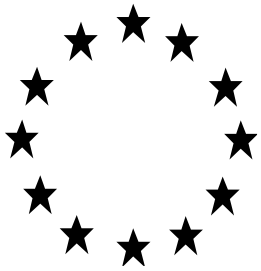
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Didecylmethylpoly(oxyethyl)ammonium propionate

Product-type 8
(Wood preservative)

December 2015

(Updated April 2021)

Italy

Version History

Date	Version	Reason for revision
March 2021	1.1	The assessment report was revised based on the submission of the following data requested in the section 2.5 of the BPC opinion (post-approval data): (1) phys-chem methods (highly specific confirmatory analytical methods - UHPLC-MS/MS, with two ion transitions validated - for residues in soil and both surface and drinking water,) (2) aerobic and anaerobic transformation in soil (OECD 307), (3) degradation in aquatic sediment systems (OECD 308) to clarify the P status; (4) data on *Daphnia Magna* reproduction test (OECD 211) as confirmatory data to clarify the T properties. The changes are marked in yellow. This revision was agreed at BPC 38 (March 2021)

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of the active substance didecylmethylpoly(oxyethyl)ammonium propionate as product-type 8 (Wood Preservative), carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.
Didecylmethylpoly(oxyethyl)ammonium propionate (CAS No. 94667-33-1) was notified as an existing active substance, by Lonza GmbH, hereafter referred to as the applicant, in product-type 8.
Commission Regulation (EC) No 1451/2007 of 4 December 2007[1] lays down the detailed rules for the evaluation of dossiers and for the decision-making process.
In accordance with the provisions of Article 7(1) of that Regulation, Italy was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for didecylmethylpoly(oxyethyl)ammonium propionate as an active substance in product-type 8 was 28th March 2004, in accordance with Annex V of Regulation (EC) No 1451/2007.
On 28th March 2004, Italian competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 28th September 2004.
On 27th June 2005 the time period was suspended, the evaluation was taken up again on 27th March 2006 and then stopped on 28th June 2006, in order to obtain from the applicant the necessary data requested. The evaluation was taken up again on 28th June 2007. After that, the evaluation phase was suspended again on the 6th July 2007 and taken up on 31th October 2007. On 20th November 2007, the Rapporteur Member State submitted to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. Didecylmethylpoly(oxyethyl)ammonium propionate was discussed at technical meeting level in 2009 (TMIII 2009).
In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Agency. Revisions agreed upon were presented at the Biocidal Products Committee and Biocides Technical Meeting (TMIII2009) and the competent authority report was amended accordingly.
To comply with the requirement for further information (Sect. 2.5 of the Opinion), the applicant provided data that were discussed at WG V 2019 and results presented for agreement at BPC level (BPC-38).

1.2. Purpose of the assessment report

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the approval of didecylmethylpoly(oxyethyl)ammonium propionate for product-type 8, and, should it be approved, to facilitate the authorisation of individual biocidal products. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.
For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available from the Agency web-site shall be taken into account. However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data for that purpose has been granted to that applicant.

[1] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

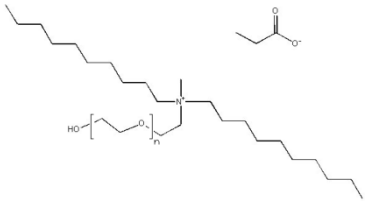
2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Didecylmethylpoly(oxyethyl)ammonium propionate is a didecyl quaternary ammonium compound. Didecylmethylpoly(oxyethyl)ammonium propionate is manufactured as a technical concentrate (TK), Bardap 26 (ca. 60% didecylmethylpoly(oxyethyl)ammonium propionate in ethylene glycol, diethylene glycol and water).

Identification of the active substance

CAS-No.	94667-33-1
EINECS-No.	None assigned
Other No. (CIPAC, ELINCS)	None assigned
IUPAC Name	alpha.-[2-(Didecylmethylammonio)ethyl]-.omega.-hydroxy-poly(oxy-1,2-ethanediyl) propionate
CAS Index name	Poly(oxy-1,2-ethanediyl), .alpha.-[2-(didecylmethylammonio)ethyl]-.omega.-hydroxy-, propanoate
Common name, synonyms	Didecylmethylpoly(oxyethyl)ammonium propionate; N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate, Bardap 26, Bardap 26 AS, DMPAP (internal abbreviation for the active substance), [redacted]
Molecular formula	$C_{26}H_{55}NO_3(C_2H_4O)_n$ where n = 0 – 3
Structural formula	 n = 0 – 3
Molecular weight (g/mol)	No. of oxyethyl moieties / Individual MW (*): Monomer (n=0) 429.726; Dimer (n=1) 473.779; Trimer (n=2) 517.832; Tetramer (n=3) 561.885. (*) AWs used: C=12.011; H=1.00794; N=14.0067; O=15.999

Purity	≥86.1% w/w dry weight (>60.5% w/w wet weight)
Impurities	The full details are confidential and can be found in the Annex of Confidential Data.

At TMIII09 the applicant explained that the degree of ethoxylation was formerly thought to be higher than it is in reality. The identifiers provided in the above table ('**Identification of the active substance**') do not give any indication for 'n'. Although the degree of ethoxylation is neither defined by the CAS entry nor by the common name and the chemical name, according to the information given by the applicant, this AR covers only an active substance with the following constituents:

n = 0	N,N-didecyl-N-(2-hydroxyethyl)-N-methylammonium propionate	C3H5O2.C23H50NO (CAS 107879-22-1)	77.5-86.4% w/w dry weight (absolute)
n = 1	N,N-didecyl-N-(2-(2-hydroxyethoxy)ethyl)-N-methylammonium propionate	C3H5O2.C25H54NO2 (CAS nya)	4.7-9.0% w/w dry weight (absolute)
n = 2	N,N-didecyl-N-(2-(2-(2-hydroxyethoxy)ethoxy)ethyl)-N-methylammonium propionate	C3H5O2.C27H58NO3 (CAS nya)	≤0.20% w/w dry weight (absolute)

The specification stated by the applicant under the Confidential Annex of the original dossier reflected the composition (purity and impurity profile) of the technical material prepared for the purpose of physico-chemical testing, by removal – as far as it was possible – of the process solvents from a batch of Bardap 26 from a typical manufacturing process. The specification of didecylmethylpoly(oxyethyl)ammonium propionate cannot rely on one batch only and a five-batch analysis from each source of the a.s. covered by the application was requested.
Lonza submitted five-batch analysis results from both sources covered by the dossier in November 2014 and August 2015. The IT-eCA derived the specification of each source, either as TK and dry weight, by statistic calculations (mean±3SD).
The eCA-IT was eventually able to establish the reference specification (dry weight) of didecylmethylpoly(oxyethyl)ammonium propionate, covering both sources. It shall be noted that a significant part of the (eco)toxicological studies was read-across to data obtained on DDAC. As for the (eco)toxicological studies conducted specifically upon Bardap 26, the composition of batches used in tests could not be considered in the derivation of the reference specification, because the applicant did not possess the necessary information. Nonetheless, impurities present or likely to be found in current batches according to the manufacturing process can be considered covered by the investigated batches, since studies were carried out on routine manufactured batches and, according to Lonza, the manufacturing process has not changed so far.

Since the reference specification (dry weight) was established by eCA-IT based on five-batch analysis data from both sources of the a.s. indicated by Lonza in the dossier both sources can be regarded as 'reference sources'.

Identification of the representative product

Trade name	[redacted] *(Lonza AG)*
Manufacturer's development code number(s)	[redacted]
Active substances	Didecylmethylpoly(oxyethyl)ammonium propionate; Copper carbonate, basic
Content of the active substances	84 g/kg of didecylmethylpoly(oxyethyl)ammonium propionate (120 g/kg as technical concentrate Bardap 26); *others details can be found in the Annex of Confidential Data* 152 g/kg of Copper carbonate, basic; *others details can be found in the Annex of Confidential Data*
Function	Fungistatic and insecticide
Physical state of preparation	Liquid
Nature of preparation	Solution

Physico-Chemical Properties

Didecylmethylpoly(oxyethyl)ammonium propionate is a quaternary ammonium compound which is manufactured as technical concentrate in diol/water (Bardap 26). Physico-chemical properties (with the exception of Doc. IIIA 3.4, 3.8, and 3.17) were studied for Bardap 26 AS/[redacted] which is didecylmethylpoly(oxyethyl) ammonium propionate 93.5% w/w pure, prepared by removal – as far as it was possible – of the process solvents (diol/water) from a batch of technical concentrate Bardap 26 from a typical manufacturing process.

Didecylmethylpoly(oxyethyl)ammonium propionate is a yellow liquid with a relative density D^4_{20} of 0.942. No freezing point is observed down to -50°C, whereas boiling ranges from 180 to 195°C. Its vapour pressure, extrapolated from the experimental vapour pressure curve Log P_{vap} vs. 1/T, is 1.8E-06 Pa, 4.0E-06 Pa, and 1.4E-05 Pa at 20, 25, and 50°C, respectively. The Henry's law constant (1.03E-011 and 4.72E-13 Pa m^3/mol for the monomer and dimer, respectively) has been estimated by QSAR using HENRYWIN v 3.10 model. The structure of the active substance is confirmed by the absorption spectra (UV/Vis, IR, NMR) and the mass spectrum.

Didecylmethylpoly(oxyethyl)ammonium propionate is completely miscible in water in the pH range 5-9 at room temperature (solubility ≈ 1000 g/L), as well as in ethanediol and octanol (solubility > 250 g/L at ca. 20°C in either case). Since the active substance is irreversibly ionised, no dissociation constant can be determined.

Partition coefficient is not determinable, either. EC method A.8 is not applicable for surface-active substances such as didecylmethylpoly(oxyethyl)ammonium Propionate. Also assessment by KOWWIN is considered inaccurate, being the software database very limited for surfactants. On the other hand, log Pow could be roughly obtained from solubility in pure n-octanol and water (log Pow ≈ 0). However, this calculation is of no use with regard to environmental fate & behaviour and secondary poisoning risk (experimental BCF_{fish} is available from structurally-related DDAC).

Since no decomposition or chemical transformation is observed below 150°C, didecylmethylpoly(oxyethyl)ammonium propionate can be considered thermally stable.

Didecylmethylpoly(oxyethyl)ammonium propionate has proved to have an auto-ignition temperature of 264 °C, with a flash point of 134 °C. On the basis of experience in use and/or

structural formula (absence of reactive groups), it does not show explosive properties or oxidizing properties. Didecylmethylpoly(oxyethyl)ammonium propionate has also proved to be a non-newtonian fluid (dynamic viscosity: 3000 mPa s and 400 mPa s at 20 and 40°C, respectively).

Polyethylene, Type Hostalen GM 6255, 7745 and 7746, has turned to be resistant against the test material [technical concentrate Bardap 26 (70% a.s. in 18% polyethylene glycol, 10% polyethylene glycol and water)]. Experience in use showed that 316 l stainless steel is satisfactory at optimum handling temperatures [for higher temperatures: stainless steel containing 6% or more molybdenum (Rolled alloys AL-6XN, Avesta 254-SMO, INCO 25-6MO)]. PVC, polyolefin, Teflon, Kynar, Kalrez and vinyl ester are satisfactory to temperatures recommended by manufacturer. Natural rubber, neoprene and Buna-N should be avoided.

There is no risk to be expected due to physical-chemical properties of the representative product [redacted] either.

Analytical Methods

HPLC-ELSD and GC-FID analytical methods for quaternary ammonium compounds different from didecylmethylpoly(oxyethyl)ammonium propionate were submitted by the applicant in the original dossier, but were not accepted by the eCA-IT, since not specific for this active substance. Didecylmethylpoly(oxyethyl)ammonium propionate was also screened by ion chromatography, but the method was not considered acceptable by the eCA-IT, either.

In November 2014, a new study report ([redacted] *(2014), "Preliminary Analysis of Bardap™ 26",* [redacted] for the determination of the a.s., impurities and process solvents in commercially available technical concentrate Bardap 26 (by [redacted] was eventually submitted. Apart from some minor deviations, the requirements provided for by SANCO/3030/99 were met and it can be concluded that valid analytical methods are now available for the a.s., its impurities >1 g/kg (on a dry weight basis) and process solvents in the technical concentrate (a.s. ca. 60% w/w wet weight). Those methods were used for the analysis of five representative batches of Bardap 26 manufactured for Lonza by [redacted] in [redacted] By means of the same methods, analysis was carried out also on five representative batches manufactured for Lonza by [redacted] [redacted]. [redacted] batch-data were submitted by Lonza in August 2015 ([redacted] *(2015), "Preliminary Analysis of Bardap™ 26",* [redacted]

The screening by ion chromatography was proposed by the applicant also for the determination of the active substance in the representative biocidal product ([redacted] in a justification for non-submission of data. The method was not deemed acceptable by eCA-IT and, hence, neither was the justification provided. In conclusion, an analytical method for the identification/quantification of the active substance in [redacted] is required for product authorization. Please, also note that in case of a preparation containing more than one active substance, such as [redacted] a method capable of determining each active ingredient, in the presence of the other, should be provided. If a combined method is not submitted, the technical reasons must be stated.

LC-MS methods have been used for the determination of residues of didecylmethylpoly(oxyethyl)ammonium propionate in soil and water down to a level of 0.01 mg/kg and 0.1 µg/L as total didecylmethylpoly(oxyethyl)ammonium propionate, respectively. Only one mass fragment related to the monomer was used for the purpose of validation. During the evaluation of the dossier, these methods were considered sufficiently specific, linear, accurate and precise, and were therefore accepted by the eCA-IT. At that time, the Addendum to TNsG on Data Requirements on Analytical Methods (based on SANCO/825/00) had not been endorsed yet and the conclusion on the specificity of the methods had been drawn on the following grounds:

- no further fragmentation was likely to occur under the LC-MS experimental conditions adopted;
- the chromatograms of untreated matrices showed no interferences;
- the m/z of the ion monitored ([monomer]+ at m/z = 356.2) was sufficiently high, so that in the eCA-IT's opinion LC-MS could be reasonably considered specific enough.

On the contrary, the Addendum (adopted in May 2009) states that a confirmatory method is not necessary in case of a highly specific technique, which means the use of three fragment ions (possibly with m/z ratio >100) when MS detection is carried out. So in this case, according to the Addendum, the available data (given for one LC-MS ion only) are not actually sufficient to prove the specificity of the submitted methods, which are necessary for post-approval control and monitoring purposes. Furthermore, post TMIII2009 a bilateral discussion with DE took place on the matter. It was agreed that highly specific confirmatory methods for residues in soil and water were necessary for the product authorization phase at national level. Therefore, additional highly-specific confirmatory methods for didecylmethylpoly(oxyethyl) ammonium propionate residues in soil and water (both drinking and surface water) were requested (to be submitted to the eCA-IT no later than 6 months before the date of approval). Acceptable UHPLC-MS/MS analytical methods, which allow the determination of the a.s. residues in soil and drinking/surface water down to 0.01 mg/kg and 0.1 µg/L, respectively, were eventually made available by the applicant:

Soil – the method is highly specific (UHPLC-MS/MS, with two ion transitions validated), linear over the range 0.003–0.2 mg/kg, accurate (with mean recovery rates of 101% and 99% for both mass transitions at LOQ and 10xLOQ, respectively, i.e. in the acceptable range 70–120%) and precise ($\%RSD_{n=5} \leq 20\%$ for both mass transitions at LOQ and 10xLOQ). The LOQ, as the lowest fortification level successfully validated, does not exceed the general limit of 0.05 mg/kg.

Drinking and surface-water – the method is highly specific (UHPLC-MS/MS, with two ion transitions validated), linear over the range 0.03–2.0 µg/L in drinking and surface water, accurate (with mean recovery rates at LOQ and 10xLOQ in the acceptable range 70–120% for both mass transitions) and precise ($\%RSD_{n=5} \leq 20\%$ at LOQ and 10xLOQ for both mass transitions). For drinking water, the LOQ (as the lowest fortification level successfully validated) complies with the EU drinking water limit based on DWD (0.1 µg/L). For surface water, the LOQ (as the lowest fortification level successfully validated) complies with the $PNEC_{water}$ (1 µg/L).

Both methods support the residue definition (decylmethylpoly(oxyethyl) ammonium propionate).

No analytical method is required for the determination of residues in air, since the active substance is non-volatile and will not be used in spray application.

No analytical method is deemed necessary for the determination of residues in body fluids and tissues, being the active substance is neither toxic nor highly toxic.

Wood treated with didecylmethylpoly(oxyethyl)ammonium propionate-containing biocidal product is not intended for and contains label restrictions against use in areas where food for human consumption is prepared, consumed or stored, or where the feedingstuff for livestock is prepared, consumed or stored. Therefore, no analytical method for the determination of residues in food/feed of plant/animal origin is required, either.

2.1.2. Intended Uses and Efficacy

Didecylmethylpoly(oxyethyl)ammonium propionate acts as a fungistatic and an insecticide. It is a cationic surfactant-type active substance. Since it is surface active, it has fair wetting properties and reacts strongly with cell walls of micro-organisms. Due to its interaction with phospholipid-bilayer structures, it severely alters the cell wall permeability, disturbs membrane-bound ion-translocation mechanisms, and may facilitate the uptake of other biocides. The field of application of didecylmethylpoly(oxyethyl)ammonium propionate includes

wood preservatives for the preventive treatment against wood-destroying organisms and against wood-discolouring moulds and fungi.
Didecylmethylpoly(oxyethyl)ammonium propionate is used for preventive protection of wood and constructional timbers in use classes 1 to 4A according to ISO draft standard as reported in the ESD (EN 335-2013).
The use concentration depends on the type of application technique, use class required and on additional formulation components.
The biocidal product [redacted] is a aqueous solution, with preventive efficacy against wood destroying basidiomycetes, against soft rot fungi and insects. It is used in drenching/dipping and vacuum pressure process applications in wood protection as a fungistatic/insecticide. The fungicidal effect depends on didecylmethylpoly(oxyethyl)ammonium propionate (and copper as co-biocide). The insecticidal effect depends on didecylmethylpoly(oxyethyl)ammonium propionate.
The biocidal product concentrate is diluted to a suitable working strength with water. The degree of dilution will vary depending on the wood species, type of wood product and anticipated use. The requirements for the final concentration of didecylmethylpoly(oxyethyl)ammonium propionate vary between 0.1% and 0.7%.
Uptakes of 3 to 6 kg/m^3 of product occur during pressure treatment; 6 kg/m^3 correspond to 0.5 kg a.i./m^3. The uptake of 40 g/m^2 is reached during dipping treatment; 40 g/m^2 corresponds to 6 kg/m^3 of product or 0.5 kg a.i./m^3 using a conversion factor of 150 based on the assumption that 1 m^3 has an area of 150 m^2. (Note: Efficacy testing of various substances suggests that conversion ratios from wood area to wood volume between 100 and 200 appeared to be more appropriate than the factor 80 proposed in the ESD. In the dossier the conversion has not be used for the environmental exposure assessment, anyway).
Against fungi, there exists a selective activity spectrum.
From practical experiences with standalone-biocides in this field of application, it is known that a local formation of "resistant" fungus strains at the application site may occur. For this reason didecylmethylpoly(oxyethyl)ammonium propionate or other biocides are normally not used as unique biocide in anti sapstain formulations. This preservative type is always made up of two or three different biocides to avoid adaptations or resistances.
Additional investigations on exposure of domestic microbial communities to quaternary ammonium biocidal substances do not result in increased antimicrobial resistance (McBain A.J. et al., 2004).
The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organisms and the evaluation of the summary data, provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.
In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling

Didecylmethylpoly(oxyethyl)ammonium propionate is currently not included in Annex VI of Regulation EC n. 1272/2008. On the basis of review of the submitted data, the classification was proposed according to criteria set out in Regulation EC n. 1272/2008 and specific concentration limits have been proposed for the environmental classification.

Proposed Classification and labelling of the active substance based on Regulation EC 1272/2008:

Classification:	
Hazard Class and Category	Acute toxicity (oral) 4 Skin Corrosion 1B Aquatic Chronic 1
Hazard Statement Codes	H302 H314 H410
Labelling:	
GHS Pictogram	GHS05, GHS09
Signal Word	Danger
Hazard Statement	H302: Harmful if swallowed. H314: Causes severe skin burns and eye damage. H410: Very toxic to aquatic life with long lasting effects.
M factor	M factor=10 (for both)
As precautionary statements are not included in Annex VI of Regulation EC 1272/2008 (with amendments), no proposal is made.	

Proposed Classification and labelling of the product [redacted] based on Regulation EC 1272/2008:

Classification:	
Hazard Class and Category	Acute toxicity (oral) 4 Acute toxicity (dermal) 4 Acute toxicity (inhalation) 4 STOT SE 3 Skin Irrit. 2 Eye Dam. 1 Aquatic Chronic 1
Hazard Statement Codes	H302 H312 H332 H335 H315 H318 H410
Labelling:	
GHS Pictogram	GHS05, GHS09
Signal Word	Danger
Hazard Statement	H302: Harmful if swallowed. H312: Harmful in contact with skin. H332: Harmful if inhaled. H335: May cause respiratory irritation. H315: Causes skin irritation. H318: Causes serious eye damage. H410: Very toxic to aquatic life with long lasting effects.
Precautionary Statements	P301+P312: IF SWALLOWED: Call a Poison Center or doctor/physician if you feel unwell. P280: Wear protective gloves/protective clothing/eye protection/face protection. P261: Avoid breathing dust/fume/gas/mist/vapours/spray. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P273: Avoid release to the environment. P391: Collect spillage. P501: Dispose of contents/container to …

Justification for the proposal: The classification of the BP is by studies and by calculation according to the conventional method. The BP is also classified with STOT SE 3_H335 on the basis of the content of one co-formulant of concern at 36.6%.

2.2. Summary of the Risk Assessment

Read across to data on the related QUAT didecyldimethylammonium chloride (DDAC) is requested for some toxicological endpoints (ADME, repeated toxicity in dog, chronic toxicity/carcinogenicity and reproductive/developmental toxicity).

The read across is supported by a set of bridging studies for DDAC demonstrating the similarity in physico-chemical and toxicological properties of these quaternary substances which are presented in details up-front to Doc. IIIA - Section 6.

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Didecylmethylpoly(oxyethyl)ammonium propionate is highly ionic and, therefore, it is expected not to be readily absorbed from the gastrointestinal tract or skin. No specific studies on didecylmethylpoly(oxyethyl)ammonium propionate toxicokinetics and metabolism are available, however, the read across from data on a structurally related compound, namely didecyldimethylammonium chloride (DDAC), has been accepted. The rationale for the read across acceptance is explained in details at the beginning of Doc. IIIA - Section 6.
Less than 3% of an oral dose of DDAC was eliminated via urine following a single oral dose, whereas more than 90% is excreted in the faeces. Although it was not possible to discriminate between unabsorbed/absorbed material, based on the chemical nature of the test substance it can be anticipated that about 90% is present in faeces as unabsorbed material. On the basis of these data on DDAC, it is expected that didecylmethylpoly(oxyethyl)ammonium propionate oral absorption is limited to ≈10% at non-corrosive concentration.
The majority of DDAC metabolism is expected to be carried out by intestinal flora giving rise to hydroxylation products in the alkyl chain.
About 0.1% of a DDAC dose delivered as aqueous solution fully penetrated human skin in vitro in 24 h; mean total DDAC absorbed was 9.41%, (rounded to 10% at non-corrosive concentration), including the radioactivity present in the dermis and epidermis at the dose site.
The lowest determined oral LD50 value for didecylmethylpoly(oxyethyl)ammonium propionate is 662 mg/kg. There was a dose-related increase in mortality. Clinical signs included hypoactivity, irregular/shallow breathing, ano-genital staining and diarrhoea. Gross necropsy findings in decedents included discoloured liver, red lungs and fluid-filled stomach. The active substance has to be classified as Acute toxicity (oral) 4 on the basis of this study and is assigned the Hazard Statement H302:Harmful if swallowed.
An acute dermal toxicity study was not available on didecylmethylpoly(oxyethyl)ammonium propionate, and data on DDAC were considered fully valid. The rabbit acute dermal LD_{50} of DDAC is 3342 mg/kg. DDAC caused skin irritation at the dose site in all animals. DDAC is corrosive to dermal tissue and only moderately toxic by the dermal route.
Didecylmethylpoly(oxyethyl)ammonium propionate is not volatile as the vapour pressure is 1.8×10^{-6} Pa. Thus, inhalation is not considered a potential route of exposure.
Didecylmethylpoly(oxyethyl)ammonium propionate induced severe erythema, desquamation and corrosive eschar in the rabbit skin, and it has to be therefore classified as Skin Corrosion 1B and is assigned the Hazard Statement H314: Causes severe skin burns and eye damage. Didecylmethylpoly(oxyethyl)ammonium propionate is also irritant to eye. Didecylmethylpoly(oxyethyl)ammonium propionate is not a skin sensitiser.
A two-week skin irritation study is available in rats treated with DDAC at different doses. Severe skin damages were observed at the highest dose, whereas moderate to well defined skin irritation was reported at 1%. No effects were reported in the 0.03/0.6% and in the 0.3% group; on this basis it can be derived a NOAEL/NOAEC for skin irritation in rats of 0.6% after 5 days application and of 0.3% DDAC in water at 2.0 mL/kg body weight per day after 2-week treatment.

2.2.1.2. Effects assessment

Didecylmethylpoly(oxyethyl)ammonium propionate intake in the diet over 90-days did not result in death in rodents. No clinically observable signs of toxicity were detected. However at high dietary administration dose level, evident toxicity is noted in rat; reduction in body weight gain, food consumption, clinical chemistry changes, small spleen in females, reduced absolute liver weight and body weight relative liver weight. The NOEL was equivalent to 90 mg a.s./kg/day and the LOEL was 275 mg a.s./kg/day.
Subchronic oral toxicity studies on a non-rodent species, dermal toxicity studies in rodents and chronic toxicity/carcinogenicity study have not been conducted on didecylmethylpoly(oxyethyl)ammonium propionate, however they have been conducted using the structurally related compound didecyldimethylammonium chloride (DDAC). The read across from data on DDAC has been accepted. The rationale for the read across acceptance is explained in details at the beginning of Doc. IIIA - Section 6.
In a 1-year oral gavage study in dogs with DDAC, the two highest doses (10 and 20 mg/kg/day) resulted in g.i.-related complications including emesis and abnormal faeces, resulting in death of 2 out of 4 animal at 20 mg/kg/day. The clinical signs observed in all the animals treated at 10 mg/kg/d (emesis, salivation, soft/loose faeces) persisted for the entire study duration; taking into account that the treatment dosage is reached with 2 different administrations within the day (lowering the entity of the bolus dose achievable with a single administration-possibly giving rise to more severe effects) this dosage cannot be considered as the NOAEL derived from the study. The NO(A)EL should be fixed equal to 3 mg/kg/d, related to local effects on gut mucosa. The clinical signs reported at 10 mg/kg/d, on which the NOAEL derivation is based, are consistent with the irritation/corrosive properties of the test item: only a small amount of DDAC becomes systemically available, without giving rise to any significant systemic effects. The systemic effects (10-15% decrease in body weight) were seen at 20/30 mg/kg/d, although secondary to effects in the gut. In conclusion, the NOAEL for local effects on gut mucosa is fixed equal to 3 mg/kg/d, whereas the systemic NOAEL is 10 mg/kg/d. In this context, the AEL cannot be regarded as a "true" systemic threshold and therefore, at WGII2015 it has been agreed that the AEL approach should not to be performed. Consequently, only a qualitative local risk assessment (including exposure assessment) have to be considered from the use of didecylmethylpoly(oxyethyl)ammonium propionate.
The NOAELs for non-neoplastic effects after chronic dietary DDAC administration were 32-41 mg/kg/day for rats and 76 – 93 mg/kg/day for mice. NOAELs values derivation was mainly based on a specific effects, such as decreased body weights, considered to be secondary to local effects on gut mucosa and intestinal microflora. No organ specific toxicity was evidenced. In line with the fact that the main outcome directly derives from the irritative/corrosive properties of the active substance, the subchronic and chronic NOAELs are similar in rodents, and little difference is expected between the 2 exposure scenarios.
Adequate studies evaluating developmental toxicity in rats and rabbits and reproductive toxicity (rat two-generation study) have been conducted on the chemical and structural analog, DDAC. DDAC does not affect reproduction or development at doses that are not toxic to the mother. The available data was considered appropriate for didecylmethylpoly(oxyethyl)ammonium propionate, taking into account both the chemical and structural similarities and the need for reducing unnecessary animal experiments. The overall NOAEL from maternal toxicity in the developmental toxicity studies on rats and rabbits was 1 mg/kg/d. The NOAEL for maternal toxicity is most likely related to the local effects on the gut mucosa elicited by the specific type of treatment (gavage).
Didecylmethylpoly(oxyethyl)ammonium propionate produced no mutagenic activity in any screening studies including in vitro (bacterial or mammalian cell mutation, mammalian cell chromosomal aberration) and in vivo (bone marrow chromosomal aberration) studies.
A carcinogenicity study using the chemical and structural analogue DDAC showed that the NOAELs for non-neoplastic end-points were 32-41 mg/kg/day (750 mg/kg feed) for rats and 76-93 mg/kg/day (500 mg/kg feed) for mice. DDAC did not result in an increase in tumors and was not considered oncogenic in either study. Thus, it is considered that didecylmethylpoly(oxyethyl)ammonium propionate will not be oncogenic.

The lack of any structural similarity to known neurotoxins or of any alert for neurotoxic effects, shown by quaternary ammonium chemicals in general, supports the conclusion that didecylmethylpoly(oxyethyl)ammonium propionate has no neurotoxic potential.

2.2.1.3. Medical data

No medical reports on the manufacturing personnel have been submitted.

2.2.1.4. Exposure assessment

The biocidal product containing the active substance is used in two wood preservative treatment applications: dipping and vacuum pressure processes. For both processes, the preservative is delivered to the processing plant by tanker in the form of a concentrate. The concentrate contains 8.4% of the active substance didecylmethylpoly(oxyethyl)ammonium propionate. It is diluted down to a suitable working strength with water. The degree of dilution varies depending on the wood species, type of wood product and anticipated use. Didecylmethylpoly(oxyethyl)ammonium propionate concentrations in both processes vary between 0.1% and 0.7%.
Didecylmethylpoly(oxyethyl)ammonium propionate is used for preventive protection of wood and constructional timbers.

2.2.1.4.1 Local exposure assessment

The local risk assessment, including both exposure and risk characterisation as presented below is reported for information only. For ATMAC/TMAC, another QUAT with similar uses (PT8), a local risk assessment has been provided in line with the Guidance for Human Health Risk Assessment (Guidance on the BPR: Volume III Human Health, Part B Risk Assessment). At WGII 2015 the Human Health Working Group agreed that the revised local risk assessment carried out for ATMAC/TMAC should be relevant for all QUATs having the same application.
Didecylmethylpoly(oxyethyl)ammonium propionate exhibits irritant/corrosive properties which mainly affect the human exposure. In order to quantify the local exposure, the scenarios adopted have been selected from TNsG on Human Exposure and RISKOFDERM Model. In this context, reduction factors from wearing clothes and/or Personal Protective Equipments have been taken into consideration; no dermal penetration has been considered.
Didecylmethylpoly(oxyethyl)ammonium propionate is a non-volatile active substance and therefore the inhalation uptake can be considered as negligible in assessing the exposure due to the local effects.

<u>Industrial/professional users (primary exposure)</u>
In the local exposure assessment the dermal route is deemed to be the most relevant one for industrial/professional users handling both concentrated (Mixing and loading process) and diluted didecylmethylpoly(oxyethyl)ammonium propionate-based solutions (dipping and vacuum-pressure applications). The resulted exposure values are reported below. Information on assumptions and input values used in the relevant scenarios are provided in Doc. IIB.

Table 2.2.1.4.1-1 Summary of the exposure local dose for industrial/professional users

EXPOSURE MODEL	Hands exposure	Body exposure
	mg/cm^2	mg/cm^2
MIXING&LOADING Riskofderm *Connecting lines*	9.3×10^{-5}	-
APPLICATION PHASE (Dipping treatment): Handling Model1	2.2×10^{-2}	4.3×10^{-3}
APPLICATION PHASE (Vacuum Pressure treatment): Handling Model1	2.7×10^{-2}	3.0×10^{-3}

Secondary exposure: Child playing on weathered structure and mouthing–ingestion (Local Exposure due to irritant effect)

The local irritant effect of didecylmethylpoly(oxyethyl)ammonium propionate deems to be more relevant in the case of the secondary exposure than the systemic effect. In particular, this is the case of the scenario in which has been taken into account the exposure for child chewing wood. Therefore, it has been drafted an exposure scenario considering that the maximum absorption of product is 0.7 mg/cm^3 (see above).

The volume of the timber chips is 16 cm^3 (4 cm x 4 cm x 1 cm) as reported in the TNsG, Part 3, p. 50 and User Guidance, p. 52.

The fraction extracted by chewing is 10% as reported in User Guidance, p. 52.

The amount of saliva produced is 1.5 mL/min median value reported for stimulated saliva production (http://www.scopevic.org.au/therapy_crc_research_saliva_anatomy.html).

A	maximum absorption a.s	mg/cm^3	0.7
B	size of chewed timber cut-off (chip)	cm^2	16
C	depth of chewed timber cut-off (chip)	cm	1
D = B x C	volume of chip	cm^3	16
E	a.s. extracted by chewing	fraction	0.1
F = A x D x E	a.s. in the mouth	mg	1.12
G	amount of saliva produced	mL/min	1.5
H	event duration	min	1

The event duration has been conservatively assumed to be of 1 min. Any increase in duration time is associated with an higher production of saliva and consequently with an higher dilution. Anyhow this has to be considered a very worst case scenario, as the release of the 10% of the active substance in a very short time (i.e. 1 min) has to be considered unrealistic.

The estimate of the concentration in the mouth has been derived with the above reported parameters revealing the following exposure calculation:

Amount of active substance in the mouth:

F = A x D x E = 1.12 mg

Concentration in the mouth = F/(G x H) = 0.75 mg/mL = 750 mg/kg

Local dose expressed as percentage of active substance = 0.075%

2.2.1.5. Risk characterisation

On request of the BPC the Human Health Working Group of the BPC has reviewed the derivation of AEL for QUATs at WGII 2015. It was concluded that due to lack of systemic effects in the absence of local effects, derivation of an AEL would not be appropriate, and thus a systemic risk characterisation was not considered necessary. In line with these conclusions the systemic risk assessment was removed from the assessment report.

2.2.1.5.1 Risk characterization for local effects

The local risk assessment, including both exposure and risk characterisation as presented below is reported for information only. For ATMAC/TMAC, another QUAT with similar uses (PT8) a local risk assessment has been provided in line with the Guidance for Human Health Risk Assessment (Guidance on the BPR: Volume III Human Health, Part B Risk Assessment). At WGII 2015 the Human Health Working Group agreed that the revised local risk assessment carried out for ATMAC/TMAC should be relevant for all QUATs having the same application.

As regards the dermal exposure, in the 2-week skin irritation study with rats no systemic effects were observed and the NOAEL for local effects has been set at 6 mg/kg bw/day (reading across with 2-week skin irritation study with rats performed on DDAC, 0.3% DDAC).

Local NOAEC derivation – Dermal route

The NOAEC derived for the DDAC is of 0.3% of active substance in water (i.e., 3 g/L or 3000 mg/L or 3 mg/mL). The total volume applied is of 2 mL/kg bw per day. Therefore, the resulted NOEL is of 6 mg/kg bw/day (=3 mg/mL x 2 mL/kg bw per day).

For didecylmethylpoly(oxyethyl)ammonium propionate a read across from the skin irritation study carried out on the analogous structurally compound DDAC has been accepted. The WGII2015 agreed that no molecular weight correction should be considered in the NOAEC derivation for didecylmethylpoly(oxyethyl)ammonium propionate (DMPAP).
In the skin irritation study the treated body surface has not been well defined and therefore, the assumption of 10% coverage of the animal body could be made based on the guideline recommendations. According to the TGD, the total surface body of rat (male and female) is 400 cm^2 and the mean body weight is 300g. Assuming that 10% of the body surface has been exposed to the test substance, the resulting exposed area is of 40 cm^2.
For the characterization of the risk due to the local dermal effects a NO(A)EC (expressed in mg/cm^2) has to be derived following the formula below:

$$NOAEC\ in\ mg/cm^2 = \frac{Total\ dose\ applied\ in\ mg}{Treated\ surface\ in\ cm^2} = \frac{(average\ animal\ weight\ in\ kg)\times(dose\ in\ mg/kg\ bw)}{Treated\ surface\ in\ cm^2}$$

NOAEC = (0.3 kg x 6 mg/kg bw/day) / 40 cm^2 = 0.045 mg/cm^2
The dermal NOAEC value of 0.045 mg/cm^2 is equivalent to a dermal NOAEC of 0.3%.

Local NOAEC derivation – Oral route

For local effects an oral NOAEL has been set at 3 mg/kg bw/d from a 1-year oral gavage study in dogs performed on DDAC. This NOAEL is particularly relevant since from the same study it was possible to differentiate a NOAEL for local effects on the g.i. mucosa (3 mg/kg bw/d) on the basis of emesis present at the higher dose (10 mg/kg bw/d), which was on the other hand considered as a systemic NOAEL, based on decrease body weight at the immediately higher dose. For the purpose of a semi-quantitative risk assessment, the NOAEL value of 3 mg/kg bw/d (1-year oral gavage toxicity study in dogs) has to be used for the oral NOAEC derivation rather than the NOAEL from the reproductive toxicity studies on rats. This taking into consideration that also in the DDACarbonate CAR it is stated that "(…) dogs appear to be more sensitive to the adverse effects of repeated oral exposure to DDAC than rats and mice and toxicity occurs at lower doses in gavage studies compared to dietary studies (…)" (Draft Final CAR – Doc.I, p.11/59).
The WGII2015 agreed that no molecular weight correction should be considered in the NOAEC derivation for didecylmethylpoly(oxyethyl)ammonium propionate. In the oral NOAEC derivation it was considered as follows: a fixed dose volume of 10 mL/kg dose, a body weight of 10 kg for dos. Therefore, using the NOAEL of 3 mg/kg bw/d as point of departure, the oral NOAEC results to be of 0.3 mg/mL equivalent to a NOAEC of 0.03%.
The oral NOAEC value of 0.3 mg/mL is equivalent to an oral NOAEC of 0.03%.

Exposure and risk from use of the product

For local dermal effects, the NOAEC expressed in terms of % should be compared with the in-use concentration of the active substance in the representative products. In this regards, the formulation [redacted] contains 8.4% didecylmethylpoly(oxyethyl)ammonium propionate, and in-use concentrations of didecylmethylpoly(oxyethyl)ammonium in the representative products range from 0.1% to 0.7%. Therefore, at a concentration of didecylmethylpoly(oxyethyl)ammonium propionate solutions of 0.7% which is higher than the (marginal) NOAEC of 0.3% a.s. for all intended uses, an unacceptable risk can occurs and personal protective equipments (PPEs) should be prescribed to protect operators against the local effects of didecylmethylpoly(oxyethyl)ammonium propionate. The conclusion from the semi-quantitative risk assessment due to the corrosive properties of didecylmethylpoly(oxyethyl)ammonium propionate is that PPE are per definition required when applying didecylmethylpoly(oxyethyl)ammonium propionate.

Exposure and risk from indirect exposure to the product

As concerns the risks arising from the secondary exposure, the only scenario considered as relevant is child mouthing treated wood. The resulting local dose is 0.075% didecylmethylpoly(oxyethyl)ammonium propionate (0.75 mg/mL).

Being the oral NOAEC of 0.03% less than the local concentration of 0.075% didecylmethylpoly(oxyethyl)ammonium propionate, a potential risk is still highlighted for children chewing and sucking timber treated cut-off.

In conclusion, as a potential risk can occur from child sucking and mouthing treated wood, the use of didecylmethylpoly(oxyethyl)ammonium propionate treated wood has to be restricted to applications where biocidal treatment is unavoidable (e.g., construction), but definitely excludes applications to treated wood composites which would otherwise come into contact with children.

The scenario estimated for the secondary exposure was agreed during the Technical Meetings when no specific guidelines were available on the risk characterization for the local effects. The assessment should not be considered as comprehensive of the overall exposure pathways. Thus, additional exposure scenarios covering any relevant exposure scenarios should be estimated at Product Authorization stage when the guidelines on the risk characterization for the local effects are finalized, depending on the use scenarios.

Therefore, based on the above discussion, it is considered inappropriate to use an AEL approach for didecylmethylpoly(oxyethyl)ammonium propionate and similar quaternary ammonium compounds, because there is no true systemic toxicity. Didecylmethylpoly(oxyethyl)ammonium propionate and other quaternary ammonium compounds do not exhibit "systemic toxicity" as based on changes to organs or effects on reproduction, development, mutagenicity, carcinogenicity, neuro-behaviour or other key toxicological endpoints. Rather, effects observed in toxicity studies occur only at irritant doses and general effects, including body weight changes at lower doses and death at high doses, are secondary to these irritant responses.

However, the above mentioned local risk assessment was assessed according to a draft guidance which was revised substantially and published on 2013. For ATMAC/TMAC, another QUAT with similar uses (PT8) discussed at WGII 2015, a local risk assessment has been provided in line with the Guidance for Human Health Risk Assessment (Guidance on the BPR: Volume III Human Health, Part B Risk Assessment). At WGII 2015 the Human Health Working Group agreed that the revised local risk assessment carried out for ATMAC/TMAC should be also relevant for all QUATs having the same application. In an ad hoc follow up, the revised secondary exposure of children was presented where it has been demonstrated that risks are acceptable for treatment of wood with which children may enter in direct contact.

The local risk assessment for secondary exposure for **Infants mouthing wood off-cut (oral exposure)** as assessed for ATMAC/TMAC is reported below.

"Derivation of oral NOAEC

An oral NOAEC for local effects can be derived from the 1-year oral gavage toxicity study in dogs performed on DDAC (Schulze, G.E. (1991). Chronic oral toxicity study of Didecyldimethylammonium Chloride in dogs). A NOAEL of 3 mg/kg bw/d was identified from this study based on local effects observed on the gastro-intestinal mucosa at the immediately higher dose (10 mg/kg bw/d). The concentration of the active substance in the vehicle was reported to be fixed at 10 ml/kg bw, thus the 3 mg/kg bw/day is equivalent to a NOAEC of 0.3 mg/ml or 0.03%. It was agreed at WGII 2015 that no molecular weight correction needs to be considered in the NOAEC derivation for ATMAC/TMAC.

The oral NOAEC value of 0.3 mg/ml is equivalent to an oral NOAEC of 0.03%

Secondary exposure: Infants chewing wood off-cut - ingestion route

Watanabe et al (1995) informs that in 15 boys and 15 girls of five years old, the mean flow of unstimulated saliva was 0.26 (+0.16 SD) ml/min and that of saliva while chewing was 3.6 (+0.8 SD) ml/min. The Watanabe study measured saliva flow when chewing foodstuffs. It can be assumed that this stimulated saliva flow would be similar for any chewing action. Dawes (2008) found that taste also stimulated saliva flow. In adults infusion of 5 % citric acid into the mouth elicited a flow rate of 7.07 ml/min compared to 4.94 ml/min. Thus the taste of the active substance could also add to the rate of saliva flow. Information taken from a study on

leachability of ATMAC/TMAC in the fate and behaviour data supporting the assessment of this substance can be used to determine the amount of active substance released from a treated wood off-cut. Section 3.3.2 of Doc IIB gives details of a study in which wooden blocks (19 x 19 x 19 mm) were vacuum pressure treated at 3 different concentrations. The ATMAC/TMAC retention levels were calculated to be 3.5, 7.0 and 14.0 kg/m^3. The blocks were then suspended in water and measurements of ATMAC/TMAC concentration in the leachate water were taken at various time points up to 14 days after initiation of leaching. The shortest interval was 6 hours after initiation of leaching. For the 6 hour time-point the level of leeching, expressed as a percentage of the original amount, was 0.63%, 1.08% and 1.97% for the 3.5, 7.0 and 14.0 kg/m^3 respectively. Whilst there appears to be some uncertainty over the value derived for the highest concentration, these data suggest less than 2.0% of ATMAC/TMAC was removed from the treated wood after soaking in water for 6 hours. Considering a retention rate of 150 g treatment solution/m^2 and an in-use treatment solution with a maximum active substance content of 1.12%, the worst case loading is 0.168 mg a.s./cm^2 (150g b.p./m^2 x 1.12/100 = 1.68 g a.s./m^2 = 0.168 mg a.s./cm^2). The total surface area of wood off-cut is 48 cm^2 (= 2 x [4cm x 4cm + 4cm x 1cm + 4cm x 1cm]) with a volume of 16 cm^3 (4 cm x 4 cm x 1 cm). Using an extraction factor of 2.0% for human health risk assessment, the concentration of active substance in saliva of an infant chewing/mouthing a 4 x 4 x 1 cm wood off-cut treated by dipping application can be calculated as follows.

Table 3.18: Estimation of exposure to infant mouthing wood off-cut treated by dipping application

Wood off-cut treated by dipping application	
Concentration of a.s. in treated wood	0.168 mg a.s./cm^2 (TMAC dossier)
total surface of wood off- cut	48 cm^2
Amount of a.s. released from off-cut – assuming 2.0% extraction	0.16 mg
Amount of saliva produced by an infant (stimulated saliva flow)	3.6 ml/minute
Duration of chewing of off-cut	1 minute
Concentration of a.s. in saliva	0.04 mg a.s./ml

For wood treated by dipping application, the predicted exposure concentration is 0.04 mg a.s./ml.

Extrapolating the environmental fate data to an infant mouthing treated wood involves a degree of uncertainty, as the treated wooden blocks used were soaked and not sucked or chewed. However, it is of note that the blocks were soaked for 360 minutes compared to 1 minute for the infant mouthing the off-cut.

Being leaching data based on vacuum-pressure treated wood, the conservatism in setting the input values to be entered into the exposure model balances this.

Conclusion

Assessments have been undertaken to address the theoretical concern of an infant accessing a treated wood off-cut, placing the off-cut in its mouth and mouthing the wood for 1 minute. The assessment uses leaching rate data for wood treated by vacuum pressure impregnation for stimulated saliva flow; chewing would stimulate saliva flow and reduce the concentration of ATMAC/TMAC in the mouth. See Document IIB for more details. The maximum oral exposure ATMAC/TMAC concentration for this scenario is predicted to be 0.04 mg a.s./ml. This is below the oral NOAEC value of 0.3 mg/ml and therefore, the risk of exposure to ATMAC/TMAC in this scenario is considered acceptable. Additional reassurance is provided by the fact that this scenario is considered an uncommon occurrence as parents would usually keep an infant away from areas where wood is being sawn.

Dermal exposure

The handling of treated wet wood, where exposure was to the diluted product, posed only a "low" hazard. When the treated wood has dried, the release of the active substance is not expected to reach a concentration that could lead to irritative effects during dermal exposure. Therefore, the potential of local effects during child playing on weathered structure is negligible. No risk to the child playing on weathered structure is identified. "

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and distribution in the environment

Biodegradation

Didecylmethylpoly(oxyethyl)ammonium propionate was found to be not readily biodegradable. The study was carried out in accordance with OECD Guideline 301B. Mineral salts inoculated with activated sludge were treated with 14C-didecylmethylpoly(oxyethyl)ammonium propionate and incubated with 29 days. Mean cumulative 14CO2 production was equivalent to 10% after 4 days and progressed rapidly until Day 8. The rate of biodegradation then slowed. 34% biodegradation of the test substance had occurred by Day 29, where the biodegradation curve was still on the upward trend, confirming a continuing mineralisation of the test substance. The percentage of biodegradation of reference substance was 65% after 6 days and 84% after 29 days the 14CO2 production 73.7 and 78.1 mg CO2 after 29 days.

To simulate sewage treatment plant conditions more realistically, two tests with high sludge density were conducted: an OECD 303A Confirmatory test and a die away study.

In the first study, the Confirmatory Test, didecylmethylpoly(oxyethyl)ammonium propionate was determined in the influent, in the effluent and as the amount of cationic surfactants adsorbed to the sludge using the DSBAS (disulfinblue active substance) analytical principle. Didecylmethylpoly(oxyethyl)ammonium propionate showed a mean primary degradation of >95% from the 21 day of incubation.

In the second study, the die away test, radiolabelled didecylmethylpoly(oxyethyl)ammonium propionate was used. The study was not conducted to any specified guideline. The TSS was adjusted to approximately 2500 mg/L. The biotic sludge was mixed overnight on a shaker table with the flask open to ambient air. The sludge used to prepare the abiotic control was amended with a 2.5% mercuric chloride buffer solution and autoclaved for 90 minutes. After the sludge was cooled to room temperature, the pH of the abiotic sludge was adjusted with 1.5 N KOH to match the pH of the biotic sludge (7.6). Two 1 gallon jugs, with gas trapping systems, containing 2 or 1 litres of either biotic or abiotic activated sludge, respectively, were dosed with 50 µg/L radiolabelled test substance.
The study was conduct to evaluate the rate and extent of primary degradation and mineralization of the test substance in the activate sludge. The test system was activated sludge previously exposed to non-labelled didecylmethylpoly(oxyethyl)ammonium propionate at a nominal concentration of 150 µg/L in a porous pot. The abiotic control was identical to the biologically active treatment with the exception that it was amended at a nominal concentration of 1 g/L with mercuric chloride and autoclaved prior to test initiation.

At test termination (28 days), 86% of the radioactivity was evolved as $^{14}CO_2$, 0.0% was recovered in the extracts and 5.79% remained in the solid. 6.34% of a polar metabolite was detected after 28 days. In the abiotic sample, 101.88% of the radioactivity was recovered in the extracts and 3.01% remained in the solid. The study has been considered as supplemental information.

Didecylmethylpoly(oxyethyl)ammonium propionate biodegrades in a waste water treatment plant die-away simulation test under aerobic conditions with a removal half-life DT_{50} of 4.7 hours and a high conversion rate to CO_2.

Didecylmethylpoly(oxyethyl)ammonium propionate is considered not ready biodegradable. However, in STPs very high elimination and complete mineralization can be assumed.

Abiotic Degradation
Didecylmethylpoly(oxyethyl)ammonium propionate was hydrolytically stable during the 5 days hydrolysis study at pH 4, 7 and 9 at 50°C; half-lives were estimated as > 1 year.

An adequate study evaluating phototransformation in water has been conducted on the chemical and structural analogous didecyldimethylammonium chloride (DDAC). In view of the chemical and structural similarities, it is considered that the available data are adequate for didecylmethylpoly(oxyethyl)ammonium propionate. DDAC was found to be photolytically stable in the absence of a photosensitiser. The half-life of the test compound was determined to be 227 days (light, exposed) and 427 days (dark, exposed) with 7% degradation after 30 days.

Distribution
A study to determine adsorption and desorption in soil for didecylmethylpoly(oxyethyl)ammonium propionate was not carried out as an adequate study has been conducted on the chemical and structural analogous DDAC. In view of the chemical and structural similarities, it is considered that the available data is adequate for didecylmethylpoly(oxyethyl)ammonium propionate.

DDAC was classified as immobile in four soil/sediment types with the adsorption (Kd) and mobility (K_{oc}) coefficients of Kd=1095 L/kg and K_{oc}=437805 L/kg for sand, Kd=8179 L/kg and K_{oc}=908757 L/kg for sandy loam, Kd=32791 L/kg and K_{oc}=1599564 L/kg for clay loam, and Kd=30851 L/kg and K_{oc}=1469081 L/kg for silt loam (Ref. No 1792).
Based on the conclusion of the Ad-hoc follow up on ATMAC/TMAC (PT 8) (opinion of the ENV WG on the K_{oc} to be used for the risk assessment) the k_{oc} value to be used for risk assessment is the mean K_{oc} from the both studies available for DDAC.

The K_{oc} value is 562314 L/kg (NOTE: the endpoint has not updated with the value reported in the LOEP).

Mobility
The results of the adsorption in soil study on a structural analogous DDAC indicate little or no potential for mobility in soil and should not pose an environmental risk for contamination of ground water. Thus, it is considered that a short or a long-term Mobility-Lysimeter study is not justified.

Bioaccumulation
The bioaccumulation of didecylmethylpoly(oxyethyl)ammonium propionate has not been experimentally determined. Also, for surfactants like didecylmethylpoly(oxyethyl)ammonium propionate the *log* K_{ow} cannot be accurately measured nor predicted, therefore an estimation of the intrinsic potential for bioaccumulation cannot be made. Based on the experimental BCF_{fish} equal to 81 L/kg measured for the read-across substance DDAC, it is expected that also didecylmethylpoly(oxyethyl)ammonium propionate has a low potential for bioaccumulation. The rationale for read across is based on similar chemical structure, higher hydrophilicity of didecylmethylpoly(oxyethyl)ammonium propionate, similar mode of action, toxicokinetics in mammals (see Doc. IIIA, Section 7 introduction Doc. IIA and Appendix I thereof). No data are available on the bioaccumulation in worms. In addition, the $BCF_{earthworm}$ cannot be estimated according to TGD (eq. 82d) as it is not applicable to ionized chemicals. Considering the low BCF of other QUATs (DDAC and ADBAC) measured in fish and the kinetics of ionic surfactants in mammals, a high potential of bioaccumulation in worms, such to pose risk of secondary poisoning to birds and mammals, is not expected for didecylmethylpoly(oxyethyl)ammonium propionate. In addition it has to be taken into account that didecylmethylpoly(oxyethyl)ammonium propionate possesses irritative/corrosive properties and acts mainly through local toxicity rather than systemically, damaging organisms before accumulation can occur.

2.2.2.2. Effects assessment

The applicant claimed for several endpoints the possibility to read across data from didecyldimethylammonium chloride (DDAC) to didecylmethylpoly(oxyethyl)ammonium propionate. The justification for acceptance/refusal of the read across is reported in Appendix I to the Doc. IIA.

Aquatic Compartment

The results of acute toxicity studies indicate that didecylmethylpoly(oxyethyl)ammonium propionate is very toxic to fish, *Daphnia magna* and algae. The most sensitive group is invertebrates (*D. magna,* 48-hour EC_{50} =0.07 mg a.s./L under semi-static conditions), whilst the less sensitive group is fish (*Lepomis macrochirus,*96-hour LC_{50} = 0.52 mg a.s./L under semi-static conditions). For algae, the test with *Scenedesmus subspicatus* provided a 72h E_rC_{50} = 0.34 mg a.s./L and a 72h NOE_rC = 0.044 mg a.s./L. For fish and invertebrates, chronic toxicity data are not available for didecylmethylpoly(oxyethyl)ammonium propionate, but they were retrieved from long term toxicity studies conducted with the read-across substance DDAC. The read across is justified based on similar acute aquatic toxicity, similar mammalian toxicity, similar mode of action, similar toxicokinetics in mammals, similar chemical structure, similar physico-chemical properties (see Doc. IIA and Appendix I thereof). Differences in fate properties (DDAC is ready biodegradable while didecylmethylpoly(oxyethyl)ammonium propionate is not) do not hamper the read across because chronic aquatic toxicity tests with DDAC were carried out under flow through conditions, i.e. mimicking stable exposure concentrations. The read across was accepted at TMIII09. Based on read across, didecylmethylpoly(oxyethyl)ammonium propionate is expected to be very toxic to fish and *Daphnia magna*.
In a test performed with DDAC under flow-through conditions, the 34d NOEC (hatching) was 0.032 mg a.s./L for *Brachydanio rerio*. *Daphnia magna* was more sensitive than fish, with a 21d NOEC (survival) of 0.010 mg a.s./L recorded in a reproduction test with DDAC conducted under flow-through conditions. The correction of the endpoints for difference in molecular weight was not carried out. In the present case, the ratio of molecular weights of didecylmethylpoly(oxyethyl)ammonium propionate (DMPAP; MW = 437.8) and the read across substance DDAC (MW= 362.1) is only 1.2, i.e. within a factor of 2 which is the "normal" variability usually accepted in ecotoxicological testing, and the correction for molecular weight would lead to higher (less conservative) endpoints. Nevertheless, the accepted read across (DDAC) endpoints had been previously corrected for molecular weight for consistency with the approach taken in the Human Health section. Following the agreement reached at the WGII2015 that no molecular weight correction should be considered even for local effects (both oral route and dermal route), eCA considered appropriate to remove this correction also from the aquatic endpoints retrieved from read across, that is justified by the rationale given above.
The PNECwater is derived from the lowest of the three available NOECs (0.010 mg/L, Daphnia magna (NOTE: the endpoint has not updated with the value reported in the LOEP), leading to:

PNECwater = 0.010 mg a.s./L / AF 10 = 0.001 mg a.s./L (based on accepted read across to DDAC)

Didecylmethylpoly(oxyethyl)ammonium propionate is harmful to microbial activity in STP, being this inhibited at concentration higher than any other aquatic group (3h respiration inhibition test EC_{50} of 16.8 mg a.s./L). For the STP compartment, the PNEC is derived as follows:

PNECmicroorganisms: 16.8 mg a.s./L / AF 100 = 0.168 mg a.s./L

Metabolites
No major metabolites have been identified.

Sediment
No data for sediment-dwelling organisms are available for didecylmethylpoly(oxyethyl)ammonium propionate, but only for DDAC to which a read across was initially proposed. Since didecylmethylpoly(oxyethyl)ammonium propionate was eventually concluded to be not ready biodegradable and its persistency has to be clarified, the read across to the ready biodegradable DDAC is not acceptable because possibly underestimating the hazard to sediment-dwelling organisms (see Doc. IIA and Appendix I).
Therefore, a PNEC for the sediment compartment cannot be derived. The available information do not permit to perform a risk assessment for use classes other than 1 and 2.

Terrestrial Compartment
The effect of didecylmethylpoly(oxyethyl)ammonium propionate on earthworms was assessed in two acute toxicity tests with *E. foetida*. In the first study, no effects were observed up to 1000 mg/kg dry soil (maximum tested concentration); in the second one, the 14-day LC_{50} was 4390 mg/kg dry soil.

No information is available for effects of didecylmethylpoly(oxyethyl)ammonium propionate to soil microbial function and to terrestrial plants. Data were provided relative to the structural analogous DDAC, to which the Applicant asked for a read across. Among the terrestrial organisms, the toxicity ranking among worms, microorganism and plants observed for DDAC is also observed for ADBAC, showing that plants are the most sensitive group. Taking into account the different fate properties (DDAC is ready biodegradable, while didecylmethylpoly(oxyethyl)ammonium propionate is not and its persistency has to be clarified), the read across is not acceptable as the chronic toxicity of didecylmethylpoly(oxyethyl)ammonium propionate to terrestrial organisms might be underestimated.

Due to the lack of initial terrestrial effects data, a reliable PNEC for the soil compartment cannot be derived. The available information do not permit to perform a risk assessment for use classes other than 1 and 2.

The acute didecylmethylpoly(oxyethyl)ammonium propionate LD_{50} for birds is calculated at 226 mg/kg bw (northern bobwhite quail).

In the two short term dietary toxicity tests with the read across substance DDAC, the lowest endpoint was retrieved for mallard duck: LC_{50} > 1633 mg a.s./kg. This estimate represents the concentration, corrected to take into account the observed food avoidance, at which no mortality was recorded; therefore, it is still a conservative estimate of the toxicity to birds. A factor of 3000 was used to derive the PNEC:

PNECbirds = 1633 mg a.s./kg food / 3000 = 0.54 mg a.s./kg

One dietary 90d test with rats was carried out with didecylmethylpoly(oxyethyl)ammonium propionate and provided a NOEC = 1143 mg a.s./kg food. In calculating the PNECoral for the secondary poisoning assessment, results from long-term studies are strongly preferred. From the available data the 18 months oral feed repeated doses study on mouse conducted with the read across substance DDAC is selected as it gives the lowest NOAEL in chronic exposure (500 mg a.s./kg (NOTE: the endpoint has not updated with the value reported in the LOEP).

PNEC mammals = 500 mg/kg / AF30 = 16.7 mg/kg food (based on read across to DDAC).

2.2.2.3. PBT and POP assessment

PBT assessment

P criterion: Half life > 40 d in freshwater (> 60 d in marine water) or > 120 d in freshwater sediment (> 180 d in marine sediment) or > 120 d in soil

Didecyldimethylpoly(oxyethyl)ammonium propionate is hydrolytically stable over an environmentally relevant pH range of 5-9.

From data of photolysis in water:

Didecyldimethylpoly(oxyethyl)ammonium propionate was found to be photolytically stable in the absence of a photosensitiser.

Didecylmethylpoly(oxyethyl)ammonium propionate is not readily biodegradable. Therefore, in order to clarify the P status of the substance, further data were considered necessary. New studies (OECD 307 and OECD 308) were provided by the Applicant. Thes studies are considered acceptable and reliable.

According to the Annex XIII and Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment Version 3.0 (June 2017), the worst-case DT_{50} value (based on mineralisation) in soil is 107.9 days at 12°C, that is lower than the trigger value for soil (120 days). The value of 107.9 days based on mineralisation is used for the persistence assessment only; the geometric mean SFO DT50 of 31 days was considered relevant for risk assessment. The worst-case DT_{50} value in sediment is 60 days that is lower than the trigger value for soil (120 days). The WG agreed on using the total system DT_{50} value for sediment excluding NER (All data, best-fit, DT_{90}/3.32) for the sediment compartment.

Table R.11—1: PBT and vPvB criteria according to Section 1 of Annex XIII to the REACH Regulation.

Property	PBT criteria	vPvB criteria
Persistence	A substance fulfils the persistence criterion (P) in any of the following situations: (a) the degradation half-life in marine water is higher than 60 days; (b) the degradation half-life in fresh or estuarine water is higher than 40 days; (c) the degradation half-life in marine sediment is higher than 180 days; (d) the degradation half-life in fresh or estuarine water sediment is higher than 120 days; (e) the degradation half-life in soil is higher than 120 days.	A substance fulfils the "very persistent" criterion (vP) in any of the following situations: (a) the degradation half-life in marine, fresh or estuarine water is higher than 60 days; (b) the degradation half-life in marine, fresh or estuarine water sediment is higher than 180 days; (c) the degradation half-life in soil is higher than 180 days.

Based on the QSAR analysis (see Doc. IIIA provided by the Applicant), the three metabolites M1a, M1b and M1c are readily biodegradable (in line with predictions of EPI Suite, which are within domain) therefore, according to Annex XIII and Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment Version 3.0 (June 2017), can be considered not P.

Table R.11—2: Screening information as listed in Section 3.1 of Annex XIII to the REACH Regulation.

Indication of P and vP properties	(a) Results from tests on ready biodegradation in accordance with Section 9.2.1.1 of Annex VII; (b) Results from other screening tests (e.g. enhanced ready test, tests on inherent biodegradability); (c) Results obtained from biodegradation (Q)SAR models in accordance with Section 1.3 of Annex XI; (d) Other information provided that its suitability and reliability can be reasonable demonstrated.

To be noted that the substance showed a special degradation behaviour, which was characterized by a pronounced lag-phase at the beginning of the water sediment test.

Thus, regarding only the water compartment, still some concern was expressed by the ENV WG about Bardap 26 possibly exceeding the persistence threshold in water. In principle, the study according to OECD 308 is not applicable to assess P in water and, in any case, even if some doubts still remain for the water compartment, this does not have any regulatory consequences as the substance is neither B nor T. As the additional study was part of the post-approval data requirement related to soil and sediment, results are deemed sufficient to conclude on the P properties of didecyldimethylpoly(oxyethyl)ammonium propionate. Further action might be considered, if this issue is deemed to be of relevance, for the approval of additional PTs and/or at renewal stage of PT8.

In conclusion, WG-V2019-ENV agreed upon didecylmethylpoly(oxyethyl)ammonium propionate and its metabolites **not fulfilling the P criterion.**

B criterion: BCF > 2000

For didecylmethylpoly(oxyethyl)ammonium propionate the measured bioconcentration factor in fish is 81 L/kg, based on read-across to the read-across substance DDAC. Experimental data on the other structurally related QUAT, ADBAC, confirmed this finding. **Therefore, it can be concluded that the B criterion is not fulfilled**.

T criterion: Long term NOEC or EC_{10} < 0.01 mg/L for marine or freshwater organisms or CMR, or other evidence of chronic toxicity

The most sensitive species is *Daphnia magna,* for which a NOEC of 0.010 mg/L has been derived from a 21 d reproduction study conducted with the read across substance DDAC. Since this toxicity endpoint practically coincides with the trigger for the T criterion, consideration should be given to the intrinsic uncertainty underlying this value, due to the fact that it derives from a read across. According to section 2.5 of the BPC Opinion, a *Daphnia Magna* Reproduction test according to OECD GL (OECD 211) was necessary to clarify the T properties of didecylmethylpoly(oxyethyl)ammonium propionate. Such study was provided by the Applicant on January 2019 and the conclusion submitted for evaluation to the WG-V 2019 ENV. The study was considered reliable (RI 2) and sufficient to fulfil the post approval data requirement. The lowest tested concentration, which corresponds to a nominal concentration of 250 µg/L test substance (considering an a.i. purity of 70.9%) provided the NOEC. A mean measured concentration of 185 µg a.i./L was determined for this testing concentration.
According to the Annex XIII and Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment Version 3.0 (June 2017), a substance fulfills the toxicity criterion (T) if the long term NOEC or EC10 is < 0.01 mg/L for marine or freshwater organisms or the substance is classified as CMR, or there is other evidence of chronic toxicity.
The WG-V-2019_ENV agreed on using a derived NOEC of 185 µg a.i./L for this study and, considering that it is far from 0.01 mg/L threshold defined for T criterion, concluded that didecylmethylpoly(oxyethyl)ammonium propionate does not meet the T criterion.
Therefore according to Annex XIII and Guidance on Information Requirements and Chemical

Safety Assessment Chapter R.11: PBT/vPvB assessment Version 3.0 (June 2017), didecylmethylpoly(oxyethyl)ammonium propionate **does not meet the T criterion**.

The substance is classified according to CLP: Dgr; GHS05; GHS09; H302; H314; H410 (M factor=10 for both).

With regard to CMR properties, no classification is required.

Conclusion for the PBT assessment:
On the basis of the available data in February 2014, a public consultation was launched because didecylmethylpoly(oxyethyl)ammonium propionate was regarded as fulfilling both the P and T criteria. However, during the public consultation several uncertainties affecting the data provided were highlighted. Therefore, in order to clarify the P and T status of the substance, further data were considered necessary and these have been requested in section 2.5 of the Opinion. It was agreed that didecylmethylpoly(oxyethyl)ammonium propionate was, after these data have been submitted, to be further assessed by the PBT Expert Group.
New studies (OECD 307, OECD 308 and OECD 211) were provided by the Applicant in January 2019. The studies are considered acceptable and reliable. According to WG-V2019_ENV, didecylmethylpoly(oxyethyl)ammonium propionate and its metabolites were agreed upon not to fulfill the P criterion nor the T criterion.
Therefore, didecylmethylpoly(oxyethyl)ammonium propionate is not a candidate for substitution as identified in the provisions of Article 10(1)(d).

POP assessment
The analysis of POPs criteria was not required when the dossier was evaluated and therefore not considered when didecylmethylpoly(oxyethyl)ammonium propionate was discussed at technical meeting level (TMIII2009).

- Didecylmethylpoly(oxyethyl)ammonium propionate does pose adverse effects to human health and to the environment (please, refer to the classification proposal under chapter 2.1.3 of this document). Furthermore, didecylmethylpoly(oxyethyl)ammonium propionate is potentially persistent (not ready biodegradable). Nonetheless:
- Didecylmethylpoly(oxyethyl)ammonium propionate was concluded to have a low potential for bioaccumulation based on the read-across from DDAC and ADBAC data;
- no potential for long-range environmental transport is expected (mean atmospheric half-life of 0.346 d; little potential for mobility in soil based on the read-across from DDAC data).

2.2.2.4. Exposure assessment

Aquatic Compartment Exposure assessment

PECs have been calculated according to the OECD Emission Scenario Document for Wood Preservatives (ESD).

		Local PEC
Scenario 1: Dipping treatment during application		
PEClocalwater		0.0024 mg/L
PEClocalsed		58.2 mg/kg$_{wwt}$
PECmicroorganism STP		0.065 mg/L
Scenario 2: dipping treatment during storage		
PEClocalwater	Time1	0.0023 mg/L
	Time2	0.0047 µg/L
PEClocalsed	Time1	51 mg/kg$_{wwt}$
	Time2	0.11 mg/kg$_{wwt}$
Scenario 3: Vacuum pressure treatment during application		

PEClocalwater		0.0007 mg/L
PEClocalsed		17.8 mg/kg_{wwt}
PECmicroorganism STP		0.02 mg/L
Scenario 4: Vacuum pressure treatment during storage		
PEClocalwater	Time1	0.0018 mg/L
	Time2	0.031 µg/L
PEClocalsed	Time1	51 mg/kg_{wwt}
	Time2	0.74 mg/kg_{wwt}
PEClocalwater		0.0018 mg/L
PEClocalsed		43 mg/kg_{wwt}
Scenario 5: Bridge over pond		
PEClocalwater STP	Time1	0.12 mg/L
	Time2	0.0004 mg/L
PEClocalsed STP	Time1	2869 mg/kg_{wwt}
	Time2	10.3 mg/kg_{wwt}
Scenario 6: Noise Barrier		
PEClocalwater STP	Time1	0.002 mg/L
	Time2	0.00004 mg/L
PEClocalsed STP	Time1	47.8 mg/kg_{wwt}
	Time2	0.96 mg/kg_{wwt}
PECmicroorganism STP	Time1	0.0195 mg/L
	Time2	0.00017 mg/L

Terrestrial Compartment Exposure assessment

In the following table has been reported the PECs calculated using the OECD Emission Scenario Document for Wood Preservatives (ESD).

	Local PEC
Scenario 2: Dipping treatment during storage	
PEClocalsoil (TIME1)	3.1 mg/kg
PEClocalsoil (TIME2)	9.9 mg/kg
PEClocalsoil, porew (TIME 1)	0.16 µg/L
PEClocalsoil, porew (TIME 2)	0.06 µg/L
Scenario 4: Vacuum pressure treatment during storage	
PEClocalsoil (TIME1)	3.1 mg/kg
PEClocalsoil (TIME2)	13.2 mg/kg
PEClocalsoil, porew (TIME 1)	0.16 µg/L
PEClocalsoil, porew (TIME 2)	0.67 µg/L
Scenario 6: Treated wood in service Noise barrier	
PEClocalsoil (TIME 1)	1.1 mg/kg
PEClocalsoil (TIME 2)	4.4 mg/kg
PECgw	0.06 µg/L
Scenario 7: Treated wood in service Fence	
PEClocalsoil (TIME 1)	2.5 mg/kg
PEClocalsoil (TIME 2)	9.8 mg/kg
PECgw max	1.3 10^{-4} mg/L
Scenario 8: Treated wood in service House	
PEClocalsoil (TIME 1)	3.0 mg/kg
PEClocalsoil (TIME 2)	11.8 mg/kg
PECgw max	1.5 10^{-4} mg/L
Scenario 9: Treated wood in service Transmission pole	
PEClocalsoil (TIME 1)	0.4 mg/kg
PEClocalsoil (TIME 2)	1.7 mg/kg
PECgw max	2.0 10^{-5} mg/L

Scenario 10: Treated wood in service fence post	
PEClocalsoil (TIME 1)	0.3 mg/kg
PEClocalsoil (TIME 2)	1.4 mg/kg
PECgw max	2.0 10^{-5} mg/L

Atmospheric Compartment Exposure assessment

	Local PEC
Dipping application	
Annual average local PEC in air	2.55E^{-7} mg/m^3
Vacuum pressure application	
Annual average local PEC in air	2.86E^{-6} mg/m^3

2.2.2.5. Risk characterization[2]

A combined LoEP has been derived for DDAC in 2015. The presented risk assessment has not been revised according to the combined LOEP. Consequently, the following data coming from read across with DDAC have not been revised on the basis of the Combined LOEP for DDAC:

- K_{oc}
- Daphnia magna
- Repeated dose toxicity to mammals

Aquatic Compartment

Scenario		PEC/PNEC values	
		Water compartment	Sewage treatment plant
Scenario 1: Dipping treatment during application		2.4	0.33
Scenario 2: Dipping treatment during storage		2.3	-
Scenario 3: Vacuum pressure treatment during application		0.7	0.12
Scenario 4: Vacuum pressure treatment during storage		1.8	-
Scenario 5: (Bridge over pond)	TIME 1	120	-
	TIME 2	0.04	-
Scenario 6: (Noise barrier)	TIME 1	2.0	0.11
	TIME 2	0.04	0.001

In aquatic compartment for all scenarios, the PEC/PNEC values are higher than 1 indicating an unacceptable risk. On the other hand, no risk is predicted for the microorganisms in sewage treatment plant. In sediment compartment for all scenarios, the PEC/PNEC values are higher than 1 indicating an unacceptable risk. For the aquatic compartment in the Noise barrier scenario the PEC/PNEC values are higher than 1 in the short-term use whilst the long-term use do not pose any risk.

Therefore, as for other PT8 CA reports, risk mitigation measures are proposed to restrict the storage of pre-treated timber to areas of impermeable hard standing so as to prevent direct exposure of the water compartment and allow the recovery of the losses for recycling or appropriate disposal. Moreover, due to the PEC/PNEC ratios higher than 1 for the aquatic compartment, it is proposed to restrict the dipping and vacuum pressure treatment allowing it only to those plants where significant losses can be contained (e.g., no drain connections to storm drains or STP) and appropriately recycled/disposed.

[2] The here presented risk assessment for the aquatic compartment has not been revised as consequence of the new PNECwater derived in 2015.

Groundwater

The PECs groundwater for the application by dipping and vacuum pressure have been compared to the limit value of 10^{-4} mg/L fixed as maximum permissible concentration of the active substance or of any other substance of concern in groundwater (directive 98/93/EC).

The PEC/PNEC ratios in groundwater are reported in the following table.

Scenario	PEC	Limit value mg/L	PEC/Limit value
Scenario 2: Storage of dipped/ immersed wood	0.00016 mg/L	0.0001	1.6
Scenario 4: Storage of vacuum-pressure-treated wood:	0.00016 mg/L		1.6
Scenario 6: Treated wood in service: Noise barrier	0.00006 mg/L		0.6
Scenario 7: Treated wood in service: Fence	0.00013 mg/L		1.3
Scenario 8: Treated wood in service: House	0.00015 mg/L		1.5
Scenario 9: Treated wood in service: Transmission pole	0.00002 mg/L		0.2
Scenario 10:Treated wood in service: Fence post	0.00002 mg/L		0.2

For scenarios 2 and 4, PEC/Limit value ratios higher than 1 are indicating a potential risk for groundwater. Anyway, in order to reduce emissions from the storage phases for aquatic compartment, the dipping and vacuum pressure treatment must be performed only by those plants where significant losses can be contained (e.g. no drain connections to storm drains or STP) and appropriately recycled/disposed.
Also for scenarios 7 and 8 PEC/Limit value ratios higher than 1 are indicating a potential risk for groundwater. However, didecylmethylpoly(oxyethyl)ammonium propionate is currently only assessed for wood preservative products in UC 1 and 2, anyway.

Terrestrial Compartment

No risk characterisation has been performed for soil because of the data gaps for effects of didecylmethylpoly(oxyethyl)ammonium propionate to terrestrial organisms. Due to the non-acceptability of the read across to DDAC data, a reliable PNECsoil cannot be calculated.

Environmental risk in the atmosphere

For the atmosphere compartment no PNEC values are available. However, for all scenarios, the PEC in air is considered to be negligible ($\leq 1 \times 10^{-5}$) suggesting that there is no concern for this compartment.

Primary and secondary poisoning (non-compartment specific effects relevant to the food chain)

Scenario	PEC/PNEC values	
	Fish-eating mammals	Fish-eating birds
Scenario 1: Dipping application	0.0571	0.1016
Scenario 2: Storage of dipping/immersed wood	0.0007	0.0012
Scenario 3: Vacuum pressure application	0.0327	0.0583
Scenario 4: Storage of Vacuum pressure treated wood	0.0036	0.0064

All PEC/PNEC values are < 1 for all scenarios, there is no concern with regard to non compartment specific effects relevant to the food chain (secondary poisoning via aquatic food chain).

2.2.3. Assessment of endocrine disruptor properties

Based on available experimental results, there is no indication that didecylmethylpoly(oxyethyl)ammonium propionate affects the endocrine system. Structural characteristics and SAR do not hint to possible effects of didecylmethylpoly(oxyethyl)ammonium propionate as endocrine disruptor.

2.3. Overall conclusions

The outcome of the assessment for didecylmethylpoly(oxyethyl)ammonium propionate in product-type PT8 is specified in the BPC opinion following discussions at the BPC13 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2.4. List of endpoints

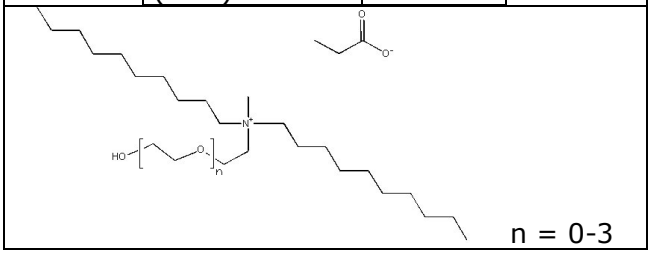
The most important endpoints, as identified during the evaluation process, are listed in Appendix I.

Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Name)	Not available. No EINECS/ELINCS name is available for didecylmethylpoly(oxyethyl)ammonium propionate, either
Product-type	PT 8

Identity

Chemical name (IUPAC)	alpha.-[2-(Didecylmethylammonio)ethyl]-.omega.-hydroxy-poly(oxy-1,2-ethanediyl) propionate **(*)**
Chemical name (CA)	Poly(oxy-1,2-ethanediyl), .alpha.-[2-(didecylmethylammonio)ethyl]-.omega.-hydroxy-, propanoate **(*)**
CAS No	94667-33-1 **(*)**
EC No	None assigned
Other substance No.	[redacted] (Company code) [redacted] (Company code)
Minimum purity of the active substance as manufactured (g/kg or g/l)	≥861 g/kg dry weight (>605 g/kg wet weight)
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	$C_{26}H_{55}NO_3(C_2H_4O)_n$ where n = 0−3
Molecular mass	No. of oxyethyl moieties / Individual MW: Monomer (n=0): 429.726 Dimer (n=1): 473.779 Trimer (n=2): 517.832 Tetramer (n=3): 561.885
Structural formula	

(*) At TMIII09 the applicant explained that the degree of ethoxylation was formerly thought to be higher than it is in reality. The provided identifiers do not give any indication for 'n'. Although the degree of ethoxylation is neither defined by the CAS entry nor by the common name and the chemical name, according to the information given by the applicant this AR covers only an active substance with the following constituents:

n = 0	N,N-didecyl-N-(2-hydroxyethyl)-N-methylammonium propionate	C3H5O2.C23H50NO (CAS 107879-22-1)	77.5-86.3% w/w dry weight (absolute)
n = 1	N,N-didecyl-N-(2-(2-hydroxyethoxy)ethyl)-N-methylammonium propionate	C3H5O2.C25H54NO2 (CAS nya)	4.7-9.0% w/w dry weight (absolute)
n = 2	N,N-didecyl-N-(2-(2-(2-hydroxyethoxy)ethoxy)ethyl)-N-methylammonium propionate	C3H5O2.C27H58NO3 (CAS nya)	≤0.20% w/w dry weight (absolute)

Physical and chemical properties

Melting point (state purity)	No freezing point down to −50 °C (93.5% w/w)
Boiling point (state purity)	180 – 195 °C (93.5% w/w)
Thermal stability / Temperature of decomposition	Thermally stable. No decomposition nor chemical transformation observed below 150°C
Appearance (state purity)	Yellow weakly aromatic liquid (93.5% w/w)
Relative density (state purity)	D_4^{20} = 0.942 (93.5% w/w)
Surface tension (state temperature and concentration of the test solution)	30.5 mN/m (1 g/l aqueous solution)
Vapour pressure (in Pa, state temperature)	1.8E−06 Pa at 20°C 4.0E−06 Pa at 25°C
Henry's law constant (Pa m^3 mol^{-1})	3.03E−11 Pa m^3 mol^{-1} (monomer) 4.72E−13 Pa m^3 mol^{-1} (dimer)
Solubility in water (g/l or mg/l, state temperature)	Completely miscible in the pH-range from 5 to 9 at room temperature (solubility ≈ 1000 g/L)
Solubility in organic solvents (in g/l or mg/l, state temperature)	Ethanediol: > 250 g/l at *ca.* 20°C
	Octanol: > 250 g/l at *ca.* 20°C
Stability in organic solvents used in biocidal products including relevant breakdown products	In biocidal products, didecylmethylpoly(oxyethyl) ammonium propionate is not formulated in organic solvents other than its process solvents. The a.s. proved to be stable in its process solvents for at least 2 years (based on storage stability of technical concentrate Bardap 26 and experience in use).
Partition coefficient (log P_{OW}) (state temperature)	Not determined. EC methods A.8 are not applicable for surface-active substances. Assessment by KOWWIN is inaccurate (software database very limited for surfactants). log P_{OW} could be roughly obtained from solubility in pure n-octanol and water (log P_{OW} ≈ 0). However, this calculation is of no use with regard to environmental fate & behaviour and secondary poisoning risk (experimental BCF_{fish} available from structurally-related DDAC).
Dissociation constant	Not applicable. The a.s. is fully dissociated in water

UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	No significant absorption
Photostability (DT_{50}) (aqueous, sunlight, state pH)	Photolytically stable in absence of a photosensitising agent (read across from DDAC). DT_{50} = 227 days (light, exposed) and 427 days (dark, exposed)
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not available
Flammability or flash point	Not flammable (flash point = 134 °C)
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Auto-ignition or relative self ignition temperature	264 °C

Classification and proposed labelling

According to Reg. EC 1272/2008 with amendments:

with regard to physical hazards	No classification
Signal Word	Danger
with regard to human health hazards	GHS05 H302: Harmful if swallowed H314: Causes severe skin burns and eye damage
with regard to environmental hazards	GHS09 H410: Very toxic to aquatic life with long lasting effects M factor=10

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	HPLC/MS
Impurities in technical active substance (principle of method)	HPLC/MS GC/FID HPLC/UV (250 nm) Karl Fischer titration

Analytical methods for residues

Soil (principle of method and LOQ)	Extraction with methanol: water (90:10, v/v) containing 0.01 M ammonium formate and 0.1% formic acid. LC-MS (m/z = 356.2 for the monomer). LOQ (total didecylmethylpoly(oxyethyl) ammonium propionate) = 0.01 mg/kg. Highly-specific confirmatory method down to 0.01 mg/kg as total didecylmethylpoly (oxyethyl)ammonium propionate. Extraction with acetonitrile: water (9:1, v/v), ammonium formate and 0.1% formic acid. Ultra-sonication and centrifugation. The combined extracts are mixed with water prior to analysis by UHPLC-MS/MS. Mass transitions: 356 → 216 (quantification) 356 → 76 (confirmation)
Air (principle of method and LOQ)	Not required. The a.s. is non-volatile and will not be used in spray application.
Water (principle of method and LOQ)	Extraction by liquid-liquid partition with 0.01 M heptanesulfonic acid and dichloromethane. Concentration by rotary evaporation and reconstitution in 0.1% formic acid in methanol. LC-MS (m/z = 356.2 for the monomer). LOQ (total didecylmethylpoly(oxyethyl) ammonium propionate) = 0.1 µg/l. Highly-specific confirmatory method down to 0.1 µg/l as total didecylmethylpoly(oxyethyl) ammonium propionate. Extraction with ethyl acetate. Evaporation and reconstitution in methanol/water (50:50, v/v). Analysis by UHPLC-MS/MS. Mass transitions: 356 → 216 (quantification) 356 → 76 (confirmation)
Body fluids and tissues (principle of method and LOQ)	Not required. The a.s. is neither toxic nor highly toxic

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required. Wood treated with didecylmethylpoly(oxyethyl)ammonium propionate-containing biocidal product is not intended for and contains label restrictions against use in areas where food for human consumption is prepared, consumed or stored, or where the feedingstuff for livestock is prepared, consumed or stored
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required. Wood treated with didecylmethylpoly(oxyethyl)ammonium propionate-containing biocidal product is not intended for and contains label restrictions against use in areas where food for human consumption is prepared, consumed or stored, or where the feedingstuff for livestock is prepared, consumed or stored

Chapter 3:Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Based on data on DDAC, and on the highly ionic nature of the a.s., it is expected that its oral absorption is limited (around 10%) and that the majority (90%) of orally administered a.s. is excreted unabsorbed via the faeces. Oral absorption: 10% at non-corrosive concentrations
Rate and extent of dermal absorption*:	Data on ^{14}C-DDAC dissolved in water. The total dermal absorption is evaluated around 10% at non-corrosive concentrations. This value of 10% is appropriate for the representative product.
Distribution:	Following DDAC oral administration, tissue residues were less than 1%.
Potential for accumulation:	None.
Rate and extent of excretion:	Following DDAC oral administration in rats: 89 – 99% excreted in faeces, 2.5% excreted in urine.
Toxicologically significant metabolite(s)	None

Acute toxicity

Rat LD_{50} oral	662 mg/kg bw
Rat LD_{50} dermal	3342 mg/kg bw (data on DDAC)
Rat LC_{50} inhalation	Study not conducted - not required

Skin corrosion/irritation	Corrosive
Eye irritation	Corrosive
Respiratory tract irritation	Study not available - estimated to be irritant on the basis of its mode of action
Skin sensitisation (test method used and result)	Buehler test - not sensitizing
Respiratory sensitisation (test method used and result)	Study not available - estimated to be not sensitizing

Repeated dose toxicity

Short term

Species / target / critical effect	Any species/ g.i. mucosa/ irritation at site of contact and reduced body weight
Relevant oral NOAEL / LOAEL	No study available
Relevant dermal NOAEL / LOAEL	Data on DDAC (short term skin irritation study on rats) NOAEC =0.6% DDAC in water at 2.0 mL/kg body weight per day after 5 days applications NOAEC =0.3% after 2-week treatment
Relevant inhalation NOAEL / LOAEL	Study not conducted - not required

Subchronic

Species/ target / critical effect	Any species/ g.i. mucosa/ irritation at site of contact and reduced body weight (systemic effects secondary to irritation)
Relevant oral NOAEL / LOAEL	NOEL = 90 mg/kg/day (rat –90 days feeding study) Data on didecylmethylpoly(oxyethyl) ammonium propionate Based on data on DDAC (1 year dog): NOEL for local effects = 3 mg/kg bw/day NOEL for systemic effects = 10 mg/kg bw/day
Relevant dermal NOAEL / LOAEL	Based on data on DDAC (90-day dermal rats) NOAEL for systemic effects = 12 mg/kg bw NOAEL for local effects = 2 mg/kg bw/d
Relevant inhalation NOAEL / LOAEL	No study available. Expected to be irritant/corrosive.

Long term

Species/ target / critical effect	Any species/ g.i. mucosa/ irritation of g.i. mucosa and reduced body weight (systemic effects secondary to irritation)
Relevant oral NOAEL / LOAEL	Data on DDAC: Non-neoplastic effects NOAEL: 27 mg/kg/day (2 y rat) The endpoint has been revised on the basis of the Combined LOEP for DDAC
Relevant dermal NOAEL / LOAEL	No study available
Relevant inhalation NOAEL / LOAEL	No study available. Expected to be irritant.

Genotoxicity	In-vitro: In vitro gene mutation study in bacteria – negative (with and without metabolic activation) Chromosomal aberration test – negative (with and without metabolic activation) Mouse lymphoma assay – negative (with and without metabolic activation) In-vivo: Cytogenetic assay – negative

Carcinogenicity	
Species/type of tumour	Rat/none, Mouse/none (DDAC)
Relevant NOAEL/LOAEL	None The carcinogenicity is negative.

Reproductive toxicity	
Developmental toxicity	
Species/ Developmental target / critical effect	Rat: maternal toxicity/ audible breathing Developmental toxicity: no effect at highest dose tested. Rabbit/maternal toxicity/audible breathing, hypoactivity; 25% lethality at top dose. Developmental toxicity/increased incidence of dead litters (secondary to maternal lethality), reduced fetal weight (read-across from DDAC)
Relevant maternal NOAEL	Lowest NOAEL for maternal toxicity (local effects) in rats, not considered relevant for systemic toxicity: 0.8 mg/kg bw
Relevant developmental NOAEL	Prenatal toxicity only seen in rabbits, clearly secondary to maternal effects: NOAEL 12 mg/kg bw The endpoint has been revised on the basis of the Combined LOEP for DDAC
Fertility	
Species/critical effect	Rat/ Reduced body weights in adults and F1/F2 offspring (read across from DDAC)
Relevant parental NOAEL	> 608 mg/kg food, corresponding to ≥ 30 mg/kg bw The endpoint has been revised on the basis of the Combined LOEP for DDAC
Relevant offspring NOAEL	608 mg/kg food, corresponding to ≥ 30 mg/kg bw The endpoint has been revised on the basis of the Combined LOEP for DDAC
Relevant fertility NOAEL	No specific potential for reproductive toxicity, overall NOAEL (parental effects) at least 31 mg/kg bw/d (608mg/kg feed) The endpoint has been revised on the basis of the Combined LOEP for DDAC

Neurotoxicity

Species/ target/critical effect	Study not conducted - not required

Developmental Neurotoxicity

Species/ target/critical effect	No effects identified based on the available studies

Immunotoxicity

Species/ target/critical effect	Study not conducted - not required

Developmental Immunotoxicity

Species/ target/critical effect	No effects identified based on the available studies

Other toxicological studies

None

Medical data

No specific effects have been reported.

Summary for Local effects

	Value	Study
Dermal NOAEC	0.3%	2-week skin irritation study with rats
Oral NOAEC	0.03%	52-week oral gavage study in dogs

Summary for systemic effects

	Value	Study	Safety factor
$AEL_{long\text{-}term}$	Not relevant		
$AEL_{medium\text{-}term}$	Not relevant		
$AEL_{short\text{-}term}$	Not relevant		
ADI[3]	Not applicable	-----	-----
ARfD	Not applicable		

MRLs

Relevant commodities	Not applicable

Reference value for groundwater

According to BPR Annex VI, point 68	0.1 µg/L (EU drinking water limit)

Dermal absorption

Study (*in vitro/vivo*), species tested	*In vitro* on human skin
Formulation (formulation type and including concentration(s) tested, vehicle)	≈0.1% of a DDAC delivered as aqueous solution fully penetrated human skin *in vitro* in 24
Dermal absorption values	10% (9.41 % rounded to 10%)

Acceptable exposure scenarios for systemic effects (including method of calculation)

Formulation of biocidal product	Not applicable
Intended uses	
Industrial users/ Professional users	Not relevant

[3] If residues in food or feed.

Non-professional users	Not relevant
General public	Not relevant
Exposure via residue in food	Not applicable

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	Hydrolytically stable
pH 5	n.a.
pH 9	pH 9: >1 year at 25°C
Other pH: pH 4 pH 7	pH 4: >1 year at 25°C pH 7: >1 year at 25°C
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	No data available
Readily biodegradable (yes/no)	No
Inherent biodegradable (yes/no)	No data available
Biodegradation in freshwater	No data available
Biodegradation in seawater	No data available
Non-extractable residues	No data available
Distribution in water / sediment systems (active substance)	Aerobic Transformation in water/sediment OECD 308. DT_{50} = 45.9 d (1WS Pfalz) DT_{50} =24.6 d (2WS Weißach) Total system
Distribution in water / sediment systems (metabolites)	No data available

Route and rate of degradation in soil

Mineralization (aerobic)	No data available
Laboratory studies (range or median, with number of measurements, with regression coefficient)	Aerobic Transformation in Soil OECD 307.
DT_{50lab} (20°C, aerobic):	DT50 (20°C, aerobic): 11.8 – 56.9 d (SFO)
DT_{90lab} (20°C, aerobic):	No data available
DT_{50lab} (10°C, aerobic):	DT50 (12°C, aerobic): 31.1 d
DT_{50lab} (20°C, anaerobic):	No data available
degradation in the saturated zone:	No data available
Field studies (state location, range or median with number of measurements)	No data available
DT_{50f}:	No data available
DT_{90f}:	No data available
Anaerobic degradation	No data available
Soil photolysis	No data available
Non-extractable residues	No data available
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	No data available
Soil accumulation and plateau concentration	No data available

Adsorption/desorption

Ka , Kd	Ka = 1095 L/kg, Kd = 591 L/kg (Sand) Ka = 8179 L/kg, Kd = 2074 L/kg (Sandy loam) Ka = 32791 L/kg, Kd = 8309 L/kg (Silt clay loam) Ka = 30851 L/kg, Kd = 7714 L/kg (Silt loam)
Ka_{oc} , Kd_{oc}	Ka_{oc} = 437805 L/kg, Kd_{oc} = 236473 L/kg (Sand) Ka_{oc} = 908757 L/kg, Kd_{oc} = 230498 L/kg (Sandy loam) Ka_{oc} = 1599564 L/kg, Kd_{oc} = 405328 L/kg (Silty clay loam) Ka_{oc} = 1469081 L/kg, Kd_{oc} = 367334 L/kg (Silty loam) K_{oc} mean: 1103801 L/kg
pH dependence (yes / no) (if yes type of dependence)	No The K_{oc} value is 562314 L/kg. The endpoint has been revised on the basis of the Combined LOEP for DDAC

Fate and behaviour in air

Direct photolysis in air	Atmospheric t½ = 0.346 days (8.314 hours) (AOPWIN)
Quantum yield of direct photolysis	Not specified
Photo-oxidative degradation in air	Latitude: ..... Season: ..... DT_{50} .....
Volatilization	Not volatile [vapour pressure 1.8 x 10^{-6} Pa at 50°C]

Reference value for groundwater

According to BPR Annex VI, point 68	0.1 µg/L (EU drinking water limit)
Monitoring data, if available	
Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study)	No data available
Ground water (indicate location and type of study)	No data available
Air (indicate location and type of study)	No data available

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity (mg a.s./L)
Fish			
Bluegill (*Lepomis macrochirus*)	96 h	Mortality	LC_{50} 0.52 (flow through, measured)
Zebra fish (*Brachydanio rerio*)	34 d	Growth	NOEC 0.032 Intermittent flow through, measured. Read across from DDAC)
Invertebrates			
Daphnia magna	48 h	Immobilisation	EC_{50} 0.07 (semistatic, measured)
Daphnia magna	21 d	Reproduction	NOEC 0.014 (flow through, measured. Read across from DDAC data) The endpoint has been revised on the basis of the Combined LOEP for DDAC
Daphnia magna	21 d	Reproduction	NOEC 185 µg/L (measured, semi static, dose response)
Chironomus tentans	28d	Mortality and growth	No data available
Algae			
Scenedesmus subspicatus	72 h	Growth rate	E_rC_{50} 0.34 NOE_rC 0.044 (static, measured)
Microorganisms			
Activated sewage sludge	3 h	Respiration inhibition	EC_{50} 16.8 (nominal)

Effects on earthworms or other soil non-target organisms

Acute toxicity to *Eisenia foetida*	14d LC_{50} 4390 mg/kg dw, in artificial soil (nominal)
Reproductive toxicity to plants	No data available
Reproductive toxicity to ……	No data available

Effects on soil micro-organisms

Nitrogen mineralization	No data available
Carbon mineralization	No data available

Effects on terrestrial vertebrates

Acute toxicity to mammals	LD_{50} 662 mg/kg bw (rat, oral)
Repeated dose toxicity to mammals	NOEC = 486 mg a.s./kg food (90d, dog) (Read across from DDAC data) The endpoint has been revised on the basis of the Combined LOEP for DDAC
Acute toxicity to birds	Northern bobwhite quail LD_{50} = 226 mg a.s./kg bw
Dietary toxicity to birds	Mallard duck 5d LC_{50} >1633 mg a.s./kg food (Read across from DDAC data)
Reproductive toxicity to birds	No data available

Effects on honeybees

Acute oral toxicity	Not required
Acute contact toxicity	Not required

Effects on other beneficial arthropods

Acute oral toxicity	Not required
Acute contact toxicity	Not required
Acute toxicity to ……..	Not required

Bioconcentration

Bioconcentration factor (BCF)	Read across from DDAC data: Measured $BCF_{fish\ whole\ body}$ = 81 L/kg $BCF_{earthworm}$ not available
Depration time (DT_{50})	7-14 d for the whole body
Depration time (DT_{90})	No data available
Level of metabolites (%) in organisms accounting for > 10 % of residues	No data available

Chapter 6: Other End Points

Appendix II: List of Intended Uses

Object and/or situation	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks
			Type	Conc. of a.s.	method kind	number min max	interval between applications (min)	g a.s./L min max	water L/m² min max	g a.s./m² min max	
CLAIM: Didecylmethylpoly (oxyethyl)ammonium propionate is a cationic surfactant and reacts strongly with cell walls of micro-organisms. Under PT 8 (wood preservative), it acts as a fungistatic and an insecticide, by control of wood destroying organisms, discolouring moulds and fungi and insects. The representative product [redacted] is an aqueous solution containing 8.4 % of didecylmethylpoly (oxyethyl)ammonium propionate. Objects to be protected: Wood,	[redacted]	Wood destroying basidiomycetes *Coniophora puteana/ Coniophora spec Coriolus versicolor Gloephyllum trabeum Poria vaillantii/ Poria spec Fomes spec Trametes spec* Wood staining molds *Aureobasidium pullulans Sclerophoma pityopila Ophistostoma piliferum Aspergillus niger Aspergillus terreus Chaetomium globosum Paecilomyces variotii Penicillium funicolosum Trichoderma viridae* Wood boring insects *Hylotrupes bajulus*	Aqueous solution under PT8	8.4 % didecylmethylpoly (oxyethyl)ammonium propionate The use concentration depends on the type of application technique, use class required and on additional formulation components.	Dipping and vacuum pressure processes	Number and timing of applications depend on application technique, wood species, moisture and hazard class.	--	-- The requirements for the final concentration of didecylmethylpoly(oxyethyl)ammonium propionate vary from 0.1% to 0.7%.	--	-- Uptakes of 3 to 6 kg/m³ of product occur during pressure treatment; 6 kg/m³ corresponds to 0.5 kg a.i./m³. The uptake of 40 g/m² is reached during dipping treatment; 40 g/m² corresponds to 6 kg/m³ of product or 0.5 kg a.i./m³ using a	Used for preventive protection of wood and constructional timbers. The fungicidal effect depends on didecylmethylpoly (oxyethyl) ammonium propionate (and copper as co-biocide). The insecticidal effect depends on didecylmethylpoly(oxyethyl)ammonium

Object and/or situation	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks
			Type	Conc. of a.s.	method kind	number min max	interval between applications (min)	g a.s./L min max	water L/m^2 min max	g a.s./m^2 min max	
use classes 1 to 4A according to ISO draft standard as reported in the ESD (EN 335-2013). USERS: industrial/ professional		*Anobium punctatum* *Lyctus brunneus* Termites								conversion factor of 150 based on the assumption that 1 m^3 has an area of 150 m^2.	propionate.

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 60 of Regulation (EU) No 528/2012.

List of studies for Active Substance (Doc. IIIA)

Section No	Author	Year	Title	Data Protected	Owner
4.1(1)	Anonymous	1990	International Standard ISO 2871-2:1990 (E). Surface active agents – Detergents – Determination of cationic-active matter content – Part 2: Cationic-active matter of low molecular mass (between 200 and 500).	No	Public Data
6.1.5 (1)	[redacted]	1994	[redacted] Buehler delayed contact hypersensitivity study in the guinea pig. [redacted] (Unpublished).	Yes	LONZA
7.1.1.2.1 (1)	[redacted]	2004	Report No. LZA/246. [redacted] (Unpublished).	Yes	LONZA
3.11 (1)	[redacted]	2004	Didecylmethylpoly(oxymethyl)ammonium Propionate Bardap 26 AS Auto ignition temperature (liquids and gases). [redacted] (Unpublished).	Yes	LONZA
3.4.1 (2)	[redacted]	2001	Investigation of [redacted] with 13C-NMR spectroscopy. [redacted] (Unpublished).	Yes	LONZA

4.2c (1)	[redacted]	2003	Didecylmethylpoly(oxymethyl)ammonium Propionate Validation of methodology for the determination of residues in drinking, ground and surface water. [redacted] (Unpublished).	Yes	LONZA
4.2a (1)	[redacted]	2003	Didecylmethylpoly(oxymethyl)ammonium Propionate Validation of methodology for the determination of residues in soil. [redacted] (Unpublished).	Yes	LONZA
7.1.2.1.1 (1)	[redacted]	1989	Evaluation of biodegradability of Bardap 26 (Disinfectant QAV) in the OECD-Confirmatory-Test. [redacted] (Unpublished).	Yes	LONZA
7.1.1.2.1 (2)	[redacted]	2001	Bardap 26 (LZ1524.1): Assessment of ready biodegradability; CO2 evolution test. [redacted] (Unpublished).	Yes	LONZA
7.4.1.4 (1)	[redacted]	2001	Bardap 26 (LZ1524.1): Assessment of the inhibitory effect on the respiration of activated sewage sludge. [redacted] (Unpublished)	Yes	LONZA

7.1.1.1.1 (1)	[redacted]	2001	Determination of abiotic degradation, hydrolysis as a function of pH. [redacted] [redacted] (Unpublished)	Yes	LONZA
7.2.3.1 (1)	[redacted]	1989	Soil/Sediment Adsorption-Desorption of 14C-Didecyldimethylammonium Chloride (DDAC). [redacted] [redacted] (Unpublished)	Yes	LONZA
7.4.1.1 (2)	[redacted]	2001	A 96 hour flow-through acute toxicity test with the bluegill (Lepomis macrochirus). Report No. 289A-154 Wildlife International Ltd. (Unpublished)	Yes	LONZA
6.6.4 (1)	[redacted]	1994	Chromosome aberration test in rat bone marrow in vivo. [redacted] [redacted] (Unpublished)	Yes	LONZA
7.1.1.1.2 (2)	[redacted]	1989	Determination of the Photolysis Rate of Didecyldimethylammonium Chloride (DDAC) in pH 7 Buffered Solution at 25 °C. [redacted] [redacted] (Unpublished)	Yes	DDAC ISC

7.4.3.5.1 (1)	[redacted]	1995	Chronic Toxicity of Sediment-Incorporated Didecyldimethylammonium Chloride (DDAC) to Chironomus tentans. [redacted] [redacted] (Unpublished)	Yes	DDAC ISC
7.4.3.3.1 (1)	[redacted]	1990	Bioconcentration and Elimination of 14C-residues by Bluegill (Lepomis machrochirus) exposed to Didecyldimethylammonium Chloride (DDAC). [redacted] [redacted] (Unpublished)	Yes	DDAC ISC
3.2 (1)	[redacted]	2002	Vapour Pressure [redacted] AS (Bardap 26 AS) [redacted] [redacted] (Unpublished)	Yes	LONZA
7.5.3.1.1 (1)	[redacted]	2001	Bardap 26: An acute oral toxicity study with the northern bobwhite. [redacted] [redacted] (Unpublished)	Yes	LONZA
6.4.2	[redacted]	1988	Ninety-day subchronic dermal toxicity study with Didecyldimethylammonium Chloride in rats. [redacted] [redacted] (Unpublished)	Yes	DDAC ISC

6.5 (2) 6.7 (2)	[redacted]	1991	Chronic dietary toxicity/oncogenicity study with Didecyldimethylammonium Chloride in rats. [redacted] (Unpublished)	Yes	DDAC ISC
6.7 (1)	[redacted]	1991	Chronic dietary oncogenicity study with Didecyldimethylammonium Chloride in mice. [redacted] (Unpublished)	Yes	DDAC ISC
7.5.1.3 (1)	[redacted]	2004	N,N-Didecyl-N,N-Dimethylammonium Chloride (DDAC) - Acute Toxicity to Terrestrial Plants. [redacted] (Unpublished)	Yes	DDAC ISC
7.5.1.1 (1)	[redacted]	2001	The assessment of the ecological effects of Didecyldimethylammonium Chloride (Guidelines OPPTS 850.5100 Soil Microbial Community Test, OECD 216 and OECD 217 and CTB section H.4.1). [redacted] (Unpublished)	Yes	DDAC ISC
6.1.4 (3)	[redacted]	1985	Hoe S 3519: Prüfung aug Augenreizung am Kaninchen. [redacted] (Unpublished)	Yes	LONZA

6.1.4 (2)	[redacted]	1985	Hoe S 3519: Prűfung auf Hautreizung am Kaninchen. [redacted] (Unpublished)	Yes	LONZA
7.4.3.4 (1)	[redacted]	2001	Intermittent Flow Through Reproduction Test with Didecyldimethylammonium Chloride and Daphnia magna. [redacted] (Unpublished)	Yes	DDAC ISC
7.4.3.2 (1)	[redacted]	2001	Early Life Stage Test under intermittent flow-thorugh conditions with Didecyldimethylammonium Chloride and the fish species, Brachydanio rerio (OECD Guideline No. 210). [redacted] [redacted])	Yes	DDAC ISC
4.1 (2)	[redacted]	2004	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate – Screening by Ion Chromatography. [redacted] (Unpublished)	Yes	LONZA
5.3.1	[redacted]	1966	Bacteriostatic, Fungistatic and Algistatic Activity of Fatty Nitrogen Compounds. [redacted]	No	Public Data

6.6.1 (1)	[redacted]	1986	[redacted] Study of the mutagentic potential in strains of Salmonella typimurium (Ames test) and E.coli. [redacted] (Unpublished)	Yes	LONZA
3.8	[redacted]	2000	Stability of Bardap 26 at 20°C, Lot No.1063366850. [redacted] (Unpublished).	Yes	LONZA
5.3.1	[redacted]	1970	Straight-Chain Alkylammonium Compounds. In "Cationic Surfactants" ed. J. Jungermann. [redacted]	No	Public Data
7.5.3.1.2 (1)	[redacted]	1991	Didecyldimethylammonium Chloride: A Dietary LC_{50} Study with the Northern Bobwhite. [redacted] (Unpublished).	Yes	DDAC ISC
7.5.3.1.2(2)	[redacted]	1991	Didecyldimethylammonium Chloride: A Dietary LC_{50} Study with the Mallard. [redacted] (Unpublished).	Yes	DDAC ISC

4.2_01 (ADDENDUM IIIA_Sec 4)	[redacted]	2016	Validation of an Analytical Method for the Determination of Bardap 26 in Soil. [redacted] [redacted] (Unpublished).	Yes	LONZA AG
4.2_03 (ADDENDUM IIIA_Sec 4)	[redacted]	2016	Validation of an Analytical Method for the Determination of Bardap 26 in Drinking Water and Surface Water. [redacted] [redacted] (Unpublished).	Yes	LONZA AG
5.7.1	[redacted]	2004	Effects of quaternary-ammonium-based formulations on bacterial community dynamics and antimicrobial susceptibility. [redacted]	No	Public Data
7.4.1.3 (1)	[redacted]	2001	Bardap 26: Algal Inhibition test. [redacted] (Unpublished)	Yes	LONZA
6.1.1 (1)	[redacted]	2001	Acute oral toxicity test with Bardap 26. [redacted] [redacted] (Unpublished)	Yes	LONZA

6.1.4 (1)	[redacted]	2001	Primary skin irritation test with Bardap 26. [redacted] (Unpublished)	Yes	LONZA
6.8.2 (1)	[redacted]	1991	Two-generation reproduction study in Sprague-Dawley (CD) rats with Didecyldimethylammonium Chloride administered in the diet. [redacted] (Unpublished)	Yes	DDAC ISC
6.8.1 (1)	[redacted]	1991	Developmental toxicity evaluation of Didecyldimethylammonium Chloride administered by gavage to CDÒ (Sprague-Dawley) rats. [redacted] (Unpublished)	Yes	DDAC ISC
6.4.1 (2)	[redacted]	1990	Subchronic oral toxicity study of Didecyldimethylammonium Chloride in dogs. [redacted] (Unpublished)	Yes	DDAC ISC
3.2.1	[redacted]	2006	Bardap 26. QSAR Estimation of Henry's Law Constant. [redacted] (Unpublished)	Yes	LONZA

4.2 (1)	[redacted]	2014	Preliminary Analysis of Bardap 26 AMENDED [redacted] (Unpublished)	Yes	LONZA
4.2 (2)	[redacted]	2015	Preliminary Analysis of Bardap26 [redacted] (Unpublished)	Yes	LONZA
7.5.1.2 (1)	[redacted]	2003	Didecylmethylpoly(oxymethyl)ammonium Propionate (Bardap 26) Acute Toxicity (LC_{50}) to the Earthworm. [redacted] (Unpublished)	Yes	LONZA
7.5.1.2 (2)	[redacted]	2003	Didecylmethylpoly(oxymethyl)ammonium Propionate (Bardap 26) Acute Toxicity (LC_{50}) to the Earthworm. [redacted] (Unpublished)	Yes	LONZA
6.2 (1)	[redacted]	2001	The In Vitro Percutaneous Absorption of [14C]-Didecyldimethylammonium Chloride (DDAC) Through Human Skin. [redacted] (Unpublished)	Yes	DDAC ISC

7.1.2.1.1 (2)	[redacted]	2001	Didecyldimethylammonium Chloride (DDAC): Dieaway in Activated Sludge. [redacted] (Unpublished)	Yes	DDAC ISC
3.1.2 (1)	[redacted]	2002	Determination of the Boiling Temperature of Bardap 26 AS/[redacted] AS. [redacted] (Unpublished)	Yes	LONZA
3.1.1 (1)	[redacted]	2002	Determination of the Freezing Temperature of Bardap 26 AS/[redacted] AS. [redacted] (Unpublished)	Yes	LONZA
3.1.3 (1)	[redacted]	2002	Determination of the Relative Density of Bardap 26 [redacted] AS. [redacted] (Unpublished)	Yes	LONZA
3.5 (1)	[redacted]	2002	Determination of the Water Solubility of Bardap 26 [redacted] (Unpublished)	Yes	LONZA
6.5 (1)	[redacted]	1991	Chronic oral toxicity study of Didecyldimethylammonium Chloride in dogs. [redacted] (Unpublished).	Yes	DDAC ISC

6.2 (2)	[redacted]	1989	Absorption, Distribution, Metabolism and Excretion Studies of Didecyldimethylammonium Chloride (DDAC) in the Rat. [redacted] (Unpublished)	Yes	DDAC ISC
6.1.2 (1)	[redacted]	1987	Acute Dermal Toxicity Study in Rabbits LD_{50} Test (EPA), Test article DMD10AC. [redacted] (Unpublished)	Yes	DDAC ISC
3.4.1 (1)	[redacted]	2001	Bardap 26-Spectral data for biocidal products directive. [redacted] (Unpublished)	Yes	LONZA
3.13(1) 3.14(2)	[redacted]	2006	Bardap 26 AS. Physicochemical Properties. [redacted] (Unpublished)	Yes	LONZA
6.4.1 (1)	[redacted]	1999	SPL project no. 102/274. [redacted] (Unpublished)	Yes	LONZA
6.8.1 (2)	[redacted]	1989	Developmental toxicity study of Didecyldimethylammonium Chloride administered by gavage to New Zealand white rabbits. [redacted] (Unpublished)	Yes	DDAC ISC

7.1.1.2.2 (1) 7.4.1.4 (2)	[redacted]	1996	Untersuchung auf Bakterienschädlichkeit Sauerstoff - Zehrungs - Hemmtest. [redacted] (Unpublished)	Yes	LONZA
7.4.1.1 (1)	[redacted]	2001	Acute toxicity to common carp Cyprinus carpio. [redacted] (Unpublished)	Yes	LONZA
7.4.1.2 (1)	[redacted]	2001	Bardap 26: Acute toxicity to Daphnia Magna. [redacted] (Unpublished)	Yes	LONZA
6.6.3 (2)	[redacted]	2001	Bardap 26 [redacted]: L5178Y TK+/- mouse lymphoma assay. [redacted] (Unpublished)	Yes	LONZA
6.6.2 (1)	[redacted]	2002	Bardap 26 [redacted]: Chromosome aberration test in human lymphocytes in vitro. [redacted] (Unpublished)	Yes	LONZA
3.12 (1)	[redacted]	2003	Didecylmethylpoly(oxyethyl)ammonium propionate (Bardap 26 AS) Flash Point. [redacted] (Unpublished)	Yes	LONZA

3.7 (1)	[redacted]	2003	Didecylmethylpoly(oxyethyl)ammonium propionate (Bardap 26 AS) Solubility in Ethanediol and Octanol. [redacted] (Unpublished)	Yes	LONZA
3.14 (1)	[redacted]	2004	Didecylmethylpoly(oxyethyl)ammonium propionate (Bardap 26 AS) Viscosity. [redacted] (Unpublished)	Yes	LONZA
7.1.2.2.2		2017 - 2019	[N-methyl-14C] Bardap 26 Aerobic Degradation and Metabolism in two Water/Sediment Systems, [redacted] Schwarzkopf A – Report amendment	Yes	LONZA
7.1.2.2.2		2019 b	Bardap 26 – Kinetic Modelling Evaluation of Data from a Water Sediment Study for Persistence Endpoints at Level PI. [redacted]	Yes	LONZA
7.1.2.2.2		2019 c	Bardap 26 – Summary of Soil and Aquatic System Degradation Data in a Regulatory Context. [redacted]	Yes	LONZA
7.2.2.1		2017 - 2019	[N-methyl-14C]Bardap 26 Aerobic Degradation and Metabolism in four Soils at 20 °C in the Dark [redacted] Schwarzkopf A – Report amendment	Yes	LONZA

7.2.2.1		2019 b	Bardap 26 – Kinetic Modelling and Evaluation of Data from Laboratory Aerobic Soil Degradation Studies for Persistence Endpoints. [redacted]	Yes	LONZA
7.4.3.4		2016 - 2017	Bardap 26 – Toxicity to the water flea Daphnia magna Straus under laboratory conditions. [redacted] [redacted] – Report amendment	Yes	LONZA

List of studies for Biocidal Product (Doc. IIIB)

Section No	Author	Year	Title	Data Protected	Owner
3.2 (1)	[redacted]	2004	Explosive properties of [redacted] Document No.: [redacted] (Unpublished)	Yes	LONZA
3.4 (1) 3.5 (1) 3.6 (1) 3.7 (1) 3.10.1 (1) 3.10.2 (2)	[redacted]	2004	Determinations of physical-chemical properties of the test item [redacted]. Study [redacted] (Unpublished)	Yes	LONZA
3.8 (2) 3.10.2 (1)	[redacted]	2005	Determination of the viscosity and the persistent foaming of the test item [redacted] (Unpublished)	Yes	LONZA

5.10.2	[redacted]	1994	Efficacy test report according EN 113. [redacted]	Yes	LONZA
5.10.2	[redacted]	2003	Efficacy test report on fungus cellar testing. [redacted]	Yes	LONZA
5.10.2	[redacted]	1966	Bacteriostatic, Fungistatic and Algistatic Activity of Fatty Nitrogen Compounds. [redacted]	No	Public Data
5.10.2	[redacted]	1970	Straight-Chain Alkylammonium Compounds. In "Cationic Surfactants" [redacted]	No	Public Data
5.10.2	[redacted]	1995	Efficacy test report according ENV 807. [redacted]	Yes	LONZA
5.10.2	[redacted]	1996	Efficacy test report according EN 113. [redacted]	Yes	LONZA
5.10.2	[redacted]	1997	Efficacy test report according EN 47. [redacted]	Yes	LONZA
5.11.2	[redacted]	2004	Effects of quaternary-ammonium-based formulations on bacterial community dynamics and antimicrobial susceptibility. [redacted]	No	Public Data
2.4.1 6.1.1(1)	[redacted]	1966	Acute Oral Toxicity Test of [redacted] in Rats. [redacted] (Unpublished)	Yes	LONZA

6.1.2 (1)	[redacted]	1996	Acute Dermal Toxicity Test of [redacted] in Rats. [redacted] [redacted] [redacted] (Unpublished)	Yes	LONZA
6.2 (1)	[redacted]	2003	Acute Skin Irritation Test (Patch Test) of [redacted] in Rabbits. [redacted] [redacted] (Unpublished)	Yes	LONZA
6.2 (2)	[redacted]	2003	Acute Eye Irritation Study of [redacted] by instillation into the conjunctival sac of Rabbits. [redacted] [redacted] (Unpublished)	Yes	LONZA
6.3 (1)	[redacted]	2003	Examination of [redacted] in the Skin Sensitisation Test in Guinea Pigs according to Magnusson and Kligman (Maximisation Test). [redacted] [redacted] (Unpublished)	Yes	LONZA

7.4 (1)	[redacted]	2004	Acute Toxicity of [redacted] to Fish. [redacted] (Unpublished)	Yes	LONZA
7.4 (2)	[redacted]	2004	Acute Toxicity of [redacted] to Daphnia magna. [redacted] (Unpublished)	Yes	LONZA
7.4 (3)	[redacted]	2004	Acute Toxicity of [redacted] to Algae. [redacted]. (Unpublished)	Yes	LONZA