SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

Diisodecyl azelate

EC No 249-044-4

CAS No 28472-97-1

Evaluating Member State: Italy

Dated: 13 July 2021

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Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2013

Before concluding the substance evaluation a Decision to request further information was issued on 15 September 2015.

Further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

This document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work. The Community rolling action plan (CoRAP) of substances subject to evaluation, is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

Contents

Part A. Conclusion

1. CONCERN(S) SUBJECT TO EVALUATION

Diisodecyl azelate was selected for substance evaluation in order to clarify concerns about:

- Suspected PBT/vPvB
- Consumer use
- High (aggregated) tonnage
- Wide dispersive use

In the course of the evaluation, the evaluating MSCA identified additional concerns In

- Potential risks to the environment

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

None.

3. CONCLUSION OF SUBSTANCE EVALUATION

Table 1

CONCLUSION OF SUBSTANCE EVALUATION Conclusions	Tick box
Need for follow-up regulatory action at EU level	
Harmonised Classification and Labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action at EU level	X

4. FOLLOW-UP AT EU LEVEL

4.1. Need for follow-up regulatory action at EU level

Not applicable.

5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5.1. No need for regulatory follow-up at EU level

Table 2

REASON FOR REMOVED CONCERN The concern could be removed because	Tick box
Clarification of hazard properties/exposure	X
Actions by the registrants to ensure safety, as reflected in the registration dossiers(e.g. change in supported uses, applied risk management measures, etc.)	

After review of the new data obtained by the Registrants due to a substance evaluation decision, the evaluating Member State considers diisodecyl azelate not persistent in the environment based on the results of the ready biodegradability study.

The additional concern (potential risks to the environment) was clarified based on the results of environmental toxicity tests and newly available information from the registration dossiers.

5.2. Other actions

Not applicable.

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Not applicable.

Part B. Substance evaluation

7. EVALUATION REPORT

7.1. Overview of the substance evaluation performed

Diisodecyl azelate was selected for substance evaluation in order to clarify concerns about:

- Suspected PBT/vPvB
- Consumer use
- High (aggregated) tonnage
- Wide dispersive use

In the course of the evaluation, the evaluating MSCA identified additional concerns as:

- potential risks to the environment

The Substance evaluation started in March 2013.

Table 3

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome/conclusion**
Persistence	Request on ready biodegradability fulfilled by the registrant(s). No further action is needed.
Long-term toxicity on aquatic invertebrates and fish	Request fulfilled by the registrant(s). No hazard for aquatic environment was observed. No further action is needed.
Long-term toxicity testing to sediment organisms (test method: Sediment-Water Chironomid Toxicity Using Spiked Sediment, OECD TG 218)	Request not addressed by the Registrants. Newly submitted data provide sufficient and suitable evidence of no concern for sediment organisms. No further action is needed.
Effects on terrestrial organisms - Long-term toxicity testing to invertebrates (test method:Earthworm reproduction test (Eisenia fetida/Eisenia andrei), OECD TG 222, or Enchytraeid reproduction test, OECD TG 220, or Collembolan reproduction test in soil, OECD TG 232)	Request fulfilled by the Registrants. No further action is needed.
Effects on soil micro-organisms (test method: Soil micro-organisms: nitrogen transformation test, OECD TG 216)	Request fulfilled by the Registrants. No further action is needed.
Effects on terrestrial organisms - Long-term toxicity testing on plants (test method:Terrestrial plants, growth test (OECD TG 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))	Request fulfilled by the Registrants. No further action is needed.
Consumer use	Consumer uses are considered to be safe for human health (see section 7.13.1)

7.2. Procedure

The Substance evaluation of the Diisodecyl azelate started on March 2013. The initial grounds for concern were relating to suspected PBT/vPvB, consumer use, high (aggregated) tonnage and wide dispersive use.

The evaluating MSCA considered that further information was required to clarify the PBT/vPvB concern.

Following an evaluation of the Substance pursuant to Article 45(4), the eMSCA concluded that further information was required in order to assess the concerns identified. The eMSCA prepared a draft decision pursuant to Article 46(1) which was submitted to the Agency on 20 March 2014.

On 28 May 2015, the MSC reached unanimous agreement by written procedure on the draft Decision. ECHA took the decision pursuant to Article 51(3) of REACH and sent the decision to the registrant on 15 September 2015.
Subsequently the Registrants provided the requested information in the updated dossier.

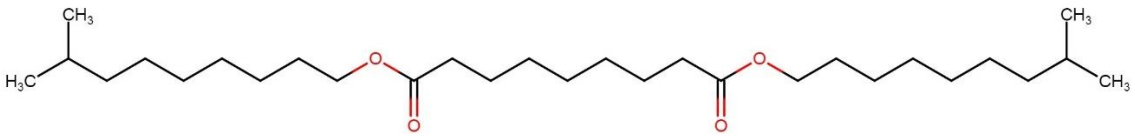
7.3. Identity of the substance

Table 4

SUBSTANCE IDENTITY	
Public name:	Diisodecyl azelate
EC number:	249-044-4
CAS number:	28472-97-1
Index number in Annex VI of the CLP Regulation:	--
Molecular formula:	C29H56O4
Molecular weight range:	
Synonyms:	

Type of substance ☐ Mono-constituent ☐ Multi-constituent ☒ UVCB

Structural formula:



7.4. Physico-chemical properties

Table 5

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES	
Property	**Value**
Physical state at 20°C and 101.3 kPa	Organic liquid at 20 °C and 1013 hPa
Vapour pressure	<0.0001 Pa at 20 °C
Water solubility	< 0.05 mg/L at 20 °C and pH = 6.7-7.0
Partition coefficient n-octanol/water (Log Kow)	log Pow >10 (calc.) The log Pow of the substance diisodecyl azelate (CAS RN 28472 -97 -1) was determined by QSAR calculation with KOWWIN (v1.68). As the calculated value (log Pow = 11.55) exceeds the applicability domain of the model, the result is reported as log Pow >10.
Flammability	Non flammable
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Granulometry	Not applicable
Stability in organic solvents and identity of relevant degradation products	Stable in organic solvents
Dissociation constant	No dissociation

7.5. Manufacture and uses

7.5.1. Quantities

Table 6

AGGREGATED TONNAGE (PER YEAR)				
☐ 1 – 10 t	☐ 10 – 100 t	☐ 100 – 1000 t	☒ 1000- 10,000 t	☐ 10,000-50,000 t
☐ 50,000 – 100,000 t	☐ 100,000 – 500,000 t	☐ 500,000 – 1000,000 t	☐ > 1000,000 t	☐ Confidential

7.5.2. Overview of uses

This substance is manufactured and/or imported in the European Economic Area in 1 000 - 10 000 tonnes per year.
This substance is used by consumers, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing.

Table 7

USES	Use(s)
Uses as intermediate	---
Formulation	Products: lubricants and greases, metal working fluids, laboratory chemicals, water treatment chemicals, hydraulic fluids and polymers. Release to the environment of this substance can occur from industrial use as formulation of mixtures and formulation in materials.
Uses at industrial sites	Products: lubricants and greases, metal working fluids, water treatment chemicals, hydraulic fluids and polymers. This substance is used in the following areas: formulation of mixtures and/or re-packaging. Manufacture of chemicals. Release to the environment of this substance can occur from industrial use in processing aids at industrial sites, of substances in closed systems with minimal release, as an intermediate step in further manufacturing of another substance (use of intermediates) and as processing aid.
Uses by professional workers	Products: lubricants and greases, metal working fluids, water treatment chemicals, anti-freeze products, coating products, explosives, fuels, heat transfer fluids, hydraulic fluids, laboratory chemicals, plant protection products and polymers. This substance is used in the following areas: formulation of mixtures and/or re-packaging. Manufacture of chemicals. Other release to the environment of this substance is likely to occur from: outdoor use, indoor use as processing aid, indoor use in close systems with minimal release (e.g. cooling liquids in refrigerators, oil-based electric heaters) and outdoor use in close systems with minimal release (e.g. hydraulic liquids in automotive suspension, lubricants in motor oil and break fluids).
Consumer Uses	Products: lubricants and greases, anti-freeze products, adhesives and sealants, biocides (e.g. disinfectants, pest control products), perfumes and fragrances and polishes and waxes. Other release to the environment of this substance is likely to occur from: outdoor use as processing aid, indoor use as processing aid, outdoor use in close systems with minimal release (e.g. hydraulic liquids in automotive suspension, lubricants in motor oil and break fluids) and indoor use in close systems with minimal release (e.g. cooling liquids in refrigerators, oil-based electric heaters).
Article service life	---

7.6. Classification and Labelling

7.6.1. Harmonised Classification (Annex VI of CLP)

The substance is not currently listed on Annex VI of CLP Regulation ((EC) No 1272/2008).

7.6.2. Self-classification

- In the registration(s)*:* None

- No additional hazard classes are notified among the aggregated self-classifications in the C&L Inventory

7.7. Environmental fate properties

Abiotic degradation of diisodecyl azelate is not a relevant pathway. Since the substance is not likely to be present in the atmosphere due to its very low vapor pressure, indirect photolysis is not to be expected. Hydrolysis is not relevant, since estimated rates of hydrolysis are low within normal pH regimes in the aquatic environments. Concerning biotic degradation, diisodecyl azelate is regarded as readily biodegradable, so the substance is expected to be rapidly degraded by microorganisms in all environmental compartments. The substance exhibits a high log Kow (calculated by KOWWIN (v1.68), suggesting potential to bioaccumulate. No experimental studies with diisodecyl azelate evaluating the bioaccumulation potential of the substance are available.

7.7.1. Degradation

Concerning abiotic degradation, a supporting QSAR calculation (HYDROWIN v2.00) indicates that hydrolysis represents a negligible pathway for the fate of the substance in the environment (DT50=2 yr at pH 7 and 25 °C; DT50= 75.4 d at pH 8 and 25 °C; Gerloff-Elias, 2013).

Based on a QSAR calculation using AOPWIN v1.92, diisodecyl azelate is susceptible to indirect photodegradation in air. The estimated half time for the reaction with OH-radicals is 11.4 hours (24h day; OH-concentration: 0.5E+06 OH/cm^3) (Gerloff-Elias, 2013). However, photodegradation is not an important environmental fate process since the substance is not expected to evaporate into the atmosphere due to its very low vapor pressure.

Concerning biotic degradation, the registrant(s) included in the updated dossier a new reliable ready biodegradation study (Roulstone 2014), conducted according to a standard test protocol (OECD TG 301B, Ready biodegradability, CO2 Evolution test) and in compliance with GLP. Diisodecyl azelate was biodegraded by 72% at day 28, meeting the ten day window. The test item, at a concentration of 10 mg carbon/L, was exposed to activated sewage sludge micro-organisms with mineral medium in sealed culture vessels in the dark at 20 to 22 °C for 28 days. Following the recommendations of the International Standards Organisation (ISO 10634 Water quality - Guidance for the preparation andtreatment of poorly-soluble organic compounds for the subsequent evaluation oftheir biodegradability in an aqueous medium) and the published literature (Handley et al, 2002), the test item was adsorbed onto granular silica gel prior to dispersion in the test medium. Control solutions with inoculum and the reference item, sodium benzoate, together with a toxicity control were used for validation purposes.

The registrant(s) concluded that the substance is readily biodegradable and based on the available information, the eMSCA can support this conclusion. However, the eMSCA noted some deviations from the recommendations of OECD TG 301B, ISO 10634 and ECHA guidance on Information Requirements and Chemical Safety Assessment R7.b: Endpoint specific guidance (version 4.0, june 2017), that do not invalidate the results of the study. Concerning water, sediment and soil simulation tests the registrant(s) proposed a data waiving since diisodecyl azelate is readily biodegradable. Based on the available information, the eMSCA does not see any concern for these compartments.

7.7.2. Environmental distribution

Diisodecyl azelate is expected to partition primarily to sediment (63.8%) and soil (29.8%) according to the results of a Level III fugacity model (Supporting Documents for Initial Risk-Based Prioritization of High Production Volume Chemicals - Diesters category, U.S. EPA, 2008). The results from another Mackay calculation (Level I) proposed by the registrant(s) are in line with these findings (sediment (50.1%) and soil (49.5%).

No experimental studies investigating the adsorption/desorption behaviour of diisodecyl azelate are available. Log Koc values of 7.2 and 6.3 were calculated using KOCWIN Program (v2.00), based on log Kow and on the molecular conductivity index (MCI), respectively (Gerloff-Elias, 2013). These models have no universally accepted definition of model domain, but since the substance is outside the Kow range of the training set, the results should be taken with caution.

7.7.3. Bioaccumulation

No experimental studies with diisodecyl azelate evaluating the bioaccumulation potential of the substance are available. The substance exhibits a high log Kow (log Kow = 11.55), suggesting potential to bioaccumulate. The estimated value provided by the registrant(s) is greater than the range (-4 to 10) where KOWWIN v. 1.68 estimates have been shown to be valid. It is reasonable to conclude that this prediction is indicative that the log Kow for this chemical is high.

Estimated bioconcentration (BCF) and bioaccumulation (BAF) values were calculated by the registrant(s) using the BCFBAF v3.01 program (Estimation Programs Interface Suite™ for Microsoft® Windows v 4.10., US EPA), including biotransformation rates (Arnot-Gobas method). The calculated BCF and BAF values are 19.8 L/kg (BCF, regression based estimate) and 0.9 and 1.1 (Arnot-Gobas method, BCF and BAF, respectively). The model has no universally accepted definition of model domain, but since the substance is outside the Kow range of the training set, the results should be taken with caution.

A read-across study that investigated the accumulation and depuration of diisononyl adipate (CAS RN 33703-08-1) in mussels (*Mytilus edulis*) was reported by the registrant(s), showing that the test substance exhibited high potential for bioaccumulation.

The registrant(s) concluded that the information gathered on environmental behaviour and metabolism in combination with QSAR-estimated values provided enough evidence to state that a low bioaccumulation potential can be expected for this substance.

The eMSCA cannot support the registrant's conclusion since the available information is not sufficient to conclude on the bioaccumulative potential of the substance.

7.8. Environmental hazard assessment

7.8.1. Aquatic compartment (including sediment)

7.8.1.1. Fish

Short-term toxicity to fish

The registrant(s) provided one limit static study (Hansonis-Jouleh, 1993) conducted on *Leuciscus idus melanotus*, exposed to 10 g/L (nominal) filtered test solution of diisodecyl azelate (OECD TG 203; reliability 2). No mortality or other adverse effects were reported after 96 h exposure to the test substance; therefore, no toxicity within the range of water solubility was observed testing a saturated test solution.

Due to very low water solubility of the substance (< 0.05 mg/L) it is expected that short term toxicity tests do not reveal any toxicity.

Long-term toxicity to fish

The registrant(s) did not provide any study on the long-term toxicity to fish, justifying that the available short term studies with fish, invertebrates and algae indicate no potential for aquatic toxicity for this substance. The registrant(s) added that due to ready biodegradability of diisodecyl azelate it is not likely that acquatic organisms are chronically exposed to this substance since it will be ultimately degraded in sewage treatment plants.

Hence to account for animal welfare reasons and to avoid unnecessary vertebrate tests, no further long-term test with fish is required for Diisodecyl azelate.

Following the requests under the Substance Evaluation Decision, no long-term fish testing (Fish Early Life Stage toxicity test, test method OECD TG 210) may need to be conducted if, based on the results of the long-term *Daphnia magna* study, no risks are observed.

The eMSCA notes that based on the results of the long-term *Daphnia magna* study, no hazard was observed and therefore it can be accepted that the long-term fish testing has not been conducted.

7.8.1.2. Aquatic invertebrates

Short-term toxicity to aquatic invertebrates

Two studies conducted on *Daphnia magna* according to OECD TG 202 (reliability 2) are provided by the Registrant(s).

These study are read-across (RAA) from supporting substances (structural analogue or surrogate): Bis(2-ethylhexyl) azelate (CAS RN 103-24-2) and Bis(2-octyldodecyl) azelate (CAS RN 897626-46-9).

In the semi-static study with Bis(2-ethylhexyl) azelate (Japan MOE, 2004), no immobility was observed during an exposure time of 48 h. Hence, the EC_{50} (48h) is determined to be > 0.0931 mg/L (measured) and thus above the solubility of the substance in water.

In the study with Bis(2-octyldodecyl) azelate (Noack, M. 2009), no immobilization was observed during a test period of 48 hours. Hence, the EC_{50} (48h) is determined to be > 0.169 mg/L (measured) loading rate.

Due to the low water solubility of diisodecyl azelate (< 0.05 mg/L), it is expected that short term toxicity tests do not reveal any toxicity. Therefore it is considered the priority of long term toxicity test instead of the short term toxicity.

Long-term toxicity to aquatic invertebrates

As requested in the Substance Evaluation Decision, the Registrants submitted a long-term toxicity study to aquatic invertebrates (Charles River, 2016), performed with the registered substance according to the OECD TG 211 (*Daphnia magna* reproduction test) and in compliance with GLP.
D. magna were exposed to diisodecyl azelate as a Water Accomodated Fraction (WAF) prepared at nominal loading rates of 0.26, 0.64, 1.6, 4.0 and 10 mg/L under semi-static conditions for 21 days. Despite exhaustive attempts, an analytical method capable of detecting the extremely low concentrations of diisodecyl azelate in WAFs could not be developed. The study was consequently performed without analytical measurements on the WAFs and study endpoints are based on loading rates. The registrant(s) concluded that the No Observable Effect Loading Rate (NOELR) for Diisodecyl azelate on the reproduction of *Daphnia magna* is 4.0 mg/L after 21 days of exposure, which is far above the water solubility (< 0.05 mg/L). An EL_{10} value of 9.2 mg/L (21d, nominal concentration) was reported. The registrant(s) stated that it was unclear if the effects resulted from the intrinsic properties of the substance or by physical effects.

Based on tha available information, the eMSCA does not consider the nominal loading rate as the no effect concentration, by far exceeding the water solubility of the substance. Assuming that the exposure concentration in the WAF is the water solubility limit (saturation), the no effect concentration would be the water solubility limit. Therefore, it can be assumed that no effects are registered up to solubility limit.

A read across to the structurally related substance, Bis(2-ethylhexyl) azelate (CAS RN 103-24-2) was conducted by the registrant(s). Long term toxicity of Bis(2-ethylhexyl) azelate was investigated according to OECD TG 211 under semi static conditions using *Daphnia*

magna as a test organism (Japan MOE, 2004). No effects on reproduction were observed throughout the 21d test period of the limit test (nominal concentration: 0.1 mg/L, measured concentration: 0.0637 mg/L). Hence, the 21 d-NOEC is determined to be ≥ 0.0637 mg/L, which is the water solubility of the substance under test conditions.

This study can be used as supporting for the key experimental study, confirming that Diisodecyl azelate is expected to exhibit no adverse effects towards aquatic invertebrates in the range of water solubility.

7.8.1.3. Algae and aquatic plants

No information on the toxicity of diisodecyl azelate to algae is available.
The Registrant(s) provided two read-across to the structurally related substances: bis(2-ethylhexyl) azelate (CAS RN 103-24-2) and bis(2-octyldodecyl) azelate (CAS RN 897626-46-9).
The static test with Bis(2-ethylhexyl) azelate (Japan MOE, 2004) was conducted according to GLP and OECD TG 201 using *Pseudokirchinella subcapitata*. The EC_{50} (72h) and the NOEC (72h) for growth rate is determined to be > 0.0845 mg/L on the basis of the initial test concentration (0.0845 mg/L) that corresponding to 0.0019 mg/L at the end of the study. The concentration after 72h was notably lower and not within 20% of nominal concentration (0.1 mg/L).

The limit static test with Bis(2-octyldodecyl) azelate (Scheerbaum, 2008) was conducted according to GLP and OECD TG 201 using *Desmodesmus subcapitatus* exposed at 100 mg/L of test substance. The EL_{10} (72h) and the EL_{50} (72h) for growth rate is determined to be > 2.99 mg/L (measured).

In all studies no significant, effects on growth rate were observed after 72 hours exposure time. Due to structural and property similarities to the analogue substances Bis(2-octyldodecyl) ester and Bis(2 -ethylhexyl) azelate, these results are also applicable to read across to Diisodecyl azelate. Therefore, Diisodecyl azelate is expected to exhibit no adverse effects towards algae in the range of water solubility.

7.8.1.4. Sediment organisms

Following the information request under Substance Evaluation Decision, long term toxicity testing on sediment organisms (test method OECD TG 218) for Diisodecyl azelate was omitted by the Registrants with the waiving justification based on ready biodegradability, ecotoxicity data and exposure considerations, as indicated below. The newly available information from registration dossier can be regarded as sufficient evidence that exposure of sediment organisms is negligible and then toxicity testing for this endpoint can be omitted.

The Registrants note that, based on the weight of evidence of all currently available information, toxicity of the registered substance to sediment organisms is not expected to be of concern.
The Registrants point out that, although this substance is poorly water soluble and has a high adsorption potential indicating a mainly distribution into sediment and soil compartment, exposure to sediment organisms is expected unlikely.
Due to its intrinsic properties, Diisodecyl azelate will be rapidly removed from natural water compartments as well as from wastewater in sewage treatment plants.
Available data show that this substance is not persistent in the environment due its ready biodegradability. Furthermore, the substance exhibits a high logKoc value (>5) and is poorly water soluble (<0.05 mg/L); according to the ECHA Guidance R.7b (ECHA, 2012b) once insoluble substance enters a standard STP, it will be extensively removed in the primary settling tank and fat trap and thus, only limited amounts is likely to be into the environment.Thus, the Registrants note that due to the its ready biodegradability and the high adsorption potential this substance will be extensively removed at high extent after passing through conventional STP and therefore only low concentrations of this substance

are likely to be (if at all) released into the environment (aqueous/sediment compartment) from STP.
Then, only negligible releases into surface waters from STP are expected to take place and thereby exposure to sediment organisms is therefore unlikely.

In view of these considerations, it can be also assumed that the availability of Diisodecyl azelate in the sediment environment is very low, which reduces the probability of chronic exposure of sediment organisms.

The Registrants also note that, being a readily biodegradable substance, once present in the aquatic compartment, further rapid and ultimate degradation will occur and only low concentrations are expected to be exposed and bioavailable to sediment organisms mainly via feed and contact with suspended organic particles.
Summarizing, discharged concentrations of this substance into the aqueous/sediment compartment are likely to be negligible.

In addition, available acute and chronic aquatic toxicity data showed no effects up to the limit of the water solubility. Moreover, no toxic effects on activated sludge microorganisms were observed. Thus, even if continuous release is assumed from identified uses of the substance, all currently available experimental studies indicate no concern for hazard to aquatic organisms and therefore, in view of these results, toxicity to sediment organisms can be expected as negligible as well.

In conclusion, evaluating MSCA notes that the outcome of revised CSA using currently available results from ready biodegradation and long term aquatic toxicity testing indicates no significant exposure to sediment organisms. Taken together, as weight of evidence, all currently available information, it is unlikely that this substance may pose a concern for sediment organisms; thus, the requested long term toxicity testing is not needed to be performed, being the concern for sediment organisms overcome.

Therefore, evaluating MSCA concludes that currently there is sufficient and consistent evidence to consider the hazard to sediment organisms not of concern under this substance evaluation.

7.8.1.5. Other aquatic organisms

No information available.

7.8.2. Terrestrial compartment

The Registrants submitted reliable long-term toxicity studies on terrestrial organisms for three different trophic levels (soil macroorganisms, terrestrial plants and soil microorganisms) in order to evaluate the hazard of the registered substance for soil organisms and, accordingly, to derive a conclusive PNEC soil. The most sensitive value was a 21dNOEC of 68,6 mg/Kg soil dw determined in a OECD TG 208 Terrestrial Plants, Growth Test.

Following the assessment of newly available data, the eMSCA supports the Registrants' conclusion that effects on soil organisms are not of concern.

Toxicity to soil macroorganisms

As requested in the Substance Evaluation Decision, the Registrants submitted a long-term toxicity study to soil macroorganisms (*Croda 2016*), performed with the registered substance according to the OECD TG 222 (Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)) and under GLP. The toxic effects of Diisodecyl azelate (CAS RN 28472-97-1) on survival, growth, and reproduction of the earthworm Eisenia fetida were assessed during the exposure observation period of eight weeks. No statistically significant effects of test substance were observed on earthworms; the overall 56dNOEC of Diisodecyl

azelate on the survival, growth and reproduction to the Earthworm, Eisenia fetida was determined to be 500 mg/kg dry weight soil.

In addition, in the technical dossier the Registrants provide test results from two read across acute studies (Huels AG, 1996;Tobor-Kaplon M.A. 2012) performed with the structurally related substances Bis(2-ethylhexyl) adipate (CAS RN 103-23-1) and Bis(tridecyl) adipate (CAS RN 16958-92-2); for both studies the LC50 values resulted to be well above 1000 mg/kg soil dw for Eisenia fetida supporting the conclusion that no adverse effects were observed on soil macroorganisms for Diisodecyl azelate and structurally related substances.

Moreover, in addition to the requested experimental toxicity data, the Registrants highlight the physico chemical properties and fate/exposure of the registered substance in order to substantiate the conclusions on this endpoint. Therefore, based on all currently available data, toxicity to soil macroorganisms cannot be considered of the concern.

Following the assessment, the eMSCA concludes that soil macroorganisms data, as provided by the Registrants in the CSR and technical dossier, are suitable and definitive for this endpoint. Consequently, under this substance evaluation, no additional information is needed to clarify the hazard on soil macroorganisms and related concern.

Toxicity to terrestrial plants

One experimental long term toxicity study has been submitted by the Registrants for this endpoint in order to investigate the toxicity effects of Diisodecyl azelate (CAS RN 28472-97-1, ECT 2017) to terrestrial plants, in line with the information request under Substance Evaluation Decision. The study was performed according to OECD TG 208 (Terrestrial Plants, Growth Test) and GLP, using six plants species (two monocotyledonae and four dicotyledonae species, respectively). In the reliable test, no phytotoxic effects on survival of seedlings in any of the six test species at any of the tested concentrations were observed with the overall lowest test results 21-d NOEC of 68.6 mg/kg soil dry weight and EC50 of 187.1 mg/kg soil dry weight used for purpose of CSA.
These test results can be considered as acceptable with all relevant test validity criteria fulfilled.
In addition to experimental results, the Registrants highlight the physico-chemical properties and fate/exposure of the registered substance in order to substantiate the conclusions on this endpoint, indicating no concern for toxicity to soil organisms.

Therefore, the eMSCA concludes that newly submitted data provided by the Registrants meet the requested information under Sustance Evaluation Decision. No further information is needed to clarify this endpoint and related concern.

Toxicity to soil microorganisms

One experimental study was provided by the Registrants in the technical dossier for assessing the toxicity to soil microorganisms of Diisodecyl azelate (CAS RN 28472-97-1,Cemas 2016). The study was performed under GLP conditions according to the OECD TG 216 - Soil Microorganisms: Nitrogen Transformation Test. The overall 28dNOEC was determined to be 455 mg/kg dry soil based on nitrate production rate.

In addition to experimental results, the Registrants highlight the physicochemical and fate/exposure properties of the registered substance, supporting that toxicity to soil microorganisms cannot be expected.
Moreover, the Registrants note that available reliable data on toxicity to aquatic microorganisms (with no inhibition of microbiological activity in STP) for this substance support the conclusion of a lack of toxicity to soil organisms, including soil microorganisms.

Following the assessment of all newly available data, the eMSCA supports the Registrants' conclusions that the effects on soil microorganisms are not of concern.

7.8.3. Microbiological activity in sewage treatment systems

The acute toxicity of diisodecyl azelate to *Pseudomonas putida* was investigated in one study (Hansonis-Jouleh, 1993). The study was performed according to DIN guideline 38412, part 8 "Pseudomonas-Cell Growth Inhibition Test". A single test concentration of 10 g/L was chosen to evaluate the growth inhibition after 16 h. Since the test substance is poorly water soluble, the filtrate from a stock solution of 10 g/L was used to analyse if there are any effects in the range of water solubility. The registrant(s) reported the EC10 beeing greater than 10 g/L since no growth inhibition of *P. putida* was registered. Moreover, the registrant(s) added that the toxicity control of an OECD TG 301B test showed no inhibition at a test substance concentration of 13 mg/L. Therefore disturbances in the biodegradation process of sewage treatment plants are not anticipated for Diisodecyl azelate.
The registrant(s) concluded that no effects of the test substance in the range of water solubility were observed testing a saturated test solution which was subsequently filtered. Based on the available information, the eMSCA supports this conclusion.

7.8.4. PNEC derivation and other hazard conclusions

Table 8

PNEC DERIVATION AND OTHER HAZARD CONCLUSIONS		
Hazard assessment conclusion for the environment compartment	**Hazard conclusion**	**Remarks/Justification**
Freshwater	No hazard identified	As no toxic effects on freshwater organisms were observed up to the limit of the water solubility of the test substance, no PNEC can be derived and a quantitative risk assessment cannot be performed.
Marine water	No hazard identified	As no toxic effects on freshwater organisms were observed up to the limit of the water solubility of the test substance, no PNEC can be derived and a quantitative risk assessment cannot be performed.
Intermittent releases to water	No hazard identified	As no toxic effects on freshwater organisms were observed up to the limit of the water solubility of the test substance, no PNEC can be derived and a quantitative risk assessment cannot be performed.
Sediments (freshwater)	No hazard identified	No direct toxicity data on sediment organisms are available and no toxic effects on pelagic aquatic organisms were observed up to the limit of the water solubility; therefore, no PNEC aqua (freshwater/marine water) exists and no PNEC sediment (freshwater and marine water) can be derived neither using the Equilibrium Partitioning Method, nor from sediment studies - and a quantitative risk assessment cannot be performed. Based on the available information, the substance is not expected to pose a risk to sediment organisms, and a quantitative risk assessment is not necessary. eMSCA can support these conclusions and no remarks are to be reported.

Sediments (marine water)	No hazard identified	No direct toxicity data on sediment organisms are available and no toxic effects on pelagic aquatic organisms were observed up to the limit of the water solubility ; therefore, no PNEC aqua (freshwater/marine water) exists and no PNEC sediment (freshwater and marine water) can be derived neither using the Equilibrium Partitioning Method, nor from sediment studies - and a quantitative risk assessment cannot be performed. Based on the available information, the substance is not expected to pose a risk to sediment organisms, and a quantitative risk assessment is not necessary. eMSCA can support these conclusions and no remarks are to be reported.
Sewage treatment plant	No hazard identified	As no toxic effects on microorganisms were observed up to the limit of the water solubility of the test substance, no PNEC can be derived and a quantitative risk assessment cannot be performed.
Soil	PNEC value: 6.86 mg/Kg dw	Assessment factor: 10 Extrapolation method: assessment factor According to ECHA Guidance R10, PNEC soil was derived from the lowest result determined in a toxicity study on terrestrial plants (21dNOEC of 68,6 mg/Kg soil dw). eMSCA can support these hazard assessment conclusions, including the related PNEC derivation.
Air	No hazard identified	As no standardised biotic testing systems and guidelines are available at present for the air compartment, the derivation of a PNEC air is not feasible. Air is not a compartment of concern as the volatility is low for this substance

7.8.5. Conclusions for classification and labelling

Based on the available information, diisodecyl azelate is considered rapidly degradable. No acute toxicity is recorded at levels up to the water solubility of the substance. Chronic toxicity data are available for algae and Daphnia, showing that the NOEC values are above the solubility of the substance in water. Hence, the eMSCA considers that classification for acute or chronic environmental hazard according to the current criteria of Regulation EC No 1272/2008 is not warranted.

7.9. Human Health hazard assessment

7.9.1. Toxicokinetics

Not evaluated.

7.9.2. Acute toxicity and Corrosion/Irritation

Not evaluated.

7.9.3. Sensitisation

Not evaluated.

7.9.4. Repeated dose toxicity

Not evaluated.

7.9.5. Mutagenicity

Not evaluated.

7.9.6. Carcinogenicity

Not evaluated.

7.9.7. Toxicity to reproduction (effects on fertility and developmental toxicity)

Not evaluated.

7.9.8. Hazard assessment of physico-chemical properties

Not relevant.

7.9.9. Selection of the critical DNEL(s)/DMEL(s) and/or qualitative/semi-quantitative descriptors for critical health effects

Not evaluated.

7.9.10. Conclusions of the human health hazard assessment and related classification and labelling

Not evaluated.

7.10. Assessment of endocrine disrupting (ED) properties

Not evaluated.

7.11. PBT and VPVB assessment

1) *Persistence,*
   Based on the results of the ready biodegradability study, the registrant(s) concluded that the substance is **not expected to be persistent** in the environment and it does not meet the P or vP criteria. The eMSCA can support this conclusion.

2) *Bioaccumulation*
   Based on the available information (estimated Log Kow > 10 and estimated BCF < 20 L/kg,) it is **not possible to conclude on the bioaccumulative potential** of the substance.

3) *Toxicity*
   Based on ecotoxicity data the substance does not meet **the criteria to be identified as T** for environmental endpoints.

4) *Overall conclusion*
   Based on the available information the eMSCA concludes that there is no concern for PBT/vPvB.

7.12. Exposure assessment

As Diisodecyl Azelate is neither to be classified as dangerous according to CLP Regulation (EC) No 1272/2008 nor assessed to be PBT or vPvB substances, according to REACH art. 14(4) no exposure assessment and risk characterisation has to be included in the CSR. Therefore, all identified uses are considered to be safe for human health and environment.

7.13. Risk characterisation

Not applicable (see section 7.12).

7.14. References

https://echa.europa.eu/it/substance-information/-/substanceinfo/100.044.571

7.15. Abbreviations

CAS	Chemical abstracts service
C&L	Classification and labelling
CLP	Classification, labelling and packaging (Regulation (EC) No 1272/2008)
CSR	Chemical Safety Report
DMEL	Derived Minimal Effect Level
DNEL	Derived no effect level
eMSCA	Evaluating Member State Competent Authority
NOEC	No Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative, Toxic
PNEC	Predicted No Effect Concentration
vPvB	Very Persistent and very Bioaccumulative