Decision number: TPE-D-0000002684-70-05/F Helsinki, 17 June 2013

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

For 3-hydroxy-1,1-dimethylbutyl 2-ethyl-2-methylheptaneperoxoate, CAS No 95718-78-8 (EC No 413-910-1), 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)(d) thereof for 3-hydroxy-1,1-dimethylbutyl 2-ethyl-2-methylheptaneperoxoate, CAS No 95718-78-8 (EC No 413-910-1), by [redacted] (Registrant):

- Viscosity (OECD 114);
- 90-day oral toxicity study (OECD 408);
- Developmental toxicity / teratogenicity study (OECD 414);
- Fish, early-life stage (FELS) toxicity test (OECD 210);
- Soil simulation testing (Aerobic and anaerobic transformation in soil, EU C.23/OECD 307);
- Sediment simulation testing (Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308);
- Earthworm, Acute Toxicity Tests (OECD 207);
- Toxicity to terrestrial plants (Terrestrial Plant Test: Seedling emergence and seedling growth test, OECD 208).
- Effects on soil micro-organisms (Soil microorganisms: nitrogen transformation test, OECD 216).

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 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.

The examination of the testing proposals was initiated upon the date when receipt of the complete registration dossier was confirmed on 07 February 2012.

ECHA held a third party consultation for the testing proposals from 17 April 2012 until 01 June 2012. ECHA did receive information from third parties (see section III below).

On 6 August 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 31 August 2012 ECHA received comments from the Registrant asking for amendments to ECHA's draft decision. On basis of the comments, the deadline in Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

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 to amend the draft decision.

On 4 March 2013 ECHA referred the draft decision to the Member State Committee.

On 19 March 2013 the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

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 25 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 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. Viscosity (Annex IX, 7.17., OECD Test method 114);
2. Sub-chronic toxicity study (90-day) in rats, oral route (Annex IX, 8.6.2.; test method: EU B.26/OECD 408);
3. Pre-natal developmental toxicity study in rats or rabbits, oral route (Annex IX, 8.7.2; test method: EU B.31/OECD 414).
4. Soil simulation testing (Annex IX, 9.2.1.3.; test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD 307);
5. Sediment simulation testing (Annex IX, 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308);
6. Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210);
7. Effects on soil micro-organisms (Annex IX, 9.4.2; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216);
8. Short-term toxicity to invertebrates (Annex IX, 9.4.1); test method: Earthworm acute toxicity test (Eisenia fetida/Eisenia andrei), (OECD 207), or, if long-term

testing is considered appropriate, 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 shall carry out the following modified tests pursuant to Article 40(3)(b) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

9. Short-term toxicity testing on plants (Annex IX, 9.4.3) test method: Terrestrial plants, growth test (OECD 208), with at least three species tested (with as a minimum one monocotyledonous species and two dicotyledonous species), or, if long-term testing is considered appropriate, Long-term toxicity testing on plants (Annex IX, 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).

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 registered substance subject to the present decision:

10. Simulation testing on ultimate degradation in surface water (Annex IX, 9.2.1.2; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25/OECD 309).

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. More specifically,

- prior to conducting the test mentioned above in point 6 above, the Registrant shall take into account the Guidance related to integrated testing strategy for aquatic toxicity testing to determine the overall necessity to conduct long-term toxicity testing on vertebrate animals;
- before conducting any of the tests mentioned above in points 4 and 5 and 10 the Registrant is advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 1.1, August 2008), Chapter R7b, Sections R.7.9.4 and R.7.9.6 and Chapter R.11.1.3 on PBT assessment to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all three simulation tests; and
- prior to conducting a second long term toxicity test to terrestrial organisms, either on invertebrates or plants (tests mentioned above in points 8 and 9), the Registrant shall take into account the Guidance on information requirements and chemical safety assessment (see later in Section III of this draft decision) related to integrated testing strategy for terrestrial toxicity testing to determine the sequence in which the tests should be conducted.

The Registrant shall determine the appropriate order of the studies in light of the reasoning provided above and retains the right to include fully justified adaptations for simulation testing.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **17 December 2015** an update of the registration dossier containing the information required by this decision.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other Registrants.

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 and scientific information submitted by third parties.

1. Viscosity

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.
A viscosity study is a standard information requirement as laid down in Annex IX, section 7.17 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.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance: Viscosity (Annex IX, 7.17, OECD Test method 114).

2. Repeated dose toxicity study

a) Examination of the testing proposal

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 did not specify the species to be tested. According to the test method EU B.26/OECD 408 the rat is the preferred rodent species. ECHA considers this species as being appropriate.

The Registrant proposed testing by the oral route but did not provide a view on the inhalation and dermal route. The substance is a liquid with low vapour pressure which is classified as skin irritant category 2. The substance has only industrial uses, where some of the uses imply generation of aerosols resulting in exposure of the respiratory tract. However, the substance is used for spray and brush application in concentrations of less than 5% and exposure concentration for all uses were estimated with 0.6 mg/m^3 maximum.

Therefore, a high risk for respiratory tract irritation is not to be expected. Furthermore, results from a repeated dose toxicity study 28-days showed important alterations in blood parameters, kidneys, liver and heart at 750 mg/kg bw/d which would need further investigation. Therefore ECHA concludes that testing by the oral route is most appropriate.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance: Sub-chronic toxicity study (90-day) in rats, oral route (Annex IX, 8.6.2; test method: EU B.26/OECD 408).

3. Pre-natal developmental toxicity study

a) Examination of the testing proposal

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 did not specify the species and route to be used 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.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance: Pre-natal developmental toxicity study in rats or rabbits, oral route (Annex IX, 8.7.2; test method: EU B.31/OECD 414).

4., 5. and 10 Simulation biodegradation testing (biodegradation in soil, aquatic sediment systems and in surface water)

a) Examination of the testing proposals

According to column 1 of Section 9.2. (9.2.1.2., 9.2.1.3. and 9.2.1.4.) of Annex IX of the REACH Regulation, simulation testing on ultimate degradation in surface water is a standard information requirement and simulation testing in soil and sediment are standard information requirements for substances with a high potential for adsorption to soil and/or sediment. The information on these endpoints is not available for the registered substance, but needs to be present in the technical dossier to meet the information requirements. Consequently, there are information gaps and it is necessary to provide information for these endpoints.

The Registrant has submitted a testing proposal for an aerobic and anaerobic transformation in soil simulation biodegradation study (OECD 307 / EU C.23) and a testing proposal for an aerobic and anaerobic transformation in aquatic sediment systems simulation biodegradation study (EU C.24/OECD 308) to cover the endpoints of Annex IX, Sections 9.2.1.3. and 9.2.1.4.
ECHA notes that the proposed tests can be used to fulfil the information requirements for simulation testing on soil and aquatic sediment systems simulation testing.

The Registrant provided the following justification for conducting the soil simulation biodegradation test:

> *'soil compartment can be exposed via the application of sewage sludge. From the production plant, the release of organic peroxide into the sewage is very limited, not to say completely negligible. The waste water from production plant is usually treated: at least a physical/chemical treatment, which will neutralize potential residual organic peroxide, and that can be followed by a biological treatment. So it can be expected that organic peroxides won't be present in sludge. However, based upon the adsorption potential of the substance of interest simulation biodegradation tests would be recommended and so are proposed in order to get more information of the fate of the concerned substance in sediment compartment.'*

The Registrant provided the following justification for conducting the aquatic sediment systems simulation biodegradation test:

> *'Sediment and water compartments exposition is likely. Besides, based upon the adsorption potential of the substance of interest, simulation biodegradation tests would be recommended and so are proposed in order to get more information of the fate of the concerned substance in sediment compartment. Nevertheless, the substance was assessed as hydrolytically unstable at environmental conditions, as a consequence no further assessment of the (bio)degradation is proposed in the water compartment. In the biodegradation test on water the substance appears as not readily biodegradable but is subject to abiotic degradation via hydrolysis'*

The Registrant has not proposed a test for fulfilling the endpoint of Annex IX, Section 9.2.1.2. In addition to the explanation for not further examining degradation in the water compartment (see previous quote) the Registrant provided the following adaptation for not conducting the surface water simulation biodegradation test:

> *'The ready biodegradability of LUPEROX 610 was evaluated in a study performed in accordance with OECD testing guideline 301 B and GLP requirements. LUPEROX 610 was tested for its ready biodegradability in the modified Sturm test at nominal concentrations of 10 and 20 mg/1. The relative degradation values calculated from the measurements performed during the test period showed a slight degradation of LUPEROX 610 at 10 mg/1 (16%) but no significant biodegradation at 20 mg/1 (4.4%). Thus under the conditions of this test, LUPEROX 610 was not readily biodegradable. Under the same conditions sodium acetate was degraded by 75.1%'.*

OECD 301 B test is not considered equivalent to a simulation biodegradation test. Furthermore, the Registrant has not justified why surface water would not be an appropriate medium for testing (Column 2 of Section 9.2. or Annex IX). Therefore, there remains an information gap for Annex IX, Section 9.2.1.2. that needs to be fulfilled.

Under Article 51 (2), a proposal for amendment was submitted on this decision, indicating that the registrant should also be offered the option to conduct an OECD 309 study, due to the contradictory hydrolysis data in the technical dossier. As there remains an information

gap for Annex IX, Section 9.2.1.2., ECHA considers this proposal of amendment acceptable and amended the draft decision accordingly.

As the dossier also contains data gaps and testing proposals for Annex IX, 9.2.1.3. and 9.2.1.4. the OECD 309 test (Annex IX, 9.2.1.2) is requested in addition to the tests proposed by the Registrant. The Registrant shall determine the appropriate order of the studies in light of the reasoning provided in the following paragraphs and retains the right to include fully justified adaptations for simulation testing in appropriate media on that basis:

- ECHA considers that based on the information available in the technical dossier, (16% degradation after 28 days using OECD 301B test method), the substance is potentially meeting the persistent (P) or the very persistent (vP) criterion. The assessment of the vP criterion as per Annex XIII of the REACH Regulation can be based on data from simulation test(s),. Therefore, the impact on the chemical safety assessment (CSA) by the results of a first simulation test and, if appropriate, other tests shall be evaluated before proceeding with the required other simulation tests. The order in which the simulations biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use and release patterns which could significantly influence the environmental fate of the registered substance. The Registrant is advised to consult the REACH guidance on information requirements chemical safety assessment Chapter R.11.1.3. and Figure R. 11-1 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the abiotic degradation of the registered substance.

- ECHA notes that based on the information available in the technical dossier, the registered substance is hydrolytically unstable at pH 4, 7 and 9 (DT50 of 50.2 hours) at 12°C. However, significant loss of the registered substance was not observed in the long term Daphnia magna or the acute fish studies conducted at 20°C.

Furthermore, ECHA advises the Registrant to consider the following notes of concerns on the intrinsic properties of the registered substance before testing:

- ECHA notes that based on the information available in the technical dossier, the registered substance is surface active and according to OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance R7b, tables R. 7.8-2 – 3. Surface activity may influence the approach for testing other physico-chemical properties, such as log Kow and may increase the adsorption potential, leading to a loss of the registered substance from the test system.
- In the selection of the most appropriate test design for the proposed environmental fate tests, valid Log Kow and Koc values as well as the extent of thermal decomposition on the screening hydrolysis values needs to be taken into consideration by the Registrant in order for the tests to be considered valid.

In his comments on the draft decision (i.e. before the proposal for amendment which led to the addition of the request for the simulation testing on ultimate degradation in surface water) the Registrant agreed on proceeding to the biodegradation simulation test following the sequential and integrated testing strategy and will choose the study to be performed first depending on testing resources availabilities and technical feasibility.

Following the above-mentioned proposal for amendment, the Registrant proposed to remove the requests for OECD 307 and OECD 308 tests and perform the OECD 309 test only. ECHA stresses that at this stage of the procedure, testing proposals cannot be withdrawn. Furthermore, as outlined above there remain information gaps for Annex IX, Sections 9.2.1.3. and 9.2.1.4. and they need to be fulfilled (or adapted). Therefore, ECHA has no reason to reject the testing proposals for the OECD 307 and OECD 308 tests.

ECHA acknowledges that the Registrant indicated that he would carry out a hydrolysis study before deciding on performing the OECD 309.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed studies: Aerobic and anaerobic transformation in soil – simulation biodegradation test (Annex IX, 9.2.1.3; test method: EU C.23/OECD 307) using the registered substance and Aerobic and anaerobic transformation in aquatic sediment systems – simulation biodegradation test (Annex IX, 9.2.1.4; test method: EU C.24/OECD 308) using the registered substance.

Furthermore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following as additional study: Simulation testing on ultimate degradation in surface water (Annex IX, 9.2.1.2; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25/OECD 309), using the registered substance.

The Registrant shall determine the appropriate order of the studies in light of the reasoning provided above and retains the right to include fully justified adaptations for simulation testing.

6. Long-term toxicity testing on fish

a) Examination of the testing proposal

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 9.1.6 of Annex IX of the REACH Regulation, long-term toxicity testing on fish 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 Long-Term toxicity testing on fish:

> *'According to claimed uses of 3-hydroxy-1,1-dimethylbutyl peroxyneodecanoate aquatic compartment exposure is likely. At the moment no data is available for characterizing the substance long-term effects on organisms inhabiting aquatic compartment. For these reasons, tests on aquatic invertebrates and fish are proposed in order to refine the PNEC value'.*

There were no indications in the dossier from the short-term toxicity studies on aquatic species that the fish would be substantially more sensitive than Daphnia.

However, in the current submission, the Registrant updated the information in the technical dossier, concerning the performance of a Long-term Daphnia study (EC10reproduction = 0.84 mg/L (calculated value) and has applied an assessment factor of 50, providing a PNECaquatic value of 9.92 µg/L. The Registrant states that '*The RCRs show that the risk is adequately controlled for the production of 3-hydroxy-1,1-dimethylbutyl Peroxyneodecanoate'.*

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 an applied assessment factor of 50 no risks are indicated, no long-term fish testing may need to be conducted.

ECHA notes that based on the information available in the technical dossier, the registered substance is considered by the Registrant to be hydrolytically unstable at pH 4, 7 and 9 (DT50 of 2.09 d (50.2 hours) at 12ºC. However, the extent of thermal decomposition on the screening hydrolysis values conducted at 50ºC needs to be considered by the Registrant. The registrant should be confident in the abiotic stability of the registered substance before conducting the chronic fish test to ensure environmentally relevant components are assessed. To assist this, the registrant is advised to conduct this study after tests 4, 5 and or as an additional option 10 are available.

OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance R7b, tables R. 7.8-2 – 3, provides guidance if a substance is likely to be unstable, a decision to test the parent substance and/or its possibly identified degradation products should be based on a consideration of the half-life of the substance under test and real-world conditions. This decision may resolve the issues observed concerning the sensitivity of the analytical method used in the available aquatic tests.

In his comments the Registrant agreed to ECHA's Draft Decision and confirmed the need for this study even in light of the third party information provided. The Registrant stated that he will perform the test on the degradation products in accordance with the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures Number 23. ECHA acknowledges that the Registrant indicated that he would carry out a hydrolysis study before deciding on performing OECD 210.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

Third party information 1:
A third party has proposed that a long-term toxicity test on fish should not be performed based on the environmental behaviour of the substance (long-term residence in water and long-term exposure of fish is not expected), and based on the already available data (three core aquatic acute toxicity studies, two long-term NOEC values and a protective PNEC value). The third party concluded that a long-term risk to fish is not identified for this substance and therefore a long-term fish toxicity study is not warranted on scientific grounds.

ECHA examined the comments and recognised that the information as provided by the third party might be scientifically valid. However it does not fulfil Annex XI requirements and is therefore not sufficient to allow ECHA to reject the testing proposal under Annex IX, 9.1 of the REACH Regulation. Nevertheless, ECHA acknowledges that the Registrant may himself supplement under its own responsibility the argumentation and information provided by the third party in order to make use of adaptation possibilities. This would require that the Registrant documents that there is a sufficient weight of evidence leading to the assumption/conclusion that a substance has or has not particular dangerous properties, according to the criteria laid down in Annex XI of the REACH Regulation.

Third party information 2:
The third party has proposed that the registrant should ensure the reason for conducting the vertebrate test is clear in their dossier and provided a strategy/alternative options for ECHA to consider before a long-term toxicity test on fish is requested. However, third parties were invited, as specified by Article 40(2) of the REACH Regulation to submit "scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal". As the proposal for a strategy/alternative options as such cannot be regarded information or studies, ECHA concludes that this is not a sufficient basis to fulfil the data/information requirement Long term testing on Fish is a standard information requirement according to Annex IX , 9.1.6, which can be waived according to column 2. The Registrant has considered long term testing on Fish as necessary after identification of a risk in aquatic compartment in its CSR.The registrant indicated that he submitted a testing proposal in order to refine the PNEC on aquatic compartment.

The intrinsic properties of the registered substance are addressed in the decision. (stated above in Section III point 6(a)).

c) Outcome

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, the Registrant is required to carry out the proposed study: Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1; test method: Fish, early-life stage toxicity test, OECD 210).

7 – 9. Effects on terrestrial organisms

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

ECHA notes that according to Section R.7.11.6, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), where there is adequate data available to sufficiently derive a PNEC for aquatic organisms, this PNEC can be used in a screening assessment for soil risks through the use of the Equilibrium

Partitioning Method (EPM) approach. However, ECHA notes that the Registrant has proposed a toxicity test on fish, which ECHA has accepted (Section II. 6 of the present decision). The data currently available to derive a PNEC for aquatic organisms is therefore not adequate. Therefore, ECHA considers that accurate allocation of an appropriate soil hazard category according to table R7.11-2 of the abovementioned guidance is not possible at this time. The results of the proposed test may however provide an adequate PNECaquatic, which may enable an adaptation of the present endpoint (Annex IX, 9.4.1) in the future if the present decision is implemented following a testing strategy.

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.

7. Effects on soil microorganisms (Annex IX, 9.4.2)

a) Examination of the testing proposal

The hazard to soil microbial communities is a standard information requirement under Annex IX, Section 9.4.2. 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 generate the data for this endpoint.

The Registrant proposed a nitrogen transformation test (EU C.21/OECD 216). The Registrant provided the following justification for conducting the proposed test:

> *'Soil compartment can be exposed via the application of sewage sludge. From the production plant, the release of organic peroxide in to the sewage is very limited, not to say completely negligible. The waste water from the production plant is usually treated: at least a physical/chemical treatment, which will neutralize potential residual organic peroxide, and that can be followed by biological treatment. So it can be expected that organic peroxides won't be present in sludge. Nevertheless, as neither toxicity test results, nor measures in treatment plan sewage are available, toxicity tests on soil organisms are proposed in order to cover these issues.'*

ECHA notes that according to Section R.7.11.6, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), where there is adequate data available to sufficiently derive a PNEC for aquatic organisms, this PNEC can be used in a screening assessment for soil risks through the use of the Equilibrium Partitioning Method (EPM) approach. However, ECHA notes that the Registrant has proposed a toxicity test on fish, which ECHA has accepted (Section II.6 of the present decision). The data currently available to derive a PNEC for aquatic organisms is therefore not adequate. Therefore, ECHA considers that accurate allocation of an appropriate soil hazard category according to table R7.11-2 of the abovementioned guidance is not possible at this time. The results of the proposed test may however provide an adequate PNECaquatic, which may enable an adaptation of the present endpoint (Annex IX, 9.4.1) in the future if the present decision is implemented following a testing strategy.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4.3 does not apply for the present endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), Chapter R.7C, p112, the nitrogen transformation test (EU C.21/OECD 216) is considered sufficient for most non-agrochemicals.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216) using the registered substance.

8. Terrestrial Invertebrates (Annex IX, 9.4.1)

a) Examination of the testing proposal

The Registrant proposed a short-term toxicity test on terrestrial invertebrates (OECD 207), with the the same justification for conducting the short-term earthworm toxicity test and the short-term terrestrial plant growth test as the nitrogen transformation test (EU C.21/OECD 216) stated above in Section III point a. This test is in principle suitable to address the standard information requirement of Annex IX, section 9.4.1.

ECHA notes that according to Section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), where there is adequate data available to sufficiently derive a PNEC for aquatic organisms, this PNEC can be used in a screening assessment for soil risks through the use of the Equilibrium Partitioning Method (EPM) approach. However, ECHA notes that the Registrant has proposed a toxicity test on fish, which ECHA has accepted (Section II. 6 of the present decision). The data currently available to derive a PNEC for aquatic organisms is therefore not adequate. Therefore, ECHA considers that accurate allocation of an appropriate soil hazard category according to table R7.11-2 of the abovementioned guidance is not possible at this time. The results of the proposed test may however provide an adequate PNECaquatic, which may enable an adaptation of the present endpoint (Annex IX, 9.4.1) in the future if the present decision is implemented following a testing strategy.

Currently, 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 9.4.1.

According to Section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), 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 has a high potential to adsorb to soil ($logK_{ow}$ range from 4.2 – 5.6) and testing proposals for simulation biodegradation testing to investigate persistence). Therefore, the Registrant shall determine the need to carry out the long-term test on terrestrial invertebrates. 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.

In his comments the Registrant agreed with ECHA's decision, but stated that the choice between the short and the long term test will depend on the outcome of the first simulation biodegradation test. So that the short term toxicity test will be chosen if it can be concluded that the substance is not persistent.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out one of the following studies: Short-term toxicity to invertebrates (Annex IX, 9.4.1); test method: Earthworm acute toxicity test (*Eisenia fetida/Eisenia andrei*), (OECD 207), or, if long-term testing is considered appropriate, 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), using the registered substance.

9. Terrestrial Plants (Annex IX, 9.4.3)

Pursuant to Article 40(3)(b) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test under modified conditions

a) Examination of the testing proposal

The Registrant proposed a short-term toxicity test on terrestrial plants (OECD 208), with the same justification for conducting the short-term earthworm toxicity test and the short-term terrestrial plant growth test as the nitrogen transformation test (EU C.21/OECD 216) stated above in Section III point 7. This test is in principle suitable to address the standard information requirement of Annex IX, section 9.4.3.

ECHA notes that according to Section R.7.11.6, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), where there is adequate data available to sufficiently derive a PNEC for aquatic organisms, this PNEC can be used in a screening assessment for soil risks through the use of the Equilibrium Partitioning Method (EPM) approach. However, ECHA notes that the Registrant has proposed a toxicity test on fish, which ECHA has accepted (Section II. 6 of the present decision). The data currently available to derive a PNEC for aquatic organisms is therefore not adequate. Therefore, ECHA considers that accurate allocation of an appropriate soil hazard category according to table R7.11-2 of the abovementioned guidance is not possible at this time. The results of the proposed test may however provide an adequate PNECaquatic, which may enable an adaptation of the present endpoint (Annex IX, 9.4.1) in the future if the present decision is implemented following a testing strategy.

However, according to Section R.7.11.5.3, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), 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 has a high potential to adsorb to soil ($logK_{ow}$ range from 4.2 – 5.6) and testing proposals for simulation biodegradation testing to investigate persistent) 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. Therefore, the Registrant shall determine the need to carry out the long-term test on terrestrial plants.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the the number of test species according to the relevant relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For short-term toxicity testing, ECHA considers three species as the minimum to achieve a reasonably broad selection. Short-term toxicity testing shall be conducted with species from different families, as a minimum with one monocotyledonous species and two dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. Alternatively, for long-term toxicity testing ECHA considers six species as the minimum to achieve a reasonably broad selection. The test shall be conducted as a minimum with two monocotyledonous species and four dicotyledonous species from different groups, selected according to the criteria indicated in the OECD 208 guideline. The Registrant should consider if testing on additional species is needed to cover the information requirement. In addition, the ISO 22030 (chronic toxicity in higher plants) test is also considered by ECHA as appropriate for the fulfilment of the standard information requirements of Annex IX, section 9.4.3 (column 2) under REACH.

In his comments, the Registrant agreed with ECHA's decision but provided the same comment for the choice between short and long term conditional to the results of the biodegradation simulation test as in point 8.

b) Outcome

Therefore, pursuant to Article 40(3)(b) of the REACH Regulation, the Registrant is required to carry out one of the following studies under modified conditions: Short-term toxicity to plants (Annex IX, 9.4.3); Terrestrial plants, growth test (OECD 208), with at least three species tested (with as a minimum one monocotyledonous species and two dicotyledonous species), or, if long-term testing is considered appropriate, Long-term toxicity testing on plants (Annex IX, 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), using the registered substance.

10. Deadline for submitting the information required under Section II

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 24 months from the date of adoption of the decision. In his comments on the draft decision, the Registrant requested for an extension to the deadline from 24 months to 30 months from the date of the final decision. To substantiate the request, the Registrant outlined he would require extra time to estimate time to plan, conduct sequentially and analyse the simulation biodegradation studies, and provided some justifications. ECHA considers that the request made by the Registrant, is adequately justified. The decision was therefore modified accordingly.
In follow-up to the proposals for amendment an additional simulation testing requirement was included amongst the tests requested by the decision. ECHA considers that 30 months suffice to conduct sequential simulation testing.

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.

Furthermore, there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the studies to be assessed.

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.

[redacted]
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Director of Regulatory Affairs