EUROPEAN CHEMICALS AGENCY

Helsinki, 14 May 2012

Final decision: TPE-D-0000002108-80-03/F

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

For Reaction mass of Octadecanamide, 12-hydroxy-N-[2-[(1-oxodecyl)amino]ethyl]- and N,N'-ethane-1,2-diylbis(12-hydroxyoctadecan-1-amide) and Decanamide, N,N'-1,2-ethanediylbis- (EC No 907-495-0), 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 testing proposals set out in the registration dossier for Reaction mass of Octadecanamide, 12-hydroxy-N-[2-[(1-oxodecyl)amino]ethyl]- and N,N'-ethane-1,2-diylbis(12-hydroxyoctadecan-1-amide) and Decanamide, N,N'-1,2-ethanediylbis (EC No 907-495-0), submitted by [redacted] (Registrant), latest submission number [redacted], for [redacted].

In accordance with Articles 10(a)(ix) and 12(1)(e) of the REACH Regulation, the Registrant submitted the following testing proposals as part of the registration dossier to fulfil the information requirements set out in Annexes IX and X:

- Bioaccumulation: bioaccumulation in sediment-dwelling benthic oligochaetes (OECD guideline 315), *Lumbriculus* sp.,
- Long-term toxicity to aquatic invertebrates: *Daphnia magna* reproduction test (OECD guideline 211), *Daphnia magna*,
- Sediment organisms: sediment-water *Lumbriculus* toxicity test using spiked sediment (OECD guideline 225), *Lumbriculus variegatus*.

The examination of the testing proposals was initiated on 24 November 2010.

On 30 November 2011 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 21 December 2011 ECHA received comments from the Registrant partially agreeing to ECHA's draft decision.

ECHA considered the Registrant's comments received and did amend the draft decision.

On 02 March 2012 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) 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 requirements of the REACH Regulation. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Testing required

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following proposed tests using the indicated test methods and the registered substance:

a) Bioaccumulation in aquatic species, sediment-dwelling benthic oligochaetes (Annex IX, 9.3.2., test method: OECD 315)
b) Long-term toxicity on invertebrates (*Daphnia* sp.) (Annex IX, 9.1.5., test method: EU C.20/OECD 211)
c) Long-term toxicity to sediment organisms (Annex X, 9.5.1., test method: OECD 225)

The Registrant shall determine the appropriate order of the studies taking into account the possible outcome and considering the possibilities for adaptations of the standard information requirements according to column 1 or 2 provisions of the relevant Annexes of the REACH Regulation.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **14 May 2014** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

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

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

a) Bioaccumulation in aquatic species

The Registrant has submitted a testing proposal for bioaccumulation in sediment-dwelling benthic oligochaetes (test method: OECD guideline 315) on *Lumbriculus* sp. The Registrant has justified the reason for performing the proposed test as to be able to estimate the bioaccumulation of the registered substance in benthic organisms.

The registered substance is poorly soluble in water and has adsorption potential. It is thus expected to partition to suspended particles in the water column and then to sediment. The benthic compartment is consequently anticipated to be the main compartment of concern.

The adsorption potential of the registered substance also implies that aquatic/sediment organisms might be exposed rather via the food than by direct contact. The chosen test organisms are endobenthic aquatic oligochaetes which burrow in the sediment and ingest sediment particles below the sediment surface. This ensures exposure to the test substance via all possible uptake routes (e.g. contact with, and ingestion of contaminated sediment particles, but also via porewater and overlying water).

The Registrant concluded that a sediment bioaccumulation study was more relevant than a fish bioconcentration study for the purpose of the bioaccumulation assessment.

The proposed test is part of the information requirements as laid down in Annex IX 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. ECHA considers the justification provided by the Registrant acceptable. Therefore and pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the following test: bioaccumulation in sediment-dwelling oligochaetes (Annex IX, 9.3.2., test method: OECD 315).

b) Long-term toxicity on invertebrates

The Registrant has submitted a testing proposal for a for long term toxicity to aquatic invertebrates (*Daphnia magna* reproduction test according to OECD guideline 211) in order to meet the information requirement of Section 9.1.5. of Annex IX 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. Furthermore, the results of the short-term test on *Daphnia* available in the technical dossier may not capture delayed effects due to the high hydrophobicity of the substance and potential long-term effects need to be further investigated. Therefore and pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the following test: *Daphnia magna* reproduction test (Annex IX, 9.1.5., test method: EU C.20/OECD 211).

c) Long-term toxicity to sediment organisms

The Registrant has submitted a testing proposal for a sediment-water *Lumbriculus* toxicity test using spiked sediment (test method: OECD guideline 225) in order to meet the information requirement of Section 9..5.1. of Annex X 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. The Chemical Safety Report indicates that releases to water can be expected. As the substance has potential for high adsorption it could end up in sediment, which is thus anticipated to be the main compartment of concern.

Furthermore, the chosen test organisms, i.e. *Lumbriculus variegatus*, are endobenthic aquatic oligochaetes which burrow in the sediment and ingest sediment particles below the sediment surface. This ensures exposure to the test substance via all possible uptake routes (e.g. contact with, and ingestion of contaminated sediment particles, but also via porewater and overlying water).

Therefore and pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the following test: sediment-water *Lumbriculus* toxicity test using spiked sediment (Annex X, 9.5.1., test method: OECD 225).

When performing the three above mentioned tests and interpreting the results, the Registrant is advised to take into account the fact that the substance is multiconstituent and highly insoluble in water. For that purpose, the Registrant can refer to OECD Monograph 23 (ENV/JM/MONO(2006)6: 'Guidance document on aquatic toxicity testing of difficult substances and mixtures' and to Appendix 7.8-1 of ECHA guidance document R.7b.

In his comments to ECHA's draft decision, the Registrant expressed consent to perform the studies listed in Section II above. However, he indicated that the initial timing of 12 months would be too short to perform the tests. ECHA acknowledges this information and has prolonged the deadline for the Registrant to update the registration dossier to 24 months from the date of the final decision.

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

ECHA always 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). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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.

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://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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Jukka Malm
Director of Regulatory Affairs