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DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For diisodecyl azelate, CAS No 28472-97-1, EC No 249-044-4

Addressee: Registrant(s)[1] of diisodecyl azelate.

This decision is addressed to all Registrants of the above substance with active registrations on the date on which the draft for the decision was first sent, with the exception of the cases listed in the following paragraph. A list of all the relevant registration numbers subject to this decision is provided as an annex to this decision.

Registrants meeting the following criteria are not addressees of this decision: i) Registrants who exclusively use the above substance as an on-site isolated intermediate and under strictly controlled conditions and ii) Registrants who have ceased manufacture/import of the above substance in accordance with Article 50(3)of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) before the decision is adopted by ECHA.

Based on an evaluation by the National Institute of Health on behalf of the Ministry of Health as the Competent Authority of Italy (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision is based on the registration dossier(s) on 29 April 2014, i.e. the day on which the draft decision was notified to the Registrant(s) pursuant to Article 50(1) of the REACH Regulation.
This decision does not take into account any updates of the registration of the Registrant(s) after 29 April 2014.

ECHA notes that the Registrant(s) had submitted an updated registration dossier on 16 December 2014 but the evaluating MSCA had not yet the possibility to evaluate it. However, the Registrant(s) are informed that this latest update of 16 December 2014 might already address some requirements of the present decision by means of newly provided studies or revised adaptations of the information requirements. These new studies/adaptations will be assessed by the evaluating MSCA during the evaluation of all the obtained information after the deadline indicated in this decision.

This decision does not imply that the information provided by the Registrant(s) in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier(s) of the Registrant(s) at a later stage, nor does it prevent a new substance evaluation process once the present substance evaluation has been completed.

[1] The term Registrant(s) is used throughout the decision, irrespective of the number of registrants addressed by the decision.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of Italy has initiated substance evaluation for diisodecyl azelate, CAS No 28472-97-1 (EC No 249-044-4) based on registration(s) submitted by the Registrant(s) and other relevant and available information and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to the initial grounds for concern relating to Environment/Suspected PBT; Exposure/Wide dispersive use; Consumer use; Aggregated tonnage the substance was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2013. The updated CoRAP was published on the ECHA website on 20 March 2013. The Competent Authority of Italy was appointed to carry out the evaluation.

In the course of the evaluation, the evaluating MSCA identified additional concerns regarding potential risks to the environment.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 20 March 2014.

On 29 April 2014, ECHA sent the draft decision to the Registrant(s) and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

Registrant(s) commenting phase

By 5 June 2014 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA without delay. The evaluating MSCA considered the comments received from the Registrant(s). The information contained therein is reflected in the Statement of Reasons (Section III) and amendments to the Information Required (Section II) were made.

Commenting by other MSCAs and ECHA

In accordance with Article 52(1) of the REACH Regulation, on 5 March 2015 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, five Competent Authorities of the Member States and ECHA submitted proposals for amendment to the draft decision. The evaluating MSCA has reviewed the proposals for amendment received and, where appropriate, the draft decision was amended accordingly.

Referral to Member State Committee

On 20 April 2015 ECHA referred the draft decision to the Member State Committee.

By 11 May 2015, in accordance to Article 51(5), the Registrant(s) provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant(s) on the proposals for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 28 May 2015 in a written procedure launched on 18 May 2015.

ECHA took the decision pursuant to Article 52(2) and Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test method and instructions (in accordance with Article 13 (3) and (4) of the REACH Regulation) and the registered substance subject to the present decision:

1. Ready biodegradability (test method: CO_2 evolution test, OECD 301B);

2. Enhanced ready biodegradability test (test method: enhancement of any of the four respirometric tests, OECD Test Guidelines for Ready Biodegradability No. 301 B, C, D or F) with the preparation and introduction of the substance into test vessels according to ISO 10634 "Water quality - Guidance for the preparation and treatment of poorly-soluble organic compounds for the subsequent evaluation of their biodegradability in an aqueous medium", as specified in Section III below;

3. Simulation testing on ultimate degradation in surface water (test method: Aerobic mineralisation in surface water - simulation biodegradation test, EU C.25/OECD 309) at a temperature of 12 °C, using Carbon 14 labelled test substance, as specified in Section III below;

4. Soil simulation testing (test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD 307) at a temperature of 12 °C, as specified in Section III below;

5. Sediment simulation testing (test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308) at a temperature of 12 °C, as specified in Section III below;

6. Identification of degradation products, as specified in Section III below;

7. Long-term toxicity testing on aquatic invertebrates (test method: *Daphnia magna* reproduction test, EU C.20/OECD 211);

8. Long-term toxicity testing on fish (test method: Fish Early Life Stage (FELS) toxicity test, OECD 210);

9. Long-term toxicity testing to sediment organisms (test method: Sediment-Water Chironomid Toxicity Using Spiked Sediment, OECD 218);

10. Effects on terrestrial organisms - Long-term toxicity testing to invertebrates (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);

11. Effects on soil micro-organisms (test method: Soil micro-organisms: nitrogen transformation test, OECD 216); and

12. Effects on terrestrial organisms - Long-term toxicity testing on plants (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 request for the enhanced ready biodegradability test (request no. 2) is conditional to a negative result of the ready biodegradability test (OECD 301B, request no. 1). The requests for simulation testings with identification of degradation products (requests no. 3 to 6) are conditional to a negative result of the ready biodegradability test (OECD 301B, request no. 1 and to a negative result of the enhanced ready biodegradability test as further specified in Section III.

The Registrant(s) may adapt the testing requested above under the conditions further specified in Section III, and in accordance with the specific rules outlined in Annexes VI to X and/or the general rules contained in Annex XI of the REACH Regulation. Any such adaptation will need to have a sound scientific justification, and an adequate and reliable documentation.

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **22 March 2019** an update of the registration(s) containing the information required by this decision[2], including robust study summaries and, where relevant, an update of the Chemical Safety Report (CSR).

III. Statement of reasons

Diisodecyl azelate is a potential PBT/vPvB substance. In order to clarify the PBT/vPvB concern of this substance, a tiered approach is applied. For animal welfare reasons, in this draft decision the P property of PBT/vPvB is addressed. The possible additional need for information on the B property will only be considered later on in the procedure if the P criterion is fulfilled. Hence, the evaluating MSCA will review the information submitted by the Registrant(s) as an outcome of this decision and evaluate if further information should be requested in order to clarify the PBT/vPvB properties.

The information on environmental toxicity is required in order to clarify the additional concern (potential risks to the environment).

1.-6. Ready biodegradability, Enhanced ready biodegradability test, Simulation testing and Identification of degradation products

Information resulting from screening tests and, if necessary, from simulation tests is required in order to enable the evaluating MSCA to assess the properties of the substance and to decide whether it is persistent (initial grounds for concern: PBT/vPvB). This information is thus needed to establish whether the suspected concern may be realised or not. Without the requested information it will not be possible to verify whether there remains an uncontrolled risk with the substance that should be subject to further risk management measures. According to the PBT assessment strategy (ECHA guidance on information requirements and chemical safety assessment, Chapter R.11 PBT/vPvB Assessment), concern on P should generally be addressed before of the B and T criteria.

For screening test on biodegradability, the Registrant(s) provided a read across (RA) key study with reliability 2, according to OECD 301 B, where the test substance (bis(2-

[2] The deadline set by the decision already takes into account the time that registrants may require to agree on who is to perform any required tests and the time that ECHA would require to designate a registrant to carry out the test(s) in the absence of the aforementioned agreement by the registrants (Article 53(1) of the REACH Regulation).

ethylhexyl) azelate, CAS 103-24-2) reached biodegradation values of 73.2-89.3% at the end of the test. Furthermore, the test substance met the 10-day window criterion for ready biodegradability. Therefore, the Registrant(s) considered the substance readily biodegradable. The RA justification provided by the Registrant(s), in Part B Justification for the Analogue approach of the CSR, reported the following sentence: "*The read across is justified, as all substances have a common metabolic fate, which involves hydrolysis to fatty acids and the corresponding alcohol*". Moreover, the Registrant(s) reported a disregarded study (reliability 3, due to relevant methodological deficiencies) carried out with the registered substance (diisodecyl azelate, CAS 28472-97-1).

The evaluating MSCA reported some information about QSAR predictions on the microbial metabolism of both substances used in read-across approach. The microbial metabolism simulator of the QSAR toolbox was used by the evaluating MSCA to predict both the metabolites of the analogue (used in the key study on ready biodegradation, CAS 103-24-2) and diisodecyl azelate. The results obtained with the QSAR toolbox by microbial metabolism can hardly be interpreted as it results in a list of many potential metabolites (62 metabolites for the registered substance and 77 metabolites for the analogue). There are more than 70 metabolites for these two substances without any confidence on degradation pathway and commonalities of these metabolites. Therefore, the read-across used is not sufficiently justified and, consequently, it cannot be accepted.

In addition, the study reported on the registered substance (disregarded study) cannot be used to confirm the ready biodegradability of the substance.

However, ECHA notes that the QSAR predictions showed that in general diisodecyl azelate is predicted as readily biodegradable with the exception of one QSAR model (BIOWIN 3, EPISUITE). Furthermore, in BIOWIN (Episuite) the following criteria are reported: if Biowin 3 (ultimate degradation) result is "weeks" or faster (i.e. "days", "days to weeks", or "weeks") AND Biowin5 (MITI linear model) probability is ≥ 0.5, then the prediction is YES (readily biodegradable). If this condition is not satisfied, the prediction is NO (not readily biodegradable). For diisodecyl azelate the result obtained with Biowin 3 is weeks-months, and the result of Biowin 5 is > 0.5, therefore, the prediction is NO (the substance does not readily biodegrade).

Therefore, more information about the degradation is necessary.

In addition, the justification for data waiving reported by the Registrant(s) for simulation tests in water, sediment and soil is the following: "*according to Regulation (EC) No. 1907/2006, Annex IX, Column 2, testing for this endpoint is not required as diisodecyl azelate (CAS No. 28472-97-1) is readily biodegradable*". ECHA notes that the justification reported by the Registrant(s) is not acceptable.

In the comments on the Draft Decision, the Registrant(s) reported "*In our opinion diisodecyl azelate (CAS No. 28472 -97 -1) is readily biodegradable. Therefore according to Column 2 of EC 1907/2006 Annex IX, testing for this endpoint is not required. We propose to carry out an OECD 301B study to support further the case that the substance is readily biodegradable. The dossier will be updated to assess if the waiver in the original dossier still holds*".

The evaluating MSCA agreed with the Registrant(s) proposal to perform a ready biodegradability study in accordance with OECD 301B on the registered substance. During the consultation phase of the draft decision, some proposals for amendments (PfAs) were received. Two MSCAs proposed to insert in the tiered strategy the request of an additional screening test before conducting simulation testing, since the QSAR models

predict that in general diisodecyl azelate is readily biodegradable. The evaluating MSCA accepted the PfA and considered that the enhanced ready biodegradability test is suitable for contributing information at a screening level for persistence assessment.

Therefore, if the requested ready biodegradability study turns out negative (regardless of whether the pass level for ready biodegradation is fulfilled within the 10 d time window), the Registrant(s) are required to perform an enhancement to the ready biodegradability.

The enhancements of some of the standard conditions of the screening tests address time for adaptation and a more environmentally realistic microbial biomass diversity. If sufficient degradation is shown in such a test, i.e. the pass level is reached, the result is used to indicate that the substance will not persist in the environment and a further simulation test is considered not necessary.

According to the ECHA guidance on information requirements and chemical safety assessment, Chapter R.7b, sections R.7.9.4 and R.7.9.5, the approaches in enhanced biodegradation screening tests could include: test duration extension, testing in larger vessels, increasing the biomass concentration, low-level pre-adaptation microorganisms test systems, semi-continuous assessments. Therefore the Registrant(s) should consult the above mentioned ECHA Guidance for more information on modifications that can be made to a ready test.

Furthermore, due to the low water solubility and the high adsorption potential of the test substance, the Registrant(s) shall decide on the appropriate test method among any of the four respirometric tests: OECD Test Guidelines No. 301 B, or C, or D, or F, as specified in the Appendix R. 7.9-3 of ECHA guidance, Chapter R.7b.

Due to the difficulties associated with the evaluation of the biodegradability of organic compounds with low water solubility, the Registrant(s) are required to prepare the substance and introduce it into test vessels according to ISO 10634 "Water quality - Guidance for the preparation and treatment of poorly-soluble organic compounds for the subsequent evaluation of their biodegradability in an aqueous medium".

However, it is highlighted that if the result of the enhanced screening test does not allow the Registrant(s) to exclude unequivocally that the substance is persistent, the Registrant(s) shall carry out the simulation tests on degradation to conclude on P or vP (definitive criteria on the persistence).

Before conducting any of the simulation tests mentioned in Section II the Registrant(s) are advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2, November 2014), Chapter R7.b and Chapter R.11 on PBT/vPvB assessment to determine the most suitable simulation test(s) and the sequence in which these tests are to be conducted. The selection of most appropriate simulation test(s) needs to take into account the intrinsic properties of the registered substance, the identified uses and release patterns (including the primary receiving compartments) which could significantly influence the environmental fate of the registered substance.

If on the one hand, the information about the release patterns is not included in the CSR due to the lack of environmental exposure assessment, on the other hand, the intrinsic properties of the substance and the data from distribution modelling studies (Mackay Level I, Fugacity model) show that once released in the environment diisodecyl azelate will be mainly distributed among the sediment (50 - 66%) and soil (49 – 30%).

According to the approach recommended by ECHA[3], in general, the aquatic pelagic study simulation test is the most meaningful to clarify the P-assessment and the OECD 309 test should be preferred over OECD 308 and 307, if it is demonstrated to be technically feasible. However, in the same approach, it is pointed out that for highly adsorbitive substances the soil or sediment simulation testings give a more realistic picture. Furthermore, according to Annex IX 9.2.1.3. and 9.2.1.4. of the REACH Regulation a condition for sediment and soil testing is that the substance has a high potential for adsorption to soil/sediment. ECHA notes that for diisodecyl azelate this condition is verified (log Koc = 6.3-7.2).

Regarding an appropriate and suitable test method, the methods will have to be substance specific. Identification, stability, behaviour and molar quantity of metabolites relative to the parent compound shall be evaluated. Further investigation (degradation half-life, log Kow and potential toxicity) might be needed if degradation/transformation products relevant for PBT/vPvB assessment are formed in the environment. The identification of degradation products is not required if the substance is considered readily biodegradable or reaches the pass level in the enhanced test.

Moreover, according to Annex XIII of the REACH Regulation the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions. The registered substance is used and released in EU within the context of the REACH Regulation. Therefore, the Registrant(s) are requested to perform the studies at 12 °C (285 K) as this temperature is indicated in the Guidance on information requirements and chemical safety assessment Chapter R.16, Table R.16-9 (October 2012) as the average environmental temperature for the EU to be used in the Chemical Safety Assessment.

In the comments on the proposals for amendment, the Registrant(s) welcomed the addition of the ready biodegradation study and the inclusion of a tiered approach in the draft decision. The Registrant(s) pointed out that the results of the OECD 301B study submitted with the updated dossier of 16 December 2014 show that diisodecyl azelate is readily biodegradable, as noted in the comments made from one MSCA. Therefore, the Registrant(s) considered the PfAs made by the other MSCAs to be no longer relevant. However, the Registrant(s) understood it was not possible to include the contents of their December dossier update into the revised draft decision. Moreover, the Registrant(s) stated that any further dossier update to incorporate the testing requirements of the final decision will be certain to address why further testing on degradability is not necessary in accordance with the tiered approach.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following studies using the registered substance subject to this decision:

Ready biodegradability (test method: CO_2 evolution test, OECD 301B);

ECHA specifies that if the result of the screening test is that the substance is not readily biodegradable, the Registrant(s)s shall carry out the following:

Enhanced ready biodegradability test (test method: enhancement of any of the four respirometric tests, OECD Test Guidelines for Ready Biodegradability No. 301 B, C, D or F) with the preparation and introduction of the substance into test vessels according to ISO 10634 "Water quality - Guidance for the preparation and treatment of poorly-soluble organic compounds for the subsequent evaluation of their biodegradability in an aqueous medium"

[3] Commission workshop on the "Assessment of Persistent, Bioaccumulative and Toxic (PBT) substances in different EU legislations", publicly available on: http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index_en.htm

If the result of the enhanced test does not allow the Registrant(s) to exclude unequivocally that the substance is persistent (i.e. the enhanced screening test failed), the Registrant(s) shall carry out the most suitable simulation test(s) from the following, including identification of degradation products:

Simulation testing on ultimate degradation in surface water (test method: Aerobic mineralisation in surface water - simulation biodegradation test, EU C.25/OECD 309) at a temperature of 12 °C, using Carbon 14 labelled test substance;

Soil simulation testing (test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD 307) at a temperature of 12 °C;

Sediment simulation testing (test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308) at a temperature of 12 °C.

7. – 8. Long-term toxicity testing on aquatic invertebrates and fish

Information on this endpoint is not provided by the Registrant(s) for the registered substance, but it is needed to assess the toxicity of the substance in the aquatic compartment in order to clarify the additional concern relating to the potential risks to the environment.

For the registered substance no data on chronic ecotoxicity are available. The justification for data waiving provided by the Registrant(s) is the ready biodegradability and "high insolubility" of the substance (as stated in the CSR), which are however not adequately demonstrated.

The use of the concept of "high insolubility in water" for waiving aquatic toxicity testing requires substance specific assessment, not provided by the Registrant(s). Only read-across (RA) data on acute toxicity for *Daphnia* and algae are provided by the Registrant(s), which show that no acute toxicity is observed for the analogue within the range of water solubility. In addition, the acute toxicity study on fish is considered inadequate as the results are based only on nominal concentrations of the test substance (very low soluble and lipophilic) without any measured concentration to confirm that the deviations is lower than 20%. On the basis of these studies the Registrant(s) do not derive a PNECwater, justifying this with the statement "*No toxic effects were observed on aquatic organisms (fish, invertebrates, algae) up to the limit of water solubility (< 0.05 mg/L) of diisodecyl azelate. Therefore, PNEC derivation was not possible and a quantitative risk assessment cannot be performed.*"

Due to the low water solubility of the substance (< 0.05 mg/L) it is expected that short term toxicity tests do not reveal any toxicity. According to Annex VIII, column 2, section 9.1.3 of the REACH Regulation and in view of the poor water solubility of the substance, it is considered the priority of the long term toxicity test instead of the short term toxicity. Since the lack of toxic effects has not been demonstrated and there are the following concerns: exposure/wide dispersive use, consumer use, aggregated tonnage (initial) and risks to the environment (additional), it is not possible to exclude chronic toxicity to aquatic species. Therefore, long-term tests should be performed to allow accurate evaluation of the potential toxicity to aquatic organisms. Furthermore, the requested tests are standard information requirements at the tonnage range declared for the susbstance.

According to ECHA Guidance on information requirements and chemical safety assessment, chapter R.7b, 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 (ITS), the *Daphnia magna* study is to be

conducted first. If, based on the results of the long-term *Daphnia magna* study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. In this case, in order to avoid any underestimation of the risk, it will be necessary to verify the relative sensitivity of fish through other data, e.g. data from non-standard studies of non standard organisms, data generated with QSAR models, read-across from available experimental data on a structurally related substance. However, if a risk is indicated, the long-term fish study needs to be conducted.

Due to the poor solubility of the substance in water, the OECD Guidance Document 23 on aquatic toxicity testing of difficult substances shall be taken into account when conducting the tests and the test results shall be based on measured concentrations.

During the commenting phase on the draft decision, the Registrant(s) confirmed the same justification for data waiving for long-term toxicity testing to aquatic organisms: "*According to EC 1907/2006, Annex IX, Column 2, long-term toxicity testing shall be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. Long-term exposure to invertebrate/fish is unlikely to occur due to the fact that diisodecyl azelate (CAS No. 28472-97-1) is highly insoluble in water and readily biodegradable. Therefore, the bioavailability of this compound in water is expected to be low. Furthermore, the results obtained from the short-term studies showed that the substance is neither toxic nor harmful to aquatic organisms after acute exposure. Thus, according to the available information and considering invertebrates/vertebrates welfare, testing is considered not necessary for this endpoint*".

As indicated in Annex XI, Section 3 of the REACH Regulation, long-term testing on aquatic organisms may be omitted based on the exposure scenario(s) developed in the CSR. However, adequate justification and documentation shall be provided. The justification shall be based on a thorough and rigorous exposure assessment. In the CSR of diisodecyl azelate an exposure assessment is not performed, therefore the aquatic compartment exposure cannot be excluded.

Moreover, the Registrant(s) proposed to perform OECD 301B study on diisodecyl azelate in order to clarify the aspect of persistence, but the result of the proposed test cannot be a reason to not perform long-term tests on aquatic organisms. The ready biodegradability is not considered a valid waiving argument because a continuous exposure of water compartment cannot be excluded. Therefore, the result of the test proposed by the Registrant(s) (OECD 301B study on diisodecyl azelate) cannot justify a waiving for long-term tests on aquatic organisms.

In the commenting phase of PfAs, the Registrant(s) noted and supported the tiered testing approach outlined above , accepting to address the chronic Daphnia end point, "*Although the current usage is narrower than all the uses included in the registration dossier since we want to keep open the option for additional uses of the substance in future*". Moreover the Registrant(s) stated also that in case the chronic Daphnia study shows cause of concern, "*we would also look to see if it would be possible to restrict the uses of the substance so that continuous exposure to the water compartment could be excluded*".

It is pointed out that restricting the uses in order to demonstrate that there is no risk for a compartment needs a thorough and rigorous exposure assessment, as well as an in-depth analysis and an adequate justification and documentation of the proposed Risk Management Measures.
Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the registered substance subject to this decision:

***Daphnia magna* reproduction test (test method: EU C.20/OECD 211)**.

According to ITS, if a risk is indicated and the concern is not clarified by this study, the Registrant(s) is requested to carry out the following study using the registered substance subject to this decision: **Fish Early Life Stage (FELS) toxicity test, (test method: OECD 210).**

9. Long-term toxicity testing to sediment organisms

Information on long-term toxicity on sediment organisms is required to enable the evaluating MSCA to assess the toxicity of the substance in the sediment compartment in order to clarify the additional concern relating to potential risks to the environment.

The Registrant(s) provided the following justification for data waiving for long-term toxicity testing to sediment organisms: "*According to Regulation (EC) No. 1907/2006, Annex X, Column 2, long-term toxicity testing with sediment organisms shall be proposed if the results of the chemical safety assessment indicate the need to investigate further the effects of the substance and/or relevant degradation products on sediment organisms. Due to the highly insoluble nature of diisodecyl azelate (CAS No. 28472-97-1) in water and the fact that it is readily biodegradable, the release of this substance from STP facilities into the environment will be limited. Therefore, the bioavailability of this substance to sediment organisms is expected to be low. Furthermore, acute studies performed with this substance exhibited no toxic effects to aquatic organisms and, additionally, no effects were reported in mammalian toxicity tests. Considering the above information, long-term testing for sediment organisms is considered not necessary*".

The evaluating MSCA disagreed with the Registrant(s) because ready biodegradability and high insolubility in water are not valid waiving arguments, as explained below.

Due to physical-chemical properties and distribution modelling, the main compartments exposed are soil and sediment. Sediment organisms can be exposed via their body surfaces to substances in solution in the overlying water and in the pore-water and to bound substances by direct contact or via ingestion of contaminated sediment particles. For strongly adsorbing or binding substances, preference should be given to test designs and test organisms that cover the exposure via sediment ingestion, as this is the most relevant exposure route for such chemicals.

According to the ECHA Guidance on information requirements and chemical safety assessment Chapter R.7b, several factors have to be considered when using the equilibrium partitioning method (EPM) for the estimation of the toxicity of chemicals to sediment organisms. This method considers only uptake via the water phase. However, because diisodecyl azelate is a highly adsorbing chemical, uptake may also occur via other exposure pathways like ingestion of and direct contact with sediment. In fact, given the high logKoc (6.3-7.1) of diisodecyl azelate, the EPM might not be sufficient for characterising risks to sediment.

During the comments phase on the draft decision, the Registrant(s) confirmed the same above mentioned justification for data waiving for long-term toxicity testing to sediment organisms. As indicated in Annex XI, Section 3 of the REACH Regulation, long-term testing on sediment organisms may be omitted based on the exposure scenario(s) developed in the CSR. However, adequate justification and documentation shall be provided. The justification shall be based on a thorough and rigorous exposure assessment. In the CSR of diisodecyl azelate an exposure assessment is not performed, therefore the sediment compartment exposure cannot be excluded.

Moreover, the Registrant(s) proposed to carry out an OECD 301B study on diisodecyl azelate to support further the case that the substance is readily biodegradable, but ready biodegradability cannot exclude a continuous exposure of sediment compartment, and water solubility does not influence the main exposure route (i.e. sediment ingestion) for strongly adsorbing substances like diisodecyl azelate. Therefore, ready biodegradability and water solubility cannot be accepted as valid waiving arguments to not perform long-term test on sediment organisms.

For these reasons the evaluating MSCA confirmed his disagreement with the Registrant(s)' justification for data waiving.

One PfA was received from a MSCA regarding long-term toxicity testing on sediment organisms, that suggested to add the following statement: *"This test would not be required if the outcome of the revised environmental risk assessment using the results from the ready biodegradation and long-term aquatic toxicity tests indicates it is not necessary*". The MSCA based the proposal on the fact that this study should depend on the results of the ready biodegradation, long-term aquatic toxicity testing, and subsequent revision of the risk assessment, and if significant sediment exposure and/or risks are indicated, the test is required. In particular the MSCA stated that the EPM method provides some estimate of sediment compartment risks.

As stated above, the EPM considers only uptake via the water phase, therefore it might not be sufficient for characterising risks to sediment for highly adsorbing substances. In order to take into account uptake of sediment-bound substance by benthic species, PEC/PNEC ratio is increased by a factor of 10 for substances with log Kow >5 or correspondingly high adsorption or binding behaviour.

In the commenting phase on PfAs, the Registrant(s) agreed with this MSCA PfA statement. The evaluating MSCA accepted the PfA, without taking into account the ready biodegradation argument which is not a valid basis to exclude long term exposure.

Moreover the Registrant(s) stated that in case of no risks for sediment compartment "*we would also look to see if it would be possible to restrict the uses of the substance so that continuous exposure to the sediment compartment could be excluded. We recognise that this is currently not the case with the uses included in the registration dossier. These reflect not only the actual use of the substance today but allow for potential new uses of the substance.*"

As already stated, it is pointed out that restricting the uses in order to demonstrate that there is no risk for a compartment needs a thorough and rigorous exposure assessment, as well as an in-depth analysis and an adequate justification and documentation of the proposed Risk Management Measures.

Therefore data waiving for long-term toxicity to sediment cannot be accepted and, in order to clarify the concern, pursuant to article 46(1) of the REACH Regulation, the Registrant(s) is required to carry out the following study using the registered substance subject to this decision: **Sediment-Water Chironomid Toxicity Using Spiked Sediment (test method: OECD 218).**

This test would not be required if the outcome of the revised environmental risk assessment using the results from the exposure evaluation and long-term aquatic toxicity tests indicates it is not necessary (PEC_{sed} /$PNEC_{sed}$,increased by a factor 10, is < 1, utilising EPM method)**.**

10 – 12. Effects on terrestrial organisms

Information on this endpoint is required to enable the evaluating MSCA to carry out the assessment of potential adverse effects of diisodecyl azelate on soil compartment in order to clarify the additional concern relating to potential risks to the environment.

Due to its physical-chemical properties and the environmental distribution, diisodecyl azelate has strong affinity to soil, and the lack of the exposure assessment does not consent to rule out a possible direct and indirect soil exposure. Therefore the data waiving provided by the Registrant(s), assuming that direct and indirect exposure to soil compartment is unlikely due to the ready biodegradability and the very low water solubility of the substance, is not fully justified.

According to the ITS strategy (ECHA guidance on information requirements and chemical safety assessment, chapter R.7C), in view of the inadequacy of the existing information for the hazard assessment (e.g. aquatic toxicity values), the Registrant(s) are required to perform a re-assessment of these endpoint by performing soil toxicity testing in accordance to the standard information requirements (Annexes IX and X) and derive the PNECsoil.

In this case, according to ECHA Guidance on information requirements and chemical safety assessment, chapter R.7C, a long term test is better to derive the PNECsoil. The long term test is suggested also by Regulation EC 1907/2006, Annex IX, column 2, section 9.4, "*In particular, for substances that have a high potential to adsorb to soil or that are very persistent, the Registrant(s) shall consider long term toxicity testing instead of short term*".

In view of the new information required, regarding other endpoints, if the substance fulfils the criteria of the hazard category 3 of the abovementioned ITS strategy, the Registrant(s) are justified to apply the PECx10/PNEC screen (based on EPM) assessment and conduct the soil micro-organisms test plus one confirmatory long-term soil toxicity testing (invertebrates or plants). If the substance falls in the soil hazard category 4 the EPM is not recommended and the Registrant(s) shall carry out the requested studies in 9, 10 and 11 (Section II).

During the commenting phase on the draft decision, the Registrant(s) confirmed the data waiving for long-term toxicity testing to soil organisms, based on ready biodegradability of the substance and no direct soil exposure. Therefore, the Registrant(s) proposed to perform OECD 301B study on diisodecyl azelate in order to clarify the aspect of persistence.

During the consultation phase, ECHA and one MSCA pointed out that both direct and indirect exposure to soil should be considered in view of the high Koc of diisodecyl azelate. The ECHA Guidance on information requirements and chemical safety assessment, chapter R7c, page 121 (version 2.0, November 2014) states: "*In the case of readily biodegradable substances which are not directly applied to soil it is generally assumed that the substance will not enter the terrestrial environment and as such there is no need for testing of soil organisms is required. Furthermore, other parameters (e.g. low log Koc/Pow) should be considered regarding the exposure pathway via STP sludge*". This last sentence indicates that, when indirect exposure through STP sludge is expected, adsorption parameter should be taken into account. The high Koc value of the substance justifies the requirement of a complete risk assessment for the soil compartment. This is supported by the table R.7.11-2 on pag.145, which suggest that, even if the substance is not persistent, high adsorption properties, as it is the case for diisodecyl azelate, lead to consider the substance in the Hazard category 3 or 4, for which at least one long-term soil toxicity testing is required.

Therefore, the evaluating MSCA accepted the PfAs and proposed that if a direct or indirect soil exposure cannot be excluded, the Registrant(s) shall perform the long-term tests on soil

organisms, regardless of the ready biodegradability test results.

In their comments on PfAs, the Registrant(s) expressed the intent to review the registered uses, in order to establish if it is possible to exclude those where there could be direct application to soil. Despite this, as already explained above, the evaluating MSCA accepted the PfAs of ECHA and MSCA which suggested to take into account also the indirect exposure to soil of the substance.

As already stated, it is pointed out that restricting the uses in order to demonstrate that there is no risk for a compartment needs a thorough and rigorous exposure assessment, as well as an in-depth analysis and an adequate justification and documentation of the proposed Risk Management Measures.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are requested to submit the following information using 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);

Soil micro-organisms: nitrogen transformation test (Test method: OECD 216);

Terrestrial plants, growth test (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).

The Registrant(s) is reminded that the PBT assessment and CSR shall be revised on the newly available data.

IV. Adequate identification of the composition of the tested material

In relation to the required experimental studies, the sample of the substance to be used shall have a composition that is within the specifications of the substance composition that are given by all Registrant(s). It is the responsibility of all the Registrant(s) to agree on the tested material to be subjected to the tests subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation. Finally, the tests must be shared by the Registrant(s).

V. Avoidance of unnecessary testing by data- and cost-sharing

In relation to the experimental studies the legal text foresees the sharing of information and costs between Registrant(s) (Article 53 of the REACH Regulation). Registrant(s) are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who is to carry out the study on behalf of the other Registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at:
https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

Further advice can be found at http://echa.europa.eu/regulations/reach/registration/data-sharing.

If ECHA is not informed of such agreement within 90 days, it will designate one of the Registrant(s) to perform the studies on behalf of all of them.

VI. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 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 the ECHA's internet page at
http://www.echa.europa.eu/regulations/appeals
The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[4] by Leena Ylä-Mononen, Director of Evaluation

Annex: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.

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