EUROPEAN CHEMICALS AGENCY

Helsinki, 20 September 2016

Addressee: [redacted]

Decision number: TPE-D-2114344024-62-01/F
Substance name: Fats and Glyceridic oils, vegetable, winterized, reaction products with ammonia-ethanolamine reaction products
EC number: 800-253-4
CAS number: 1419212-73-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 17.02.2016
Registered tonnage band: 100-1000T

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA has taken the following decision.

Your testing proposal is accepted and you are requested to carry out:

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

You 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 and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **27 June 2017**. You shall also update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.]

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

The decision of ECHA is based on the examination of the testing proposal submitted by you.

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

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

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

You have submitted a testing proposal for testing the registered substance for long-term toxicity testing on aquatic invertebrates *Daphnia magna* reproduction test, OECD 211.

ECHA notes that the registered substance is deemed to be poorly soluble. Poorly soluble substances require longer time to be significantly taken up by the test organisms and so steady state conditions are likely not to be reached within the duration of a short-term toxicity test. For this reason, short-term tests may not give a true measure of toxicity for poorly soluble substances and toxicity may actually not even occur at the water solubility limit of the substance if the test duration is too short. Therefore, long-term toxicity cannot be excluded based on short term test results and should be investigated. As consequence, Annex VIII 9.1.3. and Annex VII 9.1.1. of the REACH Regulation explicitly recommends that long-term aquatic toxicity tests be considered if the substance is poorly water soluble. Therefore, ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH Regulation.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), 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.

ECHA notes that you have waived the long-term toxicity study on fish invoking the following justification: "*The endpoint is waived as the long-term toxicity of daphnia has been proposed. In view of the outcome of the risk assessment more information needs to be made available on potential long-term effects in the aquatic compartment. The choice for a daphnia reproduction study is made as this concerns a test on non-vertebrates*". In the short-term study on fish submitted in your registration dossier, the prepared water accommodated fraction (WAF) did not induce mortality at the highest concentration tested, i.e. 3.1 mg/L, corresponding to a measured time-weighted average concentration of 0.27 mg/L. For the short-term study on *Daphnia*, 100% immobility was found at the loading rate of 100 mg/L, while no immobility was observed at lower loading rates. The NOEC for the short-term study on *Daphnia* corresponds to a loading rate of 56 mg/L and to a measured concentration of 2.1 mg/L. ECHA notes that it is not possible to definitively conclude from the available data which of the organisms, fish or *Daphnia*, is more sensitive.

In such case, according to the integrated testing strategy presented in ECHA Guidance, Chapter R7b, the *Daphnia* study is to be conducted first. However, long-term fish testing may need to be conducted in addition. In particular, ECHA notes that the dossier indicates that the registered substance could be surface active. Surface active substances affect cell membranes. The toxic effects of a surface active substance are therefore expected to be more important in unicellular species, e.g. algae, or in tissues with large surface area and thin epithelium, e.g. fish gills.

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

Notes for your consideration

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

Due to the low solubility of the substance in water you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested long-term ecotoxicity tests and for calculation and expression of the result of this test.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposal for examination pursuant to Article 40(1) on 17 February 2016.

This decision does not take into account any updates after **23 May 2016**, 30 calendar days after the end of the commenting period.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA did not receive any comments by the end of the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

2. Failure to comply with the 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.

3. In carrying out the test 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 or imported. If the registration of the substance covers different grades, the sample used for the new test must be suitable to assess these. Furthermore, there must be adequate information on substance identity for the sample tested and the grade registered to enable the relevance of the test to be assessed.