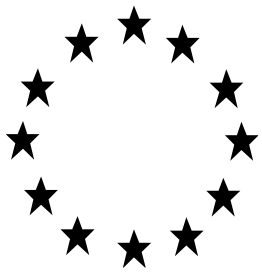
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Coco alkyltrimethylammonium chloride

Product-type 8
(Wood preservative)

April 2016

Italy

CONTENTS

1. Statement of Subject matter and Purpose

1.1. Procedure Followed

This combined assessment report has been established as a result of the evaluation of the active substance coco alkyltrimethylammonium chloride (i.e. Quaternary ammonium compounds, coco alkyltrimethyl, chlorides) 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.

Coco alkyltrimethylammonium chloride (CAS no. 61789-18-2) was notified as an existing active substance separately by Lonza Cologne GmbH and by Akzo Nobel Surface Chemistry AB, hereafter referred to as the applicants, 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 dossiers submitted by the applicants. The deadline for submission of a complete dossier for coco alkyltrimethylammonium chloride 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, the Italian competent authority received a dossier from both applicants. The Rapporteur Member State accepted the dossiers as complete for the purpose of the evaluation on 28th September 2004.

As regards Lonza Cologne GmbH, on 27th June 2005 the time period was suspended, the evaluation was taken up again on 27th March 2006 and then stopped on 27th June 2006, in order to obtain from the applicant the necessary data requested. After that, the evaluation phase was suspended again on the 27th June 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. Coco alkyltrimethylammonium chloride was discussed at technical meeting level in 2009 (TMIII 2009).

As regards Akzo Nobel Surface Chemistry AB, on 25th January 2005 the evaluation was suspended. After a meeting with the Applicant on 24th November 2005, the Italian Competent Authority received a new version of the dossier (26th January 2006), which however did not comply with the Rapporteur Member State requests for revision. The dossier was re-submitted by the Applicant on 20th March 2008, whereas the evaluation was taken up again on 31st March 2008. Additional physical-chemical data and analytical data were submitted on 20th November 2008. On 10th June 2010, 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. In May 2012, additional studies were submitted by the applicant in order to fill the data gaps identified in the evaluation. The relevant study summaries and the conclusions by the Rapporteur Member State were

[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

attached to the RCOM table submitted to ECHA on 13th June 2014.

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 its Working Groups meetings and the competent authority report was amended accordingly.

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 coco alkyltrimethylammonium chloride 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.

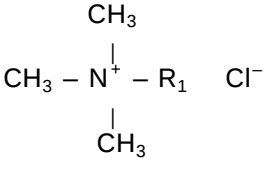
2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

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

Identification of the active substance

The active substance is a quaternary ammonium compound manufactured and marketed as a technical concentrate in water. Data were submitted in support of PT8 (wood preservation) by two different applicants, Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB, that gave their own acronym to the substance: ATMAC and TMAC, respectively.

CAS-No.	61789-18-2
EINECS-No.	263-038-9
Other No. (CIPAC, ELINCS)	None assigned
IUPAC Name	Coco alkyltrimethylammonium chloride
Chemical Name	Coco alkyltrimethylammonium chloride Quaternary ammonium compounds, coco alkyltrimethyl, chlorides (CAS name)
Common name, synonyms	Quaternary ammonium compounds, coco alkyltrimethyl, chlorides (as given in EINECS) Synonyms: **ATMAC - Lonza Cologne GmbH:** Coco Alkyltrimethylammonium Chloride; Barquat CT 35 (purity 35% in water); Barquat CT 35AS (purity 98.2%); Alkyltrimethylammonium Chloride, ATMAC (purity 98.2%); Präpagen 2916 (purity 35% in water); Genamin OC302D (purity 35% in water); HOE S 2916 (purity 35% in water); Trimethylammonium Chloride, TMAC (purity 33% in water); (Coconut oil alkyl)trimethyl-ammonium Chloride (purity 33% in water); Arquad C-33 (purity 33% in water); Arquad C-33W (purity 33% in water); Arquad MC-35 W (purity 34% in water); Arquad C-35 (purity 35.5% in water). **TMAC - Akzo Nobel Surface Chemistry AB:** Alkyltrimethylammonium chloride Cocoalkyltrimethylammonium chloride TMAC C8-18–TMAC
Molecular formula	$C_{(n+3)}H_{(2n+10)}N.Cl$ (n = 8, 10, 12, 14, 16, 18) and $C_{21}H_{44}N.Cl$ (unsaturated C18)
Structural formula	 R = alkyl C8-18 (even-numbered) and C18 (unsaturated)

Alkyl chain length distribution

ATMAC - Lonza Cologne GmbH:

Chain length	[redacted]
C_8	
C_{10}	
C_{12}	
C_{14}	
C_{16}	
C_{18}	
C_{18un}	

TMAC - Akzo Nobel Surface Chemistry AB:

Chain length	[redacted]
C_8	
C_{10}	
C_{12}	
C_{14}	
C_{16}	
C_{18}	
C_{18un}	

Due to the natural origin of the starting material, the chain length distribution can vary from batch to batch. Evidence in support of the above ranges was provided by either applicant by means of 5-batch analysis (5-BA) data.

Molecular weight (g/mol)

207.8-348.1 g/mol (range corresponding to C8/C18)

ATMAC - Lonza Cologne GmbH
Average molecular mass according to the mean chain length distribution from the 5-BA of Barquat CT 35: 273.0

TMAC - Akzo Nobel Surface Chemistry AB
Average molecular mass according to the mean chain length distribution from the 5-BA of Arquad C 35: 277.7

Purity

ATMAC - Lonza Cologne GmbH:
≥96.6% w/w (dry weight)
≥34.5% w/w as technical concentrate Barquat CT-35 (reference TK)

TMAC - Akzo Nobel Surface Chemistry AB:
≥96.9% w/w (dry weight)
≥34.7% w/w as technical concentrate Arquad C-35 (reference TK)

The minimum purity (either wet weight and dry weight) was calculated by statistical analysis as “mean – 3SD” of the 5-BA results submitted by either Applicant in 2015.

Impurities

The full details are confidential and can be found in the Annex of Confidential Data of the relevant CARs

The representative product is the same for both Applicants.

Identification of the representative product

Trade name	Sinesto B
Manufacturer's development code number(s)	None assigned by either Applicant
Active substance	ATMAC/TMAC (CAS 61789-18-2) (Sinesto B contains also a second active ingredient)
Content of the active substance	14% w/w ATMAC/TMAC
Function	Wood preservative
Physical state of preparation	Liquid
Nature of preparation	Solution (water-based concentrate)
Ingredients of preparation	*The full details are confidential and can be found in the Annex of Confidential Data of the relevant CARs*

Physico-Chemical Properties

ATMAC/TMAC is manufactured and marketed as technical concentrate (TK) in water. For the purpose of physical-chemical testing, either Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB prepared samples of ATMAC/TMAC technical material by removing water as far as it was possible from samples of their technical concentrates (Barquat CT-35 and Arquad C-35, respectively).

ATMAC/TMAC is a white/oyster-white solid with soapy odour. Its relative density D420 is ≈ 0.93. ATMAC/TMAC is non-volatile and highly soluble in water, as well as in ethanol, isopropanol and n-octanol. Water solubility was found to be independent of temperature. ATMAC/TMAC is fully ionized in water. Since no decomposition was observed up to 150°C, ATMAC/TMAC is concluded to be thermally stable.

UV/VIS, IR, NMR absorption spectra and MS spectrum were found consistent with the molecular structure of ATMAC/TMAC.

The partition coefficient n-octanol/water (Pow) was not determined, since EC methods A.8 are not applicable for surface-active substances such as ATMAC/TMAC. Also assessment by KOWWIN was considered inaccurate, being the software database very limited for surfactants. Likewise, the estimation by Hansch & Leo (log Pow = 0.66) was not deemed reliable. On the other hand, log Pow was calculated by Akzo Nobel Surface Chemistry AB to be 0.674 from individual solubilities in n-octanol and water at 20°C, as suggested by OECD 107 for surface-active materials. However, this calculation is of no use with regard to environmental fate & behaviour and secondary poisoning risk, when there is an experimental BCFfish available (as for Lonza Cologne GmbH).

ATMAC/TMAC does not show explosive properties or oxidizing properties. It proved to be not flammable according to UN Test N. 1 (Akzo Nobel Surface Chemistry AB). No self-ignition was observed, either. In conclusion, ATMAC/TMAC does not exhibit physical hazards.

Sinesto B (representative product for either Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB) is a water-based concentrate, which is not expected to pose any physical hazard, either.

Analytical Methods

Analysis of the active substance as manufactured

In 2015, new study reports for the identification/quantification of the a.s. and its impurities in technical concentrates Barquat CT-35 and Arquad C-35 were submitted by Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB, respectively, superseding the ones in Doc. IIIA under Sections 4.1(1) of their relevant CARs. It can be concluded that valid analytical methods are available for the a.s. and its impurities in water-based technical concentrates (active substance: ca. 35% w/w).

In order to set the reference specifications (one per application), a five-batch analysis of the active substance as manufactured (technical concentrate) was submitted by either Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB to cover their respective sources (one per applicant). Batch-data were obtained by means of validated analytical methods. The composition of batches was recalculated on a dry weight basis and a dry weight specification was derived for either source by statistical analysis (mean ± 3xSD). A dry weight reference specification was thus set for either applicant, and either source can be regarded as a reference source.

Residues

No analytical method is required for the determination of residues in air, since the active substance is non-volatile and will be used in automated dipping or by spraying in closed tunnel, so no occurrence in air is expected.

No analytical method was deemed necessary for the determination of residues in body fluids and tissues, since the active substance was neither toxic nor highly toxic under DSD. The active substance is now classified as toxic (H301) according to CLP regulation, but no analytical method is considered necessary, either, since systemic effects are only secondary to local effects.

Wood treated with ATMAC/TMAC-containing biocidal product is not intended for use in areas where food for human consumption is prepared, consumed or stored, or where the feedingstuff for livestock is preprared, consumed or stored. Therefore, no analytical method for the determination of residues in food/feed of plant/animal origin is required, either.

The methods submitted by either Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB for the determination of residues in soil and water, which are necessary for post-authorization control and monitoring, support the residue definition (ATMAC/TMAC).

ATMAC - Lonza Cologne GmbH

LC-MS methods for the determination of residues of the active substance in soil and water (drinking-, ground- and surface water) down to a level of 0.01 mg/kg and 0.1 µg/L as total ATMAC, respectively, were available in the original CAR. Only one mass fragment related to C12-ATMAC was used for the purpose of validation. During the evaluation of the dossier, those methods were accepted as sufficiently specific, linear, accurate and precise. Nevertheless, the Additional guidance on the TNsG on Data Requirements for Analytical Methods (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 when MS detection is carried out. So, according to the guidance, the available data (given for one LC-MS ion only) were not actually sufficient to prove specificity. The need for highly specific confirmatory methods for the analysis of ATMAC residues in soil and water was also agreed in 2010, post TMIII2009 and after bilateral discussion between DE-CA and eCA-IT.

In conclusion, additional highly-specific confirmatory methods for ATMAC residues in soil and water (both drinking- and surface-water) are necessary and should preferably be submitted to the evaluating Competent Authority (Italy) at the latest 6 months before the date of approval.

TMAC - Akzo Nobel Surface Chemistry AB

An analytical method for the determination of TMAC residues in soil by LC-MS/MS (ES+) was submitted in May 2012. Analysis was performed in isocratic mode on a C18 reversed-phase column, using external standards. For each constituent of TMAC, specificity was achieved by formation of a specific precursor ion and two specific product ions (one mass transition used for quantification, the other for identity confirmation).
The method was validated at 0.05 mg TMAC/kg and 0.50 mg TMAC/kg. For that purpose, lyophilized Arquad C-35 was used for the spiking of the soil. Additional validation was carried out at 0.00714 mg/kg and 0.0714 mg/kg for each individual constituent of TMAC. Soil fortification was performed using the relevant standards. Solutions of mixed standards at 7 different concentration levels were used for calibration.
The method is highly specific (LC-MS/MS, with two mass transitions validated), linear over the range 0.008–0.75 mg TMAC kg in soil, accurate (with recovery rates at LOQ and 10xLOQ in the acceptable range 70–120%) and precise (%$RSD_{n = 5}$ < 20% for either fortification level). The LOQ (as the lowest fortification level successfully validated) complies with the relevant end-point (< EC_{50} = 11 mg/kg dw soil; read-across from DDAC data).
Satisfactory results in terms of recovery rates and %$RSD_{n = 5}$ were also obtained for individual constituents of TMAC (C8-TMAC, C10-TMAC C12-TMAC, C14-TMAC, C16-TMAC, C18-TMAC and C18un-TMAC).

An analytical method for the determination of TMAC residues in ground-, surface- and drinking-water by LC-MS/MS (ES+) was submitted in May 2012. Analysis was performed in isocratic mode on a C18 reversed-phase column, using external standards. For each constituent of TMAC, specificity was achieved by formation of a specific precursor ion and two specific product ions (one mass transition used for quantification, the other for identity confirmation).
The method was validated at 0.1 µg TMAC/L and 1.0 µg TMAC/L. For that purpose, lyophilized Arquad C-35 was used for the spiking of the matrices.
Additional validation was carried out at 0.014 µg/L and 0.140 µg/L for each constituent of TMAC. Water fortification was performed using the relevant standards.
Solutions of mixed standards at 7 different concentration levels were used for calibration.
The method is highly specific (LC-MS/MS, with two ion transitions validated), linear over the range 0.01–1.04 µg TMAC/L in matrix, accurate (with recovery rates at LOQ and 10xLOQ in the acceptable range 70–120%) and precise (%$RSD_{n = 5}$ < 20% for either fortification level).
Ground- and drinking-water: the LOQ (as the lowest validated fortification level) complies with the EU water limit of 0.1 µg/L.
Surface water: the LOQ (as the lowest validated fortification level) complies with the relevant endpoint (<NOEC = 2.5 µg/L; read-across from C_{12-16}-BKC data).
Satisfactory results in terms of recovery rates and %$RSD_{n = 5}$ were also obtained for individual constituents of TMAC at 0.014 µg/L and 0.140 µg/L each.

2.1.2. Intended Uses and Efficacy

PT 8, Wood Preservative

Under Product Type 8, coco alkyltrimethylammonium chloride acts as fungistatic, since it controls the mycelial growth of wood destroying basidiomycetes, soft rotting and discolouring fungi. It is used for preventive protection of wood and constructional timbers in areas with moderate or subtropical climate in use classes from 1 to 4A as reported in the Emission Scenario Document for PT 8.

Mode of action

Coco alkyltrimethylammonium chloride 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. Its mode of action, therefore, is to destroy the cell walls by sticking on the exterior structures and by entering and disintegrating the inner phospholipid-bilayer-based membrane structures. 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.

Effectiveness

Quaternary ammonium (quat) biocides in the wood preservation market are always used in formulations in combination with other active substances. Efficacy studies with quats alone require considerably higher concentrations than those actually used in these formulations.

The representative product Sinesto B is an aqueous solution containing 14% active substance. It prevents the development of wood discolouring organisms by contact and controls the mycelial growth of wood destroying basidiomycetes, soft rotting and discolouring fungi by industrial and professional users.

Sinesto B is used in automated dipping applications for dipping, the product is delivered undiluted to the processing plant by tanker. Then it is diluted down 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 requirement for Sinesto B varies from 6% to 8%. Hence the requirement for active substance concentration varies from 0.84% to 1.1% depending upon duration of the required protection as well as on timber species and degree of hazard.

Timbers are treated with a concentration of 6-8 % Sinesto B (corresponding to 0.84-1.12 % a.s.). The application rate is approx. 100-150 g treatment solution/m^2 corresponding to 0.84-1.68 g a.s./m^2, covering the surface completely.

Number and timing of applications depend on application technique, wood species, moisture and hazard class. A common value applied in the dipping process is up to 30 minutes immersion per batch.

The efficacy of the product is demonstrated by one laboratory test (BAM test report 8.1/6536, Ref. B 5.10.2/01), where the efficacy against several fungal species was demonstrated for a 10% (m/m) solution of Sinesto B (68.5 g/m²), and one field test in Portugal with pine wood boards, where a long-term protection was achieved with a 6% dipping solution of Sinesto B (Ref. B 5.10.2/02) (**Akzo Nobel Surface Chemistry AB**). However, further efficacy studies as required by the efficacy guidance for PT 8 shall be submitted at product authorization.

Organism to be controlled

Wood destroying basidiomycetes:

Coniophora puteana // Coniophora spec.

Coriolus versicolor

Gloephyllum trabeum

Poria vaillantii // Poria spec.

Fomes spec.

Trametes spec.

Soft rot fungi

Chaetomium globosum

Wood discoluring fungi:

Aureobasidium pullulans

Sclerophoma pityopila

Ophistostoma piliferum

Aspergillus niger

Aspergillus terreus

Paecilomyces variotii

Penicillium funicolosum

Trichoderma viridae

Occurrence of resistance

From practical experience 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, the active substance 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 active substances 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 ([redacted] 2004, **Lonza Cologne GmbH**).

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) 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

Coco alkyltrimethylammonium chloride is currently not classified according to Annex VI of Regulation EC 1272/2008. Based on the results from studies presented in the dossier, the classification was proposed according to the criteria set out in Regulation EC 1272/2008 (with amendments). On the basis of the review of the submitted data, specific concentration limits have been proposed for the environmental classification, and the substance is readily biodegradable.

The representative product is the same for both dossiers (Sinesto B). Based on the results from the studies presented in both dossiers, classification of the product was proposed and according to Regulation EC 1272/2008 with amendments and adaptations. Sinesto B contains 14% active substance and the proposal of the classification is by calculation according to the conventional method and by studies presented in the both dossiers.

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

Classification:	
Hazard Class and Category	Acute toxicity (oral) Hazard Category 3 Acute toxicity (dermal) Hazard Category 3 Skin Corrosion Hazard Category 1B Aquatic Acute 1
Hazard Statement Codes	H301 H311 H314 EUH071 H400
Labelling:	
GHS Pictogram	GHS05, GHS06, GHS09
Signal Word	Danger
Hazard Statement	H301: Toxic if swallowed H311: Toxic in contact with skin H314: Causes severe skin burns and eye damage EUH071: Corrosive to the respiratory tract H400: Very toxic to aquatic life
Specific concentration limits for the aquatic hazard classification	M factor=10
As precautionary statements are not included in Annex VI of Regulation EC 1272/2008, no proposal is made.	

Proposed classification and labelling of the product Sinesto B based on Regulation EC 1272/2008

Classification:	
Hazard Class and Category	Acute toxicity (oral), Hazard Category 4 Skin corrosion/irritation, Hazard Category 1B STOT — SE, Hazard Category 3, Respiratory tract irritation Hazardous to the aquatic environment — Acute Hazard, Category 1
Hazard Statement Codes	H302 H314 H335 H400
Labelling:	
GHS Pictogram	GHS05, GHS07, GHS09
Signal Word	Danger
Hazard Statement	H302: Harmful if swallowed H314: Causes severe skin burns and eye damage H335:May cause respiratory irritation H400: Very toxic to aquatic life.
precautionary statements	P280: Wear protective gloves/protective clothing/eye protection/face protection P273: Avoid release to the environment P301+P330+P331: IF SWALLOWED: Rinse mouth. DO NOT induce vomiting P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P312: Call a POISON CENTER or doctor/physician if you feel unwell P391: Collect spillage P403+P223: Store in a well-ventilated place. Keep container tightly closed P501: Dispose of contents/container to … (… in accordance with local/regional/national/international regulation (to be specified)

2.2. Summary of the Risk Assessment

Read across to data on the related QUAT didecyldimethylammonium chloride (DDAC) is requested for ATMAC **(Lonza Cologne GmbH)** in relation to 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.
Analogously read across to data on two structurally related QUATs, namely didecyldimethylammonium chloride (DDAC) and benzyl-C12-16-alkyldimethyl ammonium chloride (C_{12-16}-BKC), is requested for TMAC (Akzo Nobel Surface Chemistry AB) in relation to some toxicological end-points (ADME, chronic toxicity/carcinogenicity and reproductive/ developmental toxicity). The rationale for the read across acceptance is explained in details at the beginning of Doc.IIA- Section 3 and at the end of Doc. IIIA.

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Coco alkyltrimethylammonium chloride (ATMAC/TMAC, CAS No. 61789-18-2) is highly ionic and, therefore, it is expected not to be readily absorbed from the gastrointestinal tract or skin. No specific studies on ATMAC **(Lonza Cologne GmbH)** toxicokinetics and metabolism are available, however, the read across to data on a structurally related compound, namely DDAC, has been accepted.
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 ATMAC oral absorption is limited to ≈10% at non corrosive concentration.
Similarly to DDAC, the majority of the metabolism of ATMAC should be carried out by intestinal flora, giving rise to hydroxylation products in the alkyl chain **(Lonza Cologne GmbH)**.
About 0.1% of a DDAC dose delivered as aqueous solution (composition of the test item 1.85% DDAC in water) 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 **(Lonza Cologne GmbH)**.
Two in vivo studies on rats are available in the literature reporting an oral uptake of C_{16}-TMAC (Akzo Nobel Surface Chemistry AB) of about 3.3 % (1.22 excreted by urine and around 2% in bile; 92% found back in faeces on day 3); and a dermal uptake of about 3.15% (in two days: 1.76% excreted in urine, 0.28% in faeces, organs 1.11%). Since the quality of the studies was limited and their reporting poor (i.e levels of radioactivity present in the carcass, and/or in the application site after tape stripping were not quantified), a reliable value for oral and dermal absorption could not be derived. Therefore the studies have been considered from a qualitative point of view as supporting for the read across of data on DDAC and C_{12-16}-BKC, to which TMAC is structurally related and showing similar toxicokinetic behaviour and mode of action.
Recent and GLP compliant studies are available for $_{C12-16}$-BKC & DDAC (Akzo Nobel Surface Chemistry AB) indicate they do not readily penetrate cell membranes due to their chemical nature, are very stable and do not undergo considerable degradation. The fraction of the oral dose absorbed for both was about 10%. This value was derived for DDAC summing up the urinary excretion mean value (3-4%) and biliary excretion values (2.6%), in the absence of residues in the carcass, as measured at 168h. A value of 10% is taken forward to risk characterization, considering that the recovery obtained in males was lower than in females (about 85%) and the possibility that bile elimination could be slightly higher at longer times. For C_{12-16}-BKC, the oral absorption % was based on the urinary mean value of 3-4%, with a single peak value = 8.3% and biliary excretion =3.7-4.6%).
After absorption of DDAC and $_{C12-16}$-BKC (Akzo Nobel Surface Chemistry AB), radioactivity was mainly detected in the g.i. tract, and at a much lower level in the liver and in the kidney. Excretion mainly through the faeces as unabsorbed material was rapid (within a 48 to 72-hour period). The low amount of radioactivity excreted in the urine consists partially of parent

compound, and partially accounted for conjugated more polar metabolites. No further attempts were made to identify the DDAC/C12-16-BKC metabolites.
Both DDAC and C_{12-16}-BKC do not show any bioaccumulation potential.
Due to limitation in the study design, the available data on DDAC and C_{12-16}-BKC dermal absorption (Akzo Nobel Surface Chemistry AB) do not allow to quantify exactly the % of the dose which was absorbed after dermal application, although they indicate that there are not marked differences between the oral and the dermal bioavailability. Indeed, in the case of C_{12-16}-BKC, considering the radioactivity recovered at the skin application site after removal of the stratum corneum layers (6.5-8.7% of the dose) and the ionic nature of the test item, it can be anticipated that the dermal absorption is not different from the oral one (10%).
Therefore, it is expected that DDAC, C_{12-16}-BKC and TMAC **(Akzo Nobel Surface Chemistry AB)** dermal absorption is limited to 10% (as maximum value). Exposure through the skin, the most likely exposure route for humans, is therefore anticipated not to contribute significantly to the internal body burden.
The lowest determined oral LD_{50} for ATMAC and TMAC is 207 mg a.s./kg **(Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB)**. Clinical signs were observed at early stage of the treatment and at all dosing concentrations. The signs were mainly due to gastrointestinal disturbance, respiratory distress, ataxia, lethargy, salivation and hypothermia **(Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB)**.
The rabbit acute dermal LD_{50} value of ATMAC and TMAC was 429 mg a.s./kg **(Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB)**. Mortality was observed at the highest doses applied and lethargy, ataxia laboured respiration were noted prior to death. All concentrations applied induced moderate to severe erythema and oedema. Internal abnormalities such as hemorrhagic thymus glands, brain haemorrhages, soft liver were also seen **(Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB)**. The observed lethality is secondary to the local tissue damage, rather than the result of systemic toxicity through percutaneously absorbed material (**Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB).**
Inhalation of ATMAC is not considered a potential route of exposure based on use patterns and vapour pressure (1.8×10^{-6} Pa, 20°C) **(Lonza Cologne GmbH)**. In addition the a.s is classified as irritant/corrosive therefore there is no need to perform inhalation studies **(Akzo Nobel Surface Chemistry AB)**.
ATMAC is corrosive for the skin and severely irritant to eyes **(Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB)**. ATMAC/TMAC did not result in skin sensitisation, according to the available data **(Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB)** Irritation of the respiratory tract is expected.
From a two-week skin irritation study in rats with DDAC, it can be derived a NOAEL/NOAEC of 0.6% active substance in water at 2.0 ml/kg body weight per day after a 5 day application and a NOAEL/NOAEC of 0.3% active substance in water at 2.0 ml/kg body weight per day after 2-week application **(Lonza Cologne GmbH)**.
Data on skin irritation due to C12-16-BKC application are present in the literature obtained with rabbits and rats, indicating that after repeated exposure of skin to C_{12-16}-BKC, effects ranging from slight erythema to necrosis were present and persistent also at 0.1% C_{12-16}-BKC. Data are available also on humans for concentrations ranging from 0.1 to 17% C_{12-16}-BKC. The maximum concentration reported in the literature that does not produce irritating effect on intact skin is established at 0.1% active substance, after a single patch exposure (removal after 48 h) (CIR, 1989). However, these data could not be checked for their quality and could not considered robust enough for deriving reference values **(Akzo Nobel Surface Chemistry AB)**.
Data on eye irritation are present in the literature after instillation of C_{12-16}-BKC solutions Data obtained in rabbits (n=198, strain not stated) treated twice daily for 7 days with 2, 1, 0.5, 0.1 and 0.01% C_{12-16}-BKC indicated that only at the lowest dose no damage was present. In humans the ocular irritation potential was evaluated in 51 subject after a single instillation of = 0.02% active substance: the only clinical evidence of ocular irritation was slight conjunctival hyperemia in the eye of one subject (CIR, 1989). Although these data could not be checked for their quality, it can be tentatively concluded that 0.02% can be considered as a NOAEC for eye irritation after repeated exposure **(Akzo Nobel Surface Chemistry AB)**.

CONCLUSION on 2.2.1.1 Hazard Identification:

Toxicokinetics

Coco alkyltrimethylammonium chloride is highly ionic and, therefore, it is expected not to be readily absorbed from the gastrointestinal tract or skin. No or low quality studies are available on the a.s. in both dossier to evaluate the ADME parameters. However, data on structurally related QUATs (namely DDAC in both dossiers, in addition to C_{12-16}-BKC for the Akzo Nobel dossier) for which the application of the read across principle has been accepted.
On the basis of all the data available (consistent in both dossiers), it can be concluded that coco alkyltrimethylammonium chloride oral absorption is limited to 10% at non-corrosive concentration.
Regarding the dermal absorption, no study is available in the Akzo Nobel dossier, for which the same value used for oral absorption (10%) was proposed as worst case. The value is consistent with the experimental value from the Lonza dossier (as read across to data on 1.85% DDAC in water) indicating a dermal absorption of 9.41% (rounded to 10% at non-corrosive concentration). Therefore the dermal absortion of coco alkyltrimethylammonium chloride is 10% at non-corrosive concentration.
Excretion mainly through the faeces as unabsorbed material was rapid (within a 48 to 72-hour period) and as hydroxylation products in the alkyl chain carried out by intestinal flora. The low amount of radioactivity excreted in the urine consists partially of parent compound, and partially accounted for more polar conjugated metabolites.
No bioaccumulation potential was evidenced.

Acute toxicity

The lowest determined acute oral LD_{50} =207 mg a.s./kg. was identical in both dossiers. Clinical signs were mainly due to gastrointestinal disturbance, respiratory distress, ataxia, lethargy, salivation and hypothermia.
The rabbit acute dermal LD_{50} value=429 mg a.s./kg was identical in both dossiers. All concentrations applied induced moderate to severe erythema and oedema; the clinical signs and the observed lethality are secondary to the severe local tissue damage, rather than the result of systemic toxicity through percutaneously absorbed material.
Regarding inhalation toxicity, the a.s is classified as corrosive therefore there is no need to perform inhalation studies; corrosive effects in the respiratory epithelium is expected.
According to the studies presented by both applicants, coco alkyltrimethylammonium chloride is corrosive for the skin and it is also severely irritant to eyes. The a.s. is not a skin sensitiser, according to the available data.
Regarding short term repeated dermal exposure, from a two-week skin irritation study in rats with DDAC, submitted with the Lonza dossier, it can be derived a NOAEL/NOAEC of 0.6% active substance in water at 2.0 ml/kg body weight per day after a 5 day application and a NOAEL/NOAEC of 0.3% active substance in water at 2.0 ml/kg body weight per day after 2-week appliction.
Although they could not be checked for their quality, it is reported in the literature that in humans 0.02% of C_{12-16}-BKC can be considered as a NOAEC for eye irritation after repeated exposure.

2.2.1.2. Effects assessment

The oral toxicity of repeated doses of coco alkyltrimethylammonium chloride, as for the acute effects and for other QUATs is related to its high irritancy to the mucosal surfaces of the GI-tract, and therefore more related to the concentration of the administered solution. For this reason, data from feeding studies can be given more weight in systemic NO(A)EL derivation.
Administration of 100, 500 and 2000/1000 ppm ATMAC (corresponding to 22, 113 and 273 mg/kg bw/d) to rats in the diet over 90 days did not result in treatment-related death. The highest concentration induced hunched posture, piloerection, tiptoe gait, diarrhoea and red/brown staining of external body surface of the rats and a significant increase in startle reflex in the female rats. Similar clinical signs although with lower incidence were noted also in the mid-dose group. Food consumption and body weight were reduced at all concentrations of

ATMAC except at the lowest dose. ATMAC induced an accumulation of pigments in male kidneys at 500, 2000/1000 ppm. The NOAEL derived from the study was 100 ppm (corresponding to 22 mg/kg bw/d) **(Lonza Cologne GmbH)**.

An identical NOAEL of 100 ppm was derived from the 90-days repeated dose oral toxicity study in rats with TMAC (corresponding to 22 mg/kd bw/d a.s.). The critical effect observed at LOAEL=500 ppm (113 mg a.i. /kgbw/day) was reduced food consumption with consequent lower body weight gains over the study period (10%) and the occurrence of haemosiderine in kidneys, a dose-dependence effect that has to be considered treatment-related. Only at levels when serious differences in body weight occur of more then 20% compared to the control, other clinical effects occur. Similar results were obtained from subchronic feeding studies with DDAC (NO(A)EL=42 mg/kg bw/day) and C12-16-BKC (NOAEL of 68 mg a.s./kg bw/day) in rats, where the critical effect upon oral exposure is decreased body weight gain **(Akzo Nobel Surface Chemistry AB)**.

Specific repeated toxicity studies in dogs have not been performed with TMAC, but read across from data obtained with DDAC and C_{12-16}-BKC has been accepted. Results from these dog studies do not indicate species differences towards mechanism of toxicity by quaternary ammonium compounds **(Akzo Nobel Surface Chemistry AB)**.

The 90-day dog study with DDAC resulted in a NOAEL of 15 mg a.i/kg bw/day (486 ppm), the highest dosages tested. DDAC doses tested were chosen on the basis of results from 2 range finding studies, in which the test item was administered at 500, 1000 and 2000 ppm. Since the 2 highest doses induced marked body weights reduction they were considered too high for the 90-day treatment **(Akzo Nobel Surface Chemistry AB)**.

The 90-day dog study with C_{12-16}-BKC resulted in a NOAEL of 45 mg a.s./kg bw/day (1250 ppm). However, it should be noted that from week 8, the concentration of the a.s. was reduced from 1500 to 1250 ppm in the high-dose female group, due to low food intake and reduced body weight among these animals. The reduced food consumption and body weight loss reported at 43-53 mg/kg/day in a 28-day oral toxicity study with dogs and the fact that a small change from 1500 ppm to 1250 ppm of the test item in the 90-day study lead to recovery, indicate that the NOAEL is a border line value and that the dose-response curve should be quite steep **(Akzo Nobel Surface Chemistry AB)**.

Based on DDAC data, in a 90-day subchronic dermal study with rats receiving 0, 2, 6, 12 mg/kg body weight/day, no gross effects were seen at the highest dose which can be considered the NOAEL for systemic effects. Based on skin irritation at the dose site, the local NOAEL may be considered equal to 2 mg/kg body weight/day **(Lonza Cologne GmbH)**.

The lack of any structural similarity to known neurotoxins, of any alert for neurotoxic effects shown by quaternary ammonium chemicals in general and the lack of any indications of specific neurotoxicity-related clinical signs (such as in sensory activity, grip strength, and motor activity assessment) in repeated dose toxicity studies support the conclusion that ATMAC/TMAC has no neurotoxic potential **(Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB)**.

No specific long term toxicity/carcinogenicity studies on coco alkyltrimethylammonium chloride are available, however, the read across from data on a structurally related compound, namely DDAC **(Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB)** and BKC **(Akzo Nobel Surface Chemistry AB)** has been accepted.

In a 1-year oral gavage study in dogs for 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.Those clinical signs reported at 10 mg/kg/d 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. Therefore 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 **(Lonza Cologne GmbH)**. Based on the outcome of the effect assessment, the AEL cannot be regarded as a “true” systemic threshold and therefore, at WGII2015 it was agreed that the AEL approach should not to be performed. Consequently, only a semi-quantitative local risk assessment have to be considered from the use of the active substance.

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 aspecific 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 scenario **(Lonza Cologne GmbH)**.
ATMAC displayed no genotoxic activity in the three mutagenicity tests required for the authorisation of Biocidal Products: *Salmonella* mutagenicity assay (in TA1535, TA1537, TA98 and TA100 strains), gene mutation study in mouse lymphoma L5178Y cells and *in-vitro* cytogenetic test in human lymphocytes. Moreover, no induction of micronuclei was observed in a mouse bone marrow micronucleus test, following oral administration of the test substance **(Lonza Cologne GmbH)**.
In the *in-vitro* cytogenetic test in human lymphocytes polyploidy was incidentally observed, with a dose-dependent trend only in the presence of metabolic activation. This phenomenon might reflect spindle function disturbance, possibly resulting in the induction of numerical aberrations. If this is the case, a positive result in the *in vivo* micronucleus test would be expected. Micronucleus assay, correctly performed at the MTD, resulted negative. At this dosage animals showed evident clinical signs but no local toxicity (alteration in the ratio PCE/NCE), therefore there was no direct evidence that the drug has actually reached the target organ **(Lonza Cologne GmbH)**. In conclusion, the test substance resulted negative in all the required genotoxicity studies and appeared unable to directly damage DNA. Conversely, a potential interaction with the spindle system cannot be conclusively ruled out.
TMAC was found to be not genotoxic in the Ames test and in *in vitro* cytogeneticity and gene mutation assays in mammalian cells. The compound was not genotoxic as well in an *in vivo* micronucleus test in mouse bone marrow **(Akzo Nobel Surface Chemistry AB).**
A two-generation study **(Lonza Cologne GmbH)** showed no reproductive effects; general toxicity (reduced weight gain inn adults and pups) was observed with NOAEL of 750 mg/kg feed, corresponding to at least 40 mg/kg bw Adequate two-generation study have been also conducted on the chemical and structural analogues, DDAC and C_{12-16}-BKC. Overall neither DDAC nor C_{12-16}-BKC affect reproduction at doses that are devoid or general toxicity. The lowest NOAEL for general toxicity were 600 mg/kg feed, equal to at least 32 mg/kg bw/day (DDAC) and 250 mg/kg feed, equal to at least 16 mg/kg bw/day (C_{12-16}–BKC), both based on reduced weight gain, No effects on reproduction parameters were observed with either compounds; reduced neonatal growth survival was observed only in one study on DDAC (NOAEL 1600 mg/kg feed, equal to at least 89 mg/kg bw/day).
Two prenatal developmental toxicity studies in rats and rabbits **(Akzo Nobel Surface Chemistry AB)** showed no increase the birth defect, while the occurrence of other signs of prenatal toxicity is secondary to maternal distress. The NOAEL of 3 mg/kg bw/d for maternal toxicity obtained in the reproductive toxicity study after gavage administration, can be considered as the NOAEL related to local effects on the g.i. tract mucosa.
Supportive evidence is provided by prenatal developmental toxicity studies with DDAC chloride and C_{12-16}–BKC, that did not show any developmental effect, other than those associated with maternal toxicity. Such studies provided anoverall NOAEL of 1 mg/kg bw/day for maternal toxicity in rats and rabbits: This NOAEL simply reflects lo local effects on the gut mucosa due to gavage bolus administration rather than any systemic effect.
In view of the chemical and structural similarities, the read-across from studies performed with DDAC chloride and C_{12-16}–BKC available data were considered appropriate for both **(Lonza Cologne GmbH)** or **(Akzo Nobel Surface Chemistry AB)**, taking into account both the chemical and structural similarities and the need for reducing unnecessary animal experiments.

CONCLUSION on 2.2.1.2 Effects Assessment:

As for the acute effects and for other QUATs toxicity due to repeated oral administration is related to its high irritancy to the mucosal surfaces of the GI-tract, and therefore more related to the concentration of the administered solution. For this reason, data from feeding studies can be given more weight in systemic NO(A)EL derivation.
The oral toxicity of 90 days repeated doses of coco alkyltrimethylammonium chloride in rats

gave rise to a NOAEL of 22 mg/kg bw/d (the same value was obtained from both dossiers).
The dermal toxicity of 90 days repeated doses of coco alkyltrimethylammonium chloride in rats gave rise to a NOAEL for local effects of 2 mg/kg bw/d, with no relevant systemic effects detected, so that the NOAEL for systemic effects was fixed at 12 mg/kg bw/d, that is the highest dose tested.
The NOAEL for non-neoplastic effects after chronic dietary administration to rats of the structural analogue DDAC ranged between 27 and 32 mg/kg bw/d.
As for the oral toxicity, a 1-year oral gavage study in dogs is also available. Two kinds of NOAEL can be derived: one is related to local effects on gut mucosa (equal to 3 mg/kg bw/d, consistent with the NOAEL for local effects on gut mucosa derived from the maternal toxicity study with gavage administration of TMAC); the second one is the NOAEL for systemic effects (equal to 10 mg/kg bw/d) with clinical signs consistent with the irritation/corrosive properties of the test item. However based on the outcome of the effect assessment, the AEL cannot be regarded as a "true" systemic threshold and therefore, at WGII2015 it was agreed that the AEL approach should not to be performed. Consequently, only a semi-quantitative local risk assessment have to be considered from the use of coco alkyltrimethylammonium chloride.
According to the studies presented by both applicants, genotoxic potential *in vitro* and *in vivo* of coco alkyltrimethylammonium chloride can be ruled out.
The read across with other quaternary ammonium compounds DDAC and C_{12}-$_{16}$-BKC is acceptable for carcinogenicy. According to the results coming from available reports and literature, coco alkyltrimethylammonium chloride have no carcinogenic potential.
The available studies and the read across with other quaternary ammonium compounds DDAC and C_{12}-$_{16}$-BKC show no specific potential for reproductive or developmental toxicity. The overall NOAEL (1 mg/kg bw/day for maternal toxicity in rats and rabbits) reflects lo local effects on the gut mucosa due to gavage bolus administration and is not relevant to the determination of a systemic AOEL.

Medical data

No medical reports on the manufacturing personnel have been submitted. No specific observations or sensitivity/allergenicity have been reported **(Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB)**.

2.2.1.3. Exposure assessment

The biocidal product containing the active substance is used in a number of wood preservative treatment applications: dipping application **(Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)** and spraying application in closed tunnel **(Akzo Nobel Surface Chemistry AB)**. For all these processes, the preservative is delivered to the processing plant by tanker in the form of a concentrate. The concentrate solution contains 14% of a.s. Then, 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. Therefore, the a.s. concentrations in the processes vary between 0.84% and 1.12%.
Furthermore, the use classes 1 and 2 are envisaged for the a.s. containing wood preservative product.
Due to the irritant/corrosive properties of a.s., the systemic effects can be considered as secondary in comparison to the local ones. In this regards, a small amount of active substance becomes systematically available and gives rise to some non-significant systemic effects, such as decreasing of body weight. Following to that, the AEL cannot be regarded as a "true" systemic threshold and therefore, at WGII2015 it was agreed that the AEL approach should not to be performed. Consequently, only a semi-quantitative local risk assessment should be considered from the use of a.s. A semi-quantitative risk assessment has been carried out based on the Guidance for Human Health Risk Assessment (see below under Chapter 2.2.1.4).

2.2.1.4. Risk characterisation

Considering the repeated dose studies, the main critical effects associated with coco alkyltrimethylammonium chloride are due to its corrosive prosperities. In this context, the systemic effects such as the reduction of body weight and food consumption can be considered secondary compared to the corrosive properties of ATMAC. It can be concluded that ATMAC/TMAC actually does not cause 'true' systemic effects and the derivation of a systemic AEL is not considered as relevant.

Local NOAEC derivation – Dermal route

As regards the dermal exposure, for a structurally similar compound (i.e., DDAC) no systemic effects were observed in the 2-week skin irritation study with rats and therefore the NOAEL for local effects has been set at 6 mg/kg bw/day (0.3% DDAC).
For the quantitative cross-reading from DDAC (source chemical) to ATMAC/TMAC (target chemical) there is no need to correct for difference in potency or molecular weight. Comparison of the available dose-response relations for effect and toxicity of both DDAC and ATMAC/TMAC, shows that ATMAC/TMAC is equally, or even less, toxic when compared to DDAC on mass based dose metrics (mg/kg bw or mg/L) for a number of different end-points. Molecular weight correction is normally only applied to various ionized forms of an acid or a base with the assumption that the effect of the counter ion is not significant in respect of all properties under consideration (REACH guidance R.6). TMAC and DDAC have the same mode of action and the same counter ion. Therefore, molecular weight correction for read across from source chemical DDAC to target chemical TMAC is not justified.
In conclusion the NOAEC derived for the ATMAC/TMAC 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 NOAEL is of 6 mg/kg bw/day (=3mg/mL x 2mL/kg bw per day).
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 (read-across with the structurally similar compound 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).

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 dose. 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%.

2.2.1.4.1 Semi-quantitative local risk assessment: introduction

Due to the irritating and corrosive properties of the active substance alkyl-C12-16(even numbered)trimethyl ammonium chlorides (CAS number 61789-18-2) and the lack of "true" systemic effects observed, the risk characterization for local effects is more critical than the systemic risk assessment. Based on the Guidance for Human Health Risk Assessment, Volume III – Part B) a local risk assessment has been carried out for both the biocidal product Sinesto B, and its diluted in-use solutions. A secondary exposure assessment has also been carried out. The biocidal product Sinesto B containing 14% of active substance is intended as wood preservative (Product Type 8) for industrial and professional users, only. In the Mixing&Loading phase, the concentrated product (14% of active substance) is diluted with water up to the in-use concentration containing 1.12% of a.s. The diluted solution is used for the wood treatment which takes place by either automated dipping or spraying in closed tunnel.

The description of the RMMs were based on the information provided by the Applicant but some RMMs may not be required on a case by case basis, e.g., a lower degree of automation may be acceptable for some cases.

The table below summarises the exposure scenarios assessed.

Scenario	Exposed group
Mixing and Loading	Industrial/Professional
Automated dipping	Industrial/Professional
Post-application: handling of wet treated wood	Industrial/Professional
Post-application: maintenance and cleaning	Industrial/Professional
Secondary scenario: infants mouthing wood off-cut	Bystanders

2.2.1.4.2 Description of the local hazards of the representative biocidal product and its in use dilutions

The active substance is corrosive, classified as Skin Corr 1B. A dermal NOAEC of 0.3% based on a 2-week skin irritation study was derived based on read across to a DDAC study. In the study available, rats have been treated with DDAC at different doses: 0, 0.03% (for one week than raised to 0.6% for the second week), 0.1%, 0.3%, 1.0%, 3.0%. 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 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. Although there is uncertainty in extrapolating the NOAEC for the a.s. to a formulation, the value of 0.3% has been used for the local risk assessment of the biocidal product.

For ATMAC/TMAC a read across from the skin irritation study carried out on the structurally analogous compound DDAC has been accepted. Based on all the information available the WGII2015 concluded that no molecular weight correction needs to be considered in the NOAEC derivation for ATMAC/TMAC when read-across is sought from DDAC.

As the a.s. is not volatile and does not vaporise from solutions no inhalation exposure was assessed. In addition to that, the use applications do not lead to exposure of aerosols. As concerns the risk assessment, the a.s is classified as corrosive and therefore, there is no need to perform inhalation studies. As a consequence, no NOAEC has been possible to be derived.

Sinesto B (containing 14% a.s.) is classified using both the results from the acute test performed on the product and calculations according to the conventional method.

Sinesto B results to be severely irritating/corrosive to skin and eyes. Therefore, according to the CLP regulation is classified as Skin Corr 1B (H314: Causes severe skin burns and eye damage).

Sinesto B is also irritant to respiratory tract based on the content of a co-formulant at 26% (information on the co-formulant is in the Confidential Annex of the CAR). According to the CLP regulation is classified as STOT SE 3 (H335: May cause respiratory irritation).

The diluted product containing 1.12% of a.s. is classified by calculation according to the conventional method.

According to criteria set in the CLP regulation the diluted product is classified as Skin Irrit 2 (H315: Causes skin irritation) and Eye Irrit 2 (H319: Causes serious eye irritation).

The representative biocidal product (Sinesto B containing 14% of TMAC in water) has been allocated to the “High” hazard category according to the classification as corrosive with serious and irreversible effects (CLP: Skin Corr 1B - H314). The diluted product containing an in-use concentration of 1.12% TMAC in water is allocated to the “Low” hazard category according to the classification as irritant to skin and eye with moderate and reversible effects (Skin Irrit 2 - H315; Eye Irrit 2 – H319).

2.2.1.4.3 Identification of the exposure scenarios

2.2.1.4.3.1 Dipping application - Primary Exposure

General information

Dipping treatment processes are batch processes using industrial scale process units. Dipping applications are used by industrial and professional users. The treatment itself is carried out in open dip tanks. The dip tank unit consists of a double wall dip tank and hydraulically lifting equipment with an automatic time schedule. The control of liquid level is taking place visually. Beside the dip tank there is a mixing tank. The mixing tank is on a level above the dip tank and equipped with a pipeline into the dip tank.

The formulation is added to the dipping bath, and diluted with water to the in-use concentrations of 6-8% formulation, resulting in an active substance concentration of 0.84-1.12% (the concentration of 1.12% has been considered as worst-case scenario).

The application rate is approximately of 100 - 150 g treatment solution/m² wood surface. The wood surface should be covered completely.

Mixing and loading

Preparation of treatment solution: mixing & loading phase

	Concentration of active substance on the skin	**NOAEC (%)**	**RMMs**
Tier 1	14%	0.3%	n/a
Tier 2	n/a	0.3%	Engineering controls: full automation Gloves and protection coveralls

The 14% AS in water has been allocated to the “High” hazard category according to the classification as corrosive with serious and irreversible effects (Skin Corr 1B - H314). Manual mixing & loading is not acceptable and therefore a fully automated process needs to be put in place where the concentrate is diluted with water by automated dosing systems. The working solution is transferred via pipe and pump systems to the treatment devices or storage tanks. The wood preservative concentrate Sinesto B is delivered typically in bulk-containers (1000 litres) and must be diluted with water to the recommended treatment-concentration. The bulk-containers are directly stored on a special storage yard using a forklift truck. The preparation of the treatment solution is a automated process. The operator has to fill up the necessary volume of concentrate and has to transfer this amount into the mixing container above. Generally, transfer pumps are used. The addition of water is an automatically controlled process. The exposure control related to inhalation is proposed due to a co-formulant since the active substance is non-volatile. Mixing takes place by filling the container with water.

The only possibility for worker’s exposure is during connecting the automated dosing system with the concentrate reservoir. This connecting phase needs no longer than 5 minutes. In addition, the connecting phase does not occur neither for each application process nor daily. Nevertheless, as a worst case it could be considered that the connecting phase might occur only weekly.

Exposure controls

Technical measure: Automated dosing system

Personal protective equipment

- Respiratory protection:

Wear respiratory protection if ventilation is inadequate. Combination filter for gases/vapours of organic, inorganic, acid inorganic and alkaline compounds (e.g. EN 14387 Type ABEK).

- Hand protection:

Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): *e.g.*, nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) and other

Manufacturer's directions for use should be observed because of great diversity of types.

- Eye protection:

Tightly fitting safety goggles (splash goggles) (*e.g.*, EN 166)

- Body protection:

Body protection must be chosen based on level of activity and exposure.

General safety and hygiene measures

Do not inhale gases/vapours/aerosols. Avoid contact with the skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. When using, do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift. At the end of the shift the skin should be cleaned and skin-care agents applied. Gloves must be inspected regularly and prior to each use. Replace if necessary (*e.g.*, pinhole leaks).

Automated dipping

Treatment process: automated dipping

	Concentration of active substance on the skin	**NOAEC (%)**	**RMMs**
Tier 1	1.12%	0.3%	n/a
Tier 2	Accidental exposure: 1.12 %	0.3%	Automated dipping process
Tier 3	n/a	0.3%	Automated dipping processgloves and protection coveralls

The diluted product containing an in-use concentration of 1.12% TMAC in water is allocated to the “Low” hazard category according to the classification as irritant to skin and eye with moderate and reversible effects (Skin Irrit 2 - H315; Eye Irrit 2 – H319).

At this stage, the wood preservative is applied to the wood. The advantage of a dipping process is the uniform, over-all application of the treatment solution without elaborated technical equipment. The degree of penetration can be varied by time schedule over a definite range.

The operator loads wood-piles (wood is strapped down before treatment to form piles) to be treated on the dipping lift using a forklift truck. The operator starts the dipping process and the automatic time schedule will dip the batch. After the timber is lift back from solution a drip off over the dip tank will took place. In this case, the operators lift the parcels a little bit with a forklift truck to make a better drip off.

After the timber is lifted from the solution by forklift, it is held over the dip tank to allow excess fluid to drip back into the tank. Then the wood is placed on the storage yard.

Task	Time schedule
Lift down	1 minute
Dip	4 – 8 minutes
Lift up	1 minute
Drip off	30 – 45 minutes

About 10 to 12 cycles can be conducted in each dip tank per working day, the cycle time is about 40 minutes. Both number of cycles and cycle time refer only to the application process.

Being dipping applications an industrial treatment process, all the operations are carried out using machines. A dermal contact with the wood preservative is excluded. However, a dermal contact with the treated wood or the treating equipment cannot be excluded entirely. Therefore, it is recommended to wear chemical resistant gloves and protective clothing so that do reduce the dermal exposure. Additionally, exposure control related to inhalation is proposed due to a co-formulant since the active substance is non-volatile.

Exposure controls:

Technical measure: Use of automated dipping process

Personal protective equipment

Wear respiratory protection if ventilation is inadequate. Combination filter for gases/vapours of organic, inorganic, acid inorganic and alkaline compounds (e.g. EN 14387 Type ABEK);

Face shield;

Substance/task appropriate gloves;

Tightly fitting safety goggles (splash goggles) (*e.g.*, EN 166);

Protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure);

Good standard of personal hygiene.

Table 2.2.1.4.3.1 – 1. Primary Exposure – Use of the concentrated product (Mixing&Loading phase)

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**	**Conclusion on risk**
High	Skin Corr 1B/1C (H314)	-	8	Industrial and professional users	Connecting the automated dosing system with the concentrate reservoir (14% a.s.)	Skin	Once per week	-	**Technical measure:** Automated dosing system **Personal protective equipment** • Respiratory protection: Wear respiratory protection if ventilation is inadequate. Combination filter for gases/vapours of organic, inorganic, acid inorganic and alkaline compounds (e.g. EN 14387 Type ABEK). • Hand protection: Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) and other Manufacturer's directions for use should be observed because of great diversity of types. • Eye protection: Tightly fitting safety goggles (splash goggles) (e.g. EN 166) • Body protection: Body protection must be chosen based on level of activity and exposure.	Acceptable: + Engineering controls: full automation; + Low frequency; + Minimization of manual phases; + Professionals using PPE; + Professionals following instructions for use; + Good standard of personal hygiene.

									General safety and hygiene measures Do not inhale gases/vapours/aerosols. Avoid contact with the skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. When using, do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift. At the end of the shift the skin should be cleaned and skin-care agents applied. Gloves must be inspected regularly and prior to each use. Replace if necessary (*e.g.*, pinhole leaks).	

Table 2.2.1.4.3.1 – 2. Primary Exposure – Use of the diluted product (Dipping application)

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**	**Conclusion on risk**
Low	Skin Irrit Cat 2 (H315) Eye Irrit2 (H319)	-	8	Industrial and professional users	Dipping treatment process at industrial scale. The treatment carried out in open dip tanks consisting of a double wall dip tank and hydraulically lifting equipment with an automatic time schedule. (1.12% a.s.)	Skin Eyes	***Frequency** 10 - 12 cycles per working day ***Duration** 40 minutes per cycle	-	**Technical measure:** Use of automated dipping process **Personal protective equipment** Wear respiratory protection if ventilation is inadequate. Combination filter for gases/vapours of organic, inorganic, acid inorganic and alkaline compounds (e.g. EN 14387 Type ABEK); Face shield; Substance/task appropriate gloves; Tightly fitting safety goggles (splash goggles) (e.g., EN 166); Protection coverall (EN 13034, 13962, 14605 or 943	Acceptable: + Automated dipping process; + Reversible effects; + Minimization of manual phases; + Avoidance of contact with contaminated objects; + Professionals using PPE; + Professionals following instructions for use; + Good standard of personal hygiene.

									according to pattern of exposure); Good standard of personal hygiene.	

*****Frequency and time duration refer to the actual task duration.

2.2.1.4.3.2 Dipping application - Secondary Exposure

Handling of wet treated wood

Post-application phase: Handling of wet treated wood

	Concentration of active substance on the skin	NOAEC (%)	RMMs
Tier 1	1.12%	0.3%	n/a
Tier 2	n/a	0.3%	Gloves and protection coveralls

The diluted product containing an in-use concentration of 1.12% active substance in water is allocated to the "Low" hazard category according to the classification as irritant to skin and eye with moderate and reversible effects (Skin Irrit 2 - H315; Eye Irrit 2 – H319).

Automated dipping is performed by fork-lift trucks for dipping untreated timber in dip tank. Therefore, dermal exposure is regarded as unlikely. However, if any potential exposure to wet treated wood might happened the use of proper gloves and coveralls should be prescribed as additional risk mitigation measure. Nevertheless, due to the very limited a.s. concentration entering into contact with skin (*i.e.*, leached from wood treated with product containing 1.12% a.s.), no severe health effects are expected provided that gloves and coveralls are worn.

Exposure controls

Technical measure: Automated transport of treated wood by fork-lift trucks

Personal protective equipment

Face shield;

Substance/task appropriate gloves;

Tightly fitting safety goggles (splash goggles) (*e.g.*, EN 166);

Protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure);

Good standard of personal hygiene.

Maintenance and cleaning

Post-application phase: Maintenance and cleaning

	Concentration of active substance on the skin	NOAEC (%)	RMMs
Tier 1	1.12%	0.3%	n/a
Tier 2	n/a	0.3%	Gloves and protection coveralls

As above, the diluted product is allocated to the "Low" hazard category. The task mainly involved professionals collecting fallen timber, and maintenance and cleaning of fork-lifter where potential exposure is assumed only by single contact. As the very limited concentration of a.s. leached from the treated wood, no severe health effects are expected provided that gloves and coveralls are worn.

Exposure controls

Personal protective equipment

Face shield;

Substance/task appropriate gloves;

Tightly fitting safety goggles (splash goggles) (*e.g.*, EN 166);

Protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure);

Good standard of personal hygiene.

Conclusions

	Acceptability	**RMMs required**
Mixing and loading	Acceptable	Engineering controls: gloves and protection coveralls
Automated dipping	Acceptable	Use of automated dipping Gloves and protection coveralls
Handling of wet treated wood	Acceptable	Gloves and protection coveralls
Maintenance and cleaning	Acceptable	Gloves and protection coveralls

Table 2.2.1.4.3.2 – 1. Secondary Exposure – Post-application: Handling of wet treated wood (Dipping application)

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**	**Conclusion on risk**
Low	Skin Irrit Cat 2 (H315) Eye Irrit2 (H319)	-	8	Industrial and professional users	Handling of wet treated wood following the dipping treatment process at industrial scale.	Skin	-	-	**Technical measure:** Automated transport of treated wood by fork-lift trucks **Personal protective equipment:** Face shield; Substance/task appropriate gloves; Tightly fitting safety goggles (splash goggles) (e.g., EN 166); Protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure); Good standard of personal hygiene.	Acceptable: + Reversible effects; + Minimization of manual phases; + Avoidance of contact with contaminated objects; + Professionals using PPE; + Professionals following instructions for use; + Good standard of personal hygiene.

Table 2.2.1.4.3.2 – 2. Secondary Exposure - Post-application: Maintenance and cleaning (Dipping application)

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**	**Conclusion on risk**
Low	Skin Irrit Cat 2 (H315) Eye Irrit2 (H319)	-	8	Industrial and professional users	Maintenance and cleaning	Skin	-	-	**Personal protective equipment:** Face shield; Substance/task appropriate gloves; Tightly fitting safety goggles (splash goggles) (e.g., EN 166); Protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure); Good standard of personal hygiene.	Acceptable: + Reversible effects; + Minimization of manual phases; + Avoidance of contact with contaminated objects; + Professionals using PPE; + Professionals following instructions for use; + Good standard of personal hygiene.

2.2.1.4.3.3 Spraying in close tunnel application - Primary Exposure

General information

The Mixing&loading phase is a fully automated process and occurs in the same way as for the dipping application. The spray treatment is a continuous process and needs a special equipment. The timber is automatically transported to the spray tunnel, passes through a closed spray chamber and the preservative solution is automatically applied on all timber surfaces by various types of spray jet. Impregnation solution that is not absorbed by the wood is collected at the base and returned to the treatment cycle. The fresh treated timber is packed automatically using conveyors to the closed spray chamber and treated properly. Due to the closed system there is no exposure during this phase and duration or frequency are not relevant. After treatment the fresh treated timber is stacked automatically to piles and fixed with tension straps. The piles are transported to the storage yard by forklift trucks. Due to the highly automated process direct contact to the treated wood does not occur. The actual time worker are in proximity to the wood preservative or the treated wood is only few minutes per day.

In conclusion, the operator exposure results to be very low during the whole process.

The formulation is added by spraying in closed tunnel, and diluted with water to the in-use concentrations of 6-8% formulation, resulting in an active substance concentration of 0.84 - 1.12% (the concentration of 1.12% has been considered as worst-case scenario).

The application rate is approximately of 100 - 150 g treatment solution/m² wood surface. The wood surface should be covered completely.

Mixing and loading

Preparation of treatment solution: mixing & loading phase

	Concentration of active substance on the skin	**NOAEC (%)**	**RMMs**
Tier 1	14%	0.3%	n/a
Tier 2	n/a	0.3%	Engineering controls: full automation; Gloves and protection coveralls

The 14% AS in water has been allocated to the “High” hazard category according to the classification as corrosive with serious and irreversible effects (Skin Corr 1B - H314). Manual mixing & loading is not acceptable and therefore a fully automated process needs to be put in place where the concentrate is diluted with water by dosing systems. The Mixing&loading phase is a fully automated process and occurs in the same way as for the dipping application. The concentrate is diluted with water by dosing systems and the working solution is transferred via pipe and pump systems to the treatment devices or storage tanks. The exposure control related to inhalation is proposed due to a co-formulant since the active substance is non-volatile.

The only possibility for worker’s exposure is during connecting the automated dosing system with the concentrate reservoir. This connecting phase needs no longer than 5 minutes. As a worst case the connecting phase could be considered occurring once a week only.

Exposure controls

Technical measure: Automated dosing system.

Personal protective equipment

- Respiratory protection:

Wear respiratory protection if ventilation is inadequate. Combination filter for gases/vapours of organic, inorganic, acid inorganic and alkaline compounds (e.g. EN 14387 Type ABEK).

- Hand protection:

Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): *e.g.*, nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) and other

Manufacturer's directions for use should be observed because of great diversity of types.

- Eye protection:

Tightly fitting safety goggles (splash goggles) (*e.g.*, EN 166)

- Body protection:

Body protection must be chosen based on level of activity and exposure.

General safety and hygiene measures

Do not inhale gases/vapours/aerosols. Avoid contact with the skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. When using, do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift. At the end of the shift the skin should be cleaned and skin-care agents applied. Gloves must be inspected regularly and prior to each use. Replace if necessary (*e.g.*, pinhole leaks).

Spraying in close tunnel application

Treatment process: Spraying in close tunnel application

	Concentration of active substance on the skin	**NOAEC (%)**	**RMMs**
Tier 1	1.12%	0.3%	n/a
Tier 2	Accidental exposure: 1.12 %	0.3%	Closed and automated process;
Tier 3	n/a	0.3%	Closed system process; gloves and protection coveralls

The diluted product containing an in-use concentration of 1.12% TMAC in water is allocated to the “Low” hazard category according to the classification as irritant to skin and eye with moderate and reversible effects (Skin Irrit 2 - H315; Eye Irrit 2 – H319).

The wood is treated by spraying in a continuous process with a special equipment. The timber is automatically transported to the spray tunnel, passes through a closed spray chamber and the preservative solution is automatically applied on all timber surfaces by various types of spray jet. Impregnation solution that is not absorbed by the wood is collected at the base and returned to the treatment cycle. The fresh treated timber is packed automatically using conveyors to the closed spray chamber and treated properly. Due to the closed system there is no exposure during this phase and duration or frequency are not relevant. After treatment the fresh treated timber is stacked automatically to piles and fixed with tension straps. The piles are transported to the storage yard by forklift trucks. Due to the highly automated process

direct contact to the treated wood does not occur. The exposure control related to inhalation is proposed due to a co-formulant since the active substance is non-volatile. The actual time worker are in proximity to the wood preservative or the treated wood is only few minutes per day.

Exposure controls

Technical measure: Closed spray tunnel.

Personal protective equipment

Wear respiratory protection if ventilation is inadequate. Combination filter for gases/vapours of organic, inorganic, acid inorganic and alkaline compounds (e.g. EN 14387 Type ABEK);

Face shield;

Substance/task appropriate gloves;

Tightly fitting safety goggles (splash goggles) (*e.g.*, EN 166);

Protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure);

Good standard of personal hygiene.

Table 2.2.1.4.3.3 – 1. Primary Exposure: Use of the concentrated product (Mixing&Loading phase)

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**	**Conclusion on risk**
High	Skin Corr 1B/1C (H314)	-	8	Industrial and professional users	Connecting the automated dosing system with the concentrate reservoir (14% a.s.)	Skin	Once per week	-	**Technical measure:** Automated dosing system shall be used. **Personal protective equipment** • Respiratory protection: Wear respiratory protection if ventilation is inadequate. Combination filter for gases/vapours of organic, inorganic, acid inorganic and alkaline compounds (e.g. EN 14387 Type ABEK). • Hand protection: Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) and other Manufacturer's directions for use should be observed because of great diversity of types. • Eye protection: Tightly fitting safety goggles (splash goggles) (e.g. EN 166) • Body protection: Body protection must be chosen based on level of activity and	Acceptable: + Engineering controls: full automation; + Low frequency; + Minimization of manual phases; + Professionals using PPE; + Professionals following instructions for use; + Good standard of personal hygiene.

									exposure. **General safety and hygiene measures** Do not inhale gases/vapours/aerosols. Avoid contact with the skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. When using, do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift. At the end of the shift the skin should be cleaned and skin-care agents applied. Gloves must be inspected regularly and prior to each use. Replace if necessary (e.g., pinhole leaks).	

Table 2.2.1.4.3.3 – 2. Primary Exposure – Use of the diluted product (Spraying in close tunnel application)

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**	**Conclusion on risk**
Low	Skin Irrit Cat 2 (H315) Eye Irrit2 (H319)	-	8	Industrial and professional users	Spray treatment a continuous process where timber is automatically transported to the spray tunnel, passes through a closed spray chamber and the preservative solution is automatically applied on all timber surfaces by various types of spray jet (1.12% a.s.).	Skin Eyes	Not relevant	-	**Technical measure:** Closed spray tunnel. **Personal protective equipment:** Wear respiratory protection if ventilation is inadequate. Combination filter for gases/vapours of organic, inorganic, acid inorganic and alkaline compounds (e.g. EN 14387 Type ABEK); Face shield; Substance/task appropriate gloves; Tightly fitting safety goggles (splash goggles) (e.g., EN 166) Protection coverall (EN 13034, 13962, 14605 or 943 according to pattern	Acceptable: + Closed and automated process; + Reversible effects; + Low frequency; + Minimization of manual phases; + Avoidance of contact with contaminated objects; + Professionals using PPE; + Professionals following instructions for

									of exposure); Good standard of personal hygiene.	use; + Good standard of personal hygiene.

2.2.1.4.3.4 Spraying in close tunnel application - Secondary Exposure

Handling of wet treated wood

Post-application phase: Handling of wet treated wood

	Concentration of active substance on the skin	NOAEC (%)	RMMs
Tier 1	1.12%	0.3%	n/a
Tier 2	n/a	0.3%	Gloves and protection coveralls

The diluted product containing an in-use concentration of 1.12% active substance in water is allocated to the "Low" hazard category according to the classification as irritant to skin and eye with moderate and reversible effects (Skin Irrit 2 - H315; Eye Irrit 2 – H319).

After treatment the fresh treated wood is automatically piled and fixed with tension straps. The piles are by fork-lift trucks and therefore, dermal exposure is regarded as unlikely. However, if any potential exposure to wet treated wood might happened the use of proper gloves and coveralls should be prescribed as additional risk mitigation measure. Nevertheless, due to the very limited a.s. concentration entering into contact with skin (*i.e.*, leached from wood treated with product containing 1.12% a.s.), mild health effects are expected provided that gloves and coveralls are worn.

Exposure controls

Technical measure: Treated wood automatically packed, stacked to piles and fixed with tension straps.

Personal protective equipment
Face shield;
Substance/task appropriate gloves;
Tightly fitting safety goggles (splash goggles) (e.g., EN 166);
Protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure);
Good standard of personal hygiene.

Maintenance and cleaning

Post-application phase: Maintenance and cleaning

	Concentration of active substance on the skin	NOAEC (%)	RMMs
Tier 1	1.12%	0.3%	n/a
Tier 2	n/a	0.3%	Gloves and protection coveralls

As above, the diluted product is allocated to the "Low" hazard category. The task mainly involved professionals collecting fallen timber, and maintenance and cleaning of fork-lifter where potential exposure is assumed only by single contact. As the very limited concentration of a.s. leached from the treated wood, no severe health effects are expected provided that gloves and coveralls are worn.

Exposure controls
Personal protective equipment
Face shield;
Substance/task appropriate gloves;
Tightly fitting safety goggles (splash goggles) (e.g., EN 166);
Protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure);
Good standard of personal hygiene.

Conclusions

	Acceptability	**RMMs required**
Mixing and loading	Acceptable	Engineering controls: full automation;
Spraying in close tunnel application	Acceptable	Closed and automated process; Gloves and protection coveralls
Handling of wet treated wood	Acceptable	Gloves and protection coveralls
Maintenance and cleaning	Acceptable	Gloves and protection coveralls

Table 2.2.1.4.3.4 – 1. Secondary Exposure – Post-application: Handling of wet treated wood (Spraying in close tunnel application)

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**	**Conclusion on risk**
Low	Skin Irrit Cat 2 (H315) Eye Irrit2 (H319)	-	8	Industrial and professional users	Handling of wet treated wood following the spraying in close tunnel application.	Skin	-	-	**Technical measure:** Treated wood automatically packed,stacked to piles and fixed with tension straps. **Personal protective equipment** • Hand protection: Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) and other Tightly fitting safety goggles (splash goggles) (e.g. EN 166) • Body protection: Body protection must be chosen based on level of activity and exposure.	Acceptable: + Reversible effects; + Minimization of manual phases; + Avoidance of contact with contaminated objects; + Professionals using PPE; + Professionals following instructions for use;

									General safety and hygiene measures Do not inhale gases/vapours/aerosols. Avoid contact with the skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. When using, do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift. At the end of the shift the skin should be cleaned and skin-care agents applied. Gloves must be inspected regularly and prior to each use. Replace if necessary (e.g., pinhole leaks).	+ Good standard of personal hygiene.

Table 2.2.1.4.3.4 – 2. Secondary Exposure - Post-application: Maintenance and cleaning (Spraying in close tunnel application)

Hazard			Exposure							Risk
Hazard Category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM&PPE	Conclusion on risk
Low	Skin Irrit Cat 2 (H315) Eye Irrit2 (H319)	-	8	Industrial and professional users	Maintenance and cleaning	Skin	-	-	**Personal protective equipment** • Hand protection: Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) and other Tightly fitting safety goggles (splash goggles) (e.g. EN 166) • Body protection: Body protection must be chosen based on level of activity and exposure. **General safety and hygiene measures** Do not inhale gases/vapours/aerosols. Avoid contact with the skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety	Acceptable: + Reversible effects; + Minimization of manual phases; + Avoidance of contact with contaminated objects; + Professionals using PPE; + Professionals following instructions for use; + Good

									practice. Wearing of closed work clothing is recommended. When using, do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift. At the end of the shift the skin should be cleaned and skin-care agents applied. Gloves must be inspected regularly and prior to each use. Replace if necessary (e.g., pinhole leaks).	standard of personal hygiene.

2.2.1.4.3.5 Secondary exposure: Infants mouthing wood off-cut (oral exposure)

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 ([redacted] (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 gastrointestinal 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/m2 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 2.2.1.4.3.5 - 1: 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./cm2 (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

The first study (**Lonza Cologne GmbH**) was conduct according to OECD Guideline 301 D "Ready Biodegradability: Closed Bottle Test" (1989). In the closed bottle test, a test compound is added to an aqueous solution of mineral salts under aerobic conditions for 28 days. Activated sludge was used as inoculum. The inoculum was taken from an activated sludge plant and then preconditioned to reduce the endogenous respiration rate. As preconditioning, the sludge (200 mg DW/L) was aerated for one week. This sludge was diluted to a sludge concentration in the BOD bottle of 2 mg dw/L. After 28 days the test substance showed 75% degradation, compared to the control which showed 82% degradation. The 10-d window criteria was met: the degradation at day1was 10% at day 11 was 69%.
The second study (**Lonza Cologne GmbH**) was conduct according to OECD Guide-line 301 D "Ready Biodegradability: Closed Bottle Test". The inoculum is taken from an activated sludge plant, the municipal waste water treatment plant. The sludge is preconditioned during a week: a sludge suspension of 1 g a.s./L is aerated in the dilution water. The modification is introduced to reduce high residual respiration rate. The results show a degradation of 90% after 2 weeks and 97% after 4 weeks for the test substance. The 10-d window criteria was met.
A study to determine aerobic biodegradation in a sewage treatment plant is not justified since ATMAC is readily biodegradable. However, a study with the structural analog, Didecyldimethylammonium chloride (DDAC) in a simulated treatment system showed 93.3% CO_2 evolution over 28 days indicating that DDAC is biodegraded to a high extent in aerobic acclimated activated sludge.
Both studies use sewage sludge as inoculum while the relevant guideline (OECD 301 D) states that the inoculum is normally derived from the secondary effluent of a STP. Therefore, bacterial density was presumably considerably increased in both tests which may have influenced the result. Nevertheless, based on the previous experience with other QUATs, (mainly with DDAC, a structurally similar compound to coco alkyltrimethylammonium chloride, which is ready biodegradable) it can assume that the final result on the ready biodegradability of a.s. is correct. Under environmental conditions, cationic surfactants are unlikely to pose a toxicity risk to microorganisms because these compoounds will be present in the environment in the µg/L range. The use of linear anionic surfactants, humic acid and silica gel does not lead to a false negative result and thus to a fair interpretation of the biodegradaability (Larsoon 1983; van Ginkel et al 1992; Painter et al 2003). Consequently, negative results obtained in ready biodegradability tests described in the open literature are ignored in case more appropriate tests with anionic surfactants, silica gel, or humic acids are available.

Based on the broad substrate specificity of microorganisms degrading alkyltrimethylammonium salts with respect to the alkyl chain length and the biodegradation mechanism, it is unlikely that the biodegradation potential of alkyltrimethylammonium salts differs significantly with varying chain lengths. Read-across of ready biodegradability test results therefore leads to the conclusion that alkyltrimethylammonium salts are readily biodegradable.

A biodegradation study in seawater was not carried out as coco alkyltrimethylammonium chloride should not be used in seawater.
Coco alkyltrimethylammonium chloride can be considered readily biodegradable. Due to the fact that coco alkyltrimethylammonium chloride was readily biodegradable, field

studies on accumulation in the sediment, aerobic degradation studies in soil, field soil dissipation and accumulation studies were not needed.
Two studies (**EQC**) were performed for biodegradation in soil. The first study was performed on Arquad 2.10-50 that contains 75% of didecyldimethylammonium chloride-carbon and 25% of propan-2-ol-carbon. In the soil biodegradation test, approximately 50% of the carbon is recovered as carbon dioxide within 114 days test period.
No test provided that shows complete mineralization. The DT50 of 114d is not regarded as valid. The study was not conducted under GLP, study ends before 50% degradation of Arquad 2.10-50 is reached, poor documentation (only graph), only data for one soil (OECD 307 requires three soils for estimation of degradation rate).
The second study was performed on Arquad DMMCB-50 that contains 50% C12-16-BKC in water. The study was not conducted under GLP, study ends before 50% degradation is reached, poor documentation (only graph), only data for one soil (OECD 307 requires three soils for estimation of degradation rate). The test substance is biodegraded 60% at day 28. In the soil biodegradation test, approximately 50% of the carbon is recovered as carbon dioxide within 60 days.
No degradation half-lives are available for the active substance since there was no study using coco alkyltrimethylammonium chloride as test material, the two studies were conducted with the structurally analogous substances DDAC (didecyldimethylammonium chloride-carbon) and C12-16-BKC. Half-life times could not have been calculated. Due to the high number of deficiencies and deviations from OECD 307 both he reliability factor, for both studies is 3 and they can only be used as additional information.

CONCLUSION on 2.2.2.1 Fate and distribuition in the environment-Biodegradation:

Coco alkyltrimethylammonium chloride is readily biodegradable. Further studies are not necessary because it is readily biodegradable applies.

Abiotic Degradation

An adequate study (**Lonza Cologne GmbH**) evaluating phototransformation in water has been conducted on the chemical and structural analog, DDAC. DDAC was found to be photolytically stable in the absence of a photosensitiser over a 30-day evaluation period. The half-life of the test compound was determined to be 227 days with 7% degradation after 30 days. Active substance does not absorb light above 290 nm in UV/VIS and is readily biodegradable. Furthermore it will adsorb strongly onto soil and sediment does not reach surface. When it would enter the surface water the main part will be biodegraded by microorganisms present in water. Photodegradation is not likely to occur, even if the substance is slightly photodegradable it will not be an important fate process.
Estimation of photodegradation in air was calculated using the Atmospheric Oxidation Program (AOPWIN) (Howes, D. 2004) considering 24 hours and 5 10^5 oh/cm^3. Mean atmospheric half-life = 0.563 days (13.505 hours).
Coco alkyltrimethylammonium chloride was hydrolytically stable during the 33-day hydrolysis study at pH 5, 7 or 9 at 25°C.

CONCLUSION on 2.2.2.1 Fate and distribuition in the environment-Abiotic degradation:

Coco alkyltrimethylammonium chloride is hydrolytically stable at pH 5, 7 or 9 at 25°C. Estimation of photodegradation in air was calculated using the Atmospheric Oxidation Program (AOPWIN). Atmospheric half life is 13.505 hours, assuming 24 hour according to TGD (2003) chapter 2.3.6.3.

Distribution

The study (**Lonza Cologne GmbH**) has been conduct for the analog DDAC can be considered as immobile in four soil/sediment types with the adsorption (Ka) and mobility (Ka_{oc}) coefficients of Ka=1095 L/kg and Ka_{oc}=437805 L/kg for sand, Ka=8179 L/kg and Ka_{oc}=908757 L/kg for sandy loam, Ka=32791 L/kg and Ka_{oc}=1599564 L/kg for silty clay loam, and Ka=30851 L/kg and Ka_{oc}=1,469,081 L/kg for silt loam. The desorption (Kd) and mobility (Kd_{oc}) coefficients are following reported: Kd=591 L/kg and Kd_{oc}=236473 L/kg for sand, Kd=2074 L/kg and Kd_{oc}=230498 L/kg for sandy loam, Kd=8309 L/kg and Kd_{oc}=405328 L/kg for silty clay loam, and Kd=7714 L/kg and Kd_{oc}=367334 L/kg for silt loam.
It is well known that because of their positive charge, the cationic surfactants adsorb strongly to the negatively charged surfaces of sludge, soil and sediments.
The average K_{oc} is 1.10 10^6 L/kg.
No study was performed with coco alkyltrimethylammonium chloride, bridged study (**Akzo Nobel Surface Chemistry AB**) on the analogous DDAC awas used.
Coco alkyltrimethylammonium chloride can be considered as immobile in three soil types with the adsorption (Ka) and mobility (Ka_{oc}) coefficients of Ka = 9230 L/kgand Ka_{oc} = 280547 L/kg for clay, Ka = 2868 L/kg and Ka_{oc} = 120000 L/kg for silt loam, Ka = 1456 L/kg and Ka_{oc} = 43855 L/kg for loam, Ka = 2188 L/kg and Ka_{oc} = 160882 L/kg for silt, Ka = 1787 L/kg and Ka_{oc} = 40339 L/kg for loamy sand. The K_{oc} mean value is 129125 L/kg.
Active substance will adsorb to any negatively charged surface and becomes immobile then. Also didecyldimethylammonium chloride, analogue of coco alkyltrimethylammonium chloride, can be considered as immobile in all soil/sediment types.

CONCLUSION on 2.2.2.1 Fate and distribuition in the environment-Distribuition:

No study was performed with coco alkyltrimethylammonium chloride, bridged study on the analogous QUATs were used. Active substance will adsorb to any negatively charged surface and can be considered as immobile in all soil/sediment types. The combined Doc IIA and combined assessment report (AR) for coco alkyltrimethylammonium chloride were discussed at WG-II-2015 (26 March 2015). The discussion table contained a discussion point related to the Koc. The Koc used by the eCA in the draft CAR was read-across from DDAC based on a study in the coco alkyltrimethylammonium chloride dossier (from US ISC) with a mean value of 1103801 L/Kg. During trilateral comments, DK suggested to calculate a mean Koc value based on the two studies available on DDAC. During the WG-II-2015 NL proposed to calculate a new Koc omitting the values on soils with a high clay fraction as sorption of this substance to clay is much higher than to other soils. Than an ad-hoc follow up launched. The ad-hoc follow up concluded that the Koc to be used for the risk assessment is 562314 L/Kg (mean value of all Koc values).

Mobility

The mobility of coco alkyltrimethylammonium chloride in soil was not determined, however, a study on the structural analogous, DDAC (**Lonza Cologne GmbH** and **Akzo Nobel Surface Chemistry AB**) was carried out.
The results of the adsorption/desorption study indicated that DDAC had little or no potential for mobility in soil and should not pose an environmental risk for contamination of ground water.

CONCLUSION on 2.2.2.1 Fate and distribuition in the environment-Mobility:

The adsorption/desorption study, conduct on the structural analogue DDAC, indicated that also coco alkyltrimethylammonium chloride had little or no potential for mobility in soil and

should not pose an environmental risk for contamination of ground water.

Bioaccumulation

The bioaccumulation of coco alkyltrimethylammonium chloride (ATMAC/TMAC) has not been experimentally determined. Also, for surfactants like ATMAC, the log K_{ow} cannot be accurately measured nor predicted, therefore an estimation of the intrinsic potential for bioaccumulation cannot be made. The REACH guidance also stresses that for surfactants, measured BCF is preferred. Coco alkyltrimethylammonium chloride is readily biodegradable, is rapidly excreted and does not accumulate in mammals, and it adsorbs onto the fish surface where its irritating action is expressed (therefore accumulation is more related to the concentration of the administered solution). Based on these properties bioaccumulation is not expected to be of concern for ATMAC/TMAC. An experimental $BCF_{whole\ body}$ of 81 L/kg was determined in a flow-through test with *Lepomis machrochirus* and the read across substance DDAC (**Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB**, same study). A very similar result was obtained for the other quaternary ammonium compound benzyl-C_{12-16}-alkyldimethyl ammonium chloride (C_{12-16}-BKC/ADBAC) in a fish bioconcentration test, which gave a $BCF_{whole\ body}$ = 79 L/kg (**Akzo Nobel Surface Chemistry AB, access to Lonza Cologne GmbH study**). Being both studies equally reliable, the $BCF_{whole\ body}$ = 81 L/kg is chosen because related to the lead read across substance (DDAC) and it is slightly higher than the C_{12-16} BKC/ADBAC endpoint.No data are available on the bioaccumulation of coco alkyltrimethylammonium chloride in worms. Also, the $BCF_{earthworm}$ cannot be estimated according to eq. 82d of TGD as it is not applicable to ionized chemicals. Based on the information provided above, a high potential of bioaccumulation of coco alkyltrimethylammonium chloride, such to pose risk of secondary poisoning to birds and mammals, is not expected (see the sensitivity analysis in Doc IIB 3.3.8.1).

Leaching study

The leaching values used in the calculation of Predicted Environmental Concentrations (PECs) are derived from laboratory tests (**Lonza Cologne GmbH**), which were conducted according to the American Wood-Preserver's Association Standard Method E11-97 being different from the OECD guidelines. The RMS considered this study acceptable, without an assessment factor, because it resembles a worst-case as the wooden blocks are continuously submerged in water taking into account the high water solubility for ATMAC, that was accepted at TM level (TMI 09 and TMII 09 as discussed for DDAC). The leaching study provided a worst-case leaching value that was used for Risk Assessment. No assessment factors are applied to the leaching rate of 0.19% per day (i.e. 2.6% in 14 days) because higher leaching rates would indicate a commercially non-viable situation in which the wood preservative would not be retained for sufficient time to warrant the expense of the treatment.

The FLUX and Q*Leach have been calculated according to the Appendices I and II of the OECD ESD. The FLUX and Q*Leach values are following reported:

Daily FLUX (TIME1) = 1.56×10^{-5} kg/m^2/d

Daily FLUX (TIME2) = 1.52×10^{-7} kg/m^2/d

Q*Leach (TIME1) = 5.52×10^{-4} kg/m^2

Q*Leach (TIME2) = 1.19×10^{-3} kg/m^2

The leaching values used in the calculation of Predicted Environmental Concentrations (PECs) are derived from experiments with treated boards. The study showed (**Akzo Nobel Surface Chemistry AB**) that the main active ingredient C8-18 TMAC remains fixed to the boards to an extent of about 100 % (Maier, 2003 ref. B 7.1). The samples were dipped

into a 6 % Sinesto-B solution for 1 minute. After the impregnation the samples are reweighed and the retention was determined. The retention of Sinesto-B based on the measured concentration was 14.6 g/m². The retention achieved is about 25 % higher than the retention required in practise for a good protection of the treated timber. After a leaching period of 55 days and a rainfall of 172.5 mm the leaching rate of TMAC amounts to 0.174 %. The flux rate during the first 30 days amounts to 0.324 mg/m²d. For an extended time interval the flux rate is not calculated due to the low emission.

The leaching values used in the calculation of Predicted Environmental Concentrations (PECs) are derived from experiments with treated boards. The study showed that the main active ingredient TMAC remains fixed to the boards to an extent of about 100 % (Maier, 2003 ref. B 7.1).

The FLUX and Q*Leach have been calculated according to the Appendices I and II of the OECD ESD. The FLUX and Q*Leach values are following reported:

Daily FLUX (TIME1) = $3.06\ 10^{-7}$ kg/m^2/d

Daily FLUX (TIME2) = $1.26\ 10^{-9}$ kg/m^2/d

Q*leach (TIME 1) = 1.02×10^{-8} kg/m^2

Q*leach (TIME 2) = 1.72×10^{-13} kg/m^2

CONCLUSION on 2.2.2.1 Fate and distribuition in the Environment-Leaching:

The worst-case leaching value for FLUX and Q*Leach values are those reported in the Lonza dossier based on a high load of quat of 3.5 kg/m^3 (actual calculated load was 5.4 kg/m^3 was used in the leaching study compared to 1.8 kg/m^3 used in the risk assessments.

2.2.2.2. Effects assessment

Aquatic Compartment

The studies relative to the aquatic core data-set for acute toxicity have been submitted, but only the inhibition of microbial activity test with activated sludge with ATMAC has been judged fully reliable for risk assessment.

A full relibale study with ATMAC is available only for the assessment of inhibition of aquatic microbial activity in STP. The evaluation of the effects of coco alkyltrimethylammonium chloride (ATMAC/TMAC) towards aquatic organisms heavily relies on studies conducted with the other quaternary ammonium *compound didecyldimethylammonium chloride* (DDAC), to which read across has been asked for in both **Lonza Cologne GmbH** and **Akzo Nobel Surface Chemistry AB** dossiers. Additionally, data on the chemical analogous C_{12-16}-BKC have been submitted by **Akzo Nobel Surface Chemistry AB** in further support of the read across.
The rationale which forms the basis for the read across is detailed in Appendix I to the combined doc. IIA. Significantly different toxicity due to different chain length or degree of hydrophobicity between DDAC and ATMAC are not expected, as their chemical structures are within a narrow alkyl chain range (mainly C10 to C14). Also, large difference due to the presence of one alkyl chain instead of two are unlikely based on the comparison of available toxicity information for dialkyl QUATs (DDAC, Bardap 26) and monoalkyl QUATs (ATMAC, ADBAC/BKC). Briefly, the read across is justified by the following:

- structural and functional similarities of the substances,
- similar physicochemical properties,
- similar environmental behaviour and fate properties,
- similar mammalian toxicity and kinetics,
- extended data package on aquatic toxicity showing similar values.

It should be noted that the hazardous properties of the quaternary ammonium compounds on living organisms mainly relate to the local effects of the reactive quaternary ammonium and are characterized by interaction and primary tissue damage at the site of contact. The non-specific mode of action of QUATs is confirmed by the small acute/chronic toxicity factor observed in fish and *Daphnia* tests.

Both Applicants submitted the same study for the acute toxicity to fish, the acute to *Daphnia magna* and the algal inhibition of growth. Fully reliable acute toxicity studies with fish and invertebrates are not available for ATMAC/TMAC because the endpoints are based on nominal concentration and as such may underestimate the toxicity. Nevertheless, the acute fish and daphnia endpoints represent useful data in support of the read across to DDAC/BKC (see doc. IIA and Annex III herein). The algae study (no GLP) was not accepted because conducted with a different QUAT and affected by severe deficiencies. Other chronic toxicity studies with ATMAC and TMAC on aquatic organisms were not submitted in the ATMAC nor in the TMAC dossier. The information on long-term toxicity of coco alkyltrimethylammonium chloride come from a read-across with DDAC data (see doc. IIA and Appendix II herein) which indicate that coco alkyltrimethylammonium chloride is expected to be very toxic to fish, daphnia, and algae and of low toxicity to sediment invertebrates.

The read across of ATMAC to DDAC was accepted by TMIII09, who concluded that a repeat of the core data set was not needed. The read across of ATMAC/TMAC to the DDAC multiple dossier (and to C_{12-16}-BKC) was agreed at TMII2015. A combined list of endpoint for DDAC has been also agreed at TMII2015, whose conclusions apply to the present ATMAC/TMAC multiple dossier whenever reference to read across DDAC data is made.

To take into account the difference in molecular weight between ATMAC/TMAC and DDAC and to cope with the poor quality of data available for coco alkyltrimethylammonium chloride, the DDAC endpoints have been multiplied by a correction factor. This approach was followed in the CAR for ATMAC and agreed for the multiple ATMAC/TMAC CAR at WGII2015. From the 5 batch analysis, an average weighed mean MW = 273.0 for ATMAC and a MW = 277.7 for TMAC have been calculated, and a correction factor of 0.75 has been used, based on the average MW of ATMAC of 273.0 (lowest value) and the MW of 362 for DDAC. When the selected endpoint for coco alkyltrimethylammonium chloride was a read across data to $_{12-16}$-BKC, the correction factor for MW was 0.77 ($MW_{ATMAC/TMAC}$ 273/MW_{BKC} 352.5).

Supportive information from an acute toxicity test with *Oncorhynchus mykiss* indicate that coco alkyltrimethylammonium chloride is acutely toxic to fish, with a 96h LC_{50} of 0.78 mg a.s./L based on nominal concentrations (**Lonza Cologne GmbH** and **Akzo Nobel Surface Chemistry AB**, same study). Several reliable data for different fish species are available for the read across substance DDAC in the ATMAC dossier (96h LC50 ranging from 0.19 mg/L to 1.00 mg/L) and supportive data were sumitted in the TMAC dossier for DDAC and BKC, which fall in the above toxicity range. As final endpoint for coco alkyltrimethylammonium chloride, the RMS retrieved from the ATMAC dossier a read across data to DDAC of 96h LC_{50} = 0.19 mg a.s./L (**Lonza Cologne GmbH**), referring to the most sensitive species Fathead minnow, which gives a 96h LC_{50} =0.14 mg a.s./L, upon correction for MW**.**

Reliable information on the long-term toxicity of coco alkyltrimethylammonium chloride to fish is available for the structural analogue DDAC submitted in the **Lonza Cologne GmbH** dossier (34d NOEC (growth and mortality) = 0.032 mg a.s./L, *Zebra fish, flow through*), which, after correction for MW, gives 34d NOEC = 0.024 mg a.s./L. This data is retained because the only one available, no information is present in the Akzo Nobel Surface Chemistry AB dossier.

Supportive information from an acute toxicity test indicate that coco alkyltrimethylammonium chloride is acutely toxic to *Daphnia magna* with a 48h EC_{50} = 0.093 mg a.s./L based on nominal concentrations (**Lonza Cologne GmbH** and **Akzo Nobel Surface Chemistry AB**, same study). From the **Lonza Cologne GmbH** dossier, the RMS retrieved a read across data to DDAC as 48h EC50 = 0.062 mg a.s./L, calculated as 48h EC_{50} = 0.047 mg a.s./L upon correction for MW, and from the **Akzo Nobel Surface Chemistry AB** dossier, a read across data to C_{12-16}-BKC of 48h EC50 = 0.016 mg a.s./L, calculated as 48h EC_{50} = 0.012 upon correction for MW. The two read across endpoints are equally reliable, but the C_{12-16}–BKC endpoint from the **Akzo Nobel Surface Chemistry AB** dossier is lower and therefore it is selected as worst case for coco alkyltrimethylammonium chloride. The long-term toxicity of coco alkyltrimethylammonium chloride to *Daphnia magna* is extrapolated from the 21d reproduction studies with the read across substance DDAC included in both dossiers. Since both studies are equally reliable (rated 1), have been carried out according to the same guideline, and yield similar results (within a factor of two), the toxicity of coco alkyltrimethylammonium chloride can be expressed as geometric mean of the available endpoints (21d NOEC= 0.014 mg a.s./L) corrected for MW, hence: 21d NOEC= 0.01 mg a.s./L (**Lonza Cologne GmbH** and **Akzo**

Nobel Surface_Chemistry AB). A reproduction study with BKC (rated 2) from the Akzo Nobel Surface Chemistry AB dossier provides a similar result (21d NOEC= 0.025 mg a.s./L).

Acceptable algal studies conducted with ATMAC/TMAC are not available, hence for the toxicity evaluation of coco alkyltrimethylammonium chloride, reference is made to DDAC data submitted in the Lonza Cologne GmbH dossier and to bridging data for DDAC and C_{12-16}-BKC in the Akzo Nobel dossier. The three studies available provide 72/96h E_rC_{50} similar values, while the 72h NOE_rC for C_{12-16}-BKC is lower than the 72/96h NOE_rC from the two DDAC studies.
Considering that EC_{50} is a more statistically robust endpoint than NOEC, that the comparison between NOECs is not straightforward, and that the study in the Lonza Cologne GmbH dossier is of a better quality than the other ones (because based on a full set of measured concentrations), the RMS proposes to disregard the lower NOEC endpoint for C_{12-16}-BKC and to take into account the DDAC data from the **Lonza Cologne GmbH** dossier (see also the combined LoEP for DDAC, agreed at TMII2015): 96h E_rC_{50} = 0.021 mg a.s./L and a 96h NOE_rC = 0.011 mg a.s./L (mean measured). For coco alkyltrimethylammonium chloride, upon correction for difference in MW, 96h E_rC_{50} = 0.016 mg a.s./L and 96h NOE_rC = 0.008 mg/L (mean measured) can be concluded. This procedure has been agreed upon at TMII2015.
No metabolites are known, following the degradation of coco alkyltrimethylammonium chloride in water. This is confirmed by the finding in long term tests with fish and *Daphnia magna* carried out with the read-across substance DDAC (Lonza Cologne GmbH dossier).

CONCLUSION on Aquatic Compartment-Water compartment:

As agreed at WGII2015, the hazard assessment of coco alkyltrimethylammonium chloride to aquatic organisms relies on read across data, mostly to DDAC. While on acute toxicity basis, fish appear to be less sensitive than Daphnia magna and algae, the sensitivity of the three taxa is very similar when chronic endpoints are compared.

Taking into account the chronic endpoints selected as most reliable among all those available in the ATMAC and TMAC dossier, a PNECwater for coco alkyltrimethylammonium chloride can be derived from the lowest of the chronic endpoints available for the three trophic levels, which is the algae 96h NOEC = 0.011 mg/L (mean measured, **Lonza Cologne GmbH**) corrected for difference in MW (96h NOErC = 0.008 mg/L, mean measured), hence:

PNECwater = 0.008 mg a.s./L / AF 10 = 0.0008 mg a.s./L (based on read across to DDAC and correction for MW)

STP compartment

Data from a Respiration Inhibition test with activated sludge exposed to ATMAC provide a $3hEC_{50}$ = 12.2 mg a.i./L (**Lonza Cologne GmbH**); the EC_{10} was not determined. Read across data from DDAC (3h EC_{50} = 17.9 mg a.i./L) and C_{12-16}- BKC (30 min EC_{50} = 11.0 mg a.i./L), submitted by **Akzo Nobel Surface Chemistry AB** in support of the evaluation of TMAC, provide similar results. Although the 30 min EC_{50} from the structural analogue C_{12-16}-BKC would provide an endpoint slightly lower than the 3h EC_{50} from Lonza Cologne GmbH (more so after the correction for difference in MW), it is considered more appropriate to use for the risk assessment of coco alkyltrimethylammonium chloride the endpoint from the **Lonza Cologne GmbH** dossier (3h EC_{50} = 12.2 mg a.i./L) rather than

an extrapolated data. This approach was agreed at WGII2015. It can be concluded that coco alkyltrimethylammonium chloride is slightly toxic to microbial populations in STP.

CONCLUSION on Aquatic Compartment-STP compartment:

For the risk assessment of coco alkyltrimethylammonium chloride to microorganisms in the STP compartment, the 3h EC_{50} = 12.2 mg/L for activated sludge **(Lonza Cologne GmbH)** was used for the PNEC derivation, together with an assessment factor of 100:

PNECmicroorganisms: 12.2 mg a.s./L / AF 100 = 0.122 mg a.s./L

The above approach has been agreed at WGII2015. However, taking into account the conclusion of WG-V-2014 to use the EC_{10} for the $PNEC_{STP}$ derivation (ECHA has not yet clarified by when the procedure applies), WGII2015 concluded that it would be possible at product authorisation stage to use the EC_{10} with an assessment factor of 10, provided that the endpoint is calculated from the study.

Sediment Compartment

No toxicity data for the sediment organisms are available for ATMAC/TMAC. The hazard of coco alkyltrimethylammonium chloride to sediment dwelling organisms is based on one study conducted with the read across substance DDAC, provided in the **Lonza Cologne GmbH** dossier. In a 28 days test with *Chironomus tentans*, the NOEC (emergence) was 530 mg/kg dw, corresponding to 356.16 mg a.s. /kg wwt. After correction for MW, the 28d NOEC for coco alkyltrimethylammonium chloride is calculated as 397.5 mg/kg dw, corresponding to 267.1 mg/kg wwt. As noted in doc. IIA, this endpoint might underestimate the toxicity because during the study animals were fed uncontaminated food.

CONCLUSION on Aquatic Compartment-Sediment compartment:

Information on the the toxicity of coco alkyltrimethylammonium chloride towards sediment dwellers is derived from the only experimental data available, which is relative to DDAC and included in the Lonza Cologne GmbH dossier, yielding a 28d NOEC = 397.5 mg/kg dw (corrected for difference in MW), corresponding to 28d NOEC = 267.1 mg a.s. /kg wwt (corrected for difference in MW) (**Lonza Cologne GmbH**). Hence for coco alkyltrimethylammonium chloride a $PNEC_{sed}$ has been derived from this data and an AF=100:

$PNEC_{sediment}$ = 397.5 mg/kg dw /100= 3.98 mg/kg dw, equivalent to 2.67 **mg/kg wwt** (based on read across to DDAC and correction for MW)

The above approach has been agreed at WGII2015. However, WGII2015 discussed the reliability of the toxicity endpoint for the combined LoEP of DDAC and concluded that, at the renewal stage, either the validity of the above study with *Chironomus tentans* should be verified or the EPM method should be used in additon. Then the lowest endopoint should be used for the assessment.

Terrestrial Compartment

The specific toxicity of coco alkyltrimethylammonium chloride has been investigated only in one acute study with eartworms submitted in the ATMAC dossier by Lonza Cologne GmbH. All the other information used for the hazard assessment of coco alkyltrimethylammonium chloride for terrestrial organisms come from read across data to the structural analogue DDAC (and C_{12-16}-BKC). The rationale supporting the read across is detailed in doc. IIA (Appendix I) and summarized in the chapter "Aquatic compartment" above. The common behaviour in soil and the available information on the toxicity to soil and aquatic invertebrates support the read across. The read across of ATMAC to DDAC was accepted at TMIII09, and at WGII2015 the read across of coco alkyltrimethylammonium chloride to the DDAC multiple dossier (and to C_{12-16}-BKC) was also agreed, together with a combined list of endpoint for DDAC. As done for the aquatic toxicity endpoints, the terrestrial endpoints from the read across substance DDAC and C_{12-16}-BKC have been corrected for difference in molecular weight, using a factor of 0.75 and 0.77, respectively.

Soil organisms

In both dossiers, the toxicity of coco alkyltrimethylammonium chloride to soil microbial populations is extrapolated from data of the read across substance DDAC, but quite different toxicity enpoints are retrieved for nitrogen transformation. In the DDAC study submitted by **Lonza Cologne GmbH**, no effect on nitrite, nitrate, ammonium and carbon dioxide formation was recorded at a concentration of 1000 mg a.s./kg dry soil, both in sandy loam and low humic content sand soils**,** while from the DDAC study included in the **Akzo Nobel Surface Chemistry AB** dossier, 28d EC_{50} = 135.6 mg a.s. /kg dw (120 mg a.s. /kg ww) and 28d EC_{10} = 79.1 mg a.s. /kg dw (70 mg a.s. /kg ww) were calculated. Both tests are equally reliable with the results expressed as nominal concentration, but in the study submitted by Akzo Nobel Surface Chemistry AB the stock solution was measured.

Since the latter study provides the lowest endpoints, it is chosen as conclusion for coco alkyltrimethylammonium chloride: 28d EC_{50} = 101.3 mg a.s. /kg dw (corrected for MW) and 28d EC_{10} = 59.3 mg a.s. /kg dw (corrected for MW) (**Akzo Nobel Surface Chemistry AB**). In addition, these DDAC endpoints are also in line with the toxicity of the other structural analogue C_{12-16}-BKC, for which a 28d EC50 = 153 mg a.s./kg dw and a 8d EC_{10} = 83 mg a.s. /kg dw were measured in a natural sandy loam soil (**Akzo Nobel Surface Chemistry AB**).

No data are available for carbon transformation in the Akzo Nobel dossier but the nitrogen transformation takes into account also the carbon transformation processes, hence the information from this test is considered adequate.

As for soil invertebrates, the effect of coco alkyltrimethylammonium chloride on earthworms was assessed in an acute toxicity test with *Eisenia foetida* exposed to ATMAC, giving a nominal 14d LC_{50} = 3260 mg a.s./kg dry soil and 14d NOEC = 953 mg a.s./kg d.w. (**Lonza Cologne GmbH**). The low acute toxicity of coco alkyltrimethylammonium chloride to soil dwelling organisms is confirmed by DDAC data (14d LC_{50} >1000 mg a.s./kg d.w., **Lonza Cologne GmbH**) and C_{12-16}-BKC data (14d LC_{50} > 517 mg a.s./ kg d.w, **Akzo Nobel Surface Chemistry AB**). The 14d LC50 = 3260 mg a.s./kg d.w. (**Lonza Cologne GmbH**) endpoint is selected as more appropriate because obtained with coco alkyltrimethylammonium chloride itself.

Chronic toxicity data on *Eisenia foetida* are available only in the **Akzo Nobel Surface**

Chemistry AB dossier as read across to DDAC (56d NOEC 125 mg a.s./kg d.w.), from which a 56d NOEC = 93.8 mg a.i./kg dw (corrected for MW) can be calculated for coco alkyltrimethylammonium chloride.

For the evaluation of the toxicity of coco alkyltrimethylammonium chloride to terrestrial plants, both dossiers rely on acute seedling emergence and growth tests conducted with DDAC. One study with mustard, mung bean, and wheat exposed in garden soil, gave for the most sensitive species (mustard) a $EC_{50\ (dry\ weight)}$ = 283 mg a.s./kg d.w. (**Lonza Cologne GmbH**). The second study with DDAC was carried out with *Triticum aestivum, Sinapis alba* and *Trifolium pratense* exposed in natural soil (1.4% OC) and quartz sand, which provided for the most sensitive species *T. pratense* a $EC_{50\ (wet\ weight)}$ = 148 mg/kg dw and a EC_{50} (wet weight) = 11 mg/kg d.w., respectively (**Akzo Nobel Surface Chemistry AB**). The remarkable difference in the toxicity endpoints between the two soil can be reasonably explained by the lower bioavailability the test substance in natural soil, due to the stronger sorption to the soil particles as consequence of several binding processes.
An additional seedling emergence and growth study with C_{12-16}-BKC on the same plants species and soils confirms this finding. For the most sensitive species *T. pratense*, a $EC_{50\ (wet\ weight)}$ = 309 mg/kg d.w. (natural soil with 1.4% OC) and a EC_{50} (wet weight) = 19 mg/kg d.w. (quartz sand) (**Akzo Nobel Surface Chemistry AB**).
Data obtained with quartz soil are judged unrealistically worst case, therefore they are disregarded (as agreed at TM II 1013). From the available information on toxicity in natural soils, the hazard for coco alkyltrimethylammonium chloride to plants is assessed using the lowest endpoint for the most sensitive plant among all the species tested, i.e $EC_{50\ (wet\ weight\ growth)}$ = 148 mg/kg dw soil for *T. pretense* exposed to DDAC (**Akzo Nobel Surface Chemistry AB**) corrected for MW as EC_{50} = 111.0 mg a.s./kg dw (98.3 mg a.s./kg ww).

CONCLUSION on Terrestrial Compartment - Soil organisms

Based on the lowest of the two chronic endpoints available for earthworms and micro-organisms, i.e. 28d EC_{10} = 70 mg/kg ww (79.1 mg/kg dw) for microorganisms for the DDAC data in the Akzo Nobel Surface Chemistry AB dossier (recalculated as 28d EC_{10} = 52.5 mg/kg ww and 59.3 mg/kg dw, upon correction for MW), the PNEC soil for coco alkyltrimethylammonium chloride is derived as follows:

PNEC soil = 52.5 mg/kg ww/50 = 1.05 mg/kg ww equivalent to **1.19 mg/kg dw** (based on read across to DDAC - Akzo Nobel Surface Chemistry AB, corrected for MW)

Birds

Toxicity data on birds are available only in the Lonza Cologne GmbH dossier for the read across substance DDAC. The acute LD_{50} for northern bobwhite quail is 229 mg a.s./kg bw (**Lonza Cologne GmbH**). From the two short term dietary toxicity tests with Northern bobwhite quail (5d LC_{50} > 5620 mg a.s./kg food) and mallard duck (5d LC_{50} > 1633 mg a.s./kg) (**Lonza Cologne GmbH)**, the lowest endpoint was retrieved for mallard duck. After its correction for MW (as concluded at WGII2015), a 5d LC50 > 1225 mg a.s./kg food is calculated for coco alkyltrimethylammonium chloride. 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 dietary toxicity to birds.

CONCLUSION on Terrestrial Compartment - Birds

Based on the lowest dietary endpoint of 5d LC50 > 1225 mg a.s./kg food (corrected for MW), the PNEC for coco alkyltrimethylammonium chloride is derived as follows:

PNEC $_{\text{oral predator, birds}}$ = 1225 mg a.s./kg food / 3000 = 0.41 mg/kg food (based on read across to DDAC, **Lonza Cologne GmbH**)

The above PNEC was agreed at WGII2015.

Mammals

From both the ATMAC and TMAC dossiers, a NO(A)EC value of 100 mg a.s./kg food **(Lonza Cologne GmbH** and **Akzo Nobel Surface Chemistry AB**) measured in a 90d repeated dose study with rat (body weight gain test) treated with coco alkyltrimethylammonium chloride is retrieved. Longer term studies with the read across substance are available for mammals, but the study with ATMAC was selected for the mammals' hazard assessment because it represents the most conservative NO(A)EC and provides the most conservative PNEC.

CONCLUSION on Terrestrial Compartment – Mammals

The 90d NO(A)EC = 100 mg a.s./kg food is used for the PNEC derivation applying the relevant assessment factor:

PNEC $_{\text{oral predator, mammal}}$ = 100 mg/kg / AF90 = 1.11 mg/kg food (**Lonza Cologne GmbH** and **Akzo Nobel Surface Chemistry AB**)

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

Coco alkyltrimethylammonium chloride is hydrolytically stable over an environmentally relevant pH range of 5-9.

Coco alkyltrimethylammonium chloride was found to be photolytically stable in the absence of a photosensitiser.

Studies of the distribution in the water sediment system for the analog DDAC suggest that DDAC easily migrates from the aqueous phase to the sediment phase and is also easily adsorbed to sediments (high K_{oc}). The dissipation in the sediment phase did not increase very much after the first month and the DT_{50} of the total system was not reached within the 120 days test duration.

Coco alkyltrimethylammonium chloride is ready biodegradable.

According to "Guidance on information requirements and chemical safety assessment Chapter R.11: PBT Assessment" 2012, due to the fact that the test methodology for the screening tests on ready biodegradability is stringent, a negative result does not necessarily mean that the chemical will not be degraded under environmental conditions. If sufficient degradation is shown in such a test, i.e. the pass level is reached, the substance can be considered as "not P".

Therefore, the P criterion is not fulfilled.

B criterion: BCF in aquatic species > 2000

A bioconcentration test with fish exposed to the read-across substance DDAC provided a $BCF_{\text{whole body}}$ of 81 L/kg (**Lonza Cologne GmbH** and **Akzo Nobel Surface Chemistry AB**,

same study). In addition, experimental $BCF_{whole\ body}$ = 79 L/kg measured for the other quaternary ammonium compound Alkyl (C12-16) dimethylbenzyl ammonium chloride (C_{12-16}-BKC/ADBAC) shows the same bioaccumulation potential (**Akzo Nobel Surface Chemistry AB, access to Lonza Cologne GmbH study**). Information from toxicokinetics in mammals in both dossiers, indicates that the dermal and gastrointestinal absorption of the structural analogues DDAC and C_{12-16}-BKC is limited, excretion is rapid and no bioaccumulation is evidenced.

Therefore, the B criterion is not fulfilled.

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

No reliable chronic toxicity data are available for coco alkyltrimethylammonium chloride (ATMAC/TMAC) for evaluating the T criterion, however data are available for the structural analogue DDAC (Didecyldimethylammonium chloride), to which a read across is proposed by the two Applicants, that can be used to address the point. The relevant DDAC endpoints have been retrieved from the combined LoEP agreed at TMII2015 for DDAC (multiple dossier). For fish, a study with *B. rerio* gives a 34d NOEC = 0.032 mg a.s./L (**Lonza Cologne GmbH**). For daphnia, a 21d NOEC=0.014 mg a.s./L has been calculated as geometric mean of two studies (**Lonza Cologne GmbH** and **Akzo Nobel Akzo Nobel Surface Chemistry AB**). For algae, a 96h NOE_rC = 0.011 mg a.s./L was retrieved (Lonza Cologne GmbH).

Upon correction of the read across endpoints for difference in molecular weight between ATMAC/TMAC and DDAC (273.0/362 = 0.75, worst case ratio), the following endpoints have been calculated for coco alkyltrimethylammonium chloride: fish 34d $NOEC_{ATMAC/TMAC}$ = 0.032 mg a.s./L x 0.75 = 0.024 mg a.s./L, *Daphnia magna* 21d $NOEC_{ATMAC/TMAC}$ = 0.014 mg a.s./L x 0.75 = 0.01 mg a.s./L, and algae 96d $NOE_rC_{ATMAC/TMAC}$ = 0.011 mg a.s./L x 0.75 = 0.008 mg a.s./L.

The active substance coco alkyltrimethylammonium chloride is classified in according to CLP: Dgr; GHS05; GHS06; GHS09; H301; H311; H314; EUH071; H400 (M factor=10).

As regard to CMR properties no classification is required.

Therefore, the T criterion is fulfilled.

CONCLUSION on PBT assessment:

The active substance coco alkyltrimethylammonium chloride does not meet the PBT criteria.

POP assessment

Coco alkyltrimethylammonium chloride (ATMAC/TMAC) 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). Nonetheless:

- ATMAC/TMAC is not persistent (readily biodegradable);

- ATMAC was concluded to have a low potential for bioaccumulation based on the read-across from DDAC data and C_{12-16} BKC data;

- no potential for long-range environmental transport is expected (mean atmospheric half-life of 0.563 d (**Lonza Cologne GmbH**) and 0.188 d (**Akzo Nobel Surface Chemistry AB**); little potential for mobility in soil based on the read-across from DDAC data)

In conclusion, there is no evidence indicating that coco alkyltrimethylammonium chloride has the POPs-like characteristics (outlined in Annex D 'Information Requirements & Screening Requirements' of the Convention Stockholm Convention on Persistent Organic Pollutants 2001) such that global control is necessary.

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). Different PECs values are due to different input parameter provided by the two Applicants: for the first applicant the Fwater was 10% using the Simple Treat Model according to TMIII08, TMIV08 and TMI09; for the second Applicant EQC according to TM II 2013 the STP simulation test can be used only for the effluent concentration but not for the sludge, therefore Fwater is 0.2 %.

Lonza Cologne GmbH		**Local PEC**
Scenario 1: Dipping treatment during application		
PEClocalwater STP		0.0017 mg/L
PEClocalsed STP		41.5 mg/kgwwt
PECmicroorganism STP		0.046 mg/L
Scenario 2: Dipping treatment during storage		
PEClocalwater run-off		2.3 x 10-3 mg/L
PEClocalsed run-off		51 mg/kgwwt
Scenario 5: Bridge over pond		
PEClocalwater STP	Time1	0.09 mg/L
	Time2	0.00006 mg/L
PEClocalsed STP	Time1	2152 mg/kgwwt
	Time2	1.4 mg/kgwwt
Scenario 6: Noise Barrier		
PEClocalwater STP	Time1	0.0025 mg/L
	Time2	0.00002 mg/L
PEClocalsed STP	Time1	60 mg/kgwwt
	Time2	0.5 mg/kgwwt
PECmicroorganism STP	Time1	0.02 mg/L
	Time2	0.0002 mg/L

Akzo Nobel Surface Chemistry AB	**Local PEC**
Scenario 1: Dipping treatment during application	
PEClocalwater STP	3.96×10^{-5} mg/L
PEClocalsed STP	0.16 mg/kgwwt
PECmicroorganism STP	0.007 mg/L
Scenario 2: Dipping treatment during storage	
PEClocalwater run-off	$4.5\ 10^{-5}$ mg/L
PEClocalsed run-off	0.183 mg/kgwwt

Terrestrial Compartment Exposure assessment

In the following table has been reported the PECs calculated using the OECD Emission Scenario Document for Wood Preservatives (ESD). In the following table has been reported the PECs calculated using the OECD Emission Scenario Document for Wood Preservatives (ESD). The leaching values used in the calculation of PECs are derived from laboratory tests, which were conducted according to the American Wood-Preserver's Association Standard Method E11-97 being different from the OECD guidelines. The eCA considered this study acceptable, without an assessment factor, because it resembles a worst-case as the wooden blocks are continuously submerged in water taking into account the high water solubility for coco alkyltrimethylammonium chloride, that was accepted at TM level (TMI 09 and TMII 09). The leaching study provided a worst-case leaching value that was used for Risk Assessment. No assessment factors are applied to the leaching rate of 0.19% per day (i.e. 2.6% in 14 days) because higher leaching rates would indicate a commercially non-viable situation in which the wood preservative would not be retained for sufficient time to warrant the expense of the treatment.

Lonza Cologne GmbH	**Local PEC**
Scenario 2: Dipping treatment during storage	
PEClocalsoil (TIME 1)	3.0 mg/kg
PEClocalsoil (TIME 2)	0.6 mg/kg
PEClocalsoil, porew (TIME 1)	1.5 10^{-4} mg/L
PEClocalsoil, porew (TIME 2)	3.0 10^{-5} mg/L
Scenario 6: Treated wood in service Noise barrier	
PEClocalsoil (TIME 1)	1.2 mg/kg
PEClocalsoil (TIME 2)	2.5 mg/kg
PECgw	6.0 10^{-5} mg/L
Scenario 7: Treated wood in service Fence	
PEClocalsoil (TIME 1)	2.6 mg/kg
PEClocalsoil (TIME 2)	5.6 mg/kg
PECgw max	1.3 10^{-4} mg/L
Scenario 8: Treated wood in service House	
PEClocalsoil (TIME 1)	3.1 mg/kg
PEClocalsoil (TIME 2)	6.7 mg/kg
PECgw max	1.6 10^{-4} mg/L
Scenario 9: Treated wood in service Transmission pole	
PEClocalsoil (TIME 1)	0.4 mg/kg
PEClocalsoil (TIME 2)	1.0 mg/kg
PECgw max	2.0 10^{-5} mg/L
Scenario 10: Treated wood in service fence post	
PEClocalsoil (TIME 1)	0.4 mg/kg
PEClocalsoil (TIME 2)	0.8 mg/kg
PECgw max	2.0 10^{-5} mg/L

Lonza Cologne GmbH: According to the WGII2015 conclusion, calculated a PECsoil value based upon the indirect exposure of agricultural soil via the spreading of STP sludge. Utilising this application rate results in an Elocalwater (Elocal,facilitydrain) of 1.23 kg/day. Using the worst case Elocalwater, equations 36, 37 & 60 in the TGD, a worst case PEClocalsoil assumption of 0.2 m depth and 0.5 kg.m2.yr-1 sludge application, no accumulation due to the ready biodegradation of ATMAC, a PECsoil of 2.26 mg/kg and PECgw 0.17 µg/l of was calculated.

Akzo Nobel Surface Chemistry AB	Local PEC
Scenario 2: Dipping treatment during storage	
PEClocalsoil (TIME 1)	0.059 mg/kg
PEClocalsoil (TIME 2)	0.0067 mg/kg
PEClocalsoil, porew (TIME 1)	1.8 10^{-8} mg/L
PEClocalsoil, porew (TIME 2)	2.0 10^{-9} mg/L

Akzo Nobel Surface Chemistry AB: According to the WGII2015 conclusion, calculated a PECsoil value based upon the indirect exposure of agricultural soil via the spreading of STP sludge. Utilising this application rate results in an Elocalwater (Elocal,facilitydrain) of 0.507 kg/day. Using the worst case Elocalwater, equations 36, 37 & 60 in the TGD, a worst case PEClocalsoil assumption of 0.2 m depth and 0.5 kg.m2.yr-1 sludge application, no accumulation due to the ready biodegradation of ATMAC, a PECsoil of 0.85 mg/kg and PECgw 0.38 µg/l of was calculated.

Atmospheric Compartment Exposure assessment

Lonza Cologne GmbH	Local PEC
Scenario 1: Dipping application	
Annual average local PEC in air	2.8 10^{-6} mg/m^3
Scenario 2: Storage of dipped / immersed wood	
Annual average local PEC in air	1.13 10^{-15} mg/m^3

Coco alkyltrimethylammonium chloride (**Akzo Nobel Surface Chemistry AB**) is not expected to be present in the air because it is not volatile.

2.2.2.5. Risk characterisation

The spray tunnel application assessed for human exposure was with respect to environmental risks considered to be covered by the dipping scenario. No release is expected to the environment following this application.

Akzo Nobel Surface Chemistry AB

Coco alkyltrimethylammonium chloride is used for temporary protection of wood. Sawn wood is treated by dipping, spray-tunnel (closed system) or continuous flow dip tank. The typical marketed substance is sold and produced as a solution of 33-37% (w/w) coco alkyltrimethylammonium chloride in water. This solution will be further formulated and/or diluted before actual use as wood preservative. Efficacy studies have been performed using Sinesto B, which contains 14% coco alkyltrimethylammonium chloride. Timbers are treated with a concentration of 6-8% Sinesto B (corresponding to 0.84-1.12% a.s.) depending upon duration of the required protection as well as on timber species and degree of hazard. The application rate is approx. 100-150 g treatment solution/m² wood surface, corresponding to 0.84-1.68 g a.s/m² wood surface, covering the surface completely.

Aquatic Compartment

Summary of PEC/PNEC values for aquatic compartment

Lonza Cologne GmbH

Scenario	PEC/PNEC values					
	Water compartment		Sediment compartment		Sewage treatment plant	
Scenario 1 (dipping treatment during application)	**2.13**		**15.5**		0.38	
Scenario 2 (dipping treatment during storage)	**2.88**		**19.1**		-	
Scenario 5 (Bridge over pond)	TIME1	**11.3**	TIME1	**806**	TIME1	
	TIME2	0.008	TIME2	0.52	TIME2	
Scenario 6 (Noise Barrier)	**TIME1**	3.13	**TIME1**	22.4	**TIME1**	0.16
	TIME2	0.03	**TIME2**	0.18	**TIME2**	1.4 x 10-3

The PEC/PNEC ratios for the water and sediment compartments in the scenario 1 and 2 (dipping treatment during application and storage) are higher than 1.

For scenario 5 the PEC/PNEC values for the water and sediment compartments are higher than 1 in the short-term use whilst the long-term use does not pose any risk.

For scenario 6 the PEC/PNEC values for the water and sediment compartments are higher than 1 in the short-term use whilst the long-term use does not pose any risk. For scenario 6 the PEC/PNEC values for STP are lower than 1.

In conclusion, in order to reduce emissions from the application and storage phases for aquatic compartment, the dipping 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.

Akzo Nobel Surface Chemistry AB

Summary of PEC/PNEC values for aquatic compartment

Scenario	PEC/PNEC values		
	Water compartment	Sediment compartment	Sewage treatment plant
Scenario 1 (dipping treatment during application)	0.05	0.06	0.6
Scenario 2 (dipping treatment during storage)	0.06	0.07	-

PEC/PNEC ratios only for transparency. Since the a.s. has been presented for use class 1 and 2 only, it can be concluded that for the aquatic compartment an acceptable risk is expected. In order to reduce emissions from the application and storage phases for aquatic compartment (including sediment), the dipping 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.

Terrestrial Compartment including Groundwater

Lonza Cologne GmbH

Summary of PEC/PNEC values for terrestrial compartment

Scenario	PEC/PNEC values Terrestrial compartment	
Scenario 2 (dipping treatment during storage)	After 30 days	After 15 years
	2.86	0.57
	After 30 days	After 20 years
Scenario 6: Treated wood in service: Noise barrier	**1.14**	**2.38**
Scenario 7: Treated wood in service: Fence	**2.48**	**5.33**
Scenario 8: Treated wood in service: House	**2.95**	**6.38**
Scenario 9: Treated wood in service: Transmission pole	0.38	0.95
Scenario 10: Treated wood in service: Fence post	0.38	0.76

For scenario 2 (dipping treatment during storage) the PEC/PNEC value is higher than 1 suggesting that there is unacceptable for the terrestrial compartment for short- and long-term use. Therefore, all timber treated by dipping should be stored on impermeable hard standing so as to prevent direct losses to soil and allow losses to be collected for re-use or disposal.

For scenarios 6, 7 and 8 the PEC/PNEC values are higher than 1 only in the short-term and in the long-term use.

From scenario 9 and 10 the PEC/PNEC values are lower than 1 in the short-term and in the long-term.
According to the WGII2015 conclusion, a PEC/PNEC value based upon the indirect exposure of agricultural soil via the spreading of STP sludge has been calculated. The PEC/PNEC ratio is higher than 1 (2.15)

Akzo Nobel Surface Chemistry AB

Summary of PEC/PNEC values for terrestrial compartment

Scenario	PEC/PNEC values Terrestrial compartment	
Scenario 2 (dipping treatment during storage)	After 30 days	After 15 years
	0.06	0.01

On the basis of the above results, it can be concluded that there is an acceptable risk for the terrestrial environment.The treated wood is used only under conditions corresponding to hazard class 1 and 2.

According to the WGII2015 conclusion, a PEC/PNEC value based upon the indirect exposure of agricultural soil via the spreading of STP sludge has been calculated. The PEC/PNEC ratio is lower than 1 (0.8)

In conclusion, 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 soil compartment and allow the recovery of the losses for recycling or appropriate disposal. It is also proposed to give label instructions in order to prevent application to timber where direct losses to soil are possible.

Being a potential risk identified for the terrestrial compartments, the use products should be restricted to prevent the use for treatment of wood in contact with fresh water or for treatment of wood that will be continually exposed to the weather or subject to frequent wetting. The product should be authorized in use class 1, 2 and 4A. For authorizing products in use class 3 a safe use should be demonstrated by providing a leaching study at product authorization stage. In fact, the leaching data currently used for the derivation of the PEC values were generated with a worst-case leaching value. Particularly, the leaching study simulates worst-case conditions being the wooden blocks continuously submerged in water, for a period of 14 days, taking into account the high water solubility for coco alkyltrimethylammonium chloride, that was accepted at TM level (TMI 09 and TMII 09).

Summary of ratios PEC/ Limit value for groundwater

As an indication for potential groundwater levels, the concentration in porewater of agricultural soil is taken, according to the TGD equations 67 and 68. It should be noted that this is a worst-case assumption, neglecting transformation and dilution in deeper soil layers.

Lonza Cologne GmbH

Scenario	PEC	Limit value mg/L	PEC/ Limit value
Scenario 2: Storage of dipped/ immersed wood	0.00015 mg/L	0.0001	**1.5**
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	0.00016 mg/L		**1.6**
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 scenario 2 the PEC/Limit value ratio higher than 1 is indicating a potential risk for groundwater. However, in order to reduce emissions from the storage phases for aquatic compartment, the dipping 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, the PEC/ Limit value ratios higher than 1 are indicating a potential risk for groundwater. The treated wood is not placed on the market until it is dry. Consequently, exposure through release in groundwater of treated wet surfaces is considered to be an unlikely exposure scenario.

According to the WGII2015 conclusion, a PEC/Limit value based upon the indirect exposure of agricultural soil via the spreading of STP sludge has been calculated. The ratio is higher than 1.

Akzo Nobel Surface Chemistry AB

Scenario	PEC/PNEC values Terrestrial compartment	
Scenario 2 (dipping treatment during storage)	After 30 days	After 15 years
	0.07	0.008

On the basis of the above results, it can be concluded that there is an acceptable risk for the terrestrial environment.

The treated wood is used only under conditions corresponding to hazard class 1 and 2. There is no use outdoor with soil contact. In addition leaching experiments with treated boards showed that the main active ingredient coco alkyltrimethylammonium chloride remains fixed to the boards to an extent of about 100% (Maier, 2003 ref. B 7.1). Summary of ratios PEC/ Limit value for groundwater.

As an indication for potential groundwater levels, the concentration in porewater of agricultural soil is taken, according to the TGD equations 67 and 68. It should be noted that this is a worst-case assumption, neglecting transformation and dilution in deeper soil layers. Due to the strong adsorption on soil, coco alkyltrimethylammonium chloride is immobile and will not enter shallow groundwater. Therefore PECgroundwater is below 1.8 10^{-5} µg/L. The PEC/Limit value ratio lower than 1 is indicating no risk for groundwater.

Environmental risk in the atmosphere

Lonza Cologne GmbH

For the atmosphere compartment no PNEC values are available. However, for all use patterns, the PEC in air is considered to be negligible (≤ 1.0 x 10^{-5}) suggesting that there is no concern for this compartment.

Akzo Nobel Surface Chemistry AB

Under the conditions described in document IIB, the local annual concentration in air is 0 mg/m^3. Only a qualitative environmental risk assessment can be done for the air compartment, due to the lack of specific effect data. On the basis of abiotic effects, coco alkyltrimethylammonium chloride is not expected to have adverse effects in the atmosphere. Therefore there is no need for further information and/or testing.

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

Lonza Cologne GmbH

Table PEC/PNEC values for secondary poisoning via aquatic food chain:

Scenario	PEC/PNEC values	
	Fish-eating birds	Fish-eating mammals
Scenario 1: Dipping application	0.14	0.052
Scenario 2: Storage of dipping/immersed wood	0.14	0.052

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).
The risk of secondary poisoning via the aquatic food chain is considered be unlikely.

Akzo Nobel Surface Chemistry AB

For mammals, a NO(A)EC =22 mg a.s./kg bw/d (= 100 mg/kg) from a 90d repeated study with rats treated with TMAC is retrived from the Human Health section. No avian toxicity studies were submitted neither for TMAC or for the structural analogues DDAC and C_{12-16}-BKC. TMAC is readily biodegradable and, based on BCF = 81 L/kg (read across to DDAC) and BCF = 79 L/kg (read across to C_{12-16}-BKC), has a low bioaccumulation potential. Feeding studies in mammals indicate no accumulation, show limited uptake and rapid excretion, and an overall low toxicity in case of food administration, without increase in toxicity upon chronic toxicity exposure. In addition, the exposure of environmental compartments is unlikely. Therefore no secondary poisoning is expected to occur.

$PNEC_{oral\ predator(mammal)}$ = 1.1 mg a.s./kg

2.2.3. Assessment of endocrine disruptor properties

CONCLUSIONs for ATMAC - Lonza Cologne GmbH and TMAC - Akzo Nobel Surface Chemistry AB

Structural characteristics and SAR do not hint to possible effects of coco alkyltrimethylammonium chloride as endocrine disruptor. Moreover, neither the available studies nor scientific literature provide any indication of hormonal disrupting activity by the active substance. Therefore, no need for further investigation is envisaged.

2.3. Overall conclusions

The outcome of the assessment for coco alkyltrimethylammonium chloride in product-type 8 is specified in the BPC opinion following discussions at the [number of BPC meeting] meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA web-site.

2.4. List of endpoints

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

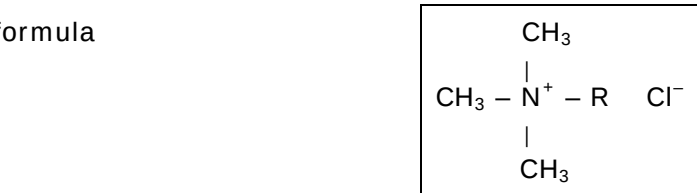
Appendix I: List of endpoints

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

Active substance (ISO Name)	Not available Registered in EINECS as quaternary ammonium compounds, coco alkyltrimethyl, chlorides
Product-type	PT8 Wood preservative

Identity

Chemical name (IUPAC)	Coco alkyltrimethylammonium chloride
Chemical name (CA)	Quaternary ammonium compounds, coco alkyltrimethyl, chlorides
CAS No	61789-18-2
EC No	263-038-9
Other substance No.	None assigned
Minimum purity of the active substance as manufactured (g/kg or g/l)	**ATMAC-Lonza Cologne GmbH:** ≥96.6% w/w (dry weight) ≥34.5% w/w as technical concentrate Barquat CT-35 (reference TK) **TMAC-Akzo Nobel Surface Chemistry AB:** ≥96.9% w/w (dry weight) ≥34.7% w/w as technical concentrate Arquad C-35 (reference TK)
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	$C_{(n+3)}H_{(2n+10)}N.Cl$ (n = 8, 10, 12, 14, 16, 18) and $C_{21}H_{44}N.Cl$ (unsaturated C18)
Molecular mass	Range (corresponding to C8/C18): 207.8–348.1 g/mol **ATMAC - Lonza Cologne GmbH** Average molecular mass according to the mean chain length distribution from the 5-BA of Barquat CT 35: 273.0 **TMAC-Akzo Nobel Surface Chemistry AB** Average molecular mass according to the mean chain length distribution from the 5-BA of Arquad C 35: 277.7

Structural formula	 R = alkyl C8-18 (even-numbered) and C18 (unsaturated)

Physical and chemical properties

Melting point (state purity)	**ATMAC-Lonza Cologne GmbH:** No melting point, the a.s. decomposes above 189°C (98.2%) **TMAC-Akzo Nobel Surface Chemistry AB:** The a.s. decomposes above 160 °C, before melting (98.4%)
Boiling point (state purity)	**ATMAC-Lonza Cologne GmbH:** No boiling point, the a.s. decomposes above 189°C (98.2%) **TMAC-Akzo Nobel Surface Chemistry AB:** No boiling point, the a.s. decomposes above 160 °C before melting (98.4%)
Thermal stability / Temperature of decomposition	**ATMAC-Lonza Cologne GmbH:** >189°C **TMAC-Akzo Nobel Surface Chemistry AB:** >160°C
Appearance (state purity)	**ATMAC-Lonza Cologne GmbH:** White solid; odour: not specific, saponaceous (98.2%) **TMAC-Akzo Nobel Surface Chemistry AB:** Oyster-white wax-like solid with tendency to form clumps and with soapy odour (99.6%)
Relative density (state purity)	**ATMAC-Lonza Cologne GmbH:** 0.935 (98.2%) **TMAC-Akzo Nobel Surface Chemistry AB:** 0.9355 (99.6%)
Surface tension (state temperature and concentration of the test solution)	**ATMAC-Lonza Cologne GmbH:** 35.8 mN/m at 21°C (1 g/L solution) **TMAC-Akzo Nobel Surface Chemistry AB:** 24.04 mN/m (20 ± 0.5 °C; test solution: 1.0 g/L aqueous solution). CMC: 1.0 g/L at 20 ± 0.5 °C

Vapour pressure (in Pa, state temperature)	**ATMAC-Lonza Cologne GmbH:** 1.8 E-6 Pa at 20°C
	3.1 E-6 Pa at 25°C
	3.8 E-5 Pa at 50°C
	TMAC-Akzo Nobel Surface Chemistry AB: < 1.5 E-3 Pa at 20°C
	< 5.8 E-3 Pa at 25°C
Henry's law constant (Pa m^3 mol^{-1})	**ATMAC-Lonza Cologne GmbH:** 1.38 E-9 Pa m^3 mol^{-1} (calculated)
	TMAC-Akzo Nobel Surface Chemistry AB: <1.24 E-6 Pa m^3 mol^{-1} (calculated)
Solubility in water (g/l or mg/l, state temperature)	**ATMAC-Lonza Cologne GmbH:** pH 5: 300 g/l at 20°C
	pH 7: 346 g/l at 20°C
	pH 9: 373 g/l at 20°C
	Un-buffered water: 358 g/l at 20°C
	TMAC-Akzo Nobel Surface Chemistry AB: pH 4: 328 g/l at 20.0 ± 0.5 °C (found independent of temperature)
	pH 9: 328 g/l at 20.0 ± 0.5 °C (found independent of temperature)
	in double-distilled water: 328 g/l at 20.0 ± 0.5 °C (found independent of temperature)
Solubility in organic solvents (in g/l or mg/l, state temperature)	**ATMAC-Lonza Cologne GmbH:** > 250 g/l in ethanol at 20°C
	200 g/l in n-octanol at 20°C
	TMAC-Akzo Nobel Surface Chemistry AB: in isopropanol: 574 g/l at 10°C; 588 g/l at 20°C; 589 g/l at 30°C
	221 g/l in n-octanol at 20°C
Stability in organic solvents used in biocidal products including relevant breakdown products	Not required. The active substance as manufactured does not include any organic solvent. No organic solvent is used in the biocidal product supported by this dossier, either.
Partition coefficient (log P_{OW}) (state temperature)	**ATMAC-Lonza Cologne GmbH:** Not determined. EC methods A.8 are not applicable for surface-active substances. Assessment by KOWWIN is inaccurate (software database very limited for surfactants). Likewise, estimation by Hansch & Leo (log P_{OW} = 0.66) is not deemed reliable. log P_{OW} could be roughly obtained from solubility in pure n-octanol and water (log $P_{OW} \approx 0$). However, this calculation is of no use with regard to environmental fate & behaviour and secondary poisoning risk

	(experimental BCF_{fish} available). **TMAC-Akzo Nobel Surface Chemistry AB:** – 0.17 (calculated from individual solubilities in n-octanol and water at 20°C)
Hydrolytic stability (DT_{50}) (state pH and temperature)	**ATMAC-Lonza Cologne GmbH:** No significant degradation was observed during the 33 day evaluation period. **TMAC-Akzo Nobel Surface Chemistry AB:** Hydrolytically stable
Dissociation constant	Not applicable. The a.s. is fully dissociated in water.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	**ATMAC-Lonza Cologne GmbH:** No significant absorption, due to the lack of chromophores in the molecular structure. **TMAC-Akzo Nobel Surface Chemistry AB:** No absorption above 290 nm
Photostability (DT_{50}) (aqueous, sunlight, state pH)	**ATMAC-Lonza Cologne GmbH:** >30 days pH 7 **TMAC-Akzo Nobel Surface Chemistry AB:** Not applicable, no absorbance above 290 nm in UV spectrum
Quantum yield of direct phototransformation in water at Σ>290 nm	Not applicable
Flammability or flash point	Not flammable
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Auto-ignition or relative self ignition temperature	No self-ignition observed

Classification and proposed labelling

	According to Regulation EC 1272/2008 with amendments
with regard to physical/chemical data	No classification
with regard to toxicological data	Danger GHS05, GHS06 H301; H311; H314; EUH071
with regard to fate and behaviour data	No classification
with regard to ecotoxicological data	GHS09 H400 M factor=10

Chapter 2: Methods of Analysis Analytical methods for the active substance

Technical active substance (principle of method)	**ATMAC-Lonza Cologne GmbH & TMAC-Akzo Nobel Surface Chemistry AB:** Analysis by RP-HPLC/MS-MS (ES^+), two mass transitions validated for each constituent
Impurities in technical active substance (principle of method)	**ATMAC-Lonza Cologne GmbH &TMAC-Akzo Nobel Surface Chemistry AB:** Analysis by RP-HPLC/MS-MS (ES^+), two mass transitions validated for each analyte
	Derivatisation and analysis by LC-DAD-MS/MS (ES^+). Identity confirmation of each analyte by comparison of UV spectra and by a specific MS/MS transition.
	Analysis by ICP-OES
	Karl-Fisher titration

Analytical methods for residues

Soil (principle of method and LOQ)	**ATMAC-Lonza Cologne GmbH:** Extraction with methanol:water (90:10, v/v) containing 0.02 M ammonium formate and 0.05 M hydrochloric acid. LC-MS (m/z = 228.2 for C12-ATMAC). LOQ (total ATMAC) = 0.01 mg/kg *Confirmatory method should preferably be submitted to the eCA-IT at the latest 6 months before the date of approval.* **TMAC-Akzo Nobel Surface Chemistry AB:** Extraction with acetonitrile + 1% TFA. LC-MS/MS (ES+), two mass transitions validated for each TMAC constituent. LOQ (TMAC) = 0.05 mg/kg. LOQ for individual constituents of TMAC = 0.00714 mg/kg
Air (principle of method and LOQ)	Not required. The a.s. is non-volatile and will be used in automated dipping or by spraying in closed tunnel, so no occurrence in air is expected
Water (principle of method and LOQ)	**ATMAC-Lonza Cologne GmbH:** Extraction by liquid-liquid partition with 0.1 M heptanesulfonic acid into dichloromethane. Concentration by rotary evaporation and reconstitution in 0.1% formic acid in methanol. LC-MS (m/z = 228.2 for C12-ATMAC). LOQ (total ATMAC) = 0.1 µg/L *Confirmatory method should preferably be submitted to the eCA-IT at the latest 6 months before the date of approval.*

	TMAC-Akzo Nobel Surface Chemistry AB: Extraction over Strata-X cartridge (eluted with acetonitrile + 0.1% TFA). Concentration by rotary evaporation and reconstitution in acetonitrile:HPLC water + 1% HCOOH (60:40). LC-MS/MS (ES+), two mass transitions validated for each TMAC constituent. LOQ (TMAC) = 0.1 µg/L. LOQ for individual constituents of TMAC = 0.014 µg/L.
Body fluids and tissues (principle of method and LOQ)	Not required. The a.s. was neither tocix nor highly toxic under DSD. Under CLP regulation the a.s. is toxic (H301), but systemic effects are secondary to local effects.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required. Wood treated with ATMAC/TMAC-containing biocidal product is not intended for areas where food for human consumption is prepared, consumed or stored, or where the feeding-stuff 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 ATMAC/TMAC -containing biocidal product is not intended for areas where food for human consumption is prepared, consumed or stored, or where the feeding-stuff for livestock is prepared, consumed or stored.

Chapter 3: Impact on Human Health

ATMAC - Lonza Cologne GmbH:

For some of the endpoints addressed in Impact on Human Health Section, tests have been conducted on the chemical and structural analog, didecyldimethylammonium chloride (DDAC). The justification for read across of coco alkyltrimethylammonium chloride (ATMAC, CAS No. 61789-18-2) with data of DDAC has been accepted and the rationale is explained in details at the beginning of Doc. IIIA-Section 6.

TMAC - Akzo Nobel Surface Chemistry AB:

For some end-points the read across principle from of data on didecyldimethylammonium chloride (DDAC) and benzyl-C12-16-alkyldimethyl ammonium chloride (C_{12-16}-BKC), to which TMAC is structurally related has been accepted. The rationale for the read across acceptance is explained in details at the beginning of Doc. IIA- Section 3 and at the end of Doc. IIIA.

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	**ATMAC - Lonza Cologne GmbH:** 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% at non-corrosive concentrations) and that the majority (90%) of orally administered a.s. is excreted unabsorbed via the faeces. **TMAC-Akzo Nobel Surface Chemistry AB:** Due to its ionic nature, TMAC is expected not to easily pass biological membranes. TMAC: ≥ 3.3% (based on 1.22 excreted by urine and 2% in bile). Supporting data. DDAC & C_{12-16}-BKC: 10%, based the urinary and biliary excretion mean values (3-4% with a single peak value = 8.3% and 3.7-4.6%, respectively as worst case values), in the absence of residues in the carcass. The oral absorption value of 10% at non-corrosive concentrations.
Rate and extent of dermal absorption for the active substance:	**ATMAC - Lonza Cologne GmbH:** Experimental data on DDAC: 9.41% rounded to 10% at non-corrosive concentrations **TMAC-Akzo Nobel Surface Chemistry AB:** Experimental data on DDAC &BKC indicate that 10% can be used (similar to oral absorption value taken as worst case). The dermal absorption value of 10 % at non-corrosive concentrations.

Rate and extent of dermal absorption for the representative product(s)	**ATMAC - Lonza Cologne GmbH:** 9.41% rounded to 10% at non-corrosive concentrations, based on data on 1.85% DDAC in water (read across approach) **TMAC-Akzo Nobel Surface Chemistry AB:** 10% estimated by data on 1.85% DDAC in water (read across approach) The dermal absorption value of 10 % at non-corrosive concentrations.
Distribution:	**ATMAC - Lonza Cologne GmbH:** Following DDAC oral administration, tissue residues were less than 1%. **TMAC-Akzo Nobel Surface Chemistry AB:** Small amounts of radioactivity were detected in the liver, kidneys, spleen, heart, lungs, and skeletal muscles, with only traces detected in the tissues by day 4. Most radioactivity in the intestine **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** limited, most radioactivity in the intestine *(data on DDAC)* **(Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)**
Potential for accumulation:	**ATMAC - Lonza Cologne GmbH:** None **TMAC-Akzo Nobel Surface Chemistry AB:** None **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** None *(data on DDAC)* **(Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)**
Rate and extent of excretion:	**ATMAC - Lonza Cologne GmbH:** Following DDAC oral administration in rats: 89 – 99% excreted in faeces, 2.5% excreted in urine.

	TMAC-Akzo Nobel Surface Chemistry AB: DDAC & C_{12-16}-BKC: Excretion was rapid (within a 48 to 72-hour period). The vast majority of the oral dose was excreted in the faeces (80-90%). Only limited amount was excreted in the urine (3-4%). **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** rapid, >90% excreted in faeces as non absorbed material *(data on DDAC)* **(Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)**
Toxicologically significant metabolite(s)	**ATMAC - Lonza Cologne GmbH:** None other than the parent **TMAC-Akzo Nobel Surface Chemistry AB:** None other than the parent **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** None other than the parent *(data on DDAC)* **(Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)**

Acute toxicity

Rat LD_{50} oral	**ATMAC - Lonza Cologne GmbH:** 207 mg a.s./kg bw **TMAC-Akzo Nobel Surface Chemistry AB:** 207 mg a.s./kg body weight **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 207 mg a.s./kg body weight **(Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)**
Rat LD_{50} dermal	**ATMAC - Lonza Cologne GmbH:** 429 mg a.s./kg bw **TMAC-Akzo Nobel Surface Chemistry AB:** 429 mg a.s./kg bw

	CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION: 429 mg a.s./kg body weight (**Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)**
Rat LC_{50} inhalation	**ATMAC - Lonza Cologne GmbH:** Not applicable **TMAC-Akzo Nobel Surface Chemistry AB:** Study not conducted – not relevant Active substance is corrosive and not volatile. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Study not conducted. Active substance is corrosive and not volatile
Skin / irritation	**ATMAC - Lonza Cologne GmbH:** Corrosive NOAEC (5 days applicaton of DDAC in rats) = 0.6% in water at 2.0 mL/kg body weight per day NOAEC (2weeks applicaton of DDAC in rats) = 0.3% in water at 2.0 ml/kg body weight per day **TMAC-Akzo Nobel Surface Chemistry AB:** Corrosive Literature data: 0.1% constitutes the Threshold Irritant Concentration (TIC) for the rabbit skin upon 24 hour exposure (supporting data) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Corrosive (**Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)** NOAEC (5 days applicaton of DDAC in rats) = 0.6% in water at 2.0 mL/kg body weight per day **(Lonza Cologne GmbH)** NOAEC (2 weeks applicaton of DDAC in rats) = 0.3% in water at 2.0 ml/kg body weight per day (**Lonza Cologne GmbH)**

Eye irritation	**ATMAC - Lonza Cologne GmbH:** Severely irritating **TMAC-Akzo Nobel Surface Chemistry AB:** Corrosive (test item: 1.85% a.s. in water; exposure time: 30 sec. before washing with tap water). Literature data: 0.1% constitutes the Threshold Irritant Concentration (TIC) for rabbit eye. In humans 0.02% of C_{12-16}-BKC can be considered as a NOAEC for eye irritation after repeated exposure. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Corrosive **(Akzo Nobel Surface Chemistry AB)**
Skin sensitization (test method used and result)	**ATMAC - Lonza Cologne GmbH:** Buehler Test – not sensitizing Guinea pig maximisation test – not sensitizing **TMAC-Akzo Nobel Surface Chemistry AB:** M&K maximization test: Not sensitizer **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No skin sensitization potential **(Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)**
Repeated dose toxicity	
Species/ target / critical effect	**ATMAC - Lonza Cologne GmbH:** Any species/ g.i. mucosa/ irritation of g.i. mucosa **TMAC-Akzo Nobel Surface Chemistry AB:** Rat/dog, no specific toxic effects/ critical effects: body weight and body weight gain reduction associated to lower food intake.
Lowest relevant oral NOAEL / LOAEL	**ATMAC - Lonza Cologne GmbH:** *90 days rat (Data on ATMAC*) NOAEL = 100 ppm (corresponding to 22

	mg/kg bw/d) *1-year oral gavage study in dogs* (*Data on DDAC*) Systemic NOEL = 10 mg/kg bw/day; Local effects NOAEL 3 mg/kg bw/day **TMAC-Akzo Nobel Surface Chemistry AB:** TMAC: 22 mg a.s./kd bw/day (90-day rat) DDAC: 15 mg a.s./kg bw/day (90-day dog) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** lowest NOAEL for systemic effects = 10 mg/kg bw/day data on DDAC **(Lonza Cologne GmbH)** lowest NOAEL for local effects on gut mucosa = 3 mg/kg bw/day data on DDAC **(Lonza Cologne GmbH)**
Lowest relevant dermal NOAEL / LOAEL	**ATMAC - Lonza Cologne GmbH:** Systemic NOAEL = 12 mg/kg bw *90 days rat* (*Data on DDAC*) Local NOAEL = 2 mg/kg bw/day **TMAC-Akzo Nobel Surface Chemistry AB:** Study not conducted **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** lowest NOAEL for systemic effects = 12 mg/kg bw/day; lowest NOAEL for local effects on skin = 2 mg/kg bw/day Data on DDAC **(Lonza Cologne GmbH)**
Lowest relevant inhalation NOAEL / LOAEL	**ATMAC - Lonza Cologne GmbH:** No study available. Expected to be irritant/corrosive. **TMAC-Akzo Nobel Surface Chemistry AB:**

No study available. Expected to be irritant/corrosive.

CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION

No study available. Expected to be irritant/corrosive.

Genotoxicity

ATMAC - Lonza Cologne GmbH:

In vitro:

Ames test – negative

Chromosomal aberration test – negative

Mouse lymphoma assay – negative

In vivo:

Micronucleus assay – negative

TMAC-Akzo Nobel Surface Chemistry AB:

In vitro:

Ames test – negative

Chromosomal aberration test – negative

Mouse lymphoma assay – negative

In vivo:

Micronucleus assay – negative

CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:

Not genotoxic in vitro gene mutation study in bacteria and in vitro cytogeneticity and gene mutation assays in mammalian cells. Not genotoxic in vivo micronucleus test in bone marrow. The potential to cause genetic damage of coco alkyltrimethylammonium chloride is negligible based on.

In vitro (Ames test, Chromosomal aberration test and Mouse lymphoma assay) and *in vivo* (Micronucleus assay) genotoxicity tests **(Akzo Nobel Surface Chemistry AB and Lonza Cologne GmbH)**

Carcinogenicity

Species/type of tumour

ATMAC - Lonza Cologne GmbH:

Rat/none, Mouse/none (*data on DDAC*)

Non neoplastic effects; no specific toxic effects/ critical effects: body weight and body weight gain reduction associated to

	lower food intake **TMAC-Akzo Nobel Surface Chemistry AB:** Rat/none Mouse/none (*data on DDAC*) Non neoplastic effects; no specific toxic effects/ critical effects: body weight and body weight gain reduction associated to lower food intake **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** No carcinogenic effects were observed *(data on DDAC)*
lowest dose with tumours	**ATMAC - Lonza Cologne GmbH:** Negative NOAEL for non neoplastic effects = 32 mg a.s./kg/day (2-year rat) **TMAC-Akzo Nobel Surface Chemistry AB:** Negative NOAEL for non-neoplastic effects *Data on DDAC* = 27-39 mg a.s./kg/day (2-year rat) *Data on C_{12-16}-BKC* = 47 mg a.s./kg/day (2-year rat) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** Not applicable. Rat study **(Lonza Cologne GmbH or Akzo Nobel Surface Chemistry AB)** Mouse study **(Lonza Cologne GmbH)**

Reproductive toxicity

Species/ Reproduction target / critical effect	**ATMAC - Lonza Cologne GmbH:** No specific studies on ATMAC - Lonza Cologne GmbH **TMAC-Akzo Nobel Surface Chemistry AB:** See dossier DDAC [N201]J and C_{12-16}-BKC[N200]J. The shared, non-specific, mode of action for toxicity and comparable toxico-kinetics with other quaternary ammonium compounds, makes it possible to use the data from DDAC and C_{12-16}-BKC dossiers for the hazard evaluation for this endpoint. Available reports and results from tests on reproduction toxicity reported in literature indicate that Quaternary ammonium compounds have no potential for developmental or reproductive toxicity. *Data on DDAC*: Rat, 2-generation, via diet. Critical effect (parental) lower food consumption and lower body weight. (postnatal) reduced pup body weights. *Data on C_{12-16}-BKC*: Rat, 2-generation, via diet. Critical effect lower food consumption and lower body weight. Dilatation of coecum in some animals. At top dose level reproductive and neonatal effect with concurrent general toxicity: lower implantation rate, litter size and pup weight **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** Available studies do not indicate any specific potential for reproductive toxicity. Observed effects are likely to be secondary to general toxicity, which is observed at lower dose levels **(Lonza Cologne GmbH or Akzo Nobel Surface Chemistry AB)**
Lowest relevant reproductive NOAEL / LOAEL	**ATMAC - Lonza Cologne GmbH:** parental, F1, F2 = 1500 and 750 mg/kg feed, corresponding to at least approx. 80 and 40 mg/kg bw **TMAC-Akzo Nobel Surface Chemistry AB:** *Data on DDAC* = NOAEL parental: at least 31 mg/kgbw/d (600 mg/kg feed)

	reproduction: at least 89 mg/kgbw/d (1600 mg/kg feed) Parental toxicity at 1600 mg/kg feed at least 89 mg/kg/day): BW reduction Postnatal toxicity at 1600 mg/kg feed: reduced pup body weights *$C_{12\text{-}16}$-BKC* = NOAEL parental: at least 16 mg/kgbw/d (250 mg/kg feed) reproduction at least 96 mg/kgbw/d (1000 mg/kg feed) Reproductive and neonatal effects at highest dose of 2000 mg/kg feed (at least 123 mg/kgbw/d): lower implantation rate, litter size and pup weight **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** No specific potential for reproductive toxicity, overall NOAEL (parental effects) at least 16 mg/kgbw/d (250 mg/kg feed) **(Akzo Nobel Surface Chemistry AB)**
Species/Developmental target / critical effect	**ATMAC - Lonza Cologne GmbH:** Rat/ maternal/ audible breathing rat, developmental: no effect at highest dose tested rabbit/maternal/audible breathing, hypoactivity rabbit/developmental/increased incidence of fetal death, reduced fetal weight (DDAC) **TMAC-Akzo Nobel Surface Chemistry AB:** *Data on TMAC*: Rabbit, according to OECD 414 developmental toxicity during gd 6-18 y, oral gavage. Critical effect: maternal toxicity, fetal weight and increased resorptions. Prenatal developmental toxicity studies with DDAC chloride and $C_{12\text{-}16}$ -BKC do not show any developmental effect. Available data on developmental toxicity of TMAC indicates that its behaviour is similar to DDAC and $C_{12\ 16}$-BKC. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** Available studies indicate that a.s. is not a developmental toxicant, litter effects are secondary to maternal toxicity

	(Lonza Cologne GmbH or Akzo Nobel Surface Chemistry AB)
Lowest relevant developmental NOAEL / LOAEL	**ATMAC - Lonza Cologne GmbH:** Rat maternal LOAEL and NOAEL = 10 and 1 mg/kg bw rat, developmental NOAEL ≥ 20 mg/kg bw rabbit, maternal LOAEL and NOAEL = 3 and 1 mg/kg bw rabbit, developmental LOAEL and NOAEL = 10 and 3 mg/kg bw **TMAC-Akzo Nobel Surface Chemistry AB:** *Data on TMAC* (OECD 414- gavage) NOAEL (both maternal and prenatal): 8.4 mg/kg bw/d; LOAEL: 17.5 mg/kg bw/d: (Maternal) decreased body weight dams (Prenatal) low body weigh foetuses and increased resorptions *Data on DDAC* (OECD 414- gavage) (Maternal): NOAEL 4 mg/kgbw/d; LOAEL: 12 mg/kgbw/d (Prenatal): NOAEL: 12 mg/kgbw/d; LOAEL 32 mg/kg bw/d *Data on $C_{12\text{-}16}$- BKC* (OECD 414- gavage) (Maternal): NOAEL 3 mg/kgbw/d; LOAEL 12 mg/kg bw/day (Prenatal): NOAEL 30 mg/kg bw/day (highest dose) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION (None: lowest NOAELs are due to local effects)** No specific potential for developmental toxicity: overall NOAEL (maternal toxicity) = 1 mg/kg bw/d

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	**ATMAC - Lonza Cologne GmbH:** Not pertinent **TMAC-Akzo Nobel Surface Chemistry AB:** None **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** Not applicable
Lowest relevant developmental NOAEL / LOAEL.	**ATMAC - Lonza Cologne GmbH:** None **TMAC-Akzo Nobel Surface Chemistry AB:** None **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** Not applicable **(Lonza Cologne GmbH or Akzo Nobel Surface Chemistry AB:** available studies provide no indication for developmental immunotoxicity**)**

Other toxicological studies

.....	**ATMAC - Lonza Cologne GmbH:** Not required **TMAC-Akzo Nobel Surface Chemistry AB:** Not applicable **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** Not applicable

Medical data

....	**ATMAC - Lonza Cologne GmbH:** No substance-specific effects have been noted. No specific observations or sensitivity/allergenicity have been reported **TMAC-Akzo Nobel Surface Chemistry AB:** No substance-specific effects have been noted. No specific observations or sensitivity/allergenicity have been reported **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No specific observations or sensitivity/allergenicity or any medical information have been reported (**Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)**

Summary for Local effects

	Value	Study
Dermal NOAEC	**0.3%**	2-week skin irritation study with rats **(Lonza Cologne GmbH**)
Oral NOAEC	**0.03%**	52-week oral gavage study in dogs **(Lonza Cologne GmbH**

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[2]	Not applicable	-----	**-----**
ARfD	Not applicable		

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	-----	-----

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

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

[2] If residues in food or feed.
[3] If residues in food or feed.

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

MRLs

Relevant commodities	Not applicable

Reference value for groundwater

According to BPR Annex VI, point 68	0.1 µg/L

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)	**ATMAC - Lonza Cologne GmbH:** Hydrolytically stable **TMAC-Akzo Nobel Surface Chemistry AB:** Hydrolytically stable **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Hydrolytically stable **(Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)**
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	**ATMAC - Lonza Cologne GmbH:** The photolysis data available for DDAC are adequate for ATMAC. The test substance is photolytically stable in absence of a photosensitising agent **TMAC-Akzo Nobel Surface Chemistry AB:** Not applicable no absorbance above 290 nm in UV spectrum **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Photolytically stable **(Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)**
Readily biodegradable (yes/no)	**ATMAC - Lonza Cologne GmbH:** Yes **TMAC-Akzo Nobel Surface Chemistry AB:** Yes **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Ready biodegradable the 10-day window critetia is fulfilled **(Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)**
Biodegradation in seawater	**ATMAC - Lonza Cologne GmbH:** Not used in seawater **TMAC-Akzo Nobel Surface Chemistry AB:** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.

Non-extractable residues	**ATMAC - Lonza Cologne GmbH:** n.a. **TMAC-Akzo Nobel Surface Chemistry AB:** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Distribution in water / sediment systems (active substance)	**ATMAC - Lonza Cologne GmbH:** n.a. **TMAC-Akzo Nobel Surface Chemistry AB:** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Distribution in water / sediment systems (metabolites)	**ATMAC - Lonza Cologne GmbH:** Not conducted **TMAC-Akzo Nobel Surface Chemistry AB:** Not conducted **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.

Route and rate of degradation in soil

Mineralization (aerobic)	**ATMAC - Lonza Cologne GmbH:** No data available **TMAC-Akzo Nobel Surface Chemistry AB:** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Laboratory studies (range or median, with number of measurements, with regression coefficient)	**ATMAC - Lonza Cologne GmbH:** DT_{50lab} (20°C, aerobic): No data available DT_{90lab} (20°C, aerobic): No data available DT_{50lab} (10°C, aerobic): No data available DT_{50lab} (20°C, anaerobic): No data available degradation in the saturated zone: No data available **TMAC-Akzo Nobel Surface Chemistry AB:** DT_{50lab} (20°C, aerobic): /

	DT_{90lab} (20°C, aerobic): /
	DT_{50lab} (10°C, aerobic): /
	DT_{50lab} (20°C, anaerobic):
	degradation in the saturated zone: /
	CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION: n.a.
Field studies (state location, range or median with number of measurements)	**ATMAC - Lonza Cologne GmbH:**
	DT_{50f}: No data available
	DT_{90f}: No data available
	TMAC-Akzo Nobel Surface Chemistry AB:
	DT_{50f}: No data available
	DT_{90f}: No data available
	CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION: n.a.
Anaerobic degradation	**ATMAC - Lonza Cologne GmbH:**
	No data available
	TMAC-Akzo Nobel Surface Chemistry AB:
	Active substance completely mineralizes
	CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION: n.a**.**
Soil photolysis	**ATMAC - Lonza Cologne GmbH:**
	No data available
	TMAC-Akzo Nobel Surface Chemistry AB:
	No data available
	CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION: n.a.
Non-extractable residues	**ATMAC - Lonza Cologne GmbH:**
	Not applicable
	TMAC-Akzo Nobel Surface Chemistry AB:
	Not applicable
	CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION: n.a.
Relevant metabolites - name and/or code, % of applied active ingredient (range and maximum)	**ATMAC - Lonza Cologne GmbH:**
	No data available
	TMAC-Akzo Nobel Surface Chemistry AB:
	Not applicable

	CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION: n.a.
Soil accumulation and plateau concentration	**ATMAC - Lonza Cologne GmbH:** No data available **TMAC-Akzo Nobel Surface Chemistry AB:** Not applicable **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Adsorption / desorption	
Ka, Kd	**ATMAC - Lonza Cologne GmbH:** 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) **TMAC-Akzo Nobel Surface Chemistry AB:** Ka = 9230 L/kg, Kd = 3718 L/kg (Clay) Ka = 2868 L/kg, Kd = 4237 L/kg Silt loam) Ka = 1456 L/kg, Kd = 2117 L/kg (Loam) Ka = 2188 L/kg, Kd = 3161 L/kg (Silt) Ka = 1787 L/kg, Kd = 2387 L/kg (Loamy sand)
Ka_{oc} , Kd_{oc}	**ATMAC - Lonza Cologne GmbH:** 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 **TMAC-Akzo Nobel Surface Chemistry AB:** Ka_{oc} = 280547 L/kg, Kd_{oc} = 113009 L/kg (Clay) Ka_{oc} = 120000 L/kg, Kd_{oc} = 177280 L/kg Silt loam) Ka_{oc} = 43855 L/kg, Kd_{oc} = 63765 L/kg

	(Loam) Ka_{oc} = 160882 L/kg, Kd_{oc} = 232426 L/kg (Silt) Ka_{oc} = 40339 L/kg, Kd_{oc} = 53883 L/kg (Loamy sand) K_{oc} mean: 186687 L/kg
pH dependence (yes / no) (if yes type of dependence)	**ATMAC - Lonza Cologne GmbH:** No **TMAC-Akzo Nobel Surface Chemistry AB:** No **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** K_{oc} mean: 562.314 L/kg. **(mean value of all DDAC results)**

Fate and behaviour in air

Direct photolysis in air	**ATMAC - Lonza Cologne GmbH:** Due to low vapour pressure (1.8 x 10^{-6} Pa) and Henry's Law constant (1.38 x 10^{-9} Pa m^3/mol), ATMAC is not expected to partition to the atmosphere to any significant extent. Estimation of the phototransformation in air of a structural and chemical analog Didecyldimethyl ammonium Chloride (DDAC) indicates that the substance would be very stable in air. It is considered that the same would apply for ATMAC. **TMAC-Akzo Nobel Surface Chemistry AB:** Not applicable, active substance is not volatile **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Stable in air **(Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)**
Quantum yield of direct photolysis	**ATMAC - Lonza Cologne GmbH: /** **TMAC-Akzo Nobel Surface Chemistry AB:** Not applicable no adsorption above 290 nm in UV spectrum **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.

Photo-oxidative degradation in air	**ATMAC - Lonza Cologne GmbH:** Latitude: ..../..... Season: ...../..... DT_{50} 13.505 h OH-radicals concentration of 0.5 $x10^6$ [molec.cm^{-3}] and 24 hours (calculated using the Atmospheric Oxidation Program) **TMAC-Akzo Nobel Surface Chemistry AB:** Latitude: ...../..... Season: ...../..... DT_{50} 13.505 h OH-radicals concentration of 0.5 $x10^6$ [molec.cm^{-3}] and 24 hours (calculated using the Atmospheric Oxidation Program) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 13.505 hours **(Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)**
Volatilization	**ATMAC - Lonza Cologne GmbH:** / **TMAC-Akzo Nobel Surface Chemistry AB:** Not applicable, active substance is not volatile **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Not volatile **(Akzo Nobel Surface Chemistry AB)**

Monitoring data, if available

Soil (indicate location and type of study)	**ATMAC - Lonza Cologne GmbH:** Not available **TMAC-Akzo Nobel Surface Chemistry AB:** Not applicable **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Surface water (indicate location and type of study)	**ATMAC - Lonza Cologne GmbH:** Not available **TMAC-Akzo Nobel Surface Chemistry AB:** Not applicable **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a

Ground water (indicate location and type of study)	**ATMAC - Lonza Cologne GmbH:** Not available **TMAC-Akzo Nobel Surface Chemistry AB:** Not applicable **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Air (indicate location and type of study)	**ATMAC - Lonza Cologne GmbH:** Not available **TMAC-Akzo Nobel Surface Chemistry AB:** Not applicable **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a**.**

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)			
Species	Time-scale	Endpoint	Toxicity
Fish			
<u>Acute toxicity</u> **ATMAC - Lonza Cologne GmbH** Fathead Minnow *(Pimephales promelas)*	96 h	Mortality	LC_{50} = 0.19 mg a.s./L (read across to DDAC) LC_{50} = 0.14 mg a.s./L (corrected for MW)
TMAC - Akzo Nobel Surface Chemistry AB *Salmo gairdneri*	96 h	Mortality	Only supportive information available **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** LC_{50} = 0.19 mg a.s./L (read across to DDAC) LC_{50} = 0.14 mg a.s./L (corrected for MW) **(Lonza Cologne GmbH)**

Chronic toxicity **ATMAC - Lonza Cologne GmbH** Zebra fish (*Brachydanio rerio*) **TMAC - Akzo Nobel Surface Chemistry AB**	34 d	Growth and mortality	NOEC = 0.0322 mg a.s./L EC10 = not available. (read across to DDAC) NOEC = 0.024 mg a.s./L (corrected for MW) No data **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** NOEC = 0.0322 mg a.s./L EC10 = not available. (read across to DDAC) NOEC = 0.024 mg a.s./L (corrected for MW) **(Lonza Cologne GmbH)**
Invertebrates			
Acute toxicity **ATMAC - Lonza Cologne GmbH** *Daphnia magna*	48 h	Immobilisation	EC_{50} = 0.062 mg a.s./L (read across to DDAC) EC_{50} = 0.047 mg a.s./L (corrected for MW)

TMAC - Akzo Nobel Surface Chemistry AB *Daphnia magna*	48h		EC_{50} = 0.016 mg a.s./L (read across to C_{12-16}-BKC) EC_{50} = 0.012 (corrected for MW) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** EC_{50} = 0.016 mg a.s./L (Read across to C_{12-16}-BKC) EC_{50} = 0.012 (corrected for MW) **(Akzo Nobel Surface Chemistry AB)**
<u>Chronic toxiciy (aquatic)</u> **ATMAC - Lonza Cologne GmbH**	21 d	Reproduction and survival	$NOEC_{survival}$ = 0.010 mg/L EC_{10} = not available. (read across to DDAC) $NOEC_{survival}$ = 0.075 mg a.s./L (corrected for MW)
TMAC - Akzo Nobel Surface Chemistry AB	21 d	Reproduction and survival	$NOEC_{sur.,repr.}$ = 0.021 mg a.s./L EC10 = not available. (read across to DDAC) $NOEC_{sur.,repr.}$ = 0.016 (corrected for MW) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 21d NOEC= 0.014 mg a.s./L (geo mean value from the two read across data to DDAC) 21d NOEC = 0.01 mg a.s./L (corrected for MW) **(Lonza Cologne GmbH** and **Akzo Nobel Surface Chemistry AB**

Chronic toxiciy (sediment) **ATMAC - Lonza Cologne GmbH** *Chironomus tentans*	28 d	Mortality and growth	$NOEC_{emergence}$=530 mg/kg dw (356.16 mg/kg wwt) (read across to DDAC) $NOEC_{emergence}$= 397.5 mg a.s./kg dw (267.1 mg/kg wwt) (corrected for MW)
TMAC - Akzo Nobel Surface Chemistry AB			No data **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** $NOEC_{emergence}$= 530 mg/kg dw (356.16 mg/kg wwt) (read across to DDAC) $NOEC_{emergence}$= 397.5 mg a.s./kg dw (267.1 mg/kg wwt) (corrected for MW) **(Lonza Cologne GmbH)**

Algae			
Inhibition of growth **ATMAC - Lonza Cologne GmbH** *Pseudokirchneriella subcapitata (ex Selenastrum capricornutum)*	96 h	Biomass production and cell density	E_rC_{50} = 0.021 mg a.s./L; EC_{10} = not available NOE_rC = 0.011 mg a.s./L (read across to DDAC, mean measured conc) NOE_rC = 0.008 mg a.s./L (corrected for MW)
TMAC - Akzo Nobel Surface Chemistry AB *Pseudokirchneriella subcapitata (ex Selenastrum capricornutum)*	72 h	Growth rate and biomass	Read across to DDAC: E_rC_{50} = 0.062 mg a.s./L NOE_rC= 0.013 mg a.s./L E_rC_{10} = 0.024 mg a.s./L (nominal conc.; partial analyses at high concentrations) Read across to C_{12-16}-BKC: E_rC_{50} = 0.026 mg a.s./L NOE_rC **=** 0.0025 mg a.s./L E_rC_{10} = 0.0057 mg a.s./L (nominal conc.; analysis at one very high concentration) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 96h E_rC_{50} = 0.021 mg a.s./L (read across to DDAC) 96h E_rC_{50} = 0.016 mg a.s./L (corrected for MW) NOE_rC = 0.011 mg a.s./L (read across to DDAC) NOE_rC = 0.008 mg a.s./L (corrected for MW) **(Lonza Cologne GmbH)**

Microorganisms			
ATMAC - Lonza Cologne GmbH Lonza Cologne GmbH Activated sewage sludge	3 h	Respiration inhibition	EC_{50} = 12.2 mg/L EC_{10} = not available
TMAC - Akzo Nobel Surface Chemistry AB Activated sewage sludge	3 h	Respiration inhibition	Read across to DDAC: 3 h EC_{50} = 17.9 mg a.i./L 3 h EC_{50} =13.8 mg a.i./L (corrected for MW) 3h EC_{10} =5.95 mg a.i./L 3h EC_{10} = 4.58 mg a.i./L (corrected for MW)
Activated sewage sludge	30 min		Read across to C_{12-16}-BKC: 30 min EC_{50} = 11 mg a.i./L 30 min EC_{50} = 8.69 mg a.s./L (corrected for MW) 30 min EC_{10} =4 mg a.i./L 30 min EC10 =3.16 mg a.i./L (corrected for MW) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** EC_{50} = 12.2 mg/L **(Lonza Cologne GmbH)**

Effects on earthworms or other soil non-target organisms

Acute toxicity to *Eisenia foetida*	**ATMAC - Lonza Cologne GmbH:** LC_{50} = 3260 mg/kg dw, in artificial soil **TMAC-Akzo Nobel Surface Chemistry AB:** Read across to BKC LC_{50} > 517 mg a.s./kg dw (corresponding to > 410 mg a.i./kg wwt) (artificial soil, nominal) $LC_{50\ (TMAC)}$ > 408.4 mg a.s./kg dw (> 323.9 mg a.i./kg wwt)(corrected for MW) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** LC_{50} = 3260 mg/kg dw, in artificial soil **(Lonza Cologne GmbH)**
Acute toxicity to plants	**ATMAC - Lonza Cologne GmbH:** EC_{50} (mustard) = 283 mg a.s./kg dw soil (Read across to DDAC) EC_{50} (mustard) = 212.3 mg/kg dw soil (corrected for MW) **TMAC-Akzo Nobel Surface Chemistry AB:** Read across to DDAC EC_{50} = 148 mg a.s./kg dw (131 mg a.s./kg wwt) (*T. pratense*, most sensitive plant; natural soil, nominal) EC_{50} = 114.0 mg a.s./kg dw (100.9 mg a.s./kg wwt (corrected for MW) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** Read across to DDAC EC_{50} = 148 mg a.s./kg dw (131 mg a.s./kg wwt) (*T. pratense*, most sensitive plant; natural soil, nominal) EC_{50} = 111 mg a.s./kg dw (98.3 mg a.s./kg wwt (corrected for MW) **(Akzo Nobel Surface Chemistry AB)**
Reproductive toxicity to *Eisenia foetida*	**ATMAC - Lonza Cologne GmbH:** No data available **TMAC-Akzo Nobel Surface Chemistry AB:** Read across to DDAC: 56d NOEC = 125 mg a.i./kg dw (nominal) 56d NOEC= 96.3 mg a.i./kg dw (corrected for MW)

CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION
Read across to DDAC:
56d NOEC = 125 mg a.i./kg dw (nominal)
56d NOEC= 93.8 mg a.i./kg dw (corrected for MW)
(Akzo Nobel Surface Chemistry AB)

Effects on soil micro-organisms

Nitrogen mineralization	**ATMAC - Lonza Cologne GmbH:** EC_{50} > 1000 mg a.s. /kg dw (Read across to DDAC data) EC_{50} > 750 mg a.s. /kg dw (corrected for MW) **TMAC-Akzo Nobel Surface Chemistry AB:** Read across to DDAC: 28d EC_{50} = 135.6 mg a.s. /kg dw (120 mg a.s. /kg ww) 28d EC_{50} = 104.4 mg a.s. /kg dw (92.4 mg a.s. /kg ww)(corrected for MW) 28d EC_{10} = 79.1 mg a.s. /kg dw (70 mg a.s. /kg ww) 28d EC_{10} = 60.9 mg a.s. /kg dw (53.9 mg a.s. /kg ww) (corrected for MW) (measured in stock solution) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** Read across to DDAC 28d EC_{50} = 135.6 mg a.s. /kg dw (120 mg a.s. /kg ww) 28d EC_{50}= 101.3 mg a.s. /kg dw (90.0 mg a.s. /kg ww) (corrected for MW) 28d EC_{10} = 79.1 mg a.s. /kg dw (70 mg a.s. /kg ww) 28d EC_{10} = 59.3 mg a.s. /kg dw (52.5 mg a.s. /kg ww) (corrected for MW) **(Akzo Nobel Surface Chemistry AB)**
Carbon mineralization	**ATMAC - Lonza Cologne GmbH:** EC_{50} > 1000 mg a.s./kg dw (Read across to DDAC data) EC_{50} > 750 mg a.s./kg dw (corrected for MW)

	TMAC-Akzo Nobel Surface Chemistry AB: No data **Conclusion:** Data of Nitrogen mineralization **(Akzo Nobel Surface Chemistry AB**) would cover this point.
Effects on terrestrial vertebrates	
Acute toxicity to mammals	**ATMAC - Lonza Cologne GmbH:** LD_{50}= 207 mg a.s. /kg bw **TMAC - Akzo Nobel Surface Chemistry AB:** LD_{50} value of 207 mg a.s./kg/ body weight (rat) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** LD_{50}= 207 mg a.s. /kg bw **(Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)**
Repeated dose toxicity to mammals	**ATMAC - Lonza Cologne GmbH:** NOEC 100 mg/kg food (90d, rat, reduction in body weight gain) **TMAC-Akzo Nobel Surface Chemistry AB:** NOEC 22 mg a.s./kg bw/d (= 100 mg/kg food) (90d, rat) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** NOEC 100 mg/kg food **(Lonza Cologne GmbH; Akzo Nobel Surface Chemistry AB)**
Acute toxicity to birds	**ATMAC - Lonza Cologne GmbH:** Northern bobwhite quail LD_{50} = 229 mg a.s./kg bw (read across to DDAC) **TMAC-Akzo Nobel Surface Chemistry AB:** Not data. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** LD_{50} = 229 mg a.s./kg bw (Northern bobwhite quail) (read across to DDAC) **(Lonza Cologne GmbH)** LD_{50} = 171.8 mg a.s./kg bw (Northern bobwhite quail)
Dietary toxicity to birds	**ATMAC - Lonza Cologne GmbH:**

	Northern bobwhite quail and mallard duck LC_{50} ≥ 1633 mg a.s./kg food (Read across to DDAC) **TMAC-Akzo Nobel Surface Chemistry AB:** No data. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** LC_{50} ≥ 1633 mg a.s./kg food (Northern bobwhite quail and mallard duck) (Read across to DDAC data) **(Lonza Cologne GmbH)** LC_{50} ≥ 1225 mg a.s./kg food (Northern bobwhite quail and mallard duck) **(Lonza Cologne GmbH)** (corrected for MW)
Reproductive toxicity to birds	**ATMAC - Lonza Cologne GmbH:** No data. **TMAC-Akzo Nobel Surface Chemistry AB:** No data.

Effects on honeybees

Acute oral toxicity	**ATMAC - Lonza Cologne GmbH:** No data available. Not required **TMAC-Akzo Nobel Surface Chemistry AB:** No data.
Acute contact toxicity	**ATMAC - Lonza Cologne GmbH:** No data available. Not required **TMAC-Akzo Nobel Surface Chemistry AB:** No data.

Effects on other beneficial arthropods

Acute oral toxicity	**ATMAC - Lonza Cologne GmbH:** No data available. Not required **TMAC-Akzo Nobel Surface Chemistry AB:** No data.
Acute contact toxicity	**ATMAC - Lonza Cologne GmbH:** No data available. Not required **TMAC-Akzo Nobel Surface Chemistry AB:** No data.
Acute toxicity to ……..	**ATMAC - Lonza Cologne GmbH:** No data available. Not required **TMAC-Akzo Nobel Surface Chemistry AB:** No data.

Bioconcentration

Bioconcentration factor (BCF)	**ATMAC - Lonza Cologne GmbH:** Measured $BCF_{fish\ whole\ body}$ = 81 (read across to DDAC) $BCF_{earthworm}$ not available **TMAC-Akzo Nobel Surface Chemistry AB:** Read across to DDAC (letter of access to Lonza Cologne GmbH) BCF = 81 L/kg **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** Measured $BCF_{fish\ whole\ body}$ = 81 (read across to DDAC data) $BCF_{earthworm}$ not available **(Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB)**
Depuration time (DT_{50}) (DT_{90})	**ATMAC - Lonza Cologne GmbH:** DT_{50} not calculated. DT_{50} between 7-14d for the whole body (Read across to DDAC) **TMAC-Akzo Nobel Surface Chemistry AB:** Read across to DDAC (letter of access to Lonza Cologne GmbH) DT_{50} not calculated. DT_{50} between 7-14d for the whole body **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** DT_{50} not calculated. DT_{50} between 7-14d for the whole body (Read across to DDAC) **(Lonza Cologne GmbH and Akzo Nobel Surface Chemistry AB)**
Level of metabolites (%) in organisms accounting for > 10 % of residues	**ATMAC - Lonza Cologne GmbH:** No data. **TMAC-Akzo Nobel Surface Chemistry AB:** No data.

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/m^2 min max	g a.s./m^2 min max	
CLAIM: Coco alkyltrimethylammonium chloride is a cationic surfactant and reacts strongly with cell walls of micro-organisms. Under PT 8 (wood preservative), it acts as fungicistatic, by control of wood destroying basidiomycetes, soft rotting and discolouring fungi. The representative product Sinesto B is an aqueous solution containing 14 % w/w a.s. (along with a second biocidal ingredient a.i.) Objects to be protected: Wood, use classes 1 to 4A according to ISO draft standard USERS: Industrials/ professionals	Sinesto B	<u>Wood destroying basidiomycetes:</u> *Coniophora puteana//* *Coniophora spec.* *Coriolus versicolor* *Gloephyllum trabeum* *Poria vaillantii //* *Poria spec.* *Fomes spec.* *Trametes spec.* <u>Soft rot fungi</u> *Chaetomium globosum* <u>Wood discolouring fungi:</u> *Aureobasidium pullulans* *Sclerophoma pityopila* *Ophistostoma piliferum* *Aspergillus niger* *Aspergillus terreus* *Paecilomyces variotii* *Penicillium funicolosum* *Trichoderma viridae*	Aqueous solution under PT 8	14% w/w active substance	Automated dipping and spray in closed tunnel	Number and timing of applications depend on application technique, wood species, moisture and hazard class. A common value applied in the dipping process is up to 30 minutes immersion per batch.	--	-- End-use conc. vary from 6% to 8% for Sinesto B i.e. from 0.84% to 1.12% for active substance	-- 100-150 g treatment solution/ m^2 which corresponds (for a post with a surface area of 4032 cm^2 and a volume of 4000 cm^3) to 0.41 kg a.s./m^3 considering a maximum active substance end-use concentration of 1.12%	0.84-1.68 g a.s./ m^2 wood surface	Used for the preventive protection of wood and constructional timbers in areas with moderate/ subtropical climate. The a.s. is always formulated with other actives to ensure that the biocidal end-use product has a wide spectrum of activity to control the range of biological agents which can decay/attack wood in service, while using the minimum effective level of actives.

Appendix III: List of studies

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

ATMAC – Lonza Cologne GmbH

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
III-A 2.10.2.2.4	[redacted]	2003	Leaching behaviour of Sinesto B treated timber, Dr Wolman GmbH(unpublished)	--	--
IIIA 3.1.1 (1)	[redacted]	2002	Determination of the melting temperature of Barquat CT 35 [redacted] Report No. B099/2001 (unpublished). GLP: Yes	Yes	Clariant GmbH and Lonza AG
IIIA 3.1.3 (1)	[redacted]	2002	Determination of the relative density of Barquat CT 35 [redacted] Report No. B 101/2001. (unpublished). GLP: Yes	Yes	Clariant GmbH and Lonza AG
IIIA 3.11 (1)	[redacted]	2004	[redacted] (2004). Alkyltrimethylammonium Chloride (ATMAC, BARQUAT CT 35 AS) Flammability (solids) Report No. LZA 255/042066 [redacted] (unpublished). GLP: Yes	Yes	Lonza AG
IIIA 3.11 (2)	[redacted]	2004	Alkyltrimethylammonium Chloride (ATMAC, BARQUAT CT 35 AS) Relative self-ignition temperature for solids. [redacted] Report No. LZA 257/042046, [redacted] (unpublished). GLP: Yes	Yes	Lonza AG
IIIA3.13 (1)	[redacted]	2004	Alkyltrimethylammonium Chloride (ATMAC, Barquat CT 35 AS) Surface Tension. Report No.: LZA258/042168 [redacted] (unpublished) GLP: Yes	Yes	Lonza AG
IIIA 3.17	--	2002	Internal data of manufacturer.	--	--
IIIA 3.2 (1)	[redacted]	2002	Vapour pressure, Barquat CT35/Präpagen 2916 AS. [redacted] KG, Report No. 20011543.01 (unpublished). GLP: Yes	Yes	Clariant GmbH and Lonza AG
IIIA 3.2.1 (1)	[redacted]	2004	Henry's law constant for Alkyltrimethylammonium Chloride. [redacted] Report No. LZA/253. [redacted] (unpublished).	--	--
IIIA 3.4.1 (1)	[redacted]	2001	Characterisation of the Structure of Barquat CT 35 AS. Report No. B 103/2001. [redacted] (unpublished). GLP: Yes	Yes	Clariant GmbH and Lonza AG
IIIA 3.5 (1)	[redacted]	2002	Determination of the water solubility of	Yes	Clariant GmbH

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
			Barquat CT 35 AS/Präpagen 2916 AS in the pH-Range 5 to 9. [redacted] Report No. B 102/200 (unpublished). GLP: Yes		and Lonza AG
IIIA 3.7 (1)	[redacted]	2003	Alkyltrimethylammonium Chloride (ATMAC, Barquat CT 35 AS) Solubility in Ethanol and Octanol. Report No.: LZA254/042373. [redacted] (unpublished) GLP: Yes	Yes	Clariant GmbH and Lonza AG
IIIA 4.1 (1)		1990	Inernational 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).	--	--
IIIA 4.1 (2)	[redacted]	2004	Alkytrimethylammonium Chloride (ATMAC) – Screening by Ion Chromatography. Report No. LZA/259. [redacted] (Unpublished) GLP: Yes	Yes	Lonza AG
IIIA 4.1 updated	[redacted]	2015	Barquat CT-35 – Five Batch Analysis, [redacted] 150331LF/CFB16490, (Unpublished) GLP: Yes	Yes	Lonza AG
IIIA 4.1 updated	[redacted]	2015	Determination of Sodium in Five Batches of Barquat CT 35 by ICP OES, (Unpublished) GLP: Yes	Yes	Lonza AG
IIIA 4.2a (1)	[redacted]	2004	Alkyltrimethylammonium chloride (ATMAC, Barquat CT 35). Validation of Methodology for the Determination of Residues in Soil. Report No.: LZA260/042006. [redacted] (Unpublished) GLP: Yes	Yes	Lonza AG
IIIA 4.2c (1)	[redacted]	2004	Alkyltrimethylammonium chloride (ATMAC, Barquat CT 35). Validation of Methodology for the Determination of Residues in Soil. Report No.: LZA260/042006. [redacted] (Unpublished) GLP: Yes	Yes	Lonza AG
IIIA 5.3.1	Linfield, W.M.	1970	Straight-Chain Alkylammonium Compounds. In "Cationic Surfactants" ed. J. Jungermann. Surfactants Science Series, Chapter 2, Marcel Dekker Inc., New York, pp. 9 – 70.	--	--
IIIA 5.3.1	Hueck, H.J.; Adema, D.M.M.; Wiegmann, J.R.	1966	Bacteriostatic, Fungistatic and Algistatic Activity of Fatty Nitrogen Compounds. Appl. Microbiol., 14(3), 308 -319 [Ref. No. A104a]	--	--
IIIA 5.7.1	McBain, A.J.	2004	Effects of quaternary-ammonium-based formulations on bacterial community dynamics and antimicrobial susceptibility. Appl. Eviron. Microbiol, 70(6), 3449-3456.	--	--
IIIA 6.1.1 (1)	[redacted]	1987	Acute Oral Toxicity (LD_{50}) Study in Albino Rats with Arquad C-33W. [redacted] project no. [redacted]-A4001. [redacted]	Yes	Akzo Nobel and Lonza AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
			[redacted] (unpublished). GLP: Yes		
IIIA 6.1.2 (1)	[redacted]	1988	Acute Dermal Toxicity (LD_{50}) Study in Albino Rabbits with Arquad C-33W. [redacted] project no: [redacted]-A104012. [redacted] (unpublished) GLP: Yes	Yes	Akzo Nobel and Lonza AG
IIIA 6.1.4 (1)	[redacted]	1982	Dodigen 2916 Prüfung auf akute dermale Reizwirkung/ Ätzwirkung am Kaninchen, [redacted] Report No. 491/82 (unpublished) GLP: No	Yes	Hoechst AG and Lonza AG
IIIA 6.1.4 (2)	[redacted]	1988	Primary Dermal Irritation Study in Albino Rabbits with Arquad C-33W. [redacted] project no: [redacted]-104013. [redacted] (unpublished). GLP: Yes	Yes	Akzo Nobel and Lonza AG
IIIA 6.1.4 (3)	[redacted]	1988	Primary Eye Irritation Study in Albino Rabbits with Arquad C-33W. [redacted] project no: [redacted]-104014. [redacted] (unpublished). GLP: Yes	Yes	Akzo Nobel and Lonza AG
IIIA 6.1.5 (1)	[redacted]	1982	Screening Test for Delayed Contact Hypersensitivity with Querton 12 Br in the Albino Guinea-pig. [redacted] report no. 82475D/CCO 13/SS. [redacted] (unpublished). GLP: Yes	Yes	Akzo Nobel and Lonza AG
IIIA 6.1.5 (2)	[redacted]	1978	DelayedContact Hypersensitivity in the Guinea pig; ECM BTS 252: E8073. [redacted] report no: 1378-110/113. [redacted] (unpublished). GLP: No	Yes	Akzo Nobel and Lonza AG
IIIA 6.2 (1)	[redacted]	2001	The In Vitro Percutaneous Absorption of [14C]-Didecyldimethylammonium Chloride (DDAC) Through Human Skin. Report No. 19128. [redacted] (Unpublished) GLP: Yes	Yes	The Dialkyl Project
IIIA 6.2 (2)	[redacted]	1989	Absorption, Distribution, Metabolism and Excretion Studies of Didecyldimethylammonium Chloride (DDAC) in the Rat. Study No. P01421. [redacted] (Unpublished) GLP: Yes	Yes	The Dialkyl Project
IIIA 6.4.1 (1)	[redacted]	2002	Arquad C-35: Ninety day repeated dose oral (dietary) toxicity study in the rat. SPL project no. 106/054. [redacted] (unpublished) GLP: Yes	Yes	Akzo Nobel and Lonza AG
IIIA 6.4.2 (1)	[redacted]	1988	Ninety-day subchronic dermal toxicity study with Didecyldimethylammonium Chloride in rats. Project No: 51-554. [redacted]	Yes	The Dialkyl Project

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
			[redacted] (Unpublished) GLP: Yes		
IIIA 6.5 (1)	[redacted]	1991	Chronic oral toxicity study of Didecyldimethylammonium Chloride in dogs. Study No. 2545-102. [redacted]. (Unpublished) GLP: Yes	Yes	The Dialkyl Project
IIIA 6.5 (2) 6.7 (2)	[redacted]	1991	Chronic dietary toxicity/oncogenicity study with Didecyldimethylammonium Chloride in rats. Report No. 53-566. [redacted] (Unpublished) GLP: Yes	Yes	The Dialkyl Project
IIIA 6.6.1 (1)	[redacted]	1989	Arquad C-33-W: Assessment of mutagenic potential in histidine auxotrophs of Salmonella typhimurium (the Ames test). [redacted] report no. 89/AKL001/0451. [redacted] (unpublished) GLP: Yes	Yes	Akzo Nobel and Lonza AG
IIIA 6.6.2 (1)	[redacted]	1989	In vitro assessment of the clastogenic activity of Arquad C-33-W in cultured human lymphocytes. [redacted] report no. 89/AKL002/0408. [redacted] (unpublished). GLP: Yes	Yes	Akzo Nobel and Lonza AG
IIIA 6.6.3 (1)	[redacted]	2002	Arquad C-35: L5178Y TK +/- mouse lymphoma assay. [redacted] project no. 106/055. [redacted] (unpublished) GLP: Yes	Yes	Akzo Nobel and Lonza AG
IIIA 6.6.4 (1)	[redacted]	1983	Micronucleus test on quaternary ammonium salt No. 1 (trimethylcocoammoniumChloride). [redacted] report no. KKM 2/83245. [redacted] (unpublished) GLP: Yes	Yes	Akzo Nobel and Lonza AG
IIIA 6.7 (1)	[redacted]	1991	Chronic dietary oncogenicity study with Didecyldimethylammonium Chloride in mice. Report No: 53-528. [redacted] (Unpublished) GLP: Yes	Yes	The Dialkyl Project
IIIA 6.8.1 (1)	[redacted]	1991	Developmental toxicity evaluation of Didecyldimethylammonium Chloride administered by gavage to CD (Sprague-Dawley) rats. Project No: 53-534. [redacted] (Unpublished) GLP: Yes	Yes	The Dialkyl Project
IIIA 6.8.1 (2)	[redacted]	1989	Developmental toxicity study of Didecyldimethylammonium Chloride administered by gavage to New Zealand white rabbits. Project No: 51-590. [redacted] (Unpublished) GLP: Yes	Yes	The Dialkyl Project
IIIA 6.8.2 (1)	[redacted]	1991	Two-generation reproduction study in	Yes	The Dialkyl

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
	[redacted]		Sprague-Dawley (CD) rats with Didecyldimethylammonium Chloride administered in the diet. Report No. 52-648. [redacted] (Unpublished) GLP: Yes		Project
IIIA 7.1.1.1.1 (1)			Akzo Nobel proprietary information- Part (page 6 to 20 out of 41) of an Akzo Inc study from 1989 on hydrolysis of Arquad C 33 W. GLP: No Data	Yes	Lonza AG and Akzo Nobel NV
IIIA 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. Report No. 37005. [redacted] (Unpublished). GLP: Yes	Yes	The Dialkyl Project
IIIA 7.1.1.2.1 (1)	[redacted]	1989	Biodegradability of Arquad C-33-W. Report No.: CRL F89090. [redacted] (unpublished) GLP: No	Yes	Lonza AG and Akzo Nobel NV
IIIA 7.1.1.2.1 (2)	[redacted]	1987	Akzo Nobel unpublished report- D 87/16/0525B. [redacted] GLP: Yes	Yes	Lonza AG and Akzo Nobel NV
IIIA 7.1.2.1.1 (2)	[redacted]	2001	Didecyldimethylammonium Chloride (DDAC): Dieaway in Activated Sludge. Project No. 289E-112. [redacted] (Unpublished). GLP: Yes	Yes	The Dialkyl Project
IIIA 7.2.3.1 (2)	[redacted]	1989	Soil/Sediment Adsorption-Desorption of 14C-Didecyldimethylammonium Chloride (DDAC). Report No. 37009. [redacted] (Unpublished). GLP: Yes	Yes	The Dialkyl Project
IIIA 7.4.1.1 (1)	[redacted]	1988	Acute toxicity of Arquad C-33-W to rainbow trout (Salmo gairdneri) under static conditions. Report #88-8-2793. [redacted] (Unpublished) GLP: Yes	Yes	Lonza AG and Akzo Chemicals Inc
IIIA 7.4.1.2 (1)	[redacted]	1988	Static acute toxicity of Arquad C-33-W to daphnids (Daphnia magna). Report #88-3-2666. [redacted] (Unpublished) GLP: Yes	Yes	Lonza AG and Akzo Chemicals Inc
IIIA 7.4.1.3 (1)	[redacted]	1992	Toxicity of Myristyltrimethylammonium Bromide to the Freshwater Alga Selenastrum capricornutum [redacted] (unpublished) GLP: No	Yes	Lonza AG and Akzo Chemicals Inc
IIIA 7.4.1.4 (1)	[redacted]	2004	ATMAC; Barquat CT 35 Activated sludge - Respiration Inhibition Test, [redacted] Report No. LZA 262/042050. [redacted]	Yes	Lonza AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
			[redacted] (unpublished) GLP: Yes		
IIIA 7.4.3.2 (2)	[redacted]	2001	Early Life Stage Test under intermittent flow-through conditions with Didecyldimethylammonium Chloride and the fish species, Brachydanio rerio (OECD Guideline No. 210). Report No. 99-9048-03. [redacted] (unpublished). GLP: Yes	Yes	The Dialkyl Project
IIIA 7.4.3.3.1 (2)	[redacted]	1990	Bioconcentration and Elimination of 14C-residues by Bluegill (Lepomis machrochirus) Exposed to Didecyldimethylammonium Chloride (DDAC). Report No. 89-7-3043. [redacted] (unpublished).	--	--
IIIA 7.4.3.4 (2)	[redacted]	2001	Intermittent Flow Through Reproduction Test with Didecyldimethylammonium Chloride and Daphnia magna. [redacted] Report V99.1171. [redacted] (unpublished). GLP: Yes	Yes	The Dialkyl Project
IIIA 7.4.3.5.1 (2)	[redacted]	1995	Chronic Toxicity of Sediment-Incorporated Didecyldimethylammonium Chloride (DDAC)to Chironomus tentans. Final report No. 41005. [redacted] (unpublished). GLP: Yes	Yes	The Dialkyl Project
IIIA 7.5.1.1 (2)	[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). Study No.: IMW-99-9048-05. [redacted] (unpublished). GLP: Yes	Yes	The Dialkyl Project
IIIA 7.5.1.2 (1)	[redacted]	2004	Coco Alkyltrimethylammonium Chloride (ATMAC; Barquat CT35) Acute Toxicity (LC_{50}) to the Earthworm. Report NO. LZA 263/042143. [redacted] (Unpublished) GLP: Yes	Yes	Lonza AG
IIIA 7.5.1.3	[redacted]	2004	N,N-Didecyl-N,N-Dimethylammonium Chloride (DDAC) - Acute Toxicity to Terrestrial Plants. [redacted] Report No. DKG/014 (unpublished).	--	--
IIIA 7.5.3.1.1 (2)	[redacted]	1991	Didecyldimethylammonium Chloride (DDAC): An Acute Oral Toxicity Study with the Northern Bobwhite. Project No. 289-103A. [redacted] (unpublished) GLP: Yes	Yes	The Dialkyl Project
IIIA 7.5.3.1.2 (2)	[redacted]	1991	Didecyldimethylammonium Chloride: A Dietary LC_{50} Study with the Northern Bobwhite. Report (No. 289-101). [redacted]	Yes	The Dialkyl Project

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
			(unpublished). GLP: Yes		
IIIA 7.5.3.1.2 (3)	[redacted]	1991	Didecyldimethylammonium Chloride: A Dietary LC_{50} Study with the Mallard. Report (No. 289-102). [redacted] (unpublished). GLP: Yes	Yes	The Dialkyl Project
IIIB 3.4 (1)	[redacted]	2002	Evaluation of physical and chemical properties according to Directive 92/69/EC, Annex A9-A17 Lab study code 02/2196 [redacted] (unpublished) GLP: Yes	Yes	Dr Wolman GmbH and Lonza AG
IIIB 3.5 (1)	[redacted]	2006	Sinesto B: Physicochemical properties - Acidity/alkalinity and if necessary pH value (1% in water). [redacted] Report No. LZA0268/062230; LONZA REPORT NO 4026 (unpublished) GLP: Yes	Yes	Lonza AG
IIIB 3.5 (2)	[redacted]	2003	Odour, physical state and pH- Sinesto B – Project Number U9584 [redacted] (unpublished) GLP: Yes	Yes	Dr Wolman GmbH and Lonza AG
IIIB 3.6 (1)	[redacted]	2006	Sinesto B: Physicochemical properties - Relative Density [redacted] Report No. LZA0268/062230; LONZA REPORT NO 4026 (unpublished). GLP: Yes	Yes	Lonza AG
IIIB 3.6 (2)	[redacted]	2003	Density – Sinesto B – Project Number U9585 [redacted] (unpublished) GLP: No	Yes	Dr Wolman GmbH
IIIB 3.7 (1)	[redacted]	2004	Low temperature stability according to CIPAC MT 39 –Sinesto B, Project number U 9583 [redacted] (unpublished) GLP: No	Yes	Dr Wolman GmbH and Lonza AG
IIIB 3.7 (2)	[redacted]	2003	Accelerated Storage Test by heating according to CIPAC MT 46 –Sinesto B, Project Number U 9503 [redacted] (unpublished) GLP: No	Yes	Dr Wolman GmbH and Lonza AG
IIIB 3.7 (3)	[redacted]	2004	Long-term storage of Sinesto B, Project Number U 9582, [redacted] (unpublished) GLP: No	Yes	Dr Wolman GmbH and Lonza AG
IIIB 3.8 (1)	[redacted]	2006	Sinesto B: Physicochemical properties – Persistent foaming [redacted] Report No. LZA0268/062230; LONZA REPORT NO 4026 (unpublished) GLP: Yes	Yes	Lonza AG
IIIB 3.10.1 (1)	[redacted]	2006	Sinesto B: Physicochemical properties – Surface tension. [redacted]	Yes	Lonza AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
			[redacted] Report No. LZA0268/062230; LONZA REPORT NO 4026 GLP: Yes		
IIIB 3.10.2 (1)	[redacted]	2006	Sinesto B: Physicochemical properties - Viscosity. [redacted] Report No. LZA0268/062230; LONZA REPORT NO 4026 (unpublished) GLP: Yes	Yes	Lonza AG
IIIB 3.10.2 (2)	[redacted]	2004	Viscosity-Sinesto B-, [redacted] Project number U 9586 (unpublished) GLP: Yes	Yes	Dr Wolman GmbH and Lonza AG
IIIB 4.1	--	1980	Analysis of boric acid or sodium borate solution (1980) Technical Service Bulletin 39, Borax Holdings Ltd, Borax house, Carlisle Place, London (unpublished) GLP: No	Yes	Borax Holding Limited
IIIB 5.10.2.1	Butcher, J.A.; Preston, A.F.; Drysdale, J.	1977	Initial screening trials of some quaternary ammonium compounds amd amine salts as wood preservatives. Forest Product Journal, Vol.27, No. 7, pp. 19 – 22.	--	--
IIIB 5.10.2.1	Tsunoda, K.; Nishimoto, K.	1983	Fungicidal and termiticidal effectiveness of alkylammonium compounds. IRG on Wood Preservation, Doc. no. IRG-WP 3232.	--	--
IIIB 5.10.2.2	Peixoto F. R., Pedroso M. M. A., Nunes L. dos Santos J. A.	1990	Evaluation of the efficacy of Sinesto B in the control of sapstain on pine in a field test in Portugal, (unpublished),	--	--
IIIB 5.10.2.2	Rudolph D.	1994	BAM test certificate, file number 8.1/6536, unpublished, Ref. B 5.10.2/01	--	--
IIIB 6.1.1	[redacted]	1983	Acute oral toxicity to rats of Sinesto B, Report No.: 83635D/KKM 5/AC [redacted] (unpublished) GLP: Yes	Yes	Dr Wolman GmbH and Lonza AG
IIIB 6.1.2	[redacted]	1987	Acute dermal toxicity to rats of Sinesto B, Report No.: 87734D/KKM 8/AC, [redacted] (unpublished) GLP: Yes	Yes	Dr Wolman GmbH and Lonza AG
IIIB 6.2 (1)	[redacted]	1983	Irritant effects of rabbit skin of Sinesto B, , Report No.: 8361 4D/KKM 6/SE (G), [redacted] (unpublished) GLP: Yes	Yes	Dr Wolman GmbH and Lonza AG
IIIB 6.3	[redacted]	1988	Delayed contact hypersensitivity in the guinea pig with Sinesto B, Report No.: 871692D/KKM 9/SS, [redacted] (unpublished) GLP: Yes	Yes	Dr Wolman GmbH and Lonza AG
IIIB 6.6	[redacted]	2004	Air concentration measurements in working zones according to TRGS 402 - Sinesto B -, [redacted] unpublished,	--	--
IIIB 7.1	[redacted]	2003	Leaching of Sinesto B treated timber, [redacted] Lab. ID No. 12111/2003 (unpublished)	--	--
IIIB 7.4 (1)	--	1986	Acute toxicity to fish. [redacted]	Yes	Dr Wolman

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
			[redacted] (unpublished) GLP: No		GmbH and Lonza AG
IIIB 7.4 (2)	--	1988	Acute toxicity to daphnia. [redacted] (unpublished) GLP: No	Yes	Dr Wolman GmbH and Lonza AG

TMAC - Akzo Nobel Surface Chemistry AB:

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
App.6.1g	Akzo Nobel Surface Chemistry AB	2003	Safety Data Sheet Arquad C-35Akzo Nobel Surface Chemistry AB, September 26, 2003 GLP: n.a., Published	N	Akzo Nobel Surface Chemistry AB
App.6.7	Akzo Nobel Surface Chemistry AB	2004	Literature search efficacy TMAC Irg, 2004 GLP: n.a., Unpublished	N	Akzo Nobel Surface Chemistry AB
App.6.7	[redacted]	2003	Literature search for TMAC Akzo Nobel Deventer, The Netherlands November 12, 2003 GLP: n.a., Unpublished	N	Akzo Nobel Surface Chemistry AB
App.6.7	[redacted]	2004	Literature search for TMAC and wood Akzo Nobel, 17 June 2004 GLP: n.a., Unpublished	N	Akzo Nobel Surface Chemistry AB
App.6.7	[redacted]	2004	Literature search for wood and EN 113 results Akzo Nobel, March 4, 2004 GLP: n.a., Unpublished	N	EQC
IIA1	[redacted]	2008	Applicability of comparing data of TMAC with DDAC & BKC Akzo Nobel Surface Chemistry, Update March 2008 GLP: n.a., Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA1.03/01	EpiWin v3.20	2008	Estimations/calculations on C8-18-TMAC Akzo Nobel Surface Chemistry AB, 2007 GLP: n.a, Unpublished	N	
IIA1.03/02	[redacted]	1996	Log Po/w for Arquad C calculation results outlined according to EC regulations Akzo Nobel Deventer, The Netherlands, Report No.: ACRD 968-09, July 16, 1996 GLP: n.a., Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA1.03/03	Akzo Nobel Surface Chemistry AB	2003	Safety Data Sheet Arquad C-35 Akzo Nobel Surface Chemistry AB, September 26, 2003 GLP: n.a., Published	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA1.04.2	[redacted]	2011	Arquad C-35, five batch analysis [redacted] Project-No.: 101025AH; study-No.: CFB14172, 12 December 2011 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
IIA1.04.2/01	Akzo Nobel Surface Chemistry AB	1995	Determination of the activity in fatty quaternary ammonium salts Akzo Nobel, Deventer, The Netherlands, Report No.: VE/2.007, May 19, 1995 GLP: n.a., Published	N	Akzo Nobel Surface Chemistry AB
IIA1.04.2/02	Akzo Nobel Surface Chemistry AB	1998	Determination of free amine and amine hydrochloride in fatty quaternary ammonium salts Akzo Nobel, Deventer, The Netherlands, Report No.: VV/2.002, December 10, 1998 GLP: n.a., Published	N	Akzo Nobel Surface Chemistry AB
IIA1.04.2/03	Akzo Nobel Surface Chemistry AB	1995	Determination of water in fatty quaternary ammonium salts Akzo Nobel, Deventer, The Netherlands, Report No.: VE/2.006, May 19, 1995 GLP: n.a., Published	N	Akzo Nobel Surface Chemistry AB
IIA1.04.3/02	[redacted]	2001	Ninety Day Repeated Dose Oral (Dietary) Toxicity Study in the Rat [redacted] Report No.:106/054, October 4, 2001 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA2.02/01	[redacted]	2003	Literature search for TMAC; Akzo Nobel Deventer, The Netherlands; November 12, 2003; GLP: n.a., Unpublished	N	Akzo Nobel Surface Chemistry AB
IIA2.02/02	[redacted]	2004	Literature search for wood and EN 113 results; Akzo Nobel, March 4, 2004 GLP: n.a., Unpublished	N	EQC
IIA2.02/03	[redacted]	2004	Literature search for TMAC and wood Akzo Nobel, 17 June 2004 GLP: n.a., Unpublished	N	Akzo Nobel Surface Chemistry AB
IIA2.02/04	Akzo Nobel Surface Chemistry AB	2004	Literature search efficacy TMAC Irg, 2004 GLP: n.a., Unpublished	N	Akzo Nobel Surface Chemistry AB
IIA2.02/05	Butcher, JA, et al.	1977	Initial screening trials of some quaternary ammonium compounds and amine salts as wood preservatives Forest Products Journal 27:(7) 19-22 GLP: n.a., Published	N	
IIA2.02/06	Hulme, MA and Thomas, JF	1979	Control of fungal sap stain with alkaline solutions of quaternary ammonium compounds and with tertiary amine salts Forest Products Journal 29:(11) 26-29 GLP: n.a., Published	N	
IIA2.02/07	Linderborg, I and Oy, KK	1986	Control agent for protecting timber against fungi employing a mixture of an organic carboxylic acid salt and quaternary ammonium salt. U.S., 9 pp. Cont.-in-part of U.S. Ser. No. 475,769, abandoned, 29 Apr 1986; Patent US4,585,795 GLP: n.a., Published	N	

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIA2.02/08	Preston, AF	1985	Termite resistance of treated wood in an above ground field test IRG, IRG Document No: IRG WP 85-2241, GLP: n.a., Published	N	
IIA2.02/09	Ruddick, JNR	1983	Field testing of alkylammonium wood preservatives; IRG, IRG document: IRG WP 83-3248, GLP: n.a., Published	N	
IIA2.02/10	Tsunoda, K and Nishimoto, K	1983	Fungicidal and termiticidal effectiveness of alkylammonium compounds IRG, IRG Document No: IRG/WP 3232, GLP: n.a., Published	N	
IIA2.02/11	[redacted]	1990	Evaluation of the efficacy of Sinesto B in the control of sapstain on pine in a field test in Portugal [redacted] GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIA2.02/12	[redacted]	1994	BAM test certificate BAM, File No.: 8.1/6536, GLP: n.a., Unpublished	Y (New/First)	Dr. Wolman GmbH
IIA2.02/13	Dr Wolman GmbH	2004	Technical leaflet Sinesto B Dr Wolman GmbH, GLP: n.a., Unpublished	Y (New/First)	Dr. Wolman GmbH
IIA2.04	Block, SS	1991	Disinfectants and antiseptics. A. By chemical type; Disinfection, Sterilization, and Preservation, 4th ed. Lea & Febiger, Philidelphia - London. pp. 250-255. (1991) GLP: n.a., Published	N	
IIA3	[redacted]	2008	Applicability of comparing data of TMAC with DDAC & BKC Akzo Nobel Surface Chemistry, Update March 2008 GLP: n.a., Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA3.01/01	Isomaa, B	1975	Absorption, Distribution and excretion of [14C]CTAB, a Quaternary Ammonium Surfactant, in the rat Fd Cosmet Toxicol 13:231-237 GLP: n.a., Published	N	
IIA3.01/02	Bartnik, F and Wingen, F	1979	Percutane Absorption von Dodecyltrimethylammoniumbromid, einem kationischen Tensid; Summary from Food and Cosmetic Toxicology 17:633 GLP: n.a., Published	N	
IIA3.02/01	[redacted]	1987	Acute oral toxicity (LD50) Study in Albino Rats with Arquad C-33 W [redacted] Report No.: [redacted]-A4001, February 4, 1987 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIA3.02/01	[redacted]	1987	Acute oral toxicity (LD50) Study in Albino Rats with Arquad C-33 W [redacted] Report No.: [redacted]-A4001, February 4, 1987 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA3.02/02	[redacted]	1987	Acute dermal toxicity (LD50) in albino rabbits with Arquad C-33 W [redacted] Report No.: [redacted]-104012, May 27, 1987 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA3.02/03	Bartnik, F and Wingen, F	1979	Percutane Absorption von Dodecyltrimethylammoniumbromid, einem kationischen Tensid Summary from Food and Cosmetic Toxicology 17:633 GLP: n.a., Published	N	
IIA3.02/03	[redacted]	1988	Primary dermal irritation study in albino rabbits with Arquad C-33 W [redacted] Report No.: [redacted] 104013, May 27, 1988 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA3.03.1/02	CIR	1994	Final report - Cetrimonium chloride and bromide and Steartrimonium chloride CIR Report No.: 78A/84 December 13, 1994 GLP: n.a., Published	N	
IIA3.03.2/01	[redacted]	1988	Primary eye irritatation study in albino rabbits with Arquad C-33 W [redacted] Report No.: [redacted] 104014, May 27, 1988 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA3.03.2/02	CIR	1994	Final report - Cetrimonium chloride and bromide and Steartrimonium chloride CIR Report No.: 78A/84 December 13, 1994 GLP: n.a., Published	N	
IIA3.04/01	[redacted]	1978	Delayed contact hypersensitivity in the Guinea pig ECM BTS 252 E8073 [redacted] Report No.: 1378-110/113, June 1, 1978 GLP: pre-GLP, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA3.04/02	[redacted]	1982	Screening test for delayed contact hypersensitivity with Querton 12 Br in the albino guinea-pig [redacted] Report No.: 82477D/CCO 13/SS, October 7, 1982 GLP: pre-GLP, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA3.05/01	[redacted]	2001	Ninety Day Repeated Dose Oral (Dietary) Toxicity Study in the Rat [redacted] Report No.:106/054, October 4, 2001 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIA3.05/02	[redacted]	2002	Alkyldimethylbenzylammonium chloride 13 week dietary study in rats. [redacted] Report No.: 22525 TSR, October 23, 2002 GLP: Y, Unpublished	Y (New/First)	EQC
IIA3.05/03	[redacted]	2004	DDAC 13 week dietary toxicity study in rats [redacted] Report No.: 24602 TCR, February 13, 2004 GLP: Y, Unpublished	Y (New/First)	EQC
IIA3.05/04	[redacted]	2006	BKC - 13-Week toxicity study by oral route (dietary admixture) in Beagle dogs. [redacted] Report No.: 26146 TCC, February 10, 2006 GLP: Y, Unpublished	Y (New/First)	EQC
IIA3.05/05	[redacted]	2007	DDAC, 4 week preliminary toxicity study by oral route (dietary admixture) in Beagle dogs [redacted] Report No.: 26151 TSC, 8 Jan 2007 GLP: Y, Unpublished	Y (New/First)	EQC
IIA3.05/06	[redacted]	2007	BKC Combined toxicity/carcinogenicity study by dietary admixture in rats. [redacted] Report No.: 25627 TCR, November 6, 2007 GLP: Y, Unpublished	Y (New/First)	EQC
IIA3.05/07	[redacted]	2008	DDAC Combined chronic toxicity / Carcinogenicity, via oral route in rats (Sprague Dawley) [redacted] Report No.: 25630 TCR, March 17, 2008 GLP: Y, Unpublished	Y (New/First)n	EQC
IIA3.05/08	CIR	1994	Final report - Cetrimonium chloride and bromide and Steartrimonium chloride CIR Report No.: 78A/84 December 13, 1994 GLP: n.a., Published	N	

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIA3.05/09	Isomaa, B, et al.	1976	The Subacute and Chronic Toxicity of Cetyltrimethylammonium Bromide (CTAB), a Cationic Surfactant, in the Rat Arch.Toxicol. 35:91-96 GLP: n.a., Published	N	
IIA3.06.1/01	[redacted]	1989	Arquad C-33-W: Assessment of mutagenic potential in histidine auxotrophs of Salmonella typhimurium [redacted] Report no.: 89/AKL001/0451, July 7, 1989 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA3.06.1/02	[redacted]	1989	In vitro assessment of the clastogenic activity in cultured human lymphocytes [redacted] Report No.: 89/AKL002/0408, July 7, 1989 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA3.06.1/03	[redacted]	2002	Arquad C-35: L5178Y TK +/- Mouse lymphoma assay [redacted] Report No.: 106/055, April 3, 2003. GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA3.06.2/01	[redacted]	1983	Micronucleus test on quaternary ammonium salt number 1. (trimethylcocoammoniumchloride) [redacted] Report No.: KKM 2/83245, April 27, 1983 GLP: pre-GLP, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA3.07/01	[redacted]	2008	DDAC Combined chronic toxicity / Carcinogenicity, via oral route in rats (Sprague Dawley) [redacted] Report No.: 25630 TCR, March 17, 2008 GLP: Y, Unpublished	Y (New/First)	EQC
IIA3.07/02	[redacted]	2007	BKC Combined toxicity/carcinogenicity study by dietary admixture in rats. [redacted] Report No.: 25627 TCR, November 6, 2007 GLP: Y, Unpublished	Y (New/First)	EQC
IIA3.07/03	Henderson, ND	1992	A review of the environmental impact and toxic effects of DDAC BC Environment Canada, 0-7726-1614-0, June, 1992 GLP: n.a., Published	N	EQC
IIA3.07/04	[redacted]	2007	BKC Combined toxicity/carcinogenicity study by dietary admixture in rats. [redacted] Report No.: 25627 TCR, November 6, 2007 GLP: Y, Unpublished	Y (New/First)	

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIA3.07/05	Cutler, RA and Drobeck, HP	1970	Toxicology of cationic surfactants Cationic surfactants 4 (Chap. 15):527-616 GLP: n.a., Published	N	
IIA3.07/06	BIBRA	1989	BIBRA Toxicity Profile - Benzalkonium chloride BIBRA Toxicology International, Report No.: CC/SI/May 1988 (g)/P. 309/(28)/T.1722/ACN 14353, May, 1988 GLP: n.a., Published	N	
IIA3.07/07	Stenbäck, F	1977	Local and systemic effects of commonly used cutaneous agents: lifetime studies of 16 compounds in mice and rabbits Acta Pharmacol Toxicol 41:(5) 41-31 GLP: n.a., Published	N	
IIA3.08.1/01	[redacted]	1980	Teratology study in rabbits (Segment II) with E 9060 [redacted] Report No.: 006209, June 12, 1980 GLP: pre-GLP, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA3.08.1/02	[redacted]	2005	Prenatal developmental toxicity study by oral route (gavage) in rabbits [redacted] Report No.: 26154 RSL, 20 Sep 2005 GLP: Y, Unpublished	Y (New/First)	EQC
IIA3.08.1/03	[redacted]	2005	BKC, Prenatal developmental toxicity by oral route (gavage) in rabbits [redacted] Report No.: 26148 RSL, April 21, 2005 GLP: Y, Unpublished	Y (New/First)	EQC
IIA3.08.1/04	Palmer, AK, et al.	1983	Absence of embryotoxic effects in rats with three quarternary ammonium compounds (cationic surfactants) Toxicology 26:(3-4) 313-315 GLP: n.a., Published	N	
IIA3.08.1/05	Henderson, ND	1992	A review of the environmental impact and toxic effects of DDAC BC Environment Canada, 0-7726-1614-0, June, 1992 GLP: n.a., Published	N	
IIA3.08.1/06	BIBRA	1989	BIBRA Toxicity Profile - Benzalkonium chloride BIBRA Toxicology International, Report No.: CC/SI/May 1988 (g)/P. 309/(28)/T.1722/ACN 14353, May, 1988 GLP: n.a., Published	N	

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIA3.08.2/01	[redacted]	2008	DDAC Two-generation study (reproduction and fertility effects) by dietary admixture in rats [redacted] Report No.: 26155 RSR, February 15, 2008 GLP: Y, Unpublished	Y (New/First)	EQC
IIA3.08.2/02	[redacted]	2008	BKC - Two-generation study (reproduction and fertility effects) by dietary admixture in rats [redacted] Report No.: 26149 RSR, February 20, 2008. GLP: Y, Unpublished	Y (New/First)	EQC
IIA3.08.2/03	Henderson, ND	1992	A review of the environmental impact and toxic effects of DDAC BC Environment Canada, 0-7726-1614-0, June, 1992 GLP: n.a., Published	N	
IIA3.08.2/04	BIBRA	1989	BIBRA Toxicity Profile - Benzalkonium chloride BIBRA Toxicology International, Report No.: CC/SI/May 1988 (g)/P. 309/(28)/T.1722/ACN 14353, May, 1988 GLP: n.a., Published	N	
IIA3.09	Cutler, RA and Drobeck, HP	1970	Toxicology of cationic surfactants Cationic surfactants 4 (Chap. 15):527-616 GLP: n.a., Published	N	
IIA3.10/01	De Groot, AC, et al.	1986	Contact allergy to preservatives II Contact Dermatitis 15:218-222 GLP: n.a., Published	N	
IIA3.10/02	[redacted]	2003	Medical data for employees working with TMAC at Akzo Nobel Surface Chemistry, Stockvick [redacted] September 12, 2003 GLP: n.a., Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA4.01.1.1.1	[redacted]	1989	Biodegradability of Arquad C-33-W [redacted] Report No.: CRL F89090, November 1, 1989 GLP: N, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA4.01.1.1.2	[redacted]	1994	A comparison of the biodegradability of Arquad 2.10-50 and Arquad DMMCB-50 [redacted] Report No.: CRL F 94023, October 2, 1994 GLP: N, Unpublished	Y (New/First)	EQC

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIA4.01.1.2.1	[redacted]	1989	Hydrolysis of Arquad C-33W as a function of pH. Akzo Nobel proprietary information - Part (page 6 to 20 out of 41) of an Akzo Inc study from 1989 on hydrolysis of Arquad C- 33W. [redacted] GLP: N, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA4.02.1/01	[redacted]	2002	Didecyldimethylammonium chloride (DDAC) - Adsorption-desorption using a Batch Equilibrium Method [redacted] Report No.: CAD84871, August 30, 2002 GLP: Y, Unpublished	Y (New/First)	EQC
IIA4.02.1/02	[redacted]	1999	Preventol R50 - Adsorption / Desorption using a Batch Equilibrium Method [redacted] Report No.: CAD61831, May 5, 1999 GLP: Y, Unpublished	Y (New/First)	EQC
IIA4.03/01	[redacted]	1996	Log Po/w for Arquad C calculation results outlined according to EC regulations [redacted] Report No.: ACRD 968-09, July 16, 1996 GLP: n.a., Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA4.03/02	European Chemicals Bureau (ECB)	2002	European Union Risk Assessment Report, Dimethyldioctadecylammonium chloride (DODMAC) European Chemicals Bureau GLP: n.a., Published	N	
IIA4.03/03	Kappeler, TU	1982	Aquatic toxicity of distearyldimethylammonium chloride (DSDMAC) Tenside Detergents 19:(3) 169-176 GLP: n.a., Published	N	
IIA4.04.1.1	[redacted]	1988	Acute toxicity of Arquad C-33 W to Rainbow trout (Salmo gairdneri) under static conditions [redacted] Report No.: #88-8-2793, September 14,1988 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIA4.04.1.2	[redacted]	1988	Static acute toxicity of Arquad C-33 W to daphnids (Daphnia magna) [redacted] Report No.: #88-3-2666, June 2, 1988 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA4.04.1.3	[redacted]	2004	Chronic toxicity to Daphnia Magna in a 21-day reproduction test under semi-static conditions [redacted] Report No.: CER F04010 March 4, 2004 GLP: Y, Unpublished	Y (New/First)	EQC
IIA4.04.1.4	[redacted]	1992	Toxicity of myristyltrimethylammonium bromide to freshwater algae, [redacted] [redacted] Report no.: CRL F92166 ECO11, December 24, 1992 GLP: N, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA4.04.1.5	[redacted]	1989	Biodegradability of Arquad C-33-W [redacted] Report No.: CRL F89090, November 1, 1989 GLP: N, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIA4.04.1.6	[redacted]	2004	Toxicity of DDAC to soil microorganisms: Nitrogen transformation inhibition test [redacted] Report No.: CER F04013, March 10, 2004 GLP: Y, Unpublished	Y (New/First)	EQC
IIA4.04.1.6	[redacted]	2004	Toxicity of BKC to soil microorganisms: Nitrogen transformation inhibition test [redacted] Report No.: CER F04012, March 10, 2004 GLP: Y, Unpublished	Y (New/First)	EQC
IIA4.06.1/01	[redacted]	2003	An artificial sediment test using the nematode Caenorhabditis elegans [redacted] Report no.: CER F00, GLP: N, Unpublished	Y (New/First)	EQC
IIA4.06.1/02	[redacted]	2008	Arquad 2.10-40 - Earthworm (Eisenia fetida), Effects on Reproduction in Natural Soil (LUFA 2.2) (ongoing) [redacted], Report no.: RRR11186, May 2008. GLP: Y, Unpublished	Y (New/First)	EQC

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIA4.06.1/03	[redacted]	1999	Earthworm (Eisena fetida), acute toxicity test in artificial soil [redacted] Report No.: D RRA61831, March 10, 1999 GLP: Y, Unpublished	Y (New/First)	EQC
IA4.06.2/01	[redacted]	2004	Laboratory assessment of the side effects of DDAC on plant growth [redacted] Report No.: 03-99-035-ES, March 4, 2004 GLP: Y, Unpublished	Y (New/First)	EQC
IIA4.06.2/02	[redacted]	2004	Laboratory assessment of the side effects of BKC on plant growth [redacted] Report No.: 03-99-036-ES, March 3, 2004 GLP: Y, Unpublished	Y (New/First)	EQC
IIB3.01	[redacted]	2003	Odour, physical state and pH - Sinesto B [redacted] GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIB3.02	[redacted]	2002	Evaluation of physical and chemical properties according to Directive 92/69/EC, Annex A9-A17 [redacted] GLP: Y, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIB3.06	[redacted]	2003	Density - Sinesto B [redacted] GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIB3.07/01	[redacted]	2003	Long-term storage of Sinesto [redacted] GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIB3.07/02	[redacted]	2003	Accelerated Storage test by heating CIPAC-MT 46 Sinesto B [redacted] GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIB3.07/03	[redacted]	2004	Low temperature stability according to CIPAC MT 39 - Sinesto B [redacted] GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIB3.11	[redacted]	2004	Viscosity - Sinesto B [redacted] GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIB5.10.2/01	[redacted]	1994	BAM test certificate BAM, File No.: 8.1/6536, GLP: n.a., Unpublished	Y (New/First)	Dr. Wolman GmbH

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIB5.10.2/02	[redacted]	1990	Evaluation of the efficacy of Sinesto B in the control of sapstain on pine in a field test in Portugal [redacted] GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIB6.01.1	[redacted]	1983	Acute oral toxicity to rats of Sinesto B [redacted] Report No.: 83635D/KKM 5/AC, October 3, 1983 GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIB6.01.2	[redacted]	1987	Acute dermal toxicity to rats of Sinesto B [redacted] Report No.: 87734D/KKM 8/AC, June 30, 1987 GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIB6.02	[redacted]	1983	Irritant effects of rabbit skin of Sinesto B [redacted] Report No.: 8361 4D/KKM 6/SE (G), September 29, 1983 GLP: pre-GLP, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIB6.03	[redacted]	1988	Delayed contact hypersensitivity in the guinea pig with Sinesto B [redacted] Report No.: 871692D/KKM 9/SS, January 8, 1988 GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIB7.04.1.1	[redacted]	1986	Acute toxicity to fish [redacted] Report No.: Z86105, January 14, 1986 GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIB7.04.1.2	[redacted]	1988	Acute toxicity to daphnia [redacted] Report No.: Z587-12, January 25, 1988 GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIA2.01	[redacted]	2004	Dossier approach for Trimethylalkyl ammonium compounds, (TMAC) Akzo Nobel Surface Chemistry, October 28, 2004 GLP: n.a., Unpublished	N	Akzo Nobel Surface Chemistry AB
IIIA3; 3.7; 3.9	[redacted]	2012	Determination of physic-chemical properties, [redacted], project 202844/A -495714, 11 May , 2012 GLP: Y Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIA.3.1.1	[redacted]	2011	Melting point / melting range [redacted] Report No.: CPM 14111, 31 oct2011 GLP: Y Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA3.1.1; 1.2; 3.10	[redacted]	2012	Determination of physico-chemical properties Thermal Stability (OECD 113) Melting Point (EC A.1., OECD 102) Boiling Point (EC A.2., OECD 103), [redacted] Report No.: CSL-11-650.01, 3apr2012 GLP: Y Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA3.02	EpiWin v3.20	2008	Estimations/calculations on C8-18-TMAC Akzo Nobel Surface Chemistry AB, 2007 GLP: n.a, Unpublished	N	
IIIA3.02	[redacted]	2012	Determination of vapour pressure of C12-16 BKC by isothermal thermogravimethry, [redacted] project 202844_499393-3apr2012. GLP: Y Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA3.09	[redacted]	1996	Log Po/w for Arquad C calculation results outlined according to EC regulations [redacted] Report No.: ACRD 968-09, July 16, 1996 GLP: n.a., Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA3.11	[redacted]	2015	Lyophilized product of Arquad C-35, Flammability of solids according to UN Test N. 1, [redacted] 150414AH/CPE16811; GLP: Y Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA3.17	[redacted]	2000	Emballage för farligt gods (packaging material for transport of goods) [redacted], GLP: n.a., Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA4-1	[redacted]	2011	Determination of the Content of the Active Ingredients and Relevant Impurities, [redacted], CBG14111 / 101025AH GLP: Y Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA4-1	[redacted]	2011	Determination of Sodium Content in TMAC (=lyophilised Arquad C-35) by ICP-OES, [redacted] B 009/2011 / VP 009/2011 GLP: Y Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA4-1 updated	[redacted]	2015	Arquad C 35 – Five Batch Analysis, [redacted] 150401AH/CFB16517 GLP: Y Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA4-1 updated	Wilbrand	2015	Determination of Sodium in Five Batches of Arquad C-35 by ICP OES GLP: Y Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIA4-2	[redacted]	2012	TMAC (lyophilised Arquad C-35) Residue Analytical Method for the Determination in Ground, Surface, Tap Water and Soil, [redacted] CRA14111 / 101025AH; GLP: Y Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA4.03	[redacted]	2001	Ninety Day Repeated Dose Oral (Dietary) Toxicity Study in the Rat Safepharm Laboratories, Ltd, England, [redacted] October 4, 2001 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA5.03/01	Butcher, JA, et al.	1977	Initial screening trials of some quaternary ammonium compounds and amine salts as wood preservatives Forest Products Journal 27:(7) 19-22 GLP: n.a., Published	N	
IIIA5.03/02	Hulme, MA and Thomas, JF	1979	Control of fungal sap stain with alkaline solutions of quaternary ammonium compounds and with tertiary amine salts Forest Products Journal 29:(11) 26-29 GLP: n.a., Published	N	
IIIA5.03/04	Linderborg, I and Oy, KK	1986	Control agent for protecting timber against fungi employing a mixture of an organic carboxylic acid salt and quaternary ammonium salt. U.S., 9 pp. Cont.-in-part of U.S. Ser. No. 475,769, abandoned, 29 Apr 1986; Patent US4,585,795 GLP: n.a., Published	N	
IIIA5.03/05	Preston, AF	1985	Termite resistance of treated wood in an above ground field test IRG, IRG Document No: IRG WP 85-2241, GLP: n.a., Published	N	
IIIA5.03/06	Ruddick, JNR	1983	Field testing of alkylammonium wood preservatives IRG, IRG document: IRG WP 83-3248, GLP: n.a., Published	N	
IIIA5.03/07	Tsunoda, K and Nishimoto, K	1983	Fungicidal and termiticidal effectiveness of alkylammonium compounds IRG, IRG Document No: IRG/WP 3232, GLP: n.a., Published	N	
IIIA5.07.1	McBain, AJ, et al.	2004	Effects of quaternary-ammonium-based formulations on bacterial community dynamics and antimicrobial susceptibility. Applied and Environmental Microbiology 70:(6) 7 GLP: n.a., Published	N	
IIIA6.01.1	[redacted]	1987	Acute oral toxicity (LD50) Study in Albino Rats with Arquad C-33 W [redacted] Report No.: WIL-A4001, February 4, 1987 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIA6.01.2	[redacted]	1987	Acute dermal toxicity (LD50) in albino rabbits with Arquad C-33 W [redacted] Report No.: [redacted]-104012, May 27, 1987 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA6.01.4/01	[redacted]	1988	Primary dermal irritation study in albino rabbits with Arquad C-33 W [redacted] Report No.: [redacted] 104013, May 27, 1988 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA6.01.4/02	[redacted]	1988	Primary eye irritatation study in albino rabbits with Arquad C-33 W [redacted] Report No.: [redacted] 104014, May 27, 1988 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA6.01.5/01	[redacted]	1978	Delayed contact hypersensitivity in the Guinea pig ECM BTS 252 E8073 [redacted] Report No.: 1378-110/113, June 1, 1978 GLP: pre-GLP, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA6.01.5/02	[redacted]	1982	Screening test for delayed contact hypersensitivity with Querton 12 Br in the albino guinea-pig. [redacted] Report No.: 82477D/CCO 13/SS, October 7, 1982 GLP: pre-GLP, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA6.02/01	Bartnik, F and Wingen, F	1979	Percutane Absorption von Dodecyltrimethylammoniumbromid, einem kationischen Tensid. Summary from Food and Cosmetic Toxicology 17:633 GLP: n.a., Published	N	
IIIA6.02/02	Isomaa, B	1975	Absorption, Distribution and excretion of [14C]CTAB, a Quaternary Ammonium Surfactant, in the rat Fd Cosmet Toxicol 13:231-237 GLP: n.a., Published	N	
IIIA6.02/03	[redacted]	2005	[14C] DDAC - Pharmacokinetics, tissue distribution and mass balance of radioactivity following single dermal application and single and repeated oral gavage administration to Sprague dawley rats [redacted] Report No.: 25629 PAR, March 12, 2005 GLP: Y, Unpublished	Y (New/First)	EQC
IIIA6.02/04	[redacted]	2006	[14C] BKC - Pharmacokinetics, tissue distribution and mass balance of radioactivity following single dermal application and single and repeated oral gavage administration to Sprague dawley rats. [redacted] Report No.: 25629 PAR, October 2, 2006 GLP: Y, Unpublished	Y (New/First)	EQC

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIA6.04.1.1	[redacted]	2001	Ninety Day Repeated Dose Oral (Dietary) Toxicity Study in the Rat [redacted] Report No.:106/054, October 4, 2001 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA6.04.1.2/02	[redacted]	2006	DDAC, 13 week toxicity study by oral route (dietary admixture) in Beagle dogs [redacted] Report No.: 26152 TSC, 3 Feb 2006 GLP: Y, Unpublished	Y (New/First)	EQC
IIIA6.04.1.2/03	[redacted]	2006	BKC - 13-Week toxicity study by oral route (dietary admixture) in Beagle dogs. [redacted] Report No.: 26146 TCC, February 10, 2006 GLP: Y, Unpublished	Y (New/First)	EQC
IIIA6.05	Isomaa, B, et al.	1976	The Subacute and Chronic Toxicity of Cetyltrimethylammonium Bromide (CTAB), a Cationic Surfactant, in the Rat Arch.Toxicol. 35:91-96 GLP: n.a., Published	N	
IIA6.06.1	[redacted]	1989	Arquad C-33-W: Assessment of mutagenic potential in histidine auxotrophs of Salmonella typhimurium [redacted] Report no.: 89/AKL001/0451, July 7, 1989 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA6.06.2	[redacted]	1989	In vitro assessment of the clastogenic activity in cultured human lymphocytes [redacted] Report No.: 89/AKL002/0408, July 7, 1989 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA6.06.3	[redacted]	2002	Arquad C-35: L5178Y TK +/- Mouse lymphoma assay [redacted] Report No.: 106/055, April 3, 2003. GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA6.06.4	[redacted]	1983	Micronucleus test on quaternary ammonium salt number 1. (trimethylcocoammoniumchloride) [redacted] Report No.: KKM 2/83245, April 27, 1983 GLP: pre-GLP, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA6.07/01	[redacted]	2008	DDAC Combined chronic toxicity / Carcinogenicity, via oral route in rats (Sprague Dawley). [redacted] Report No.: 25630 TCR, March 17, 2008 GLP: Y, Unpublished	Y (New/First)	EQC

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIA6.07/02	[redacted]	2007	BKC Combined toxicity/carcinogenicity study by dietary admixture in rats. [redacted] Report No.: 25627 TCR, November 6, 2007 GLP: Y, Unpublished	Y (New/First)	EQC
IIIA6.08.1/01	Palmer, AK, et al.	1983	Absence of embryotoxic effects in rats with three quarternary ammonium compounds (cationic surfactants) Toxicology 26:(3-4) 313-315 GLP: n.a., Published	N	
IIIA6.08.1/02	[redacted]	1980	Teratology study in rabbits (Segment II) with E 9060 [redacted] Report No.: 006209, June 12, 1980 GLP: pre-GLP, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA6.08.1/03	[redacted]	2005	Prenatal developmental toxicity study by oral route (gavage) in rabbits. Centre [redacted] Report No.: 26154 RSL, 20 Sep 2005 GLP: Y, Unpublished	Y (New/First)	EQC
IIIA6.08.1/04	[redacted]	2005	BKC, Prenatal developmental toxicity by oral route (gavage) in rabbits. Centre [redacted] Report No.: 26148 RSL, April 21, 2005 GLP: Y, Unpublished	Y (New/First)	EQC
IIIA6.08.2/02	[redacted]	2008	DDAC Two-generation study (reproduction and fertility effects) by dietary admixture in rats. Centre [redacted] Report No.: 26155 RSR, February 15, 2008 GLP: Y, Unpublished	Y (New/First)	EQC
IIIA6.08.2/03	[redacted]	2008	BKC - Two-generation study (reproduction and fertility effects) by dietary admixture in rats. Centre [redacted] Report No.: 26149 RSR, February 20, 2008. GLP: Y, Unpublished	Y (New/First)	EQC
IIIA6.10	Block, SS	1991	Disinfectants and antiseptics. A. By chemical type: Disinfection, Sterilization, and Preservation, 4th ed. Lea & Febiger, Philadelphia - London. pp. 250-255. (1991) GLP: n.a., Published	N	
IIIA6.12	[redacted]	2003	Medical data for employees working with TMAC at Akzo Nobel Surface Chemistry, Stockvick [redacted] September 12, 2003 GLP: n.a., Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIA6.15	[redacted]	2001	Ninety Day Repeated Dose Oral (Dietary) Toxicity Study in the Rat [redacted] Report No.:106/054, October 4, 2001 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.01.1.1.1	[redacted]	1989	Hydrolysis of Arquad C-33W as a function of pH. Akzo Nobel proprietary information - Part (page 6 to 20 out of 41) of an Akzo Inc study from 1989 on hydrolysis of Arquad C-33W. [redacted] GLP: N, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.01.1.1.2/01	[redacted]	1989	Biodegradability of Arquad C-33-W [redacted] Report No.: CRL F89090, November 1, 1989 GLP: N, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.01.1.1.2/02	[redacted]	2004	UV IR MS analysis of Arquad C-35 [redacted] Report No.: ANL 04003, February 23, 2004 GLP: N, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.01.1.2.1	[redacted]	1989	Biodegradability of Arquad C-33-W [redacted] Report No.: CRL F89090, November 1, 1989 GLP: N, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.02.1	Van Ginkel, C	2004	Biodegradation of Cationic Surfactants; An Environmental Perspective. Chapter 25 Handbook of Detergents Part B Environmental Impact 523-549 GLP: n.a., Published	N	
IIIA7.02.1/01	[redacted]	1994	A comparison of the biodegradability of Arquad 2.10-50 and Arquad DMMCB-50 [redacted] Report No.: CRL F 94023, October 2, 1994 GLP: N, Unpublished	Y (New/First)	EQC
IIIA7.02.2	Van Ginkel, CG	2004	Biodegradation of Cationic Surfactants; An Environmental Perspective. Chapter 25 Handbook of Detergents Part B Environmental Impact 523-549 GLP: n.a., Published	N	
IIIA7.02.3.1	[redacted]	1983	Retention of Sinesto B in sawn wood [redacted] Report No.: 41160, October 12, 1983 GLP: N, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIA7.02.3.1	[redacted]	1986	Adsorption of Sinesto on sand [redacted] Report No.: 44371, April 28, 1986 GLP: N, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.02.3.1/01	[redacted]	2002	Didecyldimethylammonium chloride (DDAC) - Adsorption-desorption using a Batch Equilibrium Method [redacted] Report No.: CAD84871, August 30, 2002 GLP: Y, Unpublished	Y (New/First)	EQC
IIIA7.02.3.1/02	[redacted]	1999	Preventol R50 - Adsorption / Desorption using a Batch Equilibrium Method [redacted] Report No.: CAD61831, May 5, 1999 GLP: Y, Unpublished	Y (New/First)	EQC
IIIA7.03.1	[redacted]	2004	UV IR MS analysis of Arquad C-35 [redacted] Report No.: ANL 04003, February 23, 2004 GLP: N, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.03.1	[redacted]	1989	Biodegradability of Arquad C-33-W [redacted] Report No.: CRL F89090, November 1, 1989 GLP: N, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.04.1.1	[redacted]	1988	Acute toxicity of Arquad C-33 W to Rainbow trout (Salmo gairdneri) under static conditions. [redacted] Report No.: #88-8-2793, September 14,1988 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.04.1.2	[redacted]	1988	Static acute toxicity of Arquad C-33 W to daphnids (Daphnia magna) [redacted] Report No.: #88-3-2666, June 2, 1988 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.04.1.3	[redacted]	1992	Toxicity of myristyltrimethylammonium bromide to freshwater algae, Akzo Research [redacted] Report no.: CRL F92166 ECO11, December 24, 1992 GLP: N, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.04.1.4	[redacted]	1989	Biodegradability of Arquad C-33-W [redacted] Report No.: CRL F89090, November 1, 1989 GLP: N, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIA7.04.2	European Chemicals Bureau (ECB)	2002	European Union Risk Assessment Report, Dimethyldioctadecylammonium chloride (DODMAC) European Chemicals Bureau GLP: n.a., Published	N	
IIIA7.04.2	[redacted]	1996	Log Po/w for Arquad C calculation results outlined according to EC regulations [redacted] Report No.: ACRD 968-09, July 16, 1996 GLP: n.a., Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.04.3/01	[redacted]	1992	Toxicity of myristyltrimethylammonium bromide to freshwater algae, [redacted] [redacted] Report no.: CRL F92166 ECO11,December 24, 1992 GLP: N, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.04.3/02	[redacted]	1988	Static acute toxicity of Arquad C-33 W to daphnids (Daphnia magna) [redacted] Report No.: #88-3-2666, June 2, 1988 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.04.3/03	[redacted]	1988	Acute toxicity of Arquad C-33 W to Rainbow trout (Salmo gairdneri) under static Conditions, [redacted] [redacted] Report No.: #88-8-2793, September 14,1988; GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.04.3/04	[redacted].	2004	Chronic toxicity to Daphnia Magna in a 21-day reproduction test under semi-static conditions , [redacted] Report No.: CER F04010, March 4, 2004 GLP: Y, Unpublished	Y (New/First)	EQC
IIIA7.04.3/05	[redacted]	1995	Chronic toxicity of Arquad DMMCB-50 to Daphnia magna , [redacted] Report No.: RGL F95035, April 12, 1995. GLP: Y, Unpublished	Y (New/First)	EQC
IIA7.05.1.1/02	[redacted]	2004	Toxicity of DDAC to soil microorganisms: Nitrogen transformation inhibition test [redacted] Report No.: CER F04013, March 10, 2004 GLP: Y, Unpublished	Y (New/First)	EQC
IIIA7.05.1.1/03	[redacted]	2004	Toxicity of BKC to soil microorganisms: Nitrogen transformation inhibition test [redacted] Report No.: CER F04012, March 10, 2004 GLP: Y, Unpublished	Y (New/First)	EQC

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIA7.05.1.2/01	[redacted]	2008	Arquad 2.10-40 - Earthworm (Eisenia fetida), Effects on Reproduction in Natural Soil (LUFA 2.2) (ongoing) [redacted], Report no.: RRR11186, May 2008. GLP: Y, Unpublished	Y (New/First)	EQC
IIIA7.05.1.2/02	[redacted]	2003	An artificial sediment test using the nematode Caenorhabditis elegans [redacted] Report no.: CER F00, GLP: N, Unpublished	Y (New/First)	EQC
IIIA7.05.1.2/03	[redacted]	1999	Earthworm (Eisena fetida), acute toxicity test in artificial soil [redacted] Report No.: D RRA61831, March 10, 1999 GLP: Y, Unpublished	Y (New/First)	EQC
IIIA7.05.1.3/02	[redacted]	2004	Laboratory assessment of the side effects of DDAC on plant growth [redacted] Report No.: 03-99-035-ES, March 4, 2004 GLP: Y, Unpublished	Y (New/First)	EQC
IIIA7.05.1.3/03	[redacted]	2004	Laboratory assessment of the side effects of BKC on plant growth [redacted] Report No.: 03-99-036-ES, March 3, 2004 GLP: Y, Unpublished	Y (New/First)	EQC
IIIA7.05.2.1/02	[redacted]	2003	An artificial sediment test using the nematode Caenorhabditis elegans [redacted] Report no.: CER F00, GLP: N, Unpublished	Y (New/First)	EQC
IIIA7.05.3.1	[redacted]	1988	21-Day acute oral LD50 study in Bobwhite quail. [redacted] Report No.: 87 QD 103, June 27, 1988 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.05.3.2/01	[redacted]	1988	8-Day acute dietary LC50 study in Bobwhite quail [redacted] Report No.: 87 QC 102, June 20, 1988 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA7.05.3.2/02	[redacted]	1988	8-Day acute dietary LC50 study in Mallard ducklings [redacted] Report No.: 87 DC 100, June 27, 1888 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIA7.05.5	[redacted]	1996	Log Po/w for Arquad C calculation results outlined according to EC regulations [redacted] Report No.: ACRD 968-09, July 16, 1996 GLP: n.a., Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIA8	Akzo Nobel Surface Chemistry AB	2003	Safety Data Sheet Arquad C-35 Akzo Nobel Surface Chemistry AB, September 26, 2003 GLP: n.a., Published	N	Akzo Nobel Surface Chemistry AB
IIIA9	Akzo Nobel Surface Chemistry AB	2003	Safety Data Sheet Arquad C-35 Akzo Nobel Surface Chemistry AB, September 26, 2003 GLP: n.a., Published	N	Akzo Nobel Surface Chemistry AB
IIIB3.01	[redacted]	2003	Odour, physical state and pH - Sinesto B [redacted] GLP: N, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIB3.02	[redacted]	2002	Evaluation of physical and chemical properties according to Directive 92/69/EC, Annex A9-A17 [redacted] October 15, 2002 GLP: Y, Unpublished	Y (New/First)	Akzo Nobel Surface Chemistry AB
IIIB3.03	[redacted]	2002	Evaluation of physical and chemical properties according to Directive 92/69/EC, Annex A9-A17 [redacted], October 15, 2002 GLP: Y, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB3.04	[redacted]	2002	Evaluation of physical and chemical properties according to Directive 92/69/EC, Annex A9-A17 [redacted] October 15, 2002 GLP: Y, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB3.05	[redacted]	2003	Odour, physical state and pH - Sinesto B [redacted] GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB3.06	[redacted]	2003	Odour, physical state and pH - Sinesto B [redacted] GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB3.07/01	[redacted]	2003	Long-term storage of Sinesto [redacted] GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB3.07/02	[redacted]	2003	Accelerated Storage test by heating CIPAC-MT 46 Sinesto B [redacted] GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIB3.07/03	[redacted]	2004	Low temperature stability according to CIPAC MT 39 - Sinesto B [redacted] GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB3.11	[redacted]	2004	Viscosity - Sinesto B [redacted] GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB4.01/01	Akzo Nobel Surface Chemistry AB	1995	Determination of the activity in fatty quaternary ammonium salts Akzo Nobel, Deventer, The Netherlands, Report No.: VE/2.007, May 19, 1995 GLP: n.a., Published	N	Akzo Nobel Surface Chemistry AB
IIIB4.01/02	Borax Holdings limited	1980	Technical Service Bulletin 39; Analysis of boric acid or sodium borate Borax Holdings limited, Borax House, Carlisle Place, London, May, 1980 GLP: n.a., Published	N	Akzo Nobel Surface Chemistry AB
IIIB5.02	Dr Wolman GmbH	2004	Technical leaflet Sinesto B Dr Wolman GmbH, GLP: n.a., Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB5.10.2/01	[redacted]	1994	BAM test certificate BAM, File No.: 8.1/6536, GLP: n.a., Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB5.10.2/02	[redacted]	1990	Evaluation of the efficacy of Sinesto B in the control of sapstain on pine in a field test in Portugal; [redacted] GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB6.01.1	[redacted]	1983	Acute oral toxicity to rats of Sinesto B [redacted] Report No.: 83635D/KKM 5/AC, October 3, 1983 GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB6.01.2	[redacted]	1987	Acute dermal toxicity to rats of Sinesto B [redacted]., [redacted] Report No.: 87734D/KKM 8/AC, June 30, 1987 GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB6.02	[redacted]	1983	Irritant effects of rabbit skin of Sinesto B [redacted] Report No.: 8361 4D/KKM 6/SE (G), September 29, 1983 GLP: pre-GLP, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB6.03	[redacted]	1988	Delayed contact hypersensitivity in the guinea pig with Sinesto B [redacted] Report No.: 871692D/KKM 9/SS, January 8, 1988 GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIB6.05/01	Trigon Chemie Gmb, H	2003	Safety data sheet of Sodium 2-Ethylhexanoate Trigon Chemie GmbH, GLP: n.a., Published	N	Trigon Chemie GmbH
IIIB6.05/02	BASF	2003	Safety data sheet of Sodium hydroxide 50% water; BASF, September 29, 2003 GLP: n.a., Published	N	BASF
IIIB6.06	[redacted]	2004	Air concentration measurements in working zones according to TRGS 402 - Sinesto B GLP: n.a., Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB7.01	[redacted]	2003	Leaching of Sinesto B treated timber [redacted] Report no.: 12111/2003, November 21, 2003 GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB7.04.1.1	[redacted]	1986	Acute toxicity to fish [redacted], Report No.: Z86105, January 14, 1986 GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB7.04.1.2	[redacted]	1988	Acute toxicity to daphnia [redacted], Report No.: Z587-12, January 25, 1988 GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB8.04	[redacted]	1985	Pyrolysis Products of Sinesto B [redacted] November 11, 1985 GLP: N, Unpublished	Y (New/First)	Dr. Wolman GmbH
IIIB9	Dr Wolman GmbH	2004	Safety data sheet of Sinesto B Dr Wolman GmbH, GLP: n.a., Published	N	Dr. Wolman GmbH