]tall-oil amides. According to the Annex IX data requirements stipulated in Regulation (EC) No 1907/2006, these tests are not required where the risk assessment based on the equilibrium partitioning method does not indicate a concern for the relevant compartment. Using the equilibrium partitioning method (TGD on risk assessment, part II, Chapter 3, section 3.6.2.1, p 117) a PNECsoil of 307.7 mg kg-1 (wet weight) is obtained. Having a PECsoil/PNECsoil ratio < 1 for all exposure scenarios, there is no need to perform a toxicity test for terrestrial compartment as the risk towards terrestrial organisms is sufficiently controlled based on the already available information."

As it is explained above under III.1., the information available on these endpoints for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for short- and long-term toxicity on terrestrial plants.

Both the Terrestrial plants, growth test (OECD 208, in the configuration as explained below) and the Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030) are considered capable of generating information appropriate for the fulfilment of the information requirement for long-term toxicity testing on plants. Each of these tests is suitable to also address the information requirement of Annex IX, section 9.4.3., as specified above. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

OECD guideline 208 (Terrestrial Plant Test: Seedling Emergence and Seedling Growth) 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 to achieve a reasonably broad selection. The long-term toxicity testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. The Registrant should consider if testing on additional species is required to cover the information requirement.

In his updated dossier (submission number: [redacted]) the Registrant has changed the justification to the same justifications as for the testing of terrestrial invertebrates (see section III.1. above).

For the same reasons as explained in section III.1. above, ECHA concludes that the adaptation provided by the Registrant is not justified.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Terrestrial Plant Test: Seedling Emergence and Seedling Growth (test method: 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 (test method: ISO 22030).

3. Soil micro-organisms (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. The registration dossier does not contain data for this endpoint. Instead, the Registrant has proposed to adapt testing on effects on soil microorganisms using the following justification:"*According to column 2 of REACH Annex*

X, a toxicity test to terrestrial organisms shall be proposed if the outcome of the CSA indicates a need on further testing. No direct toxicity data for terrestrial compartment are available for the determination of PNECsoil for Fatty acids, tall-oil, compounds with N-[3-(dimethylamio)propyl]tall-oil amides. According to the Annex IX data requirements stipulated in Regulation (EC) No 1907/2006, these tests are not required where the risk assessment based on the equilibrium partitioning method does not indicate a concern for the relevant compartment. Using the equilibrium partitioning method (TGD on risk assessment, part II, Chapter 3, section 3.6.2.1, p 117) a PNECsoil of 307.7 mg kg-1 (wet weight) is obtained. Having a PECsoil/PNECsoil ratio < 1 for all exposure scenarios, there is no need to perform a toxicity test for terrestrial compartment as the risk towards terrestrial organisms is sufficiently controlled based on the already available information."

As it is already explained above under III.1., the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for toxicity for this endpoint.
In his updated dossier (submission number: [redacted]) the Registrant has changed the justification to the same justifications as for the testing of terrestrial invertebrates (see section III.1. above).

For the same reasons as explained above in section III.1., ECHA concludes that the adaptation provided by the Registrant is not justified.

Furthermore in his comments to the draft decision and the subsequent update the Registrant has deleted the PNEC STP, claimed "No hazard identified" for micro-organisms and included a justification that the reported effect in a study on microbial degradation is not relevant as it is above the water solubility, thus, the study on microbial degradation indicates that there is no hazard at concentrations which are relevant for PNEC derivation.

ECHA notes that even in case the Registrant would want to use this information to waive the standard information requirements, ECHA does not consider this statement as a valid justification for waiving the standard information requirement of Annex IX section 9.4.3. ECHA highlights that the Guidance (ECHA Guidance R.7.C. (Version 2.0, November 2014)) does not give the possibility to adapt the standard information requirement based on no inhibition of sewage sludge microbial activity. The Registrant may, however, support this WoE line with other elements of justification.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012), Chapter R.7C, Section R.7.11.3.1., p115, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Soil microorganisms: nitrogen transformation test (test method: EU C.21./OECD 216).

Note for consideration by the Registrant:

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method. Therefore the potential weight of evidence adaptation possibility outlined in the Guidance (based on EPM and other data that is available for the substance) does not apply for the present endpoint.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. The Registrant is reminded of his responsibility to ensure that his registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

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

Furthermore, 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 an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on 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.

[redacted]
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