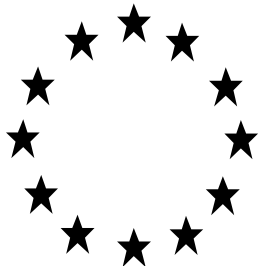
Directive 98/8/EC concerning the placing biocidal products on the market

Inclusion of active substances in Annex I to Directive 98/8/EC

Assessment Report



Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride

Product-type 8
(Wood preservative)

June 2015

Italy

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of Alkyl (C12-16) dimethylbenzyl ammonium chloride (C_{12-16}-ADBAC/BKC, CAS no 68424-85-1) 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 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Alkyl (C12-16) dimethylbenzyl ammonium chloride (CAS no. 68424-85-1) was notified as an existing active substance separately by Lonza AG & Stepan Europe & Mason Europe Ltd (US ISC) and by Akzo Nobel, Huntsman Surface Sciences and Thor (European Quat Consortium, EQC), hereafter referred to as the applicants, in product-type 8.

Commission Regulation (EC) No 2032/2003 of 4 November 2003[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 5(2) of that Regulation, Italy was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for Alkyl (C12-16) dimethylbenzyl ammonium chloride as an active substance in Product Type 8 was 28th March 2004, in accordance with Annex V of Regulation (EC) No 2032/2003.

On 28th March 2004, the Italian Competent Authority received a dossier from either applicants. The Rapporteur Member State accepted the dossiers as complete for the purpose of the evaluation on 28th September 2004.

As regards US ISC, on 27th June 2005 the time period was suspended and the evaluation taken up again on 27th March 2006 after the applicant has submitted the necessary data. After that, the evaluation phase was suspended again on the 17th July 2006 and taken up on 18th July 2007. On 31st July 2007, the Rapporteur Member State submitted, in accordance with the provisions of Article 10(5) and (7) of Regulation (EC) No 2032/2003, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 19th September 2007. The competent authority report included a recommendation for the inclusion of Alkyl (C12-16) dimethylbenzyl ammonium chloridein Annex I to the Directive for PT 8.

In accordance with Article 12 of Regulation (EC) No 2032/2003, the Commission made the competent authority report publicly available by electronic means on 10th October 2007. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

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 Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.

[1] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

[2] Commission Regulation (EC) No 2032/2003 of 4 November 2003 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 and amending Regulation (EC) No 1896/2000. OJ L 307, 24.11.2003, p. 1

On the basis of the final competent authority report, the Commission proposed the inclusion of Alkyl (C12-16) dimethylbenzyl ammonium chloridein Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 21 September 2012.

In accordance with Article 11(4) of Regulation (EC) No 2032/2003, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 21 September 2012.

As regards Akzo Nobel, Huntsman Surface Sciences and Thor (European Quat Consortium, EQC), on 25th January 2005 the evaluation was suspended. After a meeting with the Applicant on 24th November 2005 focusing on "Identity" and "Physico-chemical properties", the Italian Competent Authority received a new version of the dossier (26th January 2006), which however did not comply with RMS's requests for revision. The dossier was re-submitted by the Applicant on 16th July 2007, whereas the evaluation was taken up again on 15th October 2007. (CA-Sept06-Doc.6.1.2, CLARIFICATION ON SUBSTANCES NOTIFIED UNDER THE BKC AND DDAC GENERIC HEADINGS IN ANNEX II OF COMMISSION REGULATION (EC) NO 2032/2003).

Furthermore, the combined LoEP for human health and environment was discussed and agreed at WGII 2015 (CA-Nov14-Doc.5.15-Final, Submission of applications for product authorisations of PT08 products containing DDAC or ADBAC/BKC).

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include Alkyl (C12-16) dimethylbenzyl ammonium chloride in Annex I to Directive 98/8/EC for product-type 8. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in product-type 8 that contain Alkyl (C12-16) dimethylbenzyl ammonium chloride. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 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 at the Commission website[3], shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Directive 98/8/EC, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Overall conclusion in the context of Directive 98/8/EC

The overall conclusion from the evaluation is that it may be expected that there are products containing Alkyl (C12-16) dimethylbenzyl ammonium chloride for the product-type 8, which will fulfil the requirements laid down in Article 10(1) and (2) of Directive 98/8/EC. This conclusion is however subject to:

i. compliance with the particular requirements in the following sections of this assessment report,

ii. the implementation of the provisions of Article 5(1) of Directive 98/8/EC, and

iii. the common principles laid down in Annex VI to Directive 98/8/EC.

Furthermore, these conclusions were reached within the framework of the uses that were

[3] http://ec.europa.eu/comm/environment/biocides/index.htm

proposed and supported by the applicant (see Appendix II). Extension of the scenario beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

2. OVERALL SUMMARY AND CONCLUSIONS

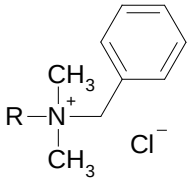
The data submitted by the two Applicants for the evaluation and approval of Alkyl (C12-16) dimethylbenzyl ammonium chloride (C_{12-16}-ADBAC/BKC, CAS 68424-85-1) are reported in the following chapters. In particular, Lonza AG & Stepan Europe & Mason Europe Ltd (members of the 'ADBAC and DDAC Issues Steering Committee') and Akzo Nobel, Huntsman Surface Sciences & Thor (members of the 'European Quats Consortium') are indicated as **US ISC** and **EQC**, respectively.

2.1. Presentation of the Active Substance

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

Identification of the active substance

Alkyl (C12-16) dimethylbenzyl ammonium chloride (C_{12-16}-ADBAC/BKC) is not manufactured solvent-free, but in process solvents as technical concentrate (in water or water/alcohol).

CAS-No.	68424-85-1
EINECS-No.	270-325-2
Other No.	None
IUPAC Name	Not applicable
CAS Name	Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides
Molecular formula	$C_{n+9}H_{2n+14}N.Cl$ (n = 12, 14, 16)
Structural formula	

$R = C_{12}H_{25}$, $C_{14}H_{29}$ or $C_{16}H_{33}$

Alkyl chain lengths distribution

Chain Length	Range
C12	39 - 76%
C14	20 - 52%
C16	<12%

Molecular weight	340.0 – 396.1 g/mol
Purity	>94.0% w/w (dry weight) for **US ISC** >98.1% w/w (dry weight) for **EQC**

The active substance does not contain any additive nor any relevant impurity. Only significant impurities are present, which are considered as confidential information by the two Applicants and, hence, described in the Annex of „Confidential data" of the respective CARs.

Identification of the representative product

US ISC

Trade name	BQ-25
Manufacturer's development code number	Not assigned
Active substance	Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides
Content of the a.s. [g/kg]	250
Function	Fungistatic, insecticide
Physical state of preparation	Liquid
Nature of preparation	Water-based concentrate (SL)

EQC

Trade name	BKC-50
Manufacture's development code number	None assigned
Active substance	Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides
Content of the a.s. [g/kg]	500
Function of preparation	Fungicide/fungistatic
Physical state of preparation	Liquid
Nature of preparation	Water-based concentrate (SL)

Detailed qualitative and quantitative composition of the representative products, including identity, content and function of non-active ingredients, is available in the Annex of „Confidential data" of either CAR.

Physico-chemical properties

The a.s. is manufactured in process solvents as technical concentrate (in water or water/alcohol). For the purpose of physico-chemical properties testing, either US ISC and EQC prepared a sample of technical material by removing process solvents as far as possible from a sample of C_{12-16}-ADBAC/BKC technical concentrate (in water/ethanol and water, respectively).

The a.s. is a white/light beige sticky solid with hygroscopic behaviour and faint marzipan-like odour. Its relative density D_4^{20} is ≈0.9. It is thermally stable, non-volatile and highly soluble in water. Water solubility was found to be independent of temperature. The a.s. is fully ionized in water.

The partition coefficient n-octanol/water is not determinable by the use of the shake-flask method, since the a.s. is a surfactant. The HPLC Method is not applicable either, due to the absence of suitable calibration compounds and to the interaction of the a.s. with the HPLC column by forces other than partitioning. Also the *log* K_{ow} assessment by KOWWIN is deemed inaccurate, being the software database very limited for surface active substances. On the other hand, *log* K_{ow} can be roughly obtained from solubility in n-octanol and water (K_{ow} =1.009, *log* K_{ow} =0.004 according to EQC). However, this result is of no use with regard to environmental fate & behaviour and secondary poisoning risk assessment, when there is an experimental BCF_{fish} available (as for US ISC).

UV/VIS, IR, NMR absorption spectra and MS spectrum are found consistent with the molecular structure. As for the UV/VIS spectra, no absorption is observed above 290 nm under the investigated conditions (neutral/acidic/basic medium).

The a.s. does not show explosive or oxidising properties; it is not classified as a flammable solid, either.

BQ-25 (representative product for US ISC) is a water-based concentrate, which is not expected to pose any physical hazard.

BKC-50 (representative product for EQC) is a water-based concentrate, which is not expected to pose any physical hazard, either.

Analytical methods

Analysis of the active substance as manufactured

US ISC: In 2011, a new study (Zehr, P.S. (2010), "Methods Validation for the Preliminary Characterization Analyses of Alkyldimethyl[ethyl]benzyl Ammonium Biocides") for the determination of the active substance, impurities and process solvents in commercially available technical concentrate Maquat MC1412-50% (nominal a.s. content: 50% w/w) was submitted, superseding those in Doc. IIIA Sections 4.1(1) and (2). Results are summarized in Section 4.1(3)(a) in Doc. IIIA and Section 4.1(3)(b)-(c) in the Annex of „Confidential data". Further, additional validation data/information were submitted by US ISC post Annex I inclusion of the a.s. under BPD. It can be concluded that valid analytical methods are available for the a.s., its impurities and process solvents in technical concentrates (nominal a.s.: 50% w/w).
Five-batch analysis data on the active substance as manufactured (technical concentrate) were submitted by US ISC post Annex I inclusion of the a.s. under BPD, to support/confirm the set reference specification (dry weight). Batch-data from Lonza covered one manufacturing site only; batch data from Mason covered one manufacturing site but two different technical concentrates, whereas batch-data from Stepan covered two different manufacturing sites and two different technical concentrates. The composition of batches was recalculated on a dry weight basis; then, a dry weight specification was derived by statistical analysis (mean ± 3xSD). The specification of each source proved to comply with the set reference specification. It can be concluded that each source of the US ISC covered by five-batch analysis is a reference source.

EQC: A new study report for the identification/quantification of the a.s. and its impurities in the technical material obtained by lyophilisation of a sample of a water-based technical concentrate (Arquad MCB-50EP) was submitted by EQC in April 2012, superseding the one in Doc. IIIA under Sections 4.1(1). It can be concluded that valid analytical methods are available for the a.s. and its impurities in the technical material.
In order to set the reference specification, five-batch analysis data on the active substance as manufactured (technical concentrate) were submitted by each member of EQC, i.e. Akzo Nobel, Huntsman and Thor. Batch-data from Akzo Nobel and Huntsman covered one manufacturing site each, whereas batch-data from two different plant locations were submitted by Thor. 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 each source by statistical analysis (mean ± 3xSD). A common dry weight reference specification was set for EQC, that accommodate the specification of the sources. Therefore, all sources covered by five-batch analysis can be regarded as reference sources.

Residues analysis

No analytical method is required for the determination of residues in air, since the a.s. is non-volatile nor expected to occur in air (representative products BQ-25 and BKC-50 are used in the following wood preservative treatment applications: automated dipping process, vacuum pressure process and spraying application in closed tunnel).

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

No analytical method for the determination of residues in food/feed of plant/animal origin is required, either. Wood treated with C_{12-16}-ADBAC/BKC-containing biocidal products is not intended for and contains label restrictions against use in areas where food for human consumption is prepared, consumed or stored, or where the feedingstuff for livestock is prepared, consumed or stored. Furthermore, the use of C_{12-16}-ADBAC/BKC-based wood preservatives must exclude applications that may lead to contact with food and feedstuffs and contaminants thereof (e.g. application on wood crates for the storage or transport of

food/feedingstuff).

The methods submitted by EQC for the determination of residues in soil and water, which are necessary for post-authorization control and monitoring, support the residue definition (C_{12-16}-ADBAC/BKC).

US ISC: LC-MS methods for the analysis of residues in soil and water (drinking, ground and surface water) down to 0.01 mg a.s./kg and 0.1 µg a.s./L, respectively, were available in the original dossier. Only one mass fragment related to the C_{12} constituent was considered for validation. During the evaluation in 2006, those methods were accepted as sufficiently specific, linear, accurate and precise by the eCA-IT. 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 C_{12-16}-ADBAC/BKC residues in soil and water was also agreed in 2010 after bilateral discussion between DE-CA and eCA-IT on structurally-related quaternary ammonium compounds. US ISC can cover the data gap by means of a letter of access to the analytical methods for residues by EQC described below.

EQC: An analytical method for the determination of the a.s. residues in soil by LC-MS/MS was submitted in April 2012. For each constituent, 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 a.s./kg and 0.50 mg a.s./kg. Additional validation was carried out at 0.0167 mg/kg and 0.167 mg/kg for each individual constituent (C12, C14 and C16).
The method is highly specific (LC-MS/MS, with two mass transitions validated), linear over the range 0.008 −0.60 mg a.s./kg in soil, accurate (with recovery rates at LOQ and 10xLOQ in the acceptable range 70−110%) and precise (%$RSD_{n=5}$ ≤ 20% for either fortification level). The LOQ (as the lowest fortification level successfully validated) complies with the relevant PNEC (i.e. LOQ<$PNEC_{soil}$ = 0.83 mg/kg dw soil).

An analytical method for the determination of the a.s. residues in ground, surface and drinking water by LC-MS/MS was submitted in April 2012. For each constituent, 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 a.s./L and 1.0 µg a.s./L. Additional validation was carried out at 0.033 µg/L and 0.333 µg/L for each constituent (C12, C14 and C16).
The method is highly specific (LC-MS/MS, with two ion transitions validated), linear over the range 0.013−0.845 µg a.s./L in matrix, accurate (with recovery rates at LOQ and 10xLOQ in the acceptable range 70−110%) and precise (%$RSD_{n=5}$ ≤ 20% for either fortification level).
Ground and drinking water: the LOQ (as the lowest fortification level validated) 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 PNEC (i.e. LOQ <$PNEC_{water}$ =0.415 µg/L).

2.1.2. Intended Uses and Efficacy

PT 8, Wood Preservative

The active substance Alkyl (C12-16) dimethylbenzyl ammonium chloride in Product Type 8 acts as fungistatic and insecticide. It is used for preventive protection of wood and constructional timbers in Hazard Classes 1 to 4A according to ISO draft standard.

Mode of action

The active substance 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. Its interaction with phospholipid-bilayer structures 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. One common used combination is with copper, but also the combination with triazole is possible. Combinations with insecticides are also on the market. Efficacy studies with quats alone require considerably higher concentrations than those actually used in these formulations. Therefore, the use of "quat only" efficacy data for risk assessment may provide an exaggerated environmental exposure level.

Biocidal product BQ-25 **(US ISC)** is used in drenching/dipping and vacuum pressure process applications. For both processes, the preservative is delivered to the processing plant by tanker in the form of a concentrate. The concentrate contains 25% of the active substance. 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 requirements for the final concentration of a.s. vary between 0.4% and 2.0%. The application rate of a.s. in wood is 2.0 kg/m^3. Number and timing of applications depends on application technique, wood species, moisture and hazard class.
In practice it is always used in formulations in combination with other active substances.

As regards biocidal product BKC-50 **(EQC dossier)**, the route of application is automated dipping in a dipping bath and spraying in a closed tunnel. According to the information provided by the Applicant, both the application processes are intended for professional workers in industrial settings only. As for the automated dipping application, the preservative is automatically delivered to the processing plant by tanker in the form of a concentrate. The concentrate contains 50% of the active substance. It is diluted down to a suitable working strength with water. Biocidal product BKC-50 is typically used in practice as a 5-10 fold dilution in water and the proposed retention is 1.5 – 3 kg a.s./m^3, corresponding to 15-30 g a.s./m^2.

Organism to be controlled

Wood destroying basidiomycetes

Brown-rot
White-rot
Coniophora puteana/
Coniophora spec
Coriolus versicolor
Gloephyllum trabeum Poria vaillantii / Poria spec.
Fomes spec.
Trametes spec

Wood staining molds

Aureobasidium pullulans
Sclerophoma pityopila
Ophistostoma piliferum
Aspergillus niger
Aspergillus terreus
Chaetomium globosum
Paecilomyces variotii
Penicillium funicolosum
Trichoderma viridae

Wood boring insects

Hylotrupes bajulus
Anobium punctatum
Lyctus brunneus termites

Occurrence of resistance

After approx. 40 years of use worldwide, no reports of selective acquisition of the active substance-resistance in the field of wood protection still exist. On the other hand, the active substance as a wood preservative works by preventing growth of organisms, not by killing organisms that are present, thus reducing the potential for resistant organisms to develop. In addition, for hard surface sanitization/disinfection (where antimicrobial activity is based on direct killing of organisms present on surfaces), investigations on exposure of domestic microbial communities to quaternary ammonium biocidal substances showed no increased antimicrobial resistance (McBain A.J. et al. 2004, **US ISC**).

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organisms and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling

The active substance is currently not classified according to Annex I of Council Directive 67/548/EC (with amendments and adaptations) and according to Regulation (EC) No 1272/2008 (CLP Regulation).

On the basis of the results from studies presented by US ISC and EQC in their respective dossiers, classification of active substance was proposed according to principles detailed in Annex VI of Council Directive 67/548/EEC () and of Regulation (EC) No 1272/2008 (CLP Regulation with amendments and adaptations).

Proposed classification and labelling of C_{12-16}-ADBAC/BKC based on Reg. EC 1272/2008:

Classification	
Hazard Class and Category	Acute Tox 3 *(this point will be revised with CLH dossier submission)* Acute Tox 4 Skin Corr. 1B_ Aquatic Acute 1_ Aquatic Chronic 1
Hazard Statement Codes	H302 H311 *(this point will be revised with CLH dossier submission)* H314 H400 H410
Labelling	
GHS Pictogram	GHS05, GHS06*, GHS09 **(this point will be revised with CLH dossier submission)*
Signal Word	Danger
Hazard Statement	H302: Harmful if swallowed H311: Toxic in contact with skin *(this point will be revised with CLH dossier submission)* H314: Causes severe skin burns and eye damage H410: Very toxic to aquatic life with long lasting effects
M Factor	M factor=10 (Acute) M factor=1 (Chronic)

Proposed Classification and labelling of product BQ-25 based on Regulation EC 1272/2008:

Classification	
Hazard Class and Category	Acute toxicity (oral), Hazard Category 4 Skin Corrosion Hazard Category 1B Aquatic Acute 1 Aquatic Chronic 1
Hazard Statement Codes	H302 H314 H400 H410
Labelling	
GHS Pictogram	GHS05, GHS09
Signal Word	Danger
Hazard Statement	H302:Harmful is swallowed H314: Causes severe skin burns and eye damage H410: Very toxic to aquatic life with long lasting effects
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. P310: Immediately call a POISON CENTER or doctor/physician P391: Collect spillage. P501: Dispose of contents/container to … (… in accordance with local/regional/national/international regulation (to be specified).

Proposed Classification and labelling of BKC-50 based on Reg. EC 1272/2008:

Classification	
Hazard Class and Category	Acute Tox 4 Acute Tox 4 Skin Corr. 1B Aquatic Acute 1 Aquatic Chronic 1
Hazard Statement Codes	H302 H312 H314 H400 H410
Labelling	
GHS Pictogram	GHS05, GHS 6*,GHS09 **(this point will be revised with CLH dossier submission)*
Signal Word	Danger
Hazard Statement	H302: Harmful if swallowed. H312: Harmful in contact with skin H314: Causes severe skin burns and eye damage H410: Very toxic to aquatic life with long lasting effect
Precautionary statements	P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection.

	P301+P330+331+310: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician. P303+353+361: IF ON SKIN (or hair): Rinse skin with water/ shower. Remove/Take off immediately all contaminated clothing. P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P391: Collect spillage. P501: Dispose of contents/ container to …

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Alkyl (C12-16) dimethylbenzyl ammonium chloride (C_{12-16}-ADBAC/BKC, CAS no 68424-85-1) is not expected to be readily absorbed from the gastrointestinal tract or skin being a highly ionic compound. The oral absorption can be considered approximately 10% based on the 5-8% of the C_{12-16}-ADBAC administered dose eliminated via urine and tissue residues (less than 1% of the administered dose 7 days after single and repeated oral dosing). More than 90% is excreted in the faeces and the pattern did not change after repeated doses. 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 **(US ISC)**.

The majority of C_{12-16}-ADBAC metabolism is expected to be carried out by intestinal flora; the metabolites, which account for less than 60% of the administered dose, include hydroxyl- and hydroxyketo- derivatives of the dodecyl, tetradecyl and hexadecyl chains. No metabolite accounted for more than 10% of the total administered dose **(US ISC)**.

The active substance Quaternary ammonium compounds, benzyl-C_{12-16}-alkyldimethyl chlorides is highly ionic and, therefore, it is expected not to be readily absorbed from the gastrointestinal tract or skin. The vast majority of the oral dose was excreted in the faeces (80%) as unabsorbed material (only about 4% of the oral dose was eliminated in the bile in a 24-hour period). The actual fraction of the oral dose absorbed was about 10%, based on the urinary mean value 3-4% (with a single peak value of 8.3%) and biliary excretion values (3.7-4.6%), as well as on the absence of residues in the carcass, as measured at 168 h. Excretion was rapid (within a 48 to 72-hour period). The radioactivity excreted in the urine was not associated with the parent compound, but with more polar metabolites which were not identified **(EQC)**.

C_{12-16}-ADBAC/BKC do not show any bioaccumulation potential **(US ISC; EQC)**.

The C_{12-16}-ADBAC dermal absorption determined in an *in vitro* study using human skin at two different concentrations (0.03% and 0.3%) of the active substance is 8.3% (rounded to 10% at non-corrosive concentration) **(US ISC)**.

The available data on BKC dermal absorption do not allow to quantify exactly the % of the dose which was absorbed after dermal application. However, due to 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% at non corrosive concentration) **(EQC)**.

The oral LD_{50} for C_{12-16} ADBAC is 344 mg/kg bw. No clinical signs or mortality were observed until a dosage or a concentration is attained that causes irritation of the gut mucosa or affects the gastrointestinal flora. Indeed, irritation and corrosivity are the major toxicity outcomes related to C_{12-16}-ADBAC exposure **(US ISC)**.

The lowest determined oral LD_{50} for C_{8-18}-BKC is 358 mg/kg bw. No specific target organ was evidenced and the major effects was associated to the corrosive action on the GI walls. Although the test was not conducted with the active substance under registration, but with a structurally related one (Cocobenzyldimethylammonium chloride, containing about 20% of C_8, C_{10} and C_{18}, in addition to C_{12}-C_{16} alkyl chains), results can be considered valid for C_{12-16}-BKC, based on the similar mechanism for oral toxicity shown by QUATs with this alkyl chain length, that is high irritancy to the mucosal surfaces of the GI-tract. Therefore, C_{12-16}-BKC is classified as harmful if swallowed **(EQC)**.

The rabbit acute dermal LD_{50} of C_{12-16}-ADBAC is 2848 mg/kg bw (at the application site clear signs of irritation and topic toxic effects were evident). Inhalation of C_{12-16}-ADBAC is not considered a potential route of exposure based on scenarios and vapour pressure (< $1x10^{-3}$ Pa at 50ºC) **(US ISC)**.

Since the product is corrosive to the skin, dermal LD_{50} testing is not justified according to animal welfare principle; however, literature values of dermal LD_{50} vary between 800 and 1400 mg/kg. Inhalation toxicity study was considered unnecessary, since the active substance is not volatile (vapour pressure < 1×10^{-5} Pa at 20°C) and only spraying with big, not inhaled, droplets with <100 µm MMAD is recommended; in addition no inhalation testing is allowed with corrosive chemicals **(EQC)**.

C_{12-16}-ADBAC/BKC is a corrosive to the skin and eye, and although no data is available, it is expected to be irritant/corrosive also for the respiratory tract **(US ISC; EQC)**.

It is not a skin sensitiser under the experimental conditions tested. Although no experimental data is available, C_{12-16}-ADBAC/BKC is not expected to be a respiratory sensitizer **(US ISC; EQC)**.

From a two-week skin irritation study in rats, it can be derived a NOAEC for short term skin irritation equal to 0.3% C_{12-16}-ADBAC in water at 2.0 mL/kg body weight per day **(US ISC)**.

2.2.1.2. Effects assessment

Similarly to acute effects, repeated C_{12-16}-ADBAC intake in the diet results in effects up to death in rodents at concentrations affecting the gastrointestinal mucosa and resulting in dehydration and wasting or affects the gastrointestinal flora. Indeed, irritation and corrosivity are again the major outcomes of toxicity related to C_{12-16}-ADBAC and BKC and no specific organ toxicity was evidenced. The effects on which the NOEL derivation could have been based, independently on the species tested, was the reduction in body weight and body weight gain, consistent with decreased food consumption **(US ISC; EQC)**. It was concluded that all effects could be attributed to local gastrointestinal irritaton/corrosion and consequent reduced food intake without observing any primary systemic effect. Therefore, the derivation of a NOAEL for systemic effects was deemed inappropriate.

The subchronic oral toxicity NO(A)ELs were 85 mg/kg/day in mice, 31 mg/kg/day in rats and 13.1 mg/kg/day in dogs, mainly based on decrease in body weights, reduced food consumption and appearance of clinical signs related to the irritation and damages to the gut mucosa. The changes in haematology and clinical biochemistry reported at high doses of treatment appear to be secondary to a reduced food intake and dehydration very likely leading to a reduced renal blood flow **(US ISC)**.

A 90-day feeding study in rats resulted in a NOAEL of 68 mg a.s./kg bw/day. In a 90-day dog study, beagle dogs were treated up to 1500 ppm of C_{12-16}-BKC; from week 8, the concentration of the active substance was reduced to 1250 ppm in the high-dose female group, due to low food intake and reduced body weight among these animals (up to 20%). The NOAEL resulted to be equal to 45 mg a.s./kg bw/day (the highest dose tested). However, the fact that a small change from 3000 ppm to 2500 ppm of the test item in the 90-day study lead to recovery, and the reduced food consumption and body weight loss reported at 43-53 mg/kg/day in a 28-day oral toxicity study with dogs indicate that the NOAEL is a borderline value highly dependent on the g.i. mucosa. Therefore, adequate caution should be taken into account in the risk characterization, considering that local effects are the primary and crucial outcome **(EQC)**.

The NOELs related to non-neoplastic effects in chronic oral toxicity studies were 44 mg/kg/day for rats and 73 mg/kg/day for mice. It appears that subchronic and chronic NOAEL are in the same order of magnitude, in line with the fact that the main outcome directly derives from the irritative/corrosive properties of the substance **(US ISC)**.

After chronic oral exposure the NOAEL in rats for non-neoplastic effects induced by BKC was

47 mg a.s./kg/day (the lowest value in the range of values among subgroups and sexes), based on the mean body weight and body weight gain reduction (10-18%) with respect to controls, correlating with a lower mean food consumption (73% of the control value) **(EQC)**.

In a 90-day subchronic dermal study in rats, no systemic effects were seen at the highest dose that could be applied without excessive skin irritation (20 mg/kg/day). No systemic effects are anticipated after higher dermal or inhalation exposure. Indeed, due to its corrosive characteristics, C_{12-16}-ADBAC will react locally and only a scant amount will become systemically available **(US ISC)**.

The active substance Alkyl (C12-16) dimethylbenzyl ammonium chloride displayed no genotoxic activity in the three mutagenicity tests required for the authorisation of Biocidal Products: Salmonella mutagenicity assay, chromosomal aberration assay in human lymphocytes in vitro and mutagenicity test in CHO/HPRT forward mutation assay **(US ISC;EQC)**

Moreover, no clastogenic activity in vivo was observed in a mouse micronucleus study **(US ISC)**.

No neoplastic lesions were found that were considered treatment related and therefore the Alkyl (C12-16) dimethylbenzyl ammonium chloride was not found to be carcinogenic under the conditions of the available study **(US ISC; EQC)**.

Alkyl (C12-16) dimethylbenzyl ammonium chloride does not affect reproduction or development at doses that are not toxic to the mother **(US ISC)**.

No developmental effects attributable to C_{12-16}-BKC were observed. The developmental toxicity study in rabbits resulted to maternal NOEL of 3 mg/kg/d based on dilated gall bladder (3/22 and 3/22 at 10 mg/kg and 30 mg/kg, respectively), accentuated lobular pattern in liver (3/22 and 4/22 at 10 mg/kg and 30 mg/kg, respectively). At top dose 5/22 dams died or were prematurely sacrificed for ethical reasons or abortion and body weight gain was transiently, but severely reduced on GD 9-12. Blackish content in stomach and intestines is indicative of local corrosive effects of C_{12-16}-BKC, related to the dosing of substance by gavage **(EQC).**

Literature and the recently completed full 2-generation study in rats following current guidelines do not indicate a concern for reproduction toxicity of C_{12-16}-BKC, either **(EQC)**.

No evidence of neurotoxicity induced by C_{12-16}-ADBAC and C_{12-16}-BKC was observed in any of the acute, subchronic or chronic studies, in line with the absence of any structural alert for neurotoxicity or similarity with any known neurotoxic agent **(US ISC; EQC)**.

Medical data

No medical reports on the manufacturing personnel have been submitted **(US ISC)**.

The few described fatalities and serious health effects in humans are caused by accidents. Occurrence of sensitisation to C_{12-16}-BKC is relatively limited, and of no great concern. Skin reactions observed after dermal exposure to C_{12-16}-BKC can be regarded as an irritant reaction rather than a true sensitisation reaction. This is supported by the results from animal tests, which do not indicate a sensitising potential **(EQC)**.

CONCLUSION on 2.2.1.2 Effects Assessment:

The results from the studies reveal a pattern of response (local irritation/corrosion followed by reduced food intake and reduction in body weight and body weight gain) that is consistent with the mode of action of a corrosive substance. Therefore, the systemic effects observed in these studies are regarded as secondary to the local irritation/corrosion caused by the test substance and as a result no adverse systemic effects were identified and no systemic risk characterisation is required.

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 **(US ISC; EQC)**, vacuum pressure process **(US ISC)** and spraying application in closed tunnel **(EQC)**. For all these processes, the preservative is delivered to the processing plant by tanker in the form of a concentrate. The concentrate solution contains from 25% of a.s. **(US ISC)** to 50% of a.s. **(EQC)**. The concentrate 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, and therefore the a.s. concentrations in the processes vary between 0.4% and 10%.

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

2.2.1.3.1 Local exposure assessment

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

US ISC

C_{12-16}-ADBAC exhibits irritant/corrosive properties which mainly affect the human exposure. In order to quantify the local exposure, the scenarios adopted have been selected from TNsG on Human Exposure and RISKOFDERM Model. In this context, reduction factors from wearing clothes and/or Personal Protective Equipments have been taken into consideration; no dermal penetration has been considered.

C_{12-16}-ADBAC is a non-volatile active substance and therefore the inhalation uptake can be considered as negligible in assessing the exposure due to the local effects.

Industrial/Professional users (primary exposure)

In the local exposure assessment the dermal route is deemed to be the most relevant one for industrial/professional users handling both concentrated (Mixing and loading process) and diluted C_{12-16}-ADBAC-based solutions (dipping and vacuum-pressure applications). The resulted exposure values are reported below. Information on assumptions and input values used in the relevant scenarios are provided in Doc. IIB.

Table 2.2.1.3.1-1 Summary of the exposure local dose for industrial/professional users

EXPOSURE MODEL	Hands exposure	Body exposure	Feet exposure
	mg/cm^2	mg/cm^2	mg/cm^2
MIXING&LOADING Riskofderm *Connecting lines*	0.000275	-	-
APPLICATION PHASE (Dipping treatment): Handling Model1	0.0617	0.005	0.036
APPLICATION PHASE (Vacuum Pressure treatment): Handling Model1	0.077	0.009	0.027

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

The local irritant effect of the C_{12-16}-ADBAC deems to be more relevant in the case of the secondary exposure than the systemic effect. In particular, this is the case of the scenario in which has taking into account the exposure for child chewing wood. Therefore it has been drafted an exposure scenario considering that the maximum absorption of product is 2 mg/cm^3 (see above).

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

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

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

A	maximum absorption a.s	mg/cm^3	2
B	size of chewed timber cut-off (chip)	cm^2	16
C	depth of chewed timber cut-off (chip)	cm	1
D = B x C	volume of chip	cm^3	16
E	a.s. extracted by chewing	fraction	0.1
F = A x D x E	a.s. in the mouth	mg	3.2
G	Amount of saliva produced	mL/min	1.5
H	Event duration	min	1

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

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

Amount of active substance in the mouth: F = A x D x E = 3.2 mg

Concentration in the mouth = F/(G x H) = 2.1 mg/mL = 2100 mg/kg

Local dose expressed as percentage of active substance = 0.21%

EQC

C_{12-16}-BKC exhibits irritant/corrosive properties which mainly affect the human exposure. Although no specific scenarios are currently available in order to quantify the local exposure, the same scenarios adopted in the systemic exposure assessment have been used. In this context, reduction factors from wearing clothes and/or Personal Protective Equipments have been taken into consideration; no dermal penetration has been considered.

C_{12-16}-BKC is a non-volatile active substance and therefore the inhalation uptake can be considered as negligible in assessing the exposure due to the local effects.

Industrial/professional users (primary exposure)

In the local exposure assessment the dermal route is deemed to be the most relevant one for industrial/professional users handling both concentrated (Mixing and loading process) and diluted C_{12-16}-BKC-based solutions (automated dipping application and spraying in closed tunnel). The resulted exposure values are reported below. Information on assumptions and input values used in the relevant scenarios are provided in Doc. IIB.

Table 2.2.1.3.1-2 Summary of the exposure local dose for industrial/professional users.

EXPOSURE MODEL	Hands exposure	Body exposure	Feet exposure	Inhalation exposure
	mg/cm^2	mg/cm^2	mg/cm^2	mg/m^3
MIXING&LOADING Riskofderm *Connecting lines*	0.00055	-	-	-
APPLICATION PHASE (Automated dipping treatment): Handling Model1	0.31	0.061		-
Spraying in a closed tunnel: Dipping and Deluge	0.22	0.038		0.1

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

The local irritant effect of C_{12-16}-BKC seems to be more relevant in the case of the secondary exposure than the systemic effect. In particular, this is the case of the scenario in which the exposure for child chewing wood has been taken into account.

The input values are reported as follows:

A	maximum absorption a.s.	mg/cm^3	2
B	size of chewed timber cut-off (chip)	cm^2	16
C	depth of chewed timber cut-off (chip)	cm	1
D = B x C	volume of chip	cm^3	16
E	active substance extracted by chewing	fraction	0.1
F = A x D x E	active substance in the mouth	mg	3.2
G	Amount of saliva produced	mL/min	1.5
H	Event duration	min	1

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

Amount of active substance in the mouth:

F = A x D x E = 3.2 mg

Concentration in the mouth = F/(G x H) = 2.1 mg/mL = 2100 mg/kg

Local dose expressed as percentage of active substance = 0.21%

2.2.1.4. Risk characterisation

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

2.2.1.4.1 Risk characterisation for local effects

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

As regards the dermal exposure, in the 2-week skin irritation study with rats, no systemic effects were observed and the NOAEL for local effects has been set at 6 mg/kg bw/day (0.3% C_{12-16}-ADBAC).

Local NOAEC derivation - Dermal route

The NOAEL derived for the C_{12-16}-ADBAC is of 0.3% of active substance in water (*i.e.*, 3 g/L or 3000 mg/L or 3 mg/mL). The total volume applied is of 2 mL/kg bw per day. Therefore, the resulted NOEL is of 6 mg/kg bw/day (= 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 300 g. 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 = 0.045mg/cm^2

The NOAEC value of 0.045 mg/cm^2 is equivalent to a NOAEC of 0.3%.

Local NOAEC derivation – Oral route

For the oral NOAEC derivation no toxicological study is available.

Exposure and risk from use of the product

For local dermal effects, the NOAEC expressed in terms of % should be compared with the in-use concentration of the active substance in the representative products. In this regards, the formulation BQ-25 **(US ISC)** and BKC-50 **(EQC)** contain 25% and 50% of C_{12-16}-ADBAC, respectively. On the other hand, the in-use concentrations of C_{12-16}-ADBAC in the representative products range from 0.4% to 10% (*i.e.*, from 0.4% to 2.0% and 10% for the formulations BQ-25 and BKC-50, respectively). Therefore, being the concentrations of the C_{12-16}-ADBAC solutions applied higher than the (marginal) NOAEC of 0.3% C_{12-16}-ADBAC for all intended uses, an unacceptable risk can occurs and personal protective equipments (PPEs) should be prescribed to protect operators against the local effects of C_{12-16}-ADBAC. The conclusion from the semi-quantitative risk assessment due to the corrosive properties of C_{12-16}-ADBAC is that PPE are per definition required when applying C_{12-16}-ADBAC.

Exposure and risk from indirect exposure to the product

As concerns the risks arising from the secondary exposure, the only scenario considered as relevant is child mouthing treated wood. The resulting local concentration is of 0.21% C_{12-16}-ADBAC (2.1 mg/mL).

Not being available an oral NOAEC as to avoid any potential risk still highlighted for children chewing and sucking timber treated cut-off the in-use product concentration should be less than the resulting local concentration of 0.21% C_{12-16}-ADBAC.

In conclusion, not being fully addressed the risk arising from child sucking and mouthing treated wood, the scenario has not been assessed. Therefore, the use of ADBAC treated wood has to be restricted to applications where biocidal treatment is unavoidable (*e.g.*, construction) but definitely excludes applications to treated wood composites which would otherwise come into contact with children.

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

Therefore, based on the above discussion, it is considered inappropriate to use an AEL approach for C_{12-16}-ADBAC and similar quaternary amines, because there is no true systemic toxicity. C_{12-16}-ADBAC, and other quaternary amine biocides, do not exhibit "systemic toxicity" as based on changes to organs or effects on reproduction, development, mutagenicity, carcinogenicity, neurobehavior or other key toxicological endpoints. Rather, effects observed in toxicity studies occur only at irritant doses and general effects, including body weight changes at lower doses and death at high doses, are secondary to these irritant responses.

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

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

"***Derivation of oral NOAEC***

An oral NOAEC for local effects can be derived from the 1-year oral gavage toxicity study in dogs performed on DDAC (Schulze, G.E. (1991). Chronic oral toxicity study of Didecyldimethylammonium Chloride in dogs). A NOAEL of 3 mg/kg bw/d was identified from this study based on local effects observed on the 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 3.18: Estimation of exposure to infant mouthing wood off-cut treated by dipping application

Wood off-cut treated by dipping application	
Concentration of a.s. in treated wood	*0.168 mg a.s./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."

US ISC

Biocidal Product

The C_{12-16}-ADBAC dermal absorption is 8.3% as determined in an in vitro study using human skin. The value as been obtained summing up the radioactivity present in the receptor fluid (0.05%), at the application site (after 20 consecutive tape stripping procedures) and the one present in tape strips (n°6-20). The two different concentrations tested (0.03% and 0.3% in a.s. content) showed no significant differences in the absorption values.

An acute oral LD_{50} = 344 mg/kg bw for C_{12-16}-ADBAC lead the classification R22 being applied to the a.s. Therefore according to the provisions of directive 1999/45/EC this product is also classified as R22 (trigger concentration is >25%) for this endpoint.

An acute dermal toxicity study performed on C_{12-16}-ADBAC (80% in aqueous: alcoholic solution) resulting in an LD_{50} = 2730 mg/kg bw and does not lead to classification being applied. Therefore according to the provisions of directive 1999/45/EC[3] this product is also not classified for this endpoint. Therefore an acute dermal toxicity study on the product is not required.

This product contains 25% C_{12-16}-ADBAC in water and no other components. C_{12-16}-ADBAC is not volatile as the vapour pressure is $<10^{-5}$ hPa ($<10^{-3}$ Pa) at 50°C. In addition, from the skin irritation endpoint the product is classified as corrosive and is assigned R34. Thus, it is considered that evaluation of the acute inhalation toxicity is not justified.

A skin irritation study performed on C_{12-16}-ADBAC (80% in aqueous: alcoholic solution) which leads to the classification Corrosive, R34 being applied. Therefore, according to the provisions of directive 1999/45/EC this product is also classified as Corrosive, R34 (trigger concentration is >10%)

C_{12-16}-ADBAC has been shown to be corrosive to the eye in a test conducted using an 80% solution of the a.s. In addition, due to the classification of corrosive effects on skin, conducting an eye irritation study on the product cannot be justified on animal welfare grounds.

A skin sensitisation study has been performed on C_{12-16}-ADBAC (80% in aqueous: alcoholic solution) which did not lead to classification being applied. Therefore, according to the provisions of directive 1999/45/EC[3] this product is also not classified for this endpoint

EQC

Biocidal Product

The biocidal product BKC-50 contains 50% C_{12-16}-BKC; full details on the composition are confidential and can be found in the Annex of „Confidential data", Doc. IIIB Section 2A. The dermal absorption estimated on the basis of some information obtained by an *in vivo* dermal absorption study and on the chemical nature of the active substance was about 10%.

An acute oral toxicity study has been performed on a formulation similar to BKC-50 (*i.e.* 50% water solution of Cocobenzyldimethylammonium chloride, containing about 20% of C_8, C_{10} and C_{18}, in addition to C_{12}-C_{16} alkyl chains), which is considered valid for BKC-50. The acceptability for the reading-across is based on the similar oral toxicity shown by QUATS with similar chain lengths, that is high irritancy to the mucosal surfaces of the GI-tract. The test resulted in an LD_{50} = 358 mg a.s./kg bw and leads to the classification Xn, R22 being applied.

No acute dermal toxicity study has been performed with BKC-50, due to the corrosive action of the active substance. However, based on literature data on structurally related compounds, BKC-50 can be considered Harmful when in contact with skin, requiring R21 risk phrase.

The BKC-50 product contains 50% C_{12-16}-BKC in water and no other components. C_{12-16}-BKC is

not volatile as the vapour pressure is < 1 x 10^{-5} Pa at 20°C and only spraying with big not inhaled droplets with <100 µm MMAD is recommended Therefore, there is no concern for inhalation exposure. In addition, the results of the skin irritation study indicate that BKC-50 is corrosive and is assigned R34 and therefore carrying out an inhalation toxicity study is not allowed.

A skin irritation study has been performed on a formulation similar to BKC-50 (*i.e.* 50% water solution of Coco benzyl dimethyl ammonium chloride, containing about 20% of C_8, C_{10} and C_{18}, in addition to C_{12}-C_{16} alkyl chains), which is considered valid for BKC-50, which lead to the classification as corrosive, R34 being applied. On this basis it was ethically unjustified to test BKC-50 for eye irritation.

BKC-50 did not show any sensitizing potential, in the experimental conditions used.

2.2.2. Environmental Risk Assessment

2.2.2.1 Fate and distribution in the environment

Biodegradation

The first study **(US ISC)** was carried out in accordance with OECD Guideline 301B – modified. Biodegradability was calculated from the released CO_2. Biodegradability in the reference flask was determined to be 88.9% in 28 days. Biodegradability in the test flask was determined to be 95.5% in 28 days. The 10-window criteria was met. A study to determine aerobic biodegradation in a sewage treatment plant is not justified since C_{12-16}-ADBAC is readily biodegradable and there is negligible release of C_{12-16}-ADBAC to the sewage treatment plant during use as a wood preservative within the EU. However, a study with the structural analogous, Didecyldimethylammonium Chloride in a simulated treatment system showed 93.3% CO_2 evolution over 28 days indicating that these quaternary amines will rapidly degrade in a treatment system. A biodegradation study in two water/sediment systems has been performed and showed partial mineralisation of the test material under the test conditions used.

A biodegradation study in seawater was not carried out as C_{12-16}-ADBAC as a wood preservative will not be used in the marine environment.

Alkyl (C12-16) dimethylbenzyl ammonium chloride can be considered readily biodegradable.

The results of the second ready biodegradability study **(EQC)** show that 63% of the active substance was degraded after 28 days in the Closed Bottle Test. The reference substance, sodium benzoate, was degraded 80% after 14 days. The 10% degradation level was reached around day 9 and the 62% degradation level around day 19; the 10-day window criteria was not met. The test substance can be considered as readily biodegradable. Alkyl (C12-16) dimethylbenzyl ammonium chloride is removed from wastewater at very high percentages in the continuous activated sludge test (OECD 303A). C_{12-16}-BKC will biodegrade almost completely in conventional biological wastewater treatment plants.

Alkyl (C12-16) dimethylbenzyl ammonium chloride can be considered readily biodegradable.

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

The reliability factor of US ISC study is 1. Therefore, the study by US ISC should be considered for the environmental risk assessment at product authorization stage. In conclusion, ADBAC/BKC is ready biodegradable being the 10-day window criterion met (OECD 301B).

On the other hand, the EQC study has a reliability factor of 2 because it cannot distinguish between the degradation of ADBAC/BKC and Propan-2-ol (solvent). If we follow the argument that Propan-2-ol is readily biodegradable and might contribute more to the oxygen consumption. This results in an overestimation of ADBAC/BKC, and the 14-day window criteria was not met (OECD 301D).

Alkyl (C12-16) dimethylbenzyl ammonium chloride is radily biodegradable.

Abiotic Degradation

Alkyl (C12-16) dimethylbenzyl ammonium chloride was found to be photolytically stable in the absence of a photosensitiser. An accurate estimate of the photolysis rate constants and the half-life for solutions containing no photosensitiser and all dark controls (both sensitised and non-sensitised) could not be determined since no significant degradation of the test substance was detected during the 30-day evaluation period. In the presence of the energy from a xenon arc lamp and the photosensitising agent, acetone, it appears that C_{12-16}-ADBAC breaks down to form a single degradate. The half-life of the test compound was determined to be 10.9 days with 83% degradation after 30 days **(US ISC)**.

Alkyl (C12-16) dimethylbenzyl ammonium chloride was hydrolytically stable during the 30-day hydrolysis study at pH 5, 7 or 9 at 25°C.

A preliminary test was conducted; the results show that less than 10% of the test substance was hydrolyzed after five days at pH 4 and 7. In this test no coefficient of correlation was calculated, corresponding to a half-life of more than one year. A photodegradation study does not need to be carried out when the UV spectrum show no UV adsorption above 290 nm.(EQC).Estimation of photodegradation in air was calculated using the Atmospheric Oxidation Program (AOPWIN). Mean atmospheric half life = 0.368 days (8.831 hours), assuming 24 hour according to TGD (2003) chapter 2.3.6.3.

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

Alkyl (C12-16) dimethylbenzyl ammonium chloride was hydrolytically stable during the 30-day hydrolysis study at pH 5, 7 or 9 at 25°C. Estimation of photodegradation in air was calculated using the Atmospheric Oxidation Program (AOPWIN). Mean atmospheric half life = 0.368 days (8.831 hours), assuming 24 hour according to TGD (2003) chapter 2.3.6.3.

Distribution

Alkyl (C12-16) dimethylbenzyl ammonium chloride can be considered as immobile in four soil/sediment types with adsorption (Ka) and mobility (K_{oc}) coefficients of Ka=6172 and K_{oc}=6171657 for sand, Ka=5123 and K_{oc}=640389 for sandy loam, Ka=32429 and K_{oc}=1663039 for clay loam, and Ka=10797 and K_{oc}=2159346 for silt loam.

The desorption (Kd) and mobility (Kd_{oc}) coefficients are following reported: Kd=7173 and Kd_{oc}=7137310 for sand, Kd=96540 and Kd_{oc}=12067457 for sandy loam, Kd=165556 and Kd_{oc}=8490062 for silty clay loam, and Kd=14083 and Kd_{oc}=2816590 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 2658608 L/kg **(US ISC)**.Due to the fact that Alkyl (C12-16) dimethylbenzyl ammonium 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.

Alkyl (C12-16) dimethylbenzyl ammonium chloride can be considered as immobile in three soil types with the adsorption (Ka) and mobility (Ka_{oc}) coefficients of Ka = 630 and Ka_{oc} = 18251 for loam, Ka = 1543 and Ka_{oc} = 16679 for loamy sand, Ka = 2032 and Ka_{oc} = 812943 for silt loam. The desorption (Kd) and mobility (Kd_{oc}) coefficients are reported as follows: Kd = 2828 and Kd_{oc} = 81971 for loam, Kd = 6795 and Kd_{oc} = 73459 for loamy sand, Kd = 2778 and Kd_{oc} = 1111200 for silt loam. This study was performed only for three soils **(EQC)**.

A mean K_{oc} of 282624.3 L/kg can be used in the exposure assessment.

The 1/n values indicate that a non-linear relationship exists between the concentrations in soil and the concentrations the water. Alkyl (C12-16) dimethylbenzyl ammonium chloride adsorbs strongly onto soil and does not desorb very easily for all soil types.

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

Alkyl (C12-16) dimethylbenzyl ammonium chloride can be considered immobile in soil. It is well known that, because of their positive charge, cationic surfactants adsorb strongly to the negatively charged surfaces of sludge, soil and sediments. Following the same approach of the Ad-hoc follow up on ATMAC/TMAC and DDAC (PT 8) (opinion of the ENV WG on the K_{oc} to be used for the risk assessment) the K_{oc} value to be used for risk assessment is the mean K_{oc} values from the both studies available. The K_{oc} value is 1640329 L/Kg.

Mobility

The results of this study indicated that Alkyl (C12-16) dimethylbenzyl ammonium chloride adsorbs strongly onto soil, therefore the leachate from wood into soil will be adsorbed immediately, it had little or no potential for mobility in soil and should not pose an environmental risk for contamination of ground water. Therefore, mobility-lysimeter studies were not justified.

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

The mobility assessment of the active substance is valid for both Applicants.

The results of the adsorption in soil studies indicate that ADBAC/BKC has little or no potential for mobility in soil and does not pose an environmental risk for contamination of groundwater. Alkyl (C12-16) dimethylbenzyl ammonium chloride had little or no potential for mobility in soil and should not pose an environmental risk for contamination of ground water.

Bioaccumulation

The bioconcentration potential of Alkyl (C12-16) dimethylbenzyl ammonium in fish was investigated in one flow through test with bluegill (35 d exposure + 21 d depuration) submitted in the US ISC dossier. Based on the measured ^{14}C residues, the steady-state BCF (whole fish) was 79 L/kg, indicating a low potential for bioaccumulation. This finding is in line with the mode of action of Alkyl (C12-16) dimethylbenzyl ammonium, which mainly possesses irritant/corrosive properties. In the EQC dossier no measured BCF is available and the reliability of the submitted literature data cannot be determined.

In mammals, the kinetics of Alkyl (C12-16) dimethylbenzyl ammonium from both the US ISC and EQC dossiers do not show any bioaccumulation potential.

No data are available on the $BCF_{earthworm}$ and it cannot be calculated from TGD equation 82d as it is not applicable to ionic substances. A sensitivity analysis carried out using TGD eq 82c indicated that risk of seconday poisoning via the terrestrial food chain would arise assuming a $BCF_{earthworm}$ unrealistically high, therefore the measurement of a terrestrial BCF is deemed not necessary.

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

Alkyl (C12-16) dimethylbenzyl ammonium chloride has a low potential for bioaccumulation.

Leaching study

Read-across between C12-16-ADBAC and DDAC was accepted at TM level (TMII 09) **(US ISC)**.

The leaching values used in the calculation of Predicted Environmental Concentrations (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 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 DDAC, 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.

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 x 10^{-5} kg/m^2/d

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

Q*Leach (TIME1) = 5.52 x 10^{-4} kg/m^2

Q*Leach (TIME2) = 1.19 x 10^{-3} kg/m^2

The leaching rate is taken from a BAM study (Schoknecht, 2002) **(EQC)**. In this study the leaching is determined on the basis of continuous exposure to water according to the EN84.

The results of Alkyl (C12-16) dimethylbenzyl ammonium chloride; (CAS 68424-85-1) are used.

Alkyl (C12-16) dimethylbenzyl ammonium chloride can leach from wood when exposed to weathering, the amount that leaches from the wood quickly goes down in time, the second day the percentage is already halved. The total loss after 14 days is 3.9%.

The FLUX and Q*Leach values are following reported:

FLUX (TIME1) = 1.62 10^{-5} kg/m^2/d

FLUX (TIME2) = 1.68 10^{-7} kg/m^2/d

Q*Leach (TIME1) = 3.99 10^{-4} kg/m^2

Q*Leach (TIME2) = 1.44 10^{-3} kg/m^2

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

The results of the two studies are very close. The first study was used in the risk assessment.

2.2.2.2 Effects assessment

Aquatic Compartment

The toxicity of Alkyl (C12-16) dimethylbenzyl ammonium chloride to aquatic organisms is documented by short- and long-term studies with fresh water species belonging to three trophic levels.

As for fish, the reliable lowest acute toxicity endpoint is 96h LC_{50}= 0.28 mg a.i./L (*P. promelas*, based on mean measured concentrations) retrieved from the US ISC dossier, which is therefore the endpoint to be taken into account**.** In this dossier other two equally reliable data are available for (*L. macrochirus*: 96h LC_{50}= 0.52 mg a.i./L and *O. mykiss*: 96h LC_{50}= 0.93 mg a.i./L**.** The supportive information on *O. mykiss* submitted in the EQC dossier (96h LC_{50}= 0.85 mg a.i./L, based on nominal concentrations) confirms the data on this same species in the US ISC dossier. The chronic toxicity to fish was investigated in one early life stage test test with *P. promelas*, resulting in 34d NOEC = 0.0322 mg a.i./L **(US ISC data)**.

From two acute tests with *D. magna*, the more reliable endpoint is 48h EC_{50} = 0.016 mg a.i./L **(EQC)**. This data has been chosen to be used for product authorization, although the other endpoint was lower in figure (48h EC_{50} = 0.0058 mg a.i./L, rated 2, **US ISC dossier**). This approach is in agreement to the conclusion of WGII2015, as reached for the evaluation of combined dossiers of other QUATs, that the main criterion for the selection of the endpoint should be its reliability.

The two reproduction studies with *D. magna* (both rated 2) provided 21d NOEC ≥ 0.00415 mg a.i./L **(US ISC dossier)**, based on mean measured concentration, and 21d NOEC=0.025 mg a.s./L and 21d EC_{10} reproduction = 0.024 mg a.s./L **(EQC dossier)**, based on nominal concentrations, whose stability was established in an extra solution of 0.5 mg a.s./L. The results of these studies show that a long term exposure does not increase the toxicity of Alkyl (C12-16) dimethylbenzyl ammonium chloride observed in the acute tests, rather the actual NOEC (or EC_{10}) value is very close or even higher than the EC_{50} (21d EC_{10} reproduction

= 0.024 mg a.s./L in the EQC dossier). This can be partly explained (beside the uncertainty in the chronic endpoint) by the non-specific mode of action of the substance which acts as irritant/corrosive. In the reproduction study in the EQC dossier, a steep effect-concentration curve was recorded for the mortality of parent animals, and all mortality occurred within 48 hours.

The decision of not calculating the geomean of the two chronic endpoints was based on the following: i) both studies are reliable with restriction, but for different reasons. This underpins some uncertainty in both studies. ii) different methodology was applied in the two reproduction tests (for details please see the respective doc IIA and IIIA). In the US ISC study, the US EPA FIFRA 72-4 and Federal Register 40 797.1330 (1987) guidelines were followed with deviation in test design (reduced number of parent animals used for the analysis of reproduction data). The exposure was static with daily renewal of test solutions. The results were based on measured concentrations (average of all the 21 measures of the fresh and old solutions). Tthe EQC study was carried out according to OECD 211, under static exposure with intervals of solutions' renewal up to three days. Stability of test solutions was assumed based on the measure in an extra vessel of a single solution much higher than the tested concentrations because they were below the detection limit of the chemical analysis method used. iii) the NOEC in both test is very close to the respective 48h EC50s and, in the EQC test, also to the 21d LC50 (0.03 mg a.s./L).

In conclusion, the lowest value 21d NOEC ≥ 0.00415 mg a.i./L **(US ISC)** is selected, which is based on mean measured concentration and it is more protective, especially considering the acute toxicity data.

For algae, the results of two tests with *P. subcapitata* are available. The more reliable endpoints are 72h E_rC_{50} =0.049 mg a.s./L and 72h E_rC_{10} = 0.009 mg a.s./L from the test included in the US ISC dossier and based on mean measured concentrations. Lower endpoints were calculated in the other test submitted by EQC (72h E_rC_{50} =0.026 mg a.s./L, 72h NOE_rC = 0.0025 mg a.i./L and 72h E_rC_{10} = 0.0057 mg a.s./L), but their reliability was lower due to uncertainty in the maintenance of substance concentrations during the test). The endpoint from US ISC (72h ErC_{10} = 0.009 mg a.s./L) is therefore selected to be used for product authorization, according to the conclusion of WGII2015, as reached for the evaluation of combined dossiers of other QUATs, that the main criterion for the selection of the endpoint should be its reliability.

In addition, toxicity data on aquatic plants were also submitted in the US ISC dossier. A seven day static test was conducted with *Lemna gibba*, resulting in a 7d E_rC_{50} = 0.25 mg a.s./L (based on initial measured concentrations, rated 2), which indicates that plants are less sensitive to Alkyl (C12-16) dimethylbenzyl ammonium chloride than algae.

CONCLUSION on Aquatic Compartment - Water compartment:

From the selected chronic toxicity data, a sensitivity ranking of aquatic organisms to Alkyl (C12-16) dimethylbenzyl ammonium chloride is *D. magna* >≈ algae > fish, that also reflects the conclusion based on acute data.

The lowest endpoint value is retrieved for *D. magna* as 21d NOEC = 0.00415 mg a.i./L **(US ISC)**. Since chronic data are available on three trophic levels, the PNEC is derived with the application of an AF of 10:

PNECwater = ≥0.00415 mg a.i./L /10 **= 0.000415 mg a.i./L**

STP compartment

The effects of Alkyl (C12-16) dimethylbenzyl ammonium chloride on the microbial activity in STP has been investigated in two respiration inhibition studies with activated sewage sludge, according to the OECD 209 guideline. The first test had the duration of 3 hours and provided 3h EC_{50} = 7.75 mg a.s./L, EC_{20} = 3.4 mg a.s./L, and 3h NOEC = 1.6 mg a.i./L **(US ISC)**. The

second test lasted 30 minutes and resulted in l30 min EC_{50} = 11 mg a.i./L mg a.i./L, 30 min NOEC = 3.52 mg a.i./L, and 30 min EC_{10} = 4 mg a.i./L **(EQC)**. Both the studies were judged reliable, but the results of the test conducted for a longer period (3h) is considered to be more appropriate and it also provides the lowest endpoints, hence the US ISC data are chosen as those to be used at the product authorization stage.

CONCLUSION on Aquatic Compartment - STP compartment:

The PNEC for microorganisms in STP is based on the results of the 3 hours study **(US ISC)**. The lowest PNEC is derived from the EC_{50} = 7.75 mg a.s./L **(US ISC)** divided by an assessment factor of 100, hence, according to TGD and to '*Guidance on the Biocidal Products Regulation, Volume IV Environment - Part B Risk Assessment (active substances), April 2015'*, this endpoint is used:

$PNEC_{microorganisms}$ = 7.75 mg a.s./L / 100 = **0.0775 mg a.s./L**

Anyhow, the eCA highlights that, when a NOEC/EC_{10} and an EC_{50} from study compliant with OECD 209 are available and both values are derived from the same study, the WG-V-2014 agreed to use the NOEC/EC_{10} with AF of 10 to derive the PNEC for microorganisms in STP. ECHA has not yet clarified when the procedure applies. Consistently with the conclusion agreed at WGII2015 in the case of another "back-log" multiple dossier for another QUAT, it would be possible at product authorisation stage to use the EC 10 (with an AF of 10) but in this case, the endpoint needs to be calculated from the study. The eCA adds that, in order to use the NOEC, WG-V-2014 pointed out that special attention should be paid to the reliability of the statistical analysis performed for its derivation.

Sediment Compartment

Experimental data on sediment dwelling organisms are only available in the US ISC dossier, giving for *Chironomus tentans* a 28 d NOEC = 520 mg a.s./kg dw (357.24 mg/kg wwt).

During this sediment-spiked test, midge larvae were fed with fresh uncontaminated food, hence the toxicity of Alkyl (C12-16) dimethylbenzyl ammonium chloride to Chironomus (not a true endobenthic ingester) might have been underestimated due to its high adsorption potential.

CONCLUSION on Aquatic Compartment - Sediment compartment:

The PNEC for the sediment compartment is derived from the 28 d NOEC =520 mg a.s./kg dw (US ISC) and the application of an assessment factor of 100:

PNEC sediments = 520 mg a.s./kg dw / 100 = **5.20 mg a.s./kg dw (3.57 mg a.s./kg wwt)**

The need to derive $PNEC_{sediment}$ also via the EPM was discussed at WGII2015 for other "back-log" multiple dossiers relative to other QUATs for which a study with analogous test desing was submitted. The WG agreed "to base the $PNEC_{sediment}$ on the study with Chironomus using an AF of 100. However, at the renewal stage either the validity of this study should be verified or the EPM method should be used in addition and the lowest endpoint should then be used for the assessment." For consistency, the eCA adopts the same conclusion for Alkyl (C12-16) dimethylbenzyl ammonium chloride.

Metabolites in water

In both the US ISC and EQC dossiers, it is concluded that no metabolites are known, following the degradation of the substance in water.

CONCLUSION on Aquatic Compartment - Metabolites:

No metabolites are known, following the degradation of Alkyl (C12-16) dimethylbenzyl ammonium chloride in water.

Terrestrial Compartment

Soil organisms

Acute toxicity data are available for soil dwelling invertebrates and plants, while chronic studies were carried out to investigate the effects on nitrogen and carbon transformation by soil microorganisms.

The effects of Alkyl (C12-16) dimethylbenzyl ammonium chloride on earthworms were assessed in two acute toxicity tests with *Eisenia fetida* **(US ISC and EQC)**. Both tests were conducted according to the OECD 207 guideline using artificial soil with 10% peat and 20% clay. No analyses were performed of the test substance, hence the results are expressed as nominal concentrations. In one test the 14-day LC_{50} was calculated equal to 7070 mg/kg dry soil, and the 14d NOEC as 953 mg/kg dry soil **(US ISC dossier)**. In the other test from the EQC dossier, no effect in behaviour, weight or mortality of the earthworms was observed up to the highest tested concentration, therefore the 14d LC_{50} was set as > 517 mg a.s./ kg d.w (LC_{50}> 410 mg a.i./kg wwt) and 14d NOEC ≥517 mg a.s./ kg d.w. The findings of the two tests, although different in absolute values, are not in contrast. Since the second test provides a "higher than" value corresponding to a complete lack of lethal or sublethal effects, the 14d LC_{50} =7070 mg/kg dry soil **(US ISC)** is selected to express the acute toxicity of Alkyl (C12-16) dimethylbenzyl ammonium chloride to soil dwelling invertebrates.

The inhibition of seedling emergence and growth in several plant species exposed to Alkyl (C12-16) dimethylbenzyl ammonium chloride was investigated in two studies carried out according to OECD 208 guideline **(US ISC and EQC**). In the first test, conducted with mustard (*Brassica alba*), mung bean (*Phaseolus aureus*) and wheat (*Triticum aestivum*) exposed in sandy soil (1.3% OC, pH 7.2, CEC not reported), the most sensitive species was *Brassica alba* with a EC_{50} = 277 mg a.s./kg dw **(US ISC)**.

In the second test **(EQC)**, *Triticum aestivum*, mustard (*Sinapis alba,* synonymous of *Brassica alba),* and *Trifolium pratense* were exposed to DDAC in two different soils: sand (99.8% SiO_2) and natural soil (48% sand, 42% silt, 9% clay, 1.4% OC, CEC= 7.4 meq/100g). In both soils, the lowest EC_{50} values were obtained for *T. pratense*: 19 mg/kg dw soil (tested in sand) and 309 mg/kg dw soil (tested in natural soil). The great deviation in the effects recorded in sand and natural soil can be attributed to the lower bioavailability of DDAC in natural soil caused by stronger adsorption to the soil particles as consequence of several binding processes. Since the results obtained in the test with silica sand are considered unrealistic worst case, only data from the tests conducted with natural soils are taken into account (this approach was agreed at TMII2013); among these, the most sensitive species was *Brassica alba* with an EC_{50} = 277 mg/kg dw soil **(US ISC)**, which is the endpoint to be taken into account at product authorization stage.

In order to assess the effects of Alkyl (C12-16) dimethylbenzyl ammonium chloride on terrestrial micro-organisms, two 28 d studies, conducted in sandy loam soil (clay 16%, silt 24% sand 60%, 0.9% OC, CEC= 10.6.0 meq/100g, pH 7.9) and low humic content sand soil (clay 2%, silt 1%, sand 97%, 0.5% OC, CEC= 4.0 meq/100g, pH 6.8), were submitted in the C_{12-16}-ADBAC − US ISC dossier. In both soils, no effect of on nitrite, nitrate, ammonium and carbon dioxide formation was observed up to a nominal concentration of 1000 mg/kg dry soil, hence a 28d EC_{50} > 1000 mg/kg dw soil and 28d NOEC ≥ 1000 mg/kg dw soil was concluded for both processes.

In another 28d study from the EQC dossier conducted in a natural sandy loam soil (1.02%, OC, 62.3% sand, 29.2% silt, 8.5% clay, CEC 10 mval/100 g, pH 6.3), only the reduction of nitrogen transformation was investigated (which also takes into account of the carbon transformation), resulting in a 28d EC_{50} = 153 mg a.i./kg dw (130 mg/kg wwt soil) and a 28d EC_{10} = 83 mg a.i./kg dw soil (70 mg a.i./kg ww soil).

The studies from the two dossiers, although all rated 1, show marked difference in the results, even when the soil characteristics were similar like in the case of tests conducted with sandy

loam soils. The endpoint with the lowest values is therefore selected to be taken into account, i.e 28d EC_{50} = 153 mg a.i./kg dw (130 mg/kg wwt soil) and a 28d EC_{10} = 83 mg a.i./kg dw soil (70 mg a.i./kg ww soil), retrieved from the EQC dossier.

CONCLUSION on Soil organisms

The available data show that the soil characteristic can strongly influence the toxicity of Alkyl (C12-16) dimethylbenzyl ammonium chloride to soil organisms by affecting its bioavailability. Consistently with the approach agreed at TMIV08, the normalization of the terrestrial endpoints to a standard natural soil with an average organic matter content of 3.4% is not carried out, as TGD states that eq. 71 is only appropriate for non-ionic organic compounds when it can be assumed that the binding behaviour is predominantly driven by its log P_{ow}, and that organisms are exposed predominantly via pore water. Since sorption of cationic surfactants to soil seems to be modulated by several factors (not only OC has a role but also other substrates with cation exchange capacity property like silt and clay), Alkyl (C12-16) dimethylbenzyl ammonium chloride is expected to sorb to different negatively charged surfaces, therefore normalization based on organic matter is considered not appropriate.

The acute toxicity data indicate the following sensitivity ranking for soil organisms: micro-organisms (28d EC_{50} = 153 mg a.i./kg dw) >plants (EC_{50}= 277 mg a.s./kg dw) > earthworms (14d LC_{50} = 7070 mg a.i./kg dw). Long-term toxicity data are available only for soil micro-organisms (most sensitive organisms in acute tests) and the 28d EC_{10} = 83 mg a.i./kg dw **(EQC)** is used to derive the PNEC with the application of an AF of 100:

$PNEC_{soil}$ = 83 mg a.i./kg dw / AF 100 **= 0.83 mg a.i./kg dw** (0.70 mg a.i./kg ww)

Birds

Acute and short-term toxicity data on birds are available only in the US ISC dossier. The acute oral toxicity of Alkyl (C12-16) dimethylbenzyl ammonium chloride to birds has been measured on northern bobwhite quail and provided a LD_{50} = 164 mg/ kg b.w. **(US ISC)**. In the two short term dietary toxicity tests conducted with bobwhite quail and mallard duck, no mortality was observed up to the highest tested concentration of 5620 mg a.s./kg food. Upon correction to account for food avoidance, the recalculated lowest endpoint is retrieved for mallard duck, i.e. LC_{50} > 2463 mg a.s./kg food **(US ISC)**.

CONCLUSION on birds:

An assessment factor of 3000 was applied to the short-term dietary LC_{50} > 2463 mg a.s./kg food for mallard duck **(US ISC)** to derive the $PNEC_{birds}$:

$PNEC_{birds}$ = >2463 mg a.s./kg food / 3000 = 0.821 mg a.s./kg food

Mammals

Several subchronic dietary toxicity studies with mammals are available. The selected values provide for dog a 52 weeks NOEC = 400 mg a.s./kg food (corresponding to NOAEL = 13.1 mg/kg/d), for mice a 93d NOEC = 500 mg a.s./kg food (corresponding to NOAEL = 85.0 mg/kg/d), and for rat a 95d NOEC = 1000 mg a.s./kg food (corresponding to NOAEL = 31.0 mg/kg/d) **(US ISC)**.

A chronic study with rat is also available with a 2y NOEC =1000 mg a.s./kg food corresponding to NOAEL = 44-47 mg active substance/kg/d **(US ISC; EQC)**.

CONCLUSION on mammals:

According to TGD, for the PNEC derivation different AF are to be applied to the results of repeated-dose tests depending on the duration of the test. The lowest $PNEC_{mammals}$ is derived applying an AF=90 to the subchronic dog 52 weeks NOEC =400 mg a.s./kg food:

$PNEC_{mammals}$ = 400 mg/kg food/ AF90 = 4.4 mg/kg food

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

From data of hydrolysis: C_{12-16}-ADBAC is hydrolytically stable over an environmentally relevant pH range of 5-9. From data of photolysis in water, C_{12-16}-ADBAC was found to be photolytically stable in the absence of a photosensitiser. C_{12-16}-ADBAC is ready biodegradable therefore, according to the screening criteria for P, vP (ECHA Guidance on information requirements and chemical safety assessment Chapter R.11: PBT Assessment), the **P criterion is not fulfilled**.

B criterion: BCF > 2000

A bioconcentration test carried with bluegill resulted in a steady-state BCF (whole fish) of 79 L/kg **(US ISC)**. In addition, from the toxicokinetics in mammals show the lack of any bioaccumulation.

Based on experimental evidence, **the B criterion is not fulfilled**.

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

From the whole long-term data set available in the US ISC and EQC dossiers, the following endpoints have been selected. The chronic toxicity Alkyl (C12-16) dimethylbenzyl ammonium chloride to fish, investigated in one early life stage test test with *P. promelas*, resulted in 34d NOEC = 0.0322 mg a.i./L **(US ISC)**. For *Daphnia magna* the lowest long-term toxicity measured in a reproduction test was 21d NOEC = 0.00415 mg a.i./L **(US ISC)**. The growth inhibition in the algae *P. subcapitata* resulted in a 72h E_rC_{10} = 0.009 mg a.s./L **(US ISC)**.

The substance is classified in according to DSD: Xn; R22 C; R34 N; R50 (Cn ≥ 0.25%) and Xn; R21/22 C; R34 N; R50 (Cn ≥ 2.5%) for US ISC and EQC respectively.

The substance is classified in according to CLP: Dgr; GHS05; GHS07; GHS09; H302; H314; H400 (M factor=100) and Dgr; GHS05; GHS06; GHS09; H302; H311; H314; H400 (M factor=10) for US ISC and EQC respectively.

With regard to CMR properties, no classification is required.

The whole evidence of the available information indicates that the **T criterion is fulfilled**.

CONCLUSION on PBT assessment:

Alkyl (C12-16) dimethylbenzyl ammonium chloride does not meet the PBT criteria.

POP assessment

The analysis of POPs criteria was not required when the dossier was evaluated and therefore not considered when Alkyl (C12-16) dimethylbenzyl ammonium chloride was discussed at technical meeting level (TMIII2009).

Alkyl (C12-16) dimethylbenzyl ammonium chloride 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:

- Alkyl (C12-16) dimethylbenzyl ammonium chloride is not persistent (readily biodegradable);
- Alkyl (C12-16) dimethylbenzyl ammonium chloride was concluded to have a low potential for bioaccumulation;
- no potential for long-range environmental transport is expected (little potential for mobility in soil, mean atmospheric half-life of 0.368 d; for both US ISC and EQC)

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 %, and different K_{oc} values.

US ISC		**Local PEC**
Scenario 1: Dipping treatment during application		
PEClocalwater STP		0.0047 mg/L
PEClocalsed STP		271 mg/kg wwt
PECmicroorganism STP		0.237 mg/L
Scenario 2: Dipping treatment during storage		
PEClocalwater run-off		2.3×10^{-3} mg/L
PEClocalsed run-off		133 mg/kg wwt
Scenario 3: Vacuum pressure treatment during application		
PEClocalwater STP		0.0014 mg/L
PEClocalsed STP		82.3 mg/kg wwt
PECmicroorganism STP		0.071 mg/L
Scenario 4: Vacuum pressure treatment during storage		
PEClocalwater		1.7×10^{-3} mg/L
PEClocalsed		98 mg/kg wwt
***Scenario 5: Bridge over pond**		
PEClocalwater	Time1	0.09 mg/L
	Time2	0.00006 mg/L
PEClocalsed	Time1	5204 mg/kg wwt
	Time2	3.5 mg/kg wwt

Scenario 6: Noise Barrier		
PEClocalwater STP	Time1	0.0025 mg/L
	Time2	0.00002 mg/L
PEClocalsed STP	Time1	60 mg/kg wwt
	Time2	0.5 mg/kg wwt

*Not being supported by the Applicant, the risks occurring from the in situ application have not been evaluated. Consequently, the risk assessment for the use scenario 5 is obsolet.

PECs have been calculated according to the OECD Emission Scenario Document for Wood Preservatives (ESD). PEC values are summarised in the following table:

EQC		**Local PEC**
Scenario 1: Dipping treatment during application		
PEClocalwater STP		0.0006 mg/L
PEClocalsed STP		3.7 mg/kg wwt
PECmicroorganism STP		0.009 mg/L
Scenario 2: Dipping treatment during storage		
PEClocalwater run-off		2.3×10^{-3} mg/L
PEClocalsed run-off		133 mg/kg wwt
Scenario 5: Bridge over pond		
PEClocalwater	Time1	0.0018 mg/L
	Time2	0.000019 mg/L
PEClocalsed	Time1	104 mg/kg wwt
	Time2	1.09 mg/kg wwt
Scenario 6: Noise Barrier		
PEClocalwater STP	Time1	0.0014 mg/L
	Time2	0.000028 mg/L
PEClocalsed STP	Time1	81 mg/kg wwt
	Time2	1.6 mg/kg wwt

Use Class: 3 (wood not covered, not in contact with ground, exposed to weather)

Bridge over pond

Only upper sides and handrails are treated (details in OECD ESD Doc., p. 161)
Reference: OECD Emission Scenario Document (ESD), part II, p. 100

Parameter/variable	Nomenclature	Unit	Value **US ISC**	Value **EQC**
Input to OECD model				
Treated wood area of bridge (TGD Appendix3)	AREAbridge	[m²]	10.36	10.36
Duration of initial assessment period	TIME1	[days]	30	30
Duration of longer term assessment period	TIME2	[days]	5475	5475
Cumulative quantity of a.s. leached out of 1 m² wood over initial assessment period	Q*leach,time1	[kg/m]	$5.52\ 10^{-4}$	$3.99\ 10^{-4}$
Cumulative quantity of a.s. leached out of 1 m² wood over a longer assessment period	Q*leach,time2	[kg/m]	$1.19\ 10^{-3}$	$1.44\ 10^{-3}$
Water volume	VOLwater	[m³]	1000*	1000*
Output from OECD model				
Cumulative quantity of a.s. leached from wood over initial assessment period	Qleach,time1	[kg]	$5.52\ 10^{-3}$	$3.99\ 10^{-3}$
Cumulative quantity of a.s. leached from wood over longer assessment period	Qleach,time2	[kg]	$1.19\ 10^{-2}$	$1.44\ 10^{-2}$
Conc. in local water after initial ass. period	Clocal,water,leach,time1	[kg/m³] [µg/L]	$5.52\ 10^{-6}$ 5.52	$3.99\ 10^{-6}$ 3.99
Conc. in local water after longer ass. period	Clocal,water,leach,time2	[kg/m³] [µg/L]	$1.19\ 10^{-5}$ 11.9	$1.44\ 10^{-5}$ 14.4

*Accepted at TMII 2013. A new scenario covering the risk from in-situ application (e.g. brushing) as well as the leaching from treated timber near or above static water bodies was developed for the revised PT08 ESD as "Draft revised emissions scenario document for wood preservatives" to be endorsed by the Task Force on Biocides (TFB) and the Task Force on Exposure Assessment (TFEA). This revised scenario should be used for the bridge over pond calculations in connection to the Annex I inclusion of a.s. as well as at the product authorisation.

Terrestrial Compartment Exposure assessment (including groundwater)

The PEC values calculated based on the OECD Emission Scenario Document for Wood Preservatives (ESD) are reported in the table below. 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 study was conduct on the analogue DDAC, the read-across between Alkyl (C12-16) dimethylbenzyl ammonium chloride and DDAC was accepted at TM level (TMII 09). 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 DDAC, 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.

	Local PEC US ISC	**Local PEC EQC**
Scenario 2: Dipping treatment during storage		
PEClocalsoil (TIME 1)	3.0 mg/kg	3.1 mg/kg
PEClocalsoil (TIME 2)	5.4 mg/kg	6.0 mg/kg
PEClocalsoil, porew (TIME 1)	2.3×10^{-4} mg/L	1.3×10^{-4} mg/L
PEClocalsoil, porew (TIME 2)	4.0×10^{-4} mg/L	2.6×10^{-4} mg/L
Scenario 4: Vacuum pressure treatment during storage		
PEClocalsoil (TIME 1)	3.0 mg/kg	
PEClocalsoil (TIME 2)	7.2 mg/kg	
PEClocalsoil, porew (TIME 1)	2.3×10^{-4} mg/L	
PEClocalsoil, porew (TIME 2)	5.5×10^{-4} mg/L	
Scenario 5: Treated wood in service Bridge over pond		
PEClocalsoil (TIME 1)	0.005 mg/kg	0.004 mg/kg
PEClocalsoil (TIME 2)	0.012 mg/kg	0.014 mg/kg
Scenario 6: Treated wood in service Noise barrier		
PEClocalsoil (TIME 1)	1.2 mg/kg	0.84 mg/kg
PEClocalsoil (TIME 2)	2.5 mg/kg	3.05 mg/kg
PECgw	1.9×10^{-5} mg/L	3.7×10^{-4} mg/L
Scenario 7: Treated wood in service Fence		
PEClocalsoil (TIME 1)	2.6 mg/kg	1.9 mg/kg
PEClocalsoil (TIME 2)	5.6 mg/kg	6.8 mg/kg
PECgw	1.9×10^{-4} mg/L	8.3×10^{-4} mg/L
Scenario 8: Treated wood in service House		
PEClocalsoil (TIME 1)	3.1 mg/kg	2.3 mg/kg
PEClocalsoil (TIME 2)	6.7 mg/kg	8.2 mg/kg
PECgw max	2.3×10^{-4} mg/L	3.5×10^{-3} mg/L
Scenario 9: Treated wood in service Transmission pole		
PEClocalsoil (TIME 1)	0.4 mg/kg	0.3 mg/kg
PEClocalsoil (TIME 2)	1.0 mg/kg	1.2 mg/kg
PECgw max	3.0×10^{-5} mg/L	1.3×10^{-4} mg/L
Scenario 10: Treated wood in service fence post		
PEClocalsoil (TIME 1)	0.4 mg/kg	0.3 mg/kg
PEClocalsoil (TIME 2)	0.8 mg/kg	0.9 mg/kg
PECgw max	3.0×10^{-5} mg/L	1.3×10^{-4} mg/L

Atmospheric Compartment Exposure assessment

In the following table has been reported the PECs calculated according ESD.

	Local PEC (OECD ESD)
Scenario 1: Dipping treatment during application	
Annual average local PEC in air	4.56×10^{-7} mg/m^3
Scenario 3: Vacuum pressure treatment during application	
Annual average local PEC in air	1.14×10^{-5} mg/m^3

Alkyl (C12-16) dimethylbenzyl ammonium chloride is not volatile and, therefore, air will not be an environmental compartment of concern for the use of Alkyl (C12-16) dimethylbenzyl ammonium chloride in wood preservatives.

2.2.2.5 Risk characterisation

Aquatic Compartment

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 %, and different K_{oc} values.

Scenario		PEC/PNEC values (US ISC)		
		Water compartment	**Sediment compartment**	**Sewage treatment plant**
Scenario 1 (dipping treatment during application)		**11.3**	**75.9**	**3.05**
Scenario 2 (dipping treatment during storage)		**5.54**	**37.3**	-
Scenario 3 (Vacuum pressure treatment during application)		**3.37**	**23.1**	0.92
Scenario 4 (Vacuum pressure treatment during storage)		**4.09**	**27.5**	-
Scenario 6 (Noise Barrier)	**Time1**	**6.02**	**40.6**	
	Time2	0.05	0.34	

The PEC/PNEC ratios for the water and sediment compartments in the scenario 1, 2, 3 and 4 (dipping treatment during application and storage, vacuum pressure treatment during application and storage) are higher than 1. For the use scenario 1, the PEC/PNEC value is higher than the trigger value of 1 also for the sediment and sewage treatment plant. For the water and sediment compartments in the scenario 6 (Noise barrier) the PEC/PNEC ratio is higher than 1 in the short term whilst the long term use does not pose any risk.

In conclusion, in order to reduce emissions from the application and storage phases for aquatic compartment, the dipping and vacuum pressure treatment must be performed only by those plants where significant losses can be contained (e.g., no drain connections to storm drains or STP) and appropriately recycled/disposed.

Scenario	PEC/PNEC values (EQC)		
	Water compartment	**Sediment compartment**	**Sewage treatment plant**
Scenario 1 (dipping treatment during application)	**1.45**	**1.03**	0.1
Scenario 2 (dipping treatment during storage)	**5.5**	**37.3**	-

Scenario 6 (Noise Barrier)	**Time1**	**3.4**	**22.7**	
	Time2	0.07	0.44	

The PEC/PNEC ratios for the water and sediment compartments in the scenario 1 and 2 (dipping treatment during application and storage) are above 1. For the use scenario 1, the PEC/PNEC value is lower than the trigger value of 1 for sewage treatment plant. For the water and sediment compartments in the scenario 6 (Noise barrier) the PEC/PNEC ratio is higher than 1 in the short term whilst the long term use does not pose any risk.

In conclusion, in order to reduce emissions from the application and storage phases of the industrial treatment for aquatic compartment, the dipping and vacuum pressure treatment must be performed only by those plants where significant losses can be contained (*e.g.*, no drain connections to storm drains or STP), freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. Similarly industrial application should be conducted within a contained area or on impermeable hard standing with bunding.

Terrestrial Compartment including Groundwater

The PEC soil values for the two applicant are similar and on this base eCA decided to report only one data set, the risk characterization do not change.

Summary of PEC/PNEC values for terrestrial compartment

Scenario	**PEC/PNEC values Terrestrial compartment**	
Scenario 2: Storage of dipped/ immersed wood	After 30 days	**4.2**
	After 15 years	**7.7**
Scenario 4: Storage of vacuum-pressure-treated wood	After 30 days	**4.2**
	After 20 years	**10.3**
Scenario 6: Treated wood in service: Noise barrier	After 30 days	**1.7**
	After 20 years	**3.6**
Scenario 7: Treated wood in service: Fence	After 30 days	**3.7**
	After 20 years	**8.0**
Scenario 8: Treated wood in service: House	After 30 days	**4.4**
	After 20 years	9.6
Scenario 9: Treated wood in service: Transmission pole	After 30 days	0.6
	After 20 years	**1.4**
Scenario 10: Treated wood in service: Fence post	After 30 days	0.6
	After 20 years	**1.1**

Thus, for scenarios 2, 4, 6, 7 and 8 the PEC/PNEC values are higher than 1 showing unacceptable risk for the terrestrial compartment.

For scenarios 2 and 4 the PEC/PNEC values are higher than 1, showing that there is unacceptable risk for the terrestrial compartment. Furthermore, an increasing risk over time has been predicted for both the scenarios. Therefore, all timber treated by dipping and vacuum pressure applications should be stored on impermeable hard standing surfaces so as to prevent direct losses to soil and allow losses to be collected for re-use or disposal.

For scenario 9 and 10 the PEC/PNEC values are below 1 in the short-term use does not pose any risk whilst the PEC/PNEC values are higer than 1 in the long-term and an unacceptable risk can occur.

Due to the potential risk identified for a number of the terrestrial compartments, the use products should be restricted in order to prevent the use for treatment of wood in contact with fresh water or used for outdoor constructions near or above water, or for treatment of wood that will be continually exposed to the weather or subject to frequent wetting. Therefore, the product should not be used in use class 3 unless, a safe use of the product is also demonstrated by providing data such as an additional 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, accepted at TM level (TMI 09 and TMII 09), simulates worst-case conditions taking into account that the wooden blocks are continuously submerged in water for a period of 14 days and taking into account the high water solubility of DDAC, that was round 400 g/L. A safe use has been identified for UC 1 and UC 2.

Summary of PEC/PNEC values 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.

Scenario	**PECgw µg/L**	**Limit value µg/L**
Scenario 2: Storage of dipped/ immersed wood	0.09 mg/L	0.1
Scenario 4: Storage of vacuum-pressure-treated wood	0.09 mg/L	
Scenario 6: Treated wood in service: Noise barrier	0.03 mg/L	
Scenario 7: Treated wood in service: Fence	0.08 mg/L	
Scenario 8: Treated wood in service: House	0.1 mg/L	
Scenario 9: Treated wood in service: Transmission pole	0.01 mg/L	
Scenario 10:Treated wood in service: Fence post	0.01 mg/L	

For all scenarios the PEC in groundwater is above the trigger value of 0.1 µg/L, indicating no risk for groundwater. However, in order to reduce emissions from the storage phases for aquatic compartment, the dipping and vacuum pressure treatment must be performed only by those plants where significant losses can be contained (e.g no drain connections to storm drains or STP) and appropriately recycled/disposed.

Environmental risk in the atmosphere

No qualitative environmental risk assessment can be done for the air compartment due to lack of specific effect data. However, for all scenarios, the PEC in air is considered to be negligible ($\leq 1 \times 10^{-5}$) suggesting that there is no concern for this compartment. In addition, on the basis of abiotic effects atmospheric half life is 8.831 hours (calculated using the Atmospheric Oxidation Program (AOPWIN)), C_{12-16}-BKC is not expected to have adverse effects in the atmosphere.

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

Based on the worst case PECsw values, the following PEC/PNEC values are calculated.

Scenario	PEC/PNEC values	
	Fish-eating mammals	Fish-eating birds
Scenario 1: Dipping application	0.37/4.4 = 0.08	0.37/0.821 = 0.45
Scenario 2 Storage of dipping/immersed wood	0.18/4.4 =0.04	0.18/0.821 = 0.22
Scenario 3 Vacuum pressure application	0.11/4.4 = 0.025	0.11/0.821 = 0.14
Scenario 4 Storage of Vacuum pressure treated wood	0.13/4.4 =0.029	0.13/0.821 = 0.16

Since the PEC/PNEC values are below 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).

No data are available on the $BCF_{earthworm}$ and it cannot be calculated from TGD equation 82d as it is not applicable to ionic substances. A sensitivity analysis carried out using TGD eq 82c indicated that risk of seconday poisoning via the terrestrial food chain would arise assuming a $BCF_{earthworm}$ unrealistically high, therefore the measurement of a terrestrial BCF is deemed not necessary.

Risk characterization for the physical-chemical properties of the biocidal product

Not applicable. The representative products of US ISC and EQC (BQ-25 and BKC-50, respectively) are water-based concentrates, which are not expected to pose any physical hazard.

2.2.3 Assessment of endocrine disruptor properties

<u>CONCLUSIONS for US ISC & EQC</u>

Based on available experimental results, there is no indication that Alkyl (C12-16) dimethylbenzyl ammonium chloride affects the endocrine system. Structural characteristics and SAR do not hint to possible effects of Alkyl (C12-16) dimethylbenzyl ammonium chloride as endocrine disruptor.

3. DECISION

3.1. Background to the Proposed Decision

On the basis of the proposed and supported uses and the evaluation conducted as summarised in chapter 2 of this document, it can be concluded that under the conditions listed in chapter 3.2 Alkyl (C12-16) dimethylbenzyl ammonium chloride (C_{12-16}-ADBAC) fulfils the requirements laid down in Article 5(1) (b), (c), and (d) of Directive 98/8/EC, apart from those corresponding to the list in chapter 3.4 below. C_{12-16}-ADBAC is proposed to be included in Annex I of the Directive pending on the submission of the data/information required by RMS under chapter 3.4.

The overall conclusion from the human health evaluation of C_{12-16}-ADBAC, for use in product type 8 (wood preservatives) is that the active substance in biocidal products containing 2% w/w C_{12-16}-ADBAC will not present an unacceptable risk to humans during the proposed normal use. This conclusion relies on the fact that users will be applying the basic principles of good practice and using appropriate and obligatory PPE (as identified in Document II-C and below); in particular for the vacuum pressure treatment where considerable contamination of the operator can be anticipated, a higher degree of protection than typical work clothing is warranted. Consequently, it is assumed impermeable coveralls will be worn. Also, to reduce exposure via the hands, operators would be required to wear protective gloves at the start of each daily dipping session.

For the secondary exposure assessment risks have been identified for the exposed populations. Therefore, mitigation measure is proposed in order to prevent that children enter in direct contact with treated wood. However, an update local risk assessment based on the Guidance for Human Health Risk Assessment (Guidance on the BPR: Volume III Human Health, Part B Risk Assessment) has been performed for similar chemical compound (ATMAC/TMAC) demonstrating that there is no reason for concern. Therefore, it was agreed by the WG that the conclusion for that RA applies to all QUATs with similar uses.

With regard to the environmental risk assessment, unacceptable risks have been identified for the aquatic compartment following industrial applications (dipping and vacuum pressure treatments) and storage of wood treated with products containing 2% w/w C_{12-16}-ADBAC. Wood preservatives containing C_{12-16}-ADBAC at 2% w/w must not be used to treat wooden structures for which direct losses to water cannot be prevented. For treated wood in service (nois barrier scenario), the PEC/PNEC values calculated for water and sediment compartment are above 1 during the initial Time 1 (30 days). For the longer period (service life) no risk was identified. For the scenarios presenting a concern risk mitigation measures are proposed.

For the terrestrial compartment unacceptable risks have been identified following storage on site and for treated wood in service. For the Noise Barrier, Fence and House scenarios the PEC/PNEC values are higher than 1 for the initial and longer assessment period. Therefore the product should be restricted to prevent use for treatment of wood in Use Class 3. For Transmission Pole and Fence Post scenarios the PEC/PNEC values are lowerer than 1 in the short-term whilst the long-term use the PEC/PNEC values are quite higher than 1. Therefore, the product should be restricted to prevent use for treatment of wood in Use Class 4A. A safe use has been identified in UC 1 and UC 2.

For these scenarios risk reduction measures are proposed in order to prevent the direct losses to the soil.

For the groundwater compartment, unacceptable risks have been identified following storage on site. Therefore, risk reduction measure is proposed in order to prevent losses which would be collected for re-use or disposal.

C_{12-16}-ADBAC is proposed to be included in Annex I of the Directive.

The Annex I – entry should, however, only include the intended uses with the conditions and restrictions proposed in this report.

3.2. Proposed Decision regarding Inclusion in Annex I

The Italian CA recommends that Alkyl (C12-16) dimethylbenzyl ammonium chloride (C_{12-16}-ADBAC) is included in Annex I to Directive 98/8/EC as an active substance for use in wood preservative products (Product-type 8), subject to the following specific provisions:

Common name: Alkyl (C12-16) dimethylbenzyl ammonium chloride

IUPAC name: Not applicable

CAS No.: 68424-85-1

EC No.: 270-325-2

Minimum degree of purity of the active substance:

The active substance as manufactured shall have a minimum purity of 94% (w/w) dry weight.

Identity and maximum content of impurities:

The identity and maximum content of impurities must not differ in such a way as to invalidate the assessment for the inclusion of the active substance on to Annex I.

Product types:

Wood preservative (product-type 8)

Specific provisions:

The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as use by non-professionals and exposure of food or feed, were excluded. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment.

Member States shall ensure that authorisations are subject to the following conditions:

(1) For industrial or professional users safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means.

(2) Products shall not be used for treatment of wood with which children may enter in direct contact, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level.

(3) Labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment on impermeable hard standing to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

(4) Products shall not be authorised for treatment of wood that will be in contact with fresh water or used for outdoor constructions near or above water, continually exposed to the weather or subject to frequent wetting, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate mitigation measures.

3.3. Elements to be taken into account by Member States when authorising products

Products containing C_{12-16}-ADBAC are intended to be used in the treatment of wood by Dipping/immersion process and vacuum pressure application by industrial/professional users only. Indeed in consideration of the potential risk derived for the in-situ treatment scenarios this application shall not be authorised.

Human Health and Environmental Risk Assessment has been performed on the knowledge that the wood treatment solution employed contains 2% a.s. Therefore any deviation from the value of 2% increasing the concentration of the substance in the final treatment solution, must undergo through a specific risk assessment.

When authorising the product use Member States Authorities should ensure that the Risk Reduction Measure described in Sections 3.2 and 3.5 are applied. In particular, due to the irritant/corrosive properties, labels and/or safety data sheets of products authorised for industrial or professional use should indicate the need of specific Personal Protective Equipments in according to the following characteristics:

Hygiene measures

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Respiratory protection

In the case of vapour formation, use a respirator with an approved filter. Respirator with a vapour filter of the following type should be used: EN 141.

Hand protection for long-term exposure

Suitable material for gloves: Nitrile rubber

Break through time / glove: > 480 min

Minimal thickness / glove: 0.7 mm

Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).

Hand protection for short-term exposure (e.g. accidental aerosols from splashing etc.)

Suitable material for gloves: Nitrile rubber

Break through time / glove: > 30 min

Minimal thickness / glove: 0.4 mm

Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).

Eye protection

Tightly fitting safety goggles; Face-shield.

Skin and body protection

Choose body protection according to the amount and concentration of the dangerous substance at the work place, Rubber or plastic apron, Rubber or plastic boots.

At the product authorisation stage, efficacy should be demonstrated according to uses claimed

As the assessment should not be considered as comprehensive of the overall exposure pathways, additional exposure scenarios covering overall exposure pathways should be estimated at Product Authorization stage when the guidelines on the risk characterization for the local effects are finalized, depending on the use patterns.

Additional leaching data should be submitted at the product authorisation stage in order to demonstrate that use class 3 (treatment of wood exposed to weathering) can be acceptable.

3.4. Requirement for further information

The need for the following studies should in particular be considered:

- Additional highly-specific confirmatory methods for C_{12-16}-ADBAC residues in soil and water (both drinking- and surface-water) are required. These methods can be provided at the product authorization stage at national level. NB: US ISC can cover the data gap by means of a letter of access to the analytical methods for residues by EQC (accepted by eCA-IT).

3.5. Updating this Assessment Report

This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of C_{12-16}-ADBAC in Annex I to the Directive. In this regards, the local risk assessment should be re-submitted based on the requirements provided in the Guidance for Human Health Risk Assessment. In this regards, the LRA methodology followed for the active substance Coco Alkyltrimethylammonium Chloride (ATMAC/TMAC) notified as PT 8 should be considered as applicable also for Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC).

Appendix I: List of endpoints

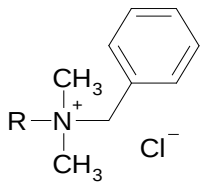
Chapter 1:Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Name)	Not available Given in EINECS as Quaternary ammonium compounds, benzyl-(C12-16)-alkyldimethyl, chlorides
Product-type	P8

Identity

Chemical name (IUPAC)	Not applicable
Chemical name (CA)	Quaternary ammonium compounds, benzyl-(C12-16)-alkyldimethyl, chlorides
CAS No	68424-85-1
EC No	270-325-2
Other substance No.	None
Minimum purity of the active substance as manufactured (g/kg or g/l)	**US ISC** 940 g/kg (dry weight) **EQC** 981 g/kg (dry weight)
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	$C_{n+9}H_{2n+14}N.Cl$ (n = 12, 14, 16) Alkyl chain lengths distribution:

Chain Length	Range
C12	39 - 76%
C14	20 - 52%
C16	<12%

Molecular mass	340.0 – 396.1 g/mol
Structural formula	 R = $C_{12}H_{25}$, $C_{14}H_{29}$ or $C_{16}H_{33}$

Physical and chemical properties

Melting point (state purity)	**US ISC** The a.s. did not melt, but was observed to decompose starting at approximately 150°C (96.6%) **EQC** Melting range at atmospheric pressure of 28.9–30.2 °C (99.2%)
Boiling point (state purity)	**US ISC** The a.s. decomposed before melting (96.6%) **EQC** No boiling point at atmospheric pressure (1013 hPa). The test item decomposed at a temperature >160 °C (99.2%)
Thermal stability / Temperature of decomposition	**US ISC** > 150°C **EQC** > 160°C
Appearance (state purity)	**US ISC** Light beige solid (96.6%) **EQC** Crystalline, tenacious and sticky solid. Hygroscopic behaviour. White colour. Faint marzipan-like odour (94.4%)
Relative density (state purity)	**US ISC** D_4^{20} = 0.96 (96.6%) **EQC** D_4^{20} = 0.929 (94.4%)
Surface tension (state temperature and concentration of the test solution)	**US ISC** 31.3 mN/m at 20°C (test solution: 1 g/l aqueous solution) **EQC** 28.27 mN/m at 20 ± 0.5 °C (test solution: 1.0 g/l aqueous solution) CMC: 0.5 g/L at 20 ± 0.5 °C
Vapour pressure (in Pa, state temperature)	**US ISC** 6.03E-04 Pa @ 20°C (extrapolated) 8.57E-04 Pa @ 25°C (extrapolated) 4.22E-03 Pa @ 50°C (extrapolated) **EQC** < 1.5E-03 Pa @ 20°C (extrapolated) < 5.8E-03 Pa@ 25°C (extrapolated)
Henry's law constant (Pa m^3 mol^{-1})	**US ISC** 5.03E-07 Pa m^3 mol^{-1} at 20°C **EQC** < 1.15E-06 Pa m^3 mol^{-1} at 20°C

Solubility in water (g/l or mg/l, state temperature)	**US ISC** pH 5.5: 409 g/l at 20°C pH 6.5: 431 g/l at 20°C pH 8.2: 379 g/l at 20°C **EQC** 455 g/l in doubled distilled water at 20.0 ± 0.5 °C 444 g/l in acidic or basic solution at 20.0 ± 0.5 °C Solubility was found to be independent of temperature
Solubility in organic solvents (in g/l or mg/l, state temperature)	**US ISC** ethanol: > 250 g/l at 20°C isopropanol: > 250 g/l at 20°C n-octanol: > 250 g/l at 20°C **EQC** isopropanol: 549 g/l at 10°C; 568 g/l at 20°C; 586 g/l at 30°C n-octanol: 459 g/l at 20°C
Stability in organic solvents used in biocidal products including relevant breakdown products	**US ISC** Ethanol: Stable – < 5% loss over 2 weeks at 55 °C Isopropanol: Stable – < 5% loss over 2 weeks at 55°C (confirmed by supporting information) **EQC** Not required: no organic solvent is used in the representative biocidal product
Partition coefficient (log P_{OW}) (state temperature)	**US ISC** Not determined (EC methods A.8 not applicable for surfactants). Assessment by KOWWIN is inaccurate (software database very limited for surfactants). log P_{OW} could be roughly obtained from solubility in n-octanol and water. However, this calculation is of no use with regard to environmental fate and behaviour and secondary poisoning risk assessment (experimental BCF available) **EQC** 0.004 @ 20°C (calculated from individual solubilities in n-octanol and water)
Dissociation constant	Not applicable. The a.s. is fully dissociated in water

UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	**US ISC** The UV/VIS absorption spectra were consistent with the assigned structure of the active substance. **EQC** No absorption above 290 nm in the neutral, acidic and basic media
Photostability (DT_{50}) (aqueous, sunlight, state pH)	**US ISC** The photolysis data available for DDAC are adequate for this active substance. The test substance is photolytically stable in absence of a photosensitising agent. **EQC** No absorption above 290 nm in UV spectrum
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not applicable: no adsorption above 290 nm in UV spectra
Flammability or flash point	Not flammable
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Auto-ignition or relative self ignition temperature	No self-ignition was observed up to the maximum test temperature (≈400°C)

Classification and proposed labelling

	According to Reg. EC 1272/2008 with amendments:
with regard to physical hazards	No classification
Signal Word	Danger
with regard to human health hazards	GHS05, GHS06 H302 H311 *(this point will be revised with CLH dossier submission)* H314
with regard to environmental hazards	GHS09 H400 (M=10) H410 (M=1)

Chapter 2:Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	**US ISC** HPLC with evaporative light scattering detection (ELSD). Confirmation by LC-MS **EQC** Analysis by RP-HPLC/DAD (confirmation of identity of each a.s. constituent by spectral match versus relevant standards)
Impurities in technical active substance (principle of method)	**US ISC** HPLC-ELSD (identification by LC-MS) Titration method IC coupled with conductivity detector; AAS Karl-Fischer titration and GC/FID for process solvents **EQC** RP-HPLC/MS-MS, with two ion transitions considered (one as quantifier, one as qualifier) GC-MS ICP-OES Karl-Fischer titration

Analytical methods for residues

Soil (principle of method and LOQ)	**EQC** Extraction with acetonitrile containing 1% TFA. After centrifugation and dilution with water, analysis by RP-HPLC/MS-MS (two mass transitions validated for each a.s. constituent). LOQ = 0.05 mg a.s./kg LOQ (for each individual constituent) = 0.0167 mg/kg
Air (principle of method and LOQ)	Not required. The a.s. is non-volatile nor expected to occur in air (representative products BQ-25 and BKC-50 are used in the following wood preservative treatment applications: automated dipping process, vacuum pressure process and spraying application in closed tunnel).
Water (principle of method and LOQ)	**EQC** Samples over SPE cartridges. After drying, elution with acetonitrile : HPLC water (60:40, v/v) + 1% HCOOH. Analysis by RP-HPLC/MS-MS (two mass transitions validated for each a.s. constituent). LOQ = 0.1 µg a.s./L LOQ (for each individual constituent) = 0.0133 µg/L

Body fluids and tissues (principle of method and LOQ)	Not required. The a.s. is neither toxic nor highly toxic
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required. Wood treated with C_{12-16}-ADBAC/BKC-containing biocidal products is not intended for and contains label restrictions against use in areas where food for human consumption is prepared, consumed or stored. Furthermore, the use of C_{12-16}-ADBAC/BKC-based wood preservatives must exclude applications that may lead to contact with food and feedstuffs and contaminants thereof (e.g. application on wood crates for the storage or transport of food/feedingstuff)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required. Wood treated with C_{12-16}-ADBAC/BKC-containing biocidal product is not intended for and contains label restrictions against use in areas where food for human consumption is prepared, consumed or stored, or where the feedingstuff for livestock is prepared, consumed or stored. Furthermore, the use of C_{12-16}-ADBAC/BKC-based wood preservatives must exclude applications that may lead to contact with food and feedstuffs and contaminants thereof (e.g. application on wood crates for the storage or transport of food/feedingstuff)

Chapter 3:Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	**US ISC** Based on data on urine excretion (5-8%) and tissue residues (<1%), and on the highly ionic nature of the a.s., it is expected that the oral absorption is around 10% at non-corrosive concentrations. **EQC** Due to its ionic nature, C_{12-16}-BKC is expected not to easily pass biological membranes. Indeed, the fraction of the oral dose absorbed was about 10%, based on the urinary mean value 3-4% (with a single peak value = 8.3%) and biliary excretion values (3.7-4.6%), as well as on the absence of residues in the carcass. The oral absorption value of 10 % at non-corrosive concentrations.
Rate and extent of dermal absorption*:	**US ISC** Based on data from an in vitro study on human skin, the % absorbable was almost identical for 2 different dilutions (0.03% and 0.3%). Summing up the radioactivity present in the receptor fluid, in the skin at the application site (after stratum corneum removal) and in the tape strips 6-20 the value for dermal absorption of the a.s. is 8.3% at non-corrosive concentrations. **EQC** Based on the level of radioactivity at the skin application site after removal of the stratum corneum layers (6.5-8.7% of the dose), and considering the ionic nature of C_{12-16}-BKC, it can be expected that the dermal absorption is not different from the oral one (10%). The dermal absorption value has to be considered of 10 % at non-corrosive concentrations.

Distribution:	**US ISC** Most radioactivity was confined to the intestines. Levels in central organs (liver and kidney) were low and decreased rapidly over time **EQC** The plasma, blood and organ radioactivity levels were essentially non-quantifiable. At the high oral dose-level only, quantifiable levels of radioactivity were found in some central organs (highest levels in the liver and kidney) at 8 hours post-dosing; otherwise, most radioactivity was confined to the intestines. Levels decreased rapidly over time **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Most radioactivity was confined to the intestines. Levels in central organs (liver and kidney) were low and decreased rapidly over time **(US ISC; EQC)**
Potential for accumulation:	**US ISC** None noted **EQC** None. No residues were measured in the carcass after 168h. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** None relevant **(US ISC; EQC)**
Rate and extent of excretion:	**US ISC** Following oral administration in rats: 87 – 99% excreted in faeces as unabsorbed material, 5 – 8% excreted in urine **EQC** Excretion was rapid (within a 48 to 72-hour period).The vast majority of the oral dose was excreted in the faeces (80%) as unabsorbed material (only about 4% of the oral dose was eliminated in the bile in a 24-hour period). **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Excretion was rapid (within a 48 to 72-hour period). The vast majority of the oral dose was excreted in the faeces (80-90%) as unabsorbed material; 5 – 8% excreted in urine. About 4% of the oral dose was eliminated in the bile in a 24-hour period **(US ISC; EQC)**

Toxicologically significant metabolite(s)	**US ISC** None. Four major metabolites of C_{12-16}-ADBAC were identified, as the product of alkyl chain hydroxylation. It can be hypothesized that C_{12-16}-ADBAC metabolism is carried out by gut microflora. **EQC** None **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** None **(US ISC; EQC)**

* the dermal absorption value is applicable for the active substance and might not be usable in product authorization

Acute toxicity

Rat LD_{50} oral	**US ISC** 344 mg/kg bw **EQC** 358 mg (obtained with C_{8-18}-BKC/kg bw) Although the test item is different, this result can be considered valid for C_{12-16}-BKC, based on the similar mechanism for oral toxicity shown by QUATS with this alkyl chain length. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 350 mg/kg bw **(US ISC; EQC)**
Rat LD_{50} dermal	**US ISC** 2848 mg/kg bw **EQC** Testing not allowed, active substance is corrosive to skin Literature LD_{50} values = 800-1400 mg/kg **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 2848 mg/kg bw **(US ISC)**
Rat LC_{50} inhalation	**US ISC** Study not conducted **EQC** Study not conducted - not relevant C_{12-16}-BKC is not volatile (calculated vp < $1x10^{-2}$ Pa at 20°C) and is corrosive **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Study not conducted - not relevant The a.s. is not volatile and is corrosive **(US ISC; EQC)**

Skin corrosion/irritation	**<u>US ISC</u>** Corrosive NOAEC = 0.3% in water at 2.0 mL/kg body weight per day (2 week-treatment) **<u>EQC</u>** Corrosive The maximum concentration reported in the literature that does not produce irritating effect on intact skin is established at 0.1% a.s. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Corrosive NOAEC = 0.3% in water at 2.0 mL/kg body weight per day (2 week-treatment/rat) The maximum concentration reported in the literature that does not produce irritating effect on intact skin is established at 0.1% a.s. **(US ISC; EQC)**
Eye irritation	**<u>US ISC</u>** Corrosive **<u>EQC</u>** Testing not allowed, active substance is corrosive to skin The maximum concentration reported in the literature without irritating effect in the eyes = 0.02% a.s **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Corrosive. The maximum concentration reported in the literature without irritating effect in the eyes = 0.02% a.s **(US ISC; EQC)**
Respiratory tract irritation	**<u>US ISC</u>** No study available, but expected to be corrosive **<u>EQC</u>** No study available, but expected to be corrosive **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No study available, but expected to be corrosive

Skin sensitisation (test method used and result)	**US ISC** None (Buehler Test on guinea pig) **EQC** None (modified Draize test, guinea pig) Result confirmed by a published study with GPMT test **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** None. **(US ISC; EQC)**
Respiratory sensitisation (test method used and result)	**US ISC** No study available, but expected to be not a sensitiser **EQC** No study available, but expected to be not a sensitiser **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No study available, but expected to be not a sensitiser
Repeated dose toxicity	
Short term	
Species / target / critical effect	**US ISC** No short-term study available **EQC** Rat/dog, 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:** Dog: no specific toxic effects/ critical effects: body weight and body weight gain reduction associated to lower food intake **(EQC)**
Relevant oral NOAEL / LOAEL	**US ISC** No short-term study available **EQC** LOAEL: 43-53 mg/kg/day (28-day dog-Supporting study) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** LOAEL: 43-53 mg/kg/day (28-day dog-Supporting study) **(EQC)**

Relevant dermal NOAEL / LOAEL	**US ISC** No short-term study available **EQC** Study not conducted – not relevant Effects are characterised by local corrosive effects related to concentration rather than systemic toxicity due to dermal uptake **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Study not conducted – not relevant Effects are characterised by local corrosive effects related to concentration rather than systemic toxicity due to dermal uptake **(US ISC; EQC)**
Relevant inhalation NOAEL / LOAEL	**US ISC** No study available. Expected to be irritant/corrosive. **EQC** 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.**(US ISC; EQC)**

Subchronic

Species/ target / critical effect	**US ISC** Local effects (irritation/corrosivity) at the site of contact in all species tested. Non specific systemic effects (e.g. reduced body weight and body weight gain), secondary to local effects. **EQC** Rat/dog, 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:** Rat/dog: Local effects (irritation/corrosivity) at the site of contact in all species tested. Non specific systemic effects (e.g. reduced body weight and body weight gain), secondary to local effects. **(US ISC; EQC)**

Relevant oral NOAEL / LOAEL	**US ISC** 13.1 mg/kg/day (1 year, Dog) **EQC** 1250 ppm = 45 mg a.s./kg bw/day (90-day, Dog) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 13.1 mg/kg/day (1 year, Dog) **(US ISC)**
Relevant dermal NOAEL / LOAEL	**US ISC** 20 mg/kg bw/day (highest dose tested) **EQC** Study not conducted – not relevant Effects are characterised by local corrosive effects related to concentration rather than systemic toxicity due to dermal uptake **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 20 mg/kg bw/day (highest dose tested) **(US ISC)**
Relevant inhalation NOAEL / LOAEL	**US ISC** No study available. Expected to be irritant/corrosive. **EQC** 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. **(US ISC; EQC)**

Long term

Species/ target / critical effect	**US ISC** Rat/mouse: Local effects (irritation/corrosivity) at the site of contact in all species tested. Non specific systemic effects (e.g. reduced body weight and body weight gain), secondary to local effects. **EQC** Rat/mouse: Local effects (irritation/corrosivity) at the site of contact in all species tested. Non specific systemic effects (e.g. reduced body weight and body weight gain), secondary to local effects. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Rat/mouse: Local effects (irritation/corrosivity) at the site of contact in all species tested. Non specific systemic effects (e.g. reduced body weight and body weight gain), secondary to local effects. **(US ISC; EQC)**
Relevant oral NOAEL / LOAEL	**US ISC** 44 mg/kg/day (2-years rats) **EQC** 47 mg/kg/day (2-years rats) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 44-47 mg/kg/day (2-years rats) **(US ISC; EQC)**
Relevant dermal NOAEL / LOAEL	**US ISC** Study not conducted **EQC** Study not conducted – not relevant Effects are characterised by local corrosive effects related to concentration rather than systemic toxicity due to dermal uptake **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Study not conducted – not relevant **(US ISC; EQC)**
Relevant inhalation NOAEL / LOAEL	**US ISC** Study not conducted **EQC** Study not conducted – not relevant Active substance is not volatile and corrosive **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Study not conducted – not relevant **(US ISC; EQC)**

Genotoxicity

US ISC

In vitro:

Ames test – negative (with and without metabolic activity)

Chromosomal aberration test – negative (with and without metabolic activity)

Mammalian cell gene mutation assay – negative (with and without metabolic activity)

In vivo:

Micronucleus assay - negative

EQC

In vitro:

Not genotoxic in vitro gene mutation study in bacteria and in vitro cytogeneticity and gene mutation assays in mammalian cells

CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:

The substance can be considered not genotoxic based on:

in vitro (Ames test, Chromosomal aberration test, Mammalian cell gene mutation assay) and in vivo test (Chromosomal aberration test in rat bone marrow) **(US ISC)**

Carcinogenicity

Species/type of tumour	**US ISC** Rat/none, Mouse/none **EQC** C_{12-16}-ADBAC is not carcinogenic **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No neoplastic lesions were found that were considered treatment related. Rat study **(US ISC; EQC)** Mouse study **(US ISC)**
Relevant NOAEL/LOAEL	**US ISC** The NOELs related to non neoplastic effects in chronic oral toxicity studies were 44 mg/kg/day for rats and 73 mg/kg/day for mice. **EQC** In rats the NOAEL for non neoplastic effects was 47 mg a.s./kg/day. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No carcinogenic effects were observed. Rat study **(US ISC; EQC)** Mouse study **(US ISC)**

Reproductive toxicity

Developmental toxicity

Species/ Developmental target / critical effect	**US ISC** Rabbit/maternal toxicity **EQC** Rat /maternal toxicity Rabbit / maternal toxicity **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No specific concern for developmental toxicity **(US ISC; EQC)**
Relevant maternal NOAEL	**US ISC** Rabbit: 4 mg/kg bw **EQC** Rat: 10 mg/kg bw/day Rabbit: 3 mg/kg bw/day **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** No specific concern for developmental toxicity. Maternal NOAELs consistently lower than developmental NOAELs. Maternal effects mostly due to gastrointestinal distress, not relevant to systemic toxicity **(US ISC; EQC)**

Relevant developmental NOAEL	**US ISC** Rabbit: 12 mg/kg bw **EQC** Rat: ≥ 100 mg/kg bw/day Rabbit: ≥ 9 mg/kg bw/day **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No specific concern for developmental toxicity **(US ISC; EQC)**

Fertility

Species/critical effect	**US ISC** Rat/ cortical adrenal hypertrophy in F0 females, lower weight gain and higher spleen weights in F1 **EQC** Rat/reduced weight gain and food consumption in parental and F1 animals **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No specific concern for reproductive toxicity **(US ISC; EQC)**
Relevant parental NOAEL	**US ISC** 608 mg/kg food (≥ 30 mg/kg bw/day) **EQC** 1000 mg/kg food (≥ 50 mg/kg bw/day) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** No specific concern for reproductive toxicity. Parental NOAELs related to general toxicity **(US ISC; EQC)**
Relevant offspring NOAEL	**US ISC** 608 mg/kg food (≥ 30 mg/kg bw/day) **EQC** 1000 mg/kg food (> 50 mg/kg bw/day) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** No specific concern for reproductive toxicity. NOAELs in F1 related to general toxicity and equal to the parental ones **(US ISC; EQC)**
Relevant fertility NOAEL	**US ISC** 1620 mg/kg food (≥ 52 mg/kg bw/day) **EQC** > 2000 mg/kg food (> 100 mg/kg bw/day) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No specific concern for reproductive toxicity **(US ISC; EQC)**

Neurotoxicity

Species/ target/critical effect

US ISC

Study not conducted/ not relevant

EQC

Study not conducted – not relevant

CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION

No specific concern for neurotoxicity **(US ISC; EQC)**

Developmental Neurotoxicity

Species/ target/critical effect

US ISC

No indication from available studies

EQC

No indication from available studies

CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:

No specific concern for developmental neurotoxicity **(US ISC; EQC)**

Immunotoxicity

Species/ target/critical effect

US ISC

Study not conducted. No indication of such an effect in the available toxicity studies

EQC

Study not conducted. No indication of such an effect in the available toxicity studies.

CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION

No specific concern for immunotoxicity. **(US ISC; EQC)**

Developmental Immunotoxicity

Species/ target/critical effect

US ISC

No indication from available studies

EQC

No indication from available studies

CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:

No specific concern for developmental immunotoxicity **(US ISC; EQC)**

Other toxicological studies

US ISC

No further study conducted/ not relevant

EQC

No further study conducted/ not relevant

CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION

No further study conducted/ not relevant

(US ISC; EQC)

Medical data

US ISC

No substance-specific effects have been noted. No specific observations or sensitivity/allergenicity have been reported.

EQC

Skin reactions observed after dermal exposure to C_{12-16}-BKC can be regarded as an irritant reaction rather than a true sensitisation reaction. This is supported by the results from animal tests, which do not indicate a sensitising potential

CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION

Skin reactions observed after dermal exposure to C_{12-16}-BKC can be regarded as an irritant reaction rather than a true sensitisation reaction. This is supported by the results from animal tests, which do not indicate a sensitising potential **(EQC)**

Summary for Local effects

	Value	Study
Dermal NOAEC	**0.3%**	2-week skin irritation study with rats **(US ISC)**
Oral NOAEC	Not data available	

Summary for systemic effects

	Value	Study	Safety factor
$AEL_{long-term}$	Not relevant		
$AEL_{medium-term}$	Not relevant		
$AEL_{short-term}$	Not relevant		
ADI[4]	Not applicable		
ARfD	Not applicable		

MRLs

Relevant commodities	Not applicable

Reference value for groundwater

According to BPR Annex VI, point 68	**US ISC** 0.1 µg/L **EQC** 0.1 µg/L

Dermal absorption

Study (*in vitro/vivo*), species tested	**US ISC** In vitro study (human skin samples) **EQC** 2 in vivo study available on rats, none of them allowing a quantitative determination (oral exposure not prevented; radioactivity in the stratum corneum included)
Formulation (formulation type and including concentration(s) tested, vehicle)	**US ISC** C_{12-16}-ADBAC aqueous solution (0.03% and 0.3% w/w) **EQC** 1: 1.5 and 15 mg a.s. /kg bw, as 6-hour exposure over 10% of the body surface 2: 0.4 mL of a 0.77% w/w aqueous solution of C_{8-18}-BKC

[4] If residues in food or feed.

Dermal absorption values	**US ISC** The sum of the absorbed dose, the exposed skin (2.18%-2.13) and the % of radioactivity present in tape strips 6-20 gave rise to a value of 8.3%. **EQC** Estimated similar to the oral absorption (10%).

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

Formulation of biocidal product	Not applicable
Intended uses	
Industrial users/ Professional users	Not relevant
Non-professional users	Not applicable
General public	Not relevant
Exposure via residue in food	Not applicable

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	**US ISC** n.a. **EQC** n.a.
pH 5	**US ISC** >30 days at 25°C **EQC** Stable (pH 4) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** stable **(US ISC; EQC)**
pH 9	**US ISC** >30 days at 25°C **EQC** Stable (pH 10) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** stable **(US ISC; EQC)**
Other pH: pH 7	**US ISC** >30 days at 25°C **EQC** **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** stable **(US ISC; EQC)**
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	**US ISC** The photolysis data available for DDAC are adequate for ATMAC. The test substance is photolytically stable in absence of a photosensitising agent. **EQC** Not applicable: no absorption above 290 nm in UV spectrum **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Photolytically stable **(US ISC)**

Readily biodegradable (yes/no)	**US ISC** yes **EQC** Yes **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Ready biodegradable The reliability factor of US ISC study is 1. Therefore, the study by US ISC should be considered for the environmental risk assessment at product authorization stage. In conclusion, ADBAC/BKC is ready biodegradable being the 10-day window criterion met (OECD 301B). On the other hand, the EQC study has a reliability factor of 2 because it cannot distinguish between the degradation of ADBAC/BKC and Propan-2-ol (solvent). If we follow the argument that Propan-2-ol is readily biodegradable and might contribute more to the oxygen consumption. This results in an overestimation of ADBAC/BKC, and the 14-day window criteria was not met (OECD 301D). **(US ISC)**
Inherent biodegradable (yes/no)	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Biodegradation in freshwater	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Biodegradation in seawater	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Non-extractable residues	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.

Distribution in water / sediment systems (active substance)	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Distribution in water / sediment systems (metabolites)	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.

Route and rate of degradation in soil

Mineralization (aerobic)	**US ISC** n.a. **EQC** 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)	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
DT_{50lab} (20°C, aerobic):	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
DT_{90lab} (20°C, aerobic):	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
DT_{50lab} (10°C, aerobic):	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.

DT_{50lab} (20°C, anaerobic):	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
degradation in the saturated zone:	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Field studies (state location, range or median with number of measurements)	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
DT_{50f}:	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
DT_{90f}:	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Anaerobic degradation	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Soil photolysis	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.

Non-extractable residues	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Soil accumulation and plateau concentration	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.

Adsorption/desorption

Ka , Kd	**US ISC** Ka = 6172 L/kg, Kd = 7173 L/kg (Sand) Ka = 5123 L/kg, Kd = 965401 L/kg (Sandy loam) Ka = 32429 L/kg, Kd = 65556 L/kg (Clay loam) Ka = 10797 L/kg, Kd = 14083 L/kg (Silt loam) **EQC** Ka = 630 L/kg, Kd = 2828 L/kg (Loam) Ka = 1543 L/kg, Kd = 6795 L/kg (Loamy Sand) Ka = 2032 L/kg, Kd = 2778 L/kg (Silt loam)
Ka_{oc} , Kd_{oc}	**US ISC** Ka_{oc} = 6171657 L/kg, Kd_{oc} = 7137310 L/kg (Sand) Ka_{oc} = 640389 L/kg, Kd_{oc} = 12067457 L/kg (Sandy loam) Ka_{oc} = 1663039 L/kg, Kd_{oc} = 84900622 L/kg (Clay loam) Ka_{oc} = 2159346 L/kg, Kd_{oc} = 2816590 L/kg (Siltyloam) K_{oc} mean: 2658607.75 L/kg **EQC** Ka_{oc} = 18251 L/kg, Kd_{oc} = 81971 L/kg (Loam) Ka_{oc} = 16679 L/kg, Kd_{oc} = 73459 L/kg (Loamy Sand) Ka_{oc} = 812943 L/kg, Kd_{oc} = 1111200 L/kg (Silty loam) K_{oc} mean: 282624.3 L/kg (only 3 soils were used)
pH dependence (yes / no) (if yes type of dependence)	**US ISC:** No **EQC:** No **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Based on the conclusion of the Ad-hoc follow up on ATMAC/TMAC (PT 8) (opinion of the ENV WG on the K_{oc} to be used for the risk assessment) the k_{oc} value to be used for risk assessment is the mean K_{oc} from the both studies available. The K_{oc} value is 1640329 L/Kg.

Fate and behaviour in air

Direct photolysis in air	**US ISC** Atmospheric t½ = 8.3 hr (AOPWIN) OH-radicals concentration of 0.5 x10^6 [molec.cm^{-3}] and 24 hours **EQC** Atmospheric t½ = 8.3 hr (AOPWIN) OH-radicals concentration of 0.5 x10^6 [molec.cm^{-3}] and 24 hours **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Atmospheric t½ = 8.3 hr **(US ISC; EQC)**
Quantum yield of direct photolysis	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** not specified
Photo-oxidative degradation in air	**US ISC** Latitude: ..... Season: ..... **EQC** Latitude: ..... Season: ..... **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Volatilization	**US ISC** Not volatile **EQC** Not volatile **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Not volatile **(US ISC; EQC)**

Reference value for groundwater

According to BPR Annex VI, point 68	**US ISC** 0.1 µg/L **EQC** 0.1 µg/L **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 0.1 µg/L **(US ISC; EQC)**

Monitoring data, if available

Soil (indicate location and type of study)	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Surface water (indicate location and type of study)	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Ground water (indicate location and type of study)	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Air (indicate location and type of study)	**US ISC** n.a. **EQC** n.a. **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			
Acute toxicity **US ISC**	96 hours	Mortality	LC_{50} = 0.28 mg a.i./L, (mean measured conc.)
EQC	96 hours	Mortality	Supportive information **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** 96h LC_{50} = 0.28 mg a.i./L **(US ISC)**
Chronic toxicity **US ISC**	34 days	Survival	NOEC = 0.0322 mg a.i./L (mean measured conc.) EC_{10} = not available
EQC			No data **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** 34d NOEC = 0.0322 mg a.i./L **(US ISC)**

Invertebrates			
Acute toxicity **US ISC**	48 hours	Immobilization	EC_{50} =0.0058 mg a.i./L, (mean measured conc., rated 2)
EQC	48 hours	Immobilization	EC_{50} =0.016 mg a.i./L, (measured conc., rated 1) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** 48h EC_{50} =0.016 mg a.i./L **(EQC)**

Chronic toxiciy (aquatic) **US ISC**	21 days	mortality, reproduction, growth	NOEC = 0.00415 mg a.i./L (mean measured conc.) EC_{10} = not available
EQC	21 days	mortality, reproduction	NOEC = 0.025 mg a.i./L EC_{10} (repr) = 0.024 mg a.s./L (nominal, measured in extra vessel at 0.5 mg a.s./L) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** NOEC = 0.00415 mg a.i./L **(US ISC)**
Chronic toxicity(sediment) **US ISC**	28 days	Emergence	NOEC= 520 mg/kg dw (357 mg/kg ww) EC_{10} = not available
EQC			No data **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** 28d NOEC= 520 mg/kg dw (357 mg/kg ww) **(US ISC)**

Algae			
US ISC	72 hours	Growth rate	E_rC_{50} =0.049 mg a.s./L E_rC_{10} = 0.009 mg a.s./L (rated 1)
EQC	72 hours	Growth rate	E_rC_{50} =0.026 mg a.s./L NOE_rC = 0.0025 mg a.i./L E_rC_{10} = 0.0057 mg a.s./L (rated 2)
			CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION E_rC_{50} =0.049 mg a.s./L E_rC_{10} = 0.009 mg a.s./L **(US ISC)**
Aquatic Plants			
US ISC	7 days	Growth inhibition (frond number)	E_rC_{50} =0.25 mg a.s./L
EQC			No data
			CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION E_rC_{50} =0.25 mg a.s./L **(US ISC)**
Microorganisms			
US ISC	3 hours	Respiration inhibition	EC_{50} = 7.75 mg a.s./L NOE_rC = 1.6 mg a.i./L EC_{20} = 3.4 mg a.s./l
EQC	30 min	Respiration inhibition	EC_{50} = 11 mg a.i./L NOEC = 3.52 mg a.i./L EC_{10} = 4 mg a.i./L
			CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION EC_{50} = 7.75 mg a.s./L NOE_rC = 1.6 mg a.i./L **(US ISC)**

Effects on earthworms or other soil non-target organisms

Acute toxicity to (*Eisenia foetida)*	**US ISC** LC_{50} = 7070 mg a.s./kg dw NOEC = 953 mg a.s./kg dw **EQC** LC_{50} >517 mg a.i./kg dw NOEC ≥517 mg a.s./kg dw **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** LC_{50} = 7070 mg a.s./kg dw NOEC = 953 mg a.s./kg dw
Short-term toxicity to plants	**US ISC** EC_{50}= 277 mg a.s./kg dw (*Brassica alba*, most sensitive species) **EQC** EC_{50}= 309 mg a.s./kg dw (*T. pratense*, most sensitive species) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** EC_{50}= 277 mg a.s./kg dw (*Brassica alba*, most sensitive species) **(US ISC)**
Reproductive toxicity to earthworms (*Eisenia foetida)*	**US ISC** No data **EQC** No data

Effects on soil micro-organisms

Nitrogen mineralization	**US ISC** 28d EC_{50} > 1000 mg a.i./kg dw 28d NOEC ≥ 1000 mg a.i./kg dw **EQC** 28d EC_{50} = 153 mg a.i./kg dw 28d EC_{10} = 83 mg a.i./kg dw **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** 28d EC_{50} = 153 mg a.i./kg dw 28d EC_{10} = 83 mg a.i./kg dw **(EQC)**

Carbon mineralization	**US ISC** 28d EC_{50} > 1000 mg a.i./kg dw 28d NOEC ≥ 1000 mg a.i./kg dw **EQC** No data **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** The nitrogen mineralization would also cover the carbon mineralization. 28d EC_{50} = 153 mg a.i./kg dw 28d EC_{10} = 83 mg a.i./kg dw **(EQC)**

Effects on terrestrial vertebrates

Acute toxicity to mammals	**US ISC** 344 mg/kg bw **EQC** 358 mg **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 350 mg/kg bw **(US ISC; EQC)**
Subchronic toxicity to mammals	**US ISC** NOEC 400 mg a.s. /kg food (52 weeks, dog) **EQC** NOEC =1000 mg a.s./kg food (2 year, rat) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** NOEC 400 mg a.s. /kg food (52 weeks, dog) **(US ISC)**
Acute toxicity to birds	**US ISC** LD_{50} = 164 mg a.s./kg bw **EQC** No data **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** LD_{50} = 164 mg a.s./kg bw **(US ISC)**
Dietary toxicity to birds	**US ISC** LC_{50} = >2463 mg a.s. /kg food (Mallard duck) LC_{50} = >3813 mg a.s. /kg food (Northern bobwhite quail) **EQC** No data **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** LC_{50} = >2463 mg a.s. /kg food (Mallard duck) **(US ISC)**

Reproductive toxicity to birds	**US ISC** No data **EQC** No data

Effects on honeybees

Acute oral toxicity	**US ISC** No data available. Not required **EQC** No data available. Not required
Acute contact toxicity	**US ISC** No data available. Not required **EQC** No data available. Not required

Effects on other beneficial arthropods

Acute oral toxicity	**US ISC** No data available. Not required **EQC** No data available. Not required
Acute contact toxicity	**US ISC** No data available. Not required **EQC** No data available. Not required
Acute toxicity to ……..	**US ISC** No data available. Not required **EQC** No data available. Not required

Bioconcentration

Bioconcentration factor (BCF)	**US ISC** $BCF_{fish\ whole\ body}$ = 79 L/kg $BCF_{edible\ tissues}$ = 33 L/kg $BCF_{non\ edible\ tissues}$ = 160 L/kg **EQC** No data **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** $BCF_{fish\ whole\ body}$ = 79 L/kg **(US ISC)**
Depuration time (DT_{50})	**US ISC** 14-21 d (non-edible tissues) **EQC** No data **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** DT_{50} = 14-21 d (non-edible tissues) **(US ISC)**

Depuration time (DT_{90})	**US ISC** >21d (edible tissues and whole body) **EQC** No data **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** DT_{90} = >21d (edible tissues and whole body) **(US ISC)**
Level of metabolites (%) in organisms accounting for > 10 % of residues	**US ISC** No data available **EQC** No data

Chapter 6: Other End Points

Appendix II: List of Intended Uses/ US ISC

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: C_{12-16}-ADBAC 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. Under PT 8 C_{12-16}-ADBAC acts as a fungistatic and an insecticide, by control of wood destroying organisms and against wood discolouring moulds and fungi. The representative product BQ-25 is an aqueous solution containing 25 % of C_{12-16}-ADBAC. Objects to be protected: preventive protection of wood and constructional timbers in Hazard classes 1 to 4A according to ISO draft standard USERS: Industrial/professional	BQ-25	<u>Wood destroying basidiomycetes</u> Coniophora puteana/ Coniophora spec Coriolus versicolor Gloephyllum trabeum Poria vaillantii / Poria spec. Fomes spec. Trametes spec <u>Wood staining molds</u> Aureobasidium pullulans Sclerophoma pityopila Ophistostoma piliferum Aspergillus niger Aspergillus terreus Chaetomium globosum Paecilomyces variotii Penicillium funicolosum Trichoderma viridae <u>Wood boring insects</u> Hylotrupes bajulus Anobium punctatum Lyctus brunneus termites	Aqueous solution under PT8	25% $C_{12\ 16}$-ADBAC	Dipping and vacuum pressure processes	Number and timing of applications depends on application technique, wood species, moisture and hazard class.	--	-- The requirements for the final concentration of C_{12-16}-ADBAC vary between 0.4% and 2.0%.	--	-- An uptake of approximately 2.0 kg/m^3 should be achieved by these application methods in order to ensure the protection level for the different use classes required	Used for preventive protection of wood and constructional timbers in areas with moderate or subtropical climate. However, tunderstand the efficacy of the quaternary amine (quat) biocides in the wood preservation market, it is necessary to recognized that they are always used in formulations in combination with other active substances. Efficacy studies with quats alone require considerably higher concentrations than actually used in these formulations

Appendix II: List of Intended Uses/ EQC

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: Under PT 8 C_{12-16}-BKC acts as fungicidal/fungistatic, by control a wood rot fungi, like Brown-rot and/or White-rot and/or Sapstain. Adsorption of the +charged compound on the −charged cell wall, diffusion of the substance trough the cell wall, binding to the cytoplasmic membrane, disruption of the cytoplasmic membrane, release of K+ ions and other cytoplasmic constituents, precipitation of cell content and the death of the cell. The representative product BKC-50 is an water-based concentrate containing 50% w/w C_{12-16}-BKC. Objects to be protected: Wood preservative for Hazard Class 1 to 4A USERS: Industrial/professional	BKC-50	<u>Wood rot fungi</u> *Brown-rot* *White-rot* <u>Sapstain</u> *Gloephyllum trabeum* *Coniophora puteana,* *Poria placenta* *Serpula lacrymans* *Coriolus versicolor* *Donkioporia expansa* *Sapstain* *White mycelium*	Water-based concentrate under PT8	50% w/w C_{12-16}-BKC	Dipping in dipping bath and spraying in a closed tunnel.	Number and timing of applications depends on application technique, wood species, moisture and hazard class	--	-- BKC-50 is typically diluted 5-10 fold with water. This means that the typically applied in-use concentration is 5-10% C_{12-16}-BKC in water.	--	15-30 g a.s./m^2	Quaternary ammonium compounds are also used in combination with other active substances in wood preservation. One common used combination is with copper, but also the combination with triazole is possible. Combinations with insecticides are also on the market.

Appendix III: List of studies

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

US ISC

Document IIIA

Section No. / Reference No.	**Author**	**Year**	**Title** **Source (where different from company)** **Report No.** **GLP** **(Un)Published** *Non-Key Studies are italicized.*	**Data Protection Claimed (Yes/No)**	**Owner**
Doc IIIA 3.1.1 – Melting point	Fischer, A.	2001	Determination of the melting point of Barquat MB AS in accordance with OECD-Guideline 102. Clariant GmbH, Frankfurt, Germany. Report No. B 013/2001 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 3.1.3 – Density	Fischer, A.	2001	Determination of the relative density of Barquat MBAS in accordance with OECD-Guideline 109. Clariant GmbH, Frankfurt, Germany. Report No. B 011/2001 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 3.2 – Vapour pressure	Franke, J.	2001	Barquat MB AS, KP01/03 - Vapour pressure. Siemens Axiva GmbH & Co. KG for Clariant GmbH, Frankfurt, Germany. Report No. 20010308.01 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 3.4.1 – UV/Vis	Sydney, P.	2006	N-Alkyl(C12-C16)-N,N-dimethyl-Nbenzylammonium chloride (ADBAC) (Supplied as Barquat MB 80): Ultraviolet/visible absorption spectrum. Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England. Report No. ADB0030/062227 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 3.4.2 – IR 3.4.3 – NMR	Petrovic, P.	2001	Characterization of the structure of Barquat MB AS. Clariant GmbH, Frankfurt, Germany. Report No. B 016/2001	Yes	ADBAC ISC

Section No. / Reference No.	Author	Year	Title Source (where different from company) Report No. GLP (Un)Published *Non-Key Studies are italicized.*	Data Protection Claimed (Yes/No)	Owner
			GLP Unpublished		
Doc IIIA 3.4.4 – MS	Young, S.	2004	N-Alkyl(C12-16)-N,N-dimethyl-Nbenzylammonium chloride (ADBAC): Mass spectrum. Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England. Report No. ADB/022 042073 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 3.5 – Solubility in water	Fischer, A.	2001	Determination of the water solubility of Barquat MB AS. Clariant GmbH, Frankfurt, Germany. Report No. B015/2001 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 3.7(1) – Solubility in organic solvents	Young, S.	2004	N-Alkyl(C12-16)-N,N-dimethyl-Nbenzylammonium chloride (ADBAC): Solubility in ethanol and isopropanol. Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England. Report No. ADB/021 042021 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 3.7(2) – Solubility in organic solvents	Young, S.	2004	N-Alkyl(C12-16)-N,N-dimethyl-Nbenzylammonium chloride (ADBAC): Solubility in octanol. Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England. Report No. ADB/020 042020 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 3.8 – Stability in organic solvents	Young, S.	2004	N-Alkyl(C12-16)-N,N-dimethyl-Nbenzylammonium chloride (ADBAC): Stability in ethanol and isopropanol. Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England. Report No. ADB/025 042266 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 3.9 – Partition Coefficient	Nixon, W.B.	1998	DDAC octanol/water partition coefficient test. Letter report dated August 14, 1998;	Yes	ADBAC ISC

Section No. / Reference No.	**Author**	**Year**	**Title** **Source (where different from company)** **Report No.** **GLP** **(Un)Published** *Non-Key Studies are italicized.*	**Data Protection Claimed (Yes/No)**	**Owner**
			from Wildlife International Ltd., Easton, MD, USA. GLP status: not applicable Unpublished		
Doc IIIA 3.10 – Thermal stability, identity of relevant breakdown product	Keipert, W.	2001	Determination of the thermal stability and stability in air of Barquat MB AS in accordance with OECD Guideline 113. Clariant GmbH, Frankfurt, Germany. Report No. B 017/2001 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 3.11(1) – Flammability (solids) & Autoflammability	Keipert, W.	2001	Determination of the relative self-ignition temperature of Barquat MB AS in accordance with ECGuideline A.16. Clariant GmbH, Frankfurt, Germany. Report No. B 019/2001 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 3.11(2) – Flammability (solids) & Autoflammability	Keipert, W.	2001	Determination of the flammability of Barquat MB AS in accordance with EEC-Guideline A.10. Clariant GmbH, Frankfurt, Germany. Report No. B 018/2001 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 3.13 – Surface tension	Schneider, S.	2001	Determination of the surface tension of an aqueous solution (1 g/L) of Barquat MB AS in accordance with OECD-Guideline 115 [and according to EEC-Guideline A.5]. Clariant GmbH, Germany. Report No. B 082/2001 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 3.15 – Explosive properties	Keipert, W.	2001	Determination of the explosive properties of Barquat MB AS in accordance with EEC-Guideline A.14. Clariant GmbH, Frankfurt, Germany. Report No. B 020/2001 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 4.1(1)	Wells, D.F.	1996	Chemical characterization of alkyl dimethyl benzyl ammonium chloride	Yes	ADBAC ISC

Section No. / Reference No.	Author	Year	Title Source (where different from company) Report No. GLP (Un)Published *Non-Key Studies are italicized.*	Data Protection Claimed (Yes/No)	Owner
– Analytical methods for purity/impurity			(ADBAC, Lot 7293K). Springborn Laboratories, Inc., Wareham, MA, USA. Report No. 95-8-6025 GLP Unpublished		
Doc IIIA 4.1(2) – Analytical methods for purity/impurity (new submission)	Ranft V. and Kurz M.	2007	Determination of quaternary ammonium compounds and related quaternary impurities by HPLC-ELSD. Lonza AG, Basal, Switzerland. Study No.CSPE-44/BS-07-70 Non-GLP (ISO 9001 compliant) Unpublished	Yes	ADBAC ISC
Doc IIIA 4.1(3) – Analytical methods for purity/impurity (new submission 2013 March)	Veliath-Houston, L.	2013	Method Validation for the Determination of Sodium Chloride and Total Amines in Alkyldimethylbenzylammonium Chloride. Product Safety Labs, Dayton, NJ, USA. Study No. 35527 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 4.2 (a) – Analytical methods for determination of residues in soil	Brewin, S.	2003	Alkyldimethylbenzylammonium chloride (ADBAC: CAS RN 68424-85-1): Validation of methodology for the determination of residues in soil. Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England. Report No. ADB/016 033181 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 4.2 (c) – Analytical methods for determination of residues in drinking water	Brewin, S.	2003	Alkyldimethylbenzylammonium chloride (ADBAC: CAS RN 68424-85-1): Validation of methodology for the determination of residues in drinking, ground and surface water. Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England. Report No. ADB/017 033171 GLP Unpublished	Yes	ADBAC ISC

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Doc IIIA 5.1.3 – Effects on Target Organisms	Linfield, W.M.	1969	Chapter 2: Straight-chain alkylammonium compounds. In E. Jungermann (Ed.), "Cationic Surfactants". Marcel Dekker: New York, NY, USA, pp 9-70. GLP status: not applicable Published	No	n/a
	Wazny, J. and R. Rudniewski	1997	Fungitoxic effect of the quaternary ammonium compounds wood preservatives against *Basidiomycetes* by using agar-plate and agar-block methods. International Research Group on Wood Preservation. Document No. IRG/WP/96-30118. GLP Status: not applicable Published	No	n/a
Doc IIIA 6.1.1 – Acute oral toxicity	Wallace, J.M.	1975	Acute oral LD50 toxicity study. Bio- Toxicology Laboratories, Inc., Moorestown, NJ, USA. Non-GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.1.2 – Acute dermal tox.	Levenstein, I.	1977	Barquat MB-80: Dermal LD50. Leberco Laboratories, Roselle Park, NJ, USA. Study No. 73130 Non-GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.1.2 – Acute dermal tox.	*De Azevedo, J.P.*	*1971*	*Report on dermal toxicity in rabbits using Barquat MS-100.* *Wells Laboratories Inc., Jersey City NJ, USA.* *Report No. 0709* *Non-GLP* *Unpublished*	*Yes*	*ADBAC ISC*
Doc IIIA 6.1.4(1) – Skin irritation	Wallace, J.M.	1975	Toxicity studies: Primary irritation study, Federal Hazardous Substances Labeling Act - Barquat MB-80. Bio-Toxicology Laboratories, Inc., Moorestown, NJ, USA. Non-GLP Unpublished	Yes	ADBAC ISC

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Doc IIIA 6.1.4 – Skin irritation	*De Azevedo, J.P.*	*1970*	*Report on primary skin irritation studies in rabbits using Barquat MS-100.* *Wells Laboratories Inc., Jersey City, NJ, USA.* *Report No. 0712* *Non-GLP* *Unpublished*	*Yes*	*ADBAC ISC*
Doc IIIA 6.1.4(2) – Eye irritation	Wallace, J.M.	1975	Toxicity studies: Primary irritation study, Federal Hazardous Substances Labeling Act - Barquat MB-80. Bio-Toxicology Laboratories, Inc., Moorestown, NJ, USA. Non-GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.1.5(1) – Skin sensitisation	Kreuzmann, J.J.	1988	Photoallergy study in guinea pigs with alkyldimethyl benzyl ammonium chloride (ADBAC). Hill Top Biolabs Inc., Miamiville, OH, USA. Report No. 88-3226-21 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.1.5(2) – Skin sensitisation	Clement, C.	1992	BARDAC-22: Test to evaluate the sensitising potential by topical applications in the guinea pig. Hazleton-Institute Français de Toxicologie, L'Arbresle, France. Report No. 704323 RE GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.1.5(3) – Skin sensitisation	Durando, J.	2005	Barquat MB 80: Dermal sensitization study in guinea pigs (Buehler method). Product Safety Laboratories, Dayton, NJ, USA. Study No. 17426 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.2(1) – Toxicokinetics, Metabolism and Distribution	Salim, S.	1989	Absorption, distribution, metabolism and excretion studies of alkyl dimethyl benzyl ammonium chloride (ADBAC) in the rat. Biological Test Center, Irvine, CA, USA. Study No. P01359	Yes	ADBAC ISC

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			GLP Unpublished		
Doc IIIA 6.2(2) – Toxicokinetics, Metabolism and Distribution	Roper, C. and Toner, F.	2006	The In Vitro Percutaneous Absorption of Radiolabelled Alkyl(C12-C16)dimethylbenzylammonium Chloride (ADBAC; CAS RN 68424-85-1) in Two Test Preparations Through Human Skin. Charles River Laboratories, Tranent, Edinburgh, UK. Report No. 25982 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.3.2 – Repeated dose toxicity (dermal)	*Luy, T.*	*1972*	*Twenty day subacute dermal toxicity testing on rabbits using Barquat MS-100.* *Wells Laboratories, Inc. Jersey City, NJ, USA* *Study No. E-594* *Non-GLP* *Unpublished*	*Yes*	*ADBAC ISC*
Doc IIIA 6.4.1(1) – Subchronic oral toxicity test; 90-day, rat	Van Miller, J.P. and E.V. Weaver	1988	Ninety-day dietary toxicity study with alkyl dimethyl benzyl ammonium chloride (ADBAC) in rats. Bushy Run Research Center, Export, PA, USA. Report No. 51-503 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.4.1(2) – Subchronic oral toxicity test; 8-week; dog	Goldenthal, E.I.	1994; 1993; and 1993	Evaluation of ADBAC in an eight week dietary toxicity study in dogs. International Research and Development Corporation, Mattawan, MI, USA. Project No. 638-003 GLP Unpublished; Evaluation of ADBAC in a two-week gavage study in dogs. Project No. 638-002 GLP Unpublished; and Evaluation of ADBAC in a two-week palatability study in dogs.	Yes	ADBAC ISC

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			Project No. 638-001 GLP Unpublished		
Doc IIIA 6.4.1(3) – Subchronic oral toxicity test; 90-Day; mouse	Van Miller, J.P. and Weaver, E.V.	1988	Ninety-day dietary dose range-finding study with alkyl dimethyl benzyl ammonium chloride (ADBAC) in mice. Bushy Run Research Center, Export, PA, USA. Report No. 51-504 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.4.2 – Subchronic dermal toxicity test; rat	Gill, M.W. and Wagner, C.L	1990	Ninety-day subchronic dermal toxicity study with alkyl dimethyl benzyl ammonium chloride (ADBAC) in rats. Bushy Run Research Center, Export, PA, USA. Report No. 52-623 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.5(1) – Chronic toxicity; dog	Goldenthal, E.I.	1994	Evaluation of ADBAC in a one-year chronic dietary toxicity study in dogs. International Research and Development Corp, Mattawan, MI, USA. Project No. 638-004 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.5(2) – Chronic toxicity; rat	Gill, M.W., Hermansky, S.J. and C.L. Wagner	1991	Chronic dietary toxicity/oncogenicity study with alkyl dimethyl benzyl ammonium chloride(ADBAC) in rats. Bushy Run Research Center, Export, PA, USA. Report No. 53-543 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.6.1 – In-vitro gene mutation study in bacteria	Thompson, P.W.	2001	LZ1392 (Alkyl(C10-C18) (Dimethylbenzylammoniumchloride): Reverse mutation assay "Ames Test" using *Salmonella typhimurium*. Safepharm Laboratories Ltd., Derby, UK. Project No. 102/367 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.6.2 – In-vitro	Durward, R.	2001	LZ1392 (Alkyl (C10-C18) (Dimethylbenzylammoniumchloride):	Yes	ADBAC ISC

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cytogenicity study in mammalian cells			Chromosomal aberrations assay in human lymphocytes *in vitro*. Safepharm Laboratories Ltd., Derby, UK. Project No. 102/366 GLP Unpublished		
Doc IIIA 6.6.3 – In-vitro gene mutation assay in mammalian cells	Young, R.R.	1989	Mutagenicity test on alkyl dimethyl benzyl ammonium chloride (ADBAC) in the CHO/HGPRT forward mutation assay. Hazleton Laboratories America, Inc., Kensington, MD, USA. Study No. 10238-0-435 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.6.4 – In-vivo mutagenicity study (micronucleus test)	Kallesen, T.	1985	Assessment of the mutagenic activity of Hyamine 3500 in the mouse micronucleus test. The Scantox Laboratories Ltd., Skensved, Denmark. Project No. 10753 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.7(1) – Carcinogenicity study; mouse	Gill, M.W., Hermansky, S.J. and C.L. Wagner	1991	Chronic dietary oncogenicity study with alkyldimethylbenzylammonium chloride in mice. Union Carbide, Bushy Run Research Center, Export, PA, USA. Report No. 53-515 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.7(2) – Carcinogenicity study; rat	Gill, M.W., Hermansky, S.J. and C.L. Wagner	1991	Chronic dietary toxicity/oncogenicity study with alkyl dimethyl benzyl ammonium chloride (ADBAC) in rats. Bushy Run Research Center, Export, PA, USA. Report No. 53-543 GLP Unpublished [REPORT FILED UNDER ENDPOINT 6.5]	Yes	ADBAC ISC
Doc IIIA 6.8.1(1) – Teratogenicity test	Neeper-Bradley, T.L.	1992	Developmental toxicity evaluation II of alkyldimethylbenzylammonium chloride (ADBAC) administered by gavage to CD rats.	Yes	ADBAC ISC

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			Union Carbide, Bushy Run Research Center, Export, PA, USA. Project No. 91N0031 GLP Unpublished		
Doc IIIA 6.8.1(2) – Teratogenicity test	Neeper-Bradley, T.L. and M.F. Kubena	1992	Developmental toxicity evaluation of alkyl dimethyl benzyl ammonium chloride (ADBAC) administered by gavage to New Zealand white rabbits. Union Carbide, Bushy Run Research Center, Export, PA, USA. Project No. 91N0032 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.8.2 – Two generations reproduction study	Neeper-Bradley, T.L.	1990	Two-generation reproduction study in Sprague-Dawley (CD) rats with alkyl dimethyl benzyl ammonium chloride (ADBAC) administered in the diet. Union Carbide, Bushy Run Research Center, Export, PA, USA. Report No. 52-524 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 6.11 – Studies on other routes of administration (parenteral routes) – Acute IV study in rats	*Larson, P.S.*	*1958*	*Acute intravenous toxicity of Hyamine 3500 to rats.* *Non-GLP* *Unpublished*	*Yes*	*ADBAC ISC*
Doc IIIA 7.1.1.1.1 – Hydrolysis	Carpenter, M. and M. Fennessey	1988	Hydrolysis of ADBAC as a function of pH at 25 ºC. Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, USA. Report No. 35712 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.1.1.1.2 – Phototransformation in water	Carpenter, M. and M. Fennessey	1988	Determination of the photolysis rate of ADBAC in pH 7 buffered solution at 25ºC. Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, USA. Report No. 35713 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA	Bazzon, M and	2002	Biotic degradation biodegradability	Yes	ADBAC ISC

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7.1.1.2.1(1) – Ready Biodegradability	F. Deschamps		evaluation on aqueous medium ultimate aerobia of the referenced compounds, CATIGENE T 50. INERIS, Vert-le-petit, France. Study No. 506223 Non-GLP (Study conducted under the principles of GLP but not in full compliance – well documented study) Unpublished		
Doc IIIA 7.1.1.2.1(2) – Ready Biodegradability	*Hirschen, M., Ziemer, M. and D. Seifert.*	*1997*	*Prüfung der biologischen Abbaubarkeit (ready biodegradability) gemäß OECD-Richtlinie 301A (DOC Die-Away Test).* *Clariant GmbH, Frankfurt, Germany.* *Report No. D0457* *Non-GLP* *Unpublished*	*Yes*	*ADBAC ISC*
Doc IIIA 7.1.1.2.1(3) – Ready Biodegradability	*Corby, J.E.*	*1992*	*Semi-continuous activated sludge (SCAS) removability test - Hyamine 3500-80.* *Roy F. Weston, Inc., Lionville, PA, USA.* *No. 91-065* *GLP* *Unpublished*	*Yes*	*ADBAC ISC*
Doc IIIA 7.1.1.2.1(4) – Ready Biodegradability	*Corby, J.E.*	*1992*	*CO2 Production test - Hyamine3500-80.* *Roy F. Weston, Inc., Lionville, PA, USA.* *Report No.91-066* *GLP* *Unpublished*	*Yes*	*ADBAC ISC*
Doc IIIA 7.1.1.2.1(5) – Ready Biodegradability	Van Dievoet, F. and V. Bouillon	2005	Biodegradability test report according to OECD 301 B – Modified. BfB Oil Research S.A. Report No. ST49132.01.01 Non-GLP (conducted in compliance with ISO 17025) Unpublished	Yes	ADBAC ISC
Doc IIIA 7.1.2.1.1(1) – Aerobic biodegradation	Schaefer, E.C.	2001	Didecyldimethylammoniumchloride (DDAC): Die away in Activated Sludge. Wildlife International Inc., Easton, MA, USA. Project No. 289E-112 GLP Unpublished	Yes	ADBAC ISC

Section No. / Reference No.	Author	Year	Title Source (where different from company) Report No. GLP (Un)Published *Non-Key Studies are italicized.*	Data Protection Claimed (Yes/No)	Owner
Other Non-Key Biodegradability Reports Included in This Submission	*Daly, D. and W. Cranor*	*1989*	*Anaerobic aquatic metabolism of alkyl dimethyl benzyl ammonium chloride.* *Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO,* *USA. Report No. 35714* *GLP* *Unpublished*	*Yes*	*ADBAC ISC*
	Daly, D. and W. Cranor	*1988*	*Aerobic aquatic metabolism of alkyl dimethyl benzyl ammonium chloride.* *Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, USA.* *Report No. 35715* *GLP* *Unpublished*	*Yes*	*ADBAC ISC*
	de Vette, H.Q.M. and J.G. van Austen (2001) A water/	*2001*	*A water/sediment degradation study of alkyldimethylbenzyl ammonium chloride (ADBAC) using [14C]ADBAC.* *TNO Chemistry, Department of Environmental Toxicology, Delft, The Netherlands.* *Report No. V99.1172* *GLP* *Unpublished*	*Yes*	*ADBAC ISC*
	Fisher, J.D.	*1971*	*Dissipation study of Hyamine 3500 in soil and its effects on microbial activity.* *Rohm & Haas Company, Philadelphia, PE, USA.* *Report No. 6* *Non-GLP* *Unpublished*	*Yes*	*ADBAC ISC*
Doc IIIA 7.2.3.1 – Adsorption and desorption	Daly, D. and W. Cranor	1988	Soil/sediment adsorption desorption of alkyl dimethyl ammonium chloride. Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, USA. Report No. 35716 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.4.1.1(1)– Acute toxicity to fish *(Lepomis macrochirus*)	Pate, H.O. and D.O. McIntyre	1991	Daily static-renewal acute 96-hour toxicity test of alkyl dimethyl benzyl ammonium chloride (ADBAC) to bluegill sunfish. Battelle Columbus Division, Columbus, OH, USA.	Yes	ADBAC ISC

Section No. / Reference No.	**Author**	**Year**	**Title** **Source (where different from company)** **Report No.** **GLP** **(Un)Published** *Non-Key Studies are italicized.*	**Data Protection Claimed (Yes/No)**	**Owner**
			Study No. SC890050 GLP Unpublished		
Doc IIIA 7.4.1.1(2)– Acute toxicity to fish (*Pimephales promelas*)	Sword, M.C. and L. Stuerman	1994	Static-renewal acute toxicity of alkyl dimethyl benzyl ammonium chloride (ADBAC) to fathead minnow (*Pimephales promelas*). ABC Laboratories, Columbia, MO, USA. Report No. 41237 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.4.1.1(3)– Acute toxicity to fish (*Pimephales promelas*)	Sword, M.C. and L. Stuerman	1994	Static-renewal acute toxicity of alkyl dimethyl benzyl ammonium chloride (ADBAC) to fathead minnow (*Pimephales promelas*) in dilution water amended with 10 mg/L humic acid. ABC Laboratories, Columbia, MO, USA. Report No. 41236 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.4.1.1(4)– Acute toxicity to fish (*Pimephales promelas*)	Sword, M.C. and L. Stuerman	1994	Static-renewal acute toxicity of alkyl dimethyl benzyl ammonium chloride (ADBAC) to fathead minnow (*Pimephales promelas*) in dilution water amended with 20 mg/L humic acid. ABC Laboratories, Columbia, MO, USA. Report No. 41235 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.4.1.1(5)– Acute toxicity to fish (*Oncorhynchus mykiss*)	Pate, H.O. an D.O. McIntyre	1991	Daily static-renewal acute 96-hour toxicity test of alkyl dimethyl benzyl ammonium chloride (ADBAC) to rainbow trout. Battelle Columbus Division, Columbus, OH, USA. Study No. SC890051 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.4.1.1– Acute toxicity to fish (Cyprinodon variegatus)	*Sved, D.W., Swigert, J.P. and G.J. Smith*	*1992*	*A 96-hour static-renewal acute toxicity test with alkyl dimethyl benzyl ammonium chloride (ADBAC) in the sheepshead minnow (Cyprinodon variegatus).* *Wildlife International Ltd., Easton, MD, USA.*	*Yes*	*ADBAC ISC*

Section No. / Reference No.	Author	Year	Title Source (where different from company) Report No. GLP (Un)Published *Non-Key Studies are italicized.*	Data Protection Claimed (Yes/No)	Owner
			Project No. 350A-102 *GLP* *Unpublished*		
Doc IIIA 7.4.1.1– Acute toxicity to fish (Lepomis macrochirus)	*Bevier Hasbruck Sleight III*	*1971*	*Acute toxicity of 1971 Hyamine 3500 to bluegill (Lepomis macrochirus).* *Bionomics Inc., Wareham, MA, USA.* *Report No. 350A-102* *Non-GLP* *Unpublished*	*Yes*	*ADBAC ISC*
Doc IIIA 7.4.1.1– Acute toxicity to fish	*Binns, R. and G.C. Clark*	*1969*	*The acute toxicity to fish of Hyamine 3500.* *Huntingdon Research Centre Ltd., Huntingdon, Cambridgeshire, England.* *Report No. 2938/69/364* *Non-GLP* *Unpublished*	*Yes*	*ADBAC ISC*
Doc IIIA 7.4.1.2– Acute toxicity to invertebrates (*Daphnia magna*)	Pate, H.O. and D.O. McIntyre	1991	Daily static-renewal acute 48-hour toxicity test of alkyl dimethyl benzyl ammonium chloride (ADBAC) to *Daphnia magna*. Battelle Columbus Division, Columbus, OH, USA. Study No. SC890052 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.4.1.2(1) – Acute toxicity tin invertebrates (*Daphnia magna*)	Jenkins, C. A.	2007	N-Alkyl(C_{12}-C_{16})-N,N-Dimethyl-N-Benzylammonium Chloride (ADBAC) (Supplied as Barquat DM 50): Acute Toxicity to *Daphnia magna*. Huntingdon Life Sciences, Ltd., Huntingdon, Cambridgeshire, England. Report No. ADB 0037/072526 GLP Unpublished	Yes	ADBAC ISC
DOC IIIA 7.4.1.2– Acute toxicity to invertebrates (Mysidopsis bahia)	*Sved, D.W., Swigert, J.P. and G.J. Smith*	*1992*	*A 96-hour static-renewal acute toxicity test with alkyl dimethyl benzyl ammoniumchloride (ADBAC) in the saltwater mysid (Mysidopsis bahia).* *Wildlife International Ltd., Easton, MD, USA.* *Project No. 350A-101A* *GLP* *Unpublished*	*Yes*	*ADBAC ISC*

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Doc IIIA 7.4.1.2– Acute toxicity to invertebrates (Crassostrea virginica)	*Sved, D.W., Swigert, J.P. and G.J. Smith*	*1992*	*A 48-hour static acute toxicity test with alkyl dimethyl benzyl ammonium chloride (ADBAC) in embryo larvae of the eastern oyster (Crassostrea virginica).* *Wildlife International Ltd., Easton, MD, USA.* *Project No. 350A-103* *GLP* *Unpublished*	*Yes*	*ADBAC ISC*
Doc IIIA 7.4.1.3– Growth inhibition test on algae (Selenastrum capricornutum)	Mayer, P., Oldersma, H. and J.A. Schoonmade	2001	Determination of the effect of alkyldimethylbenzylammonium chloride (ADBAC) on the growth of fresh water green alga *Selenastrum capricornutum* (OECD Guideline No. 201and EU C.3). TNO Chemistry, Delft, The Netherlands. Report No. V99.1176 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.4.1.3– Growth inhibition test on algae (Skeletonema costatum)	*Desjardins, D., MacGregor, J.A. and H.O. Krueger*	*2005*	*A 96-hour toxicity test of alkyl dimethyl benzyl ammonium chloride (ADBAC; 40% C12, 50% C14, 10% C16; CAS RN 68424-85-1) with the marine diatom Skeletonema costatum).* *Wildlife International Ltd., Easton, MD, USA.* *Project No. 350A-104* *GLP* *Unpublished*	*Yes*	*ADBAC ISC*
Doc IIIA 7.4.1.4(1) – Inhibition to microbiological activity	Mayer, P.H., Schoonmade J.A. and A.O. Hanstveit	2001	Screening of the effect of alkyldimethylbenzylammonium chloride on the respiration rate of activated cludge (OECD Guideline No. 209). TNO Nutrition and Food Research, Delft, The Netherlands. Report No. V99.1151 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.4.1.4(2) – Inhibition to microbiological activity	Corby, J.E.	1992	Determination of the acute toxicity of chemicals and wastewaters to aquatic microorganisms. Roy F. Weston, Inc., Lionville, PA, USA. Report No. 91-062 GLP Unpublished	Yes	ADBAC ISC

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Doc IIIA 7.4.1.4 – Inhibition to microbiological activity	*Janßen, U.*	*1989*	*Prüfung auf Bakterientoxizität n. OECD 209 Belebtschlamm Respirationshemmtest Journal-Nr: 8.680.* *Dr. U.Noack-Laboratorium Für Angewandte Biologie, Technologiezentrum, Hildesheim, Germany.* *Non-GLP* *Unpublished*	*Yes*	*ADBAC ISC*
Doc IIIA 7.4.2(1)– Bioconcentration	Fackler, P.H.	1989	Bioconcentration and elimination of 14Cresidues by bluegill (*Lepomis macrochirus*) exposed to alkyl dimethyl benzyl ammonium chloride (ADBAC). Springborn Life Sciences, Inc., Wareham, MA, USA. Report No. 89-1-2921 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.4.2(2)– Bioconcentration	Krzeminski, S.F.	1971	The accumulation and elimination of Hyamine 3500 residues by fish (bluegill). Bristol Research Laboratories, Philadelphia, PA, USA. Report No. 23-42 Non-GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.4.3.2– Fish reproduction and growth rate (*Pimphales promelas*)	McIntyre, D.O. and H.O. Pate	1992	Daily static-renewal early life stage toxicity test of alkyl dimethyl benzyl ammonium chloride (ADBAC) to fathead minnows. Battelle Columbus Operations, Columbus, OH, USA. Study No. SC890057 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.4.3.4 – Invertebrate reproduction and growth rate (*Daphnia magna*)	McIntyre, D.O. and H.O. Pate	1992	Daily static-renewal chronic 21-day toxicity test of alkyl dimethyl benzyl ammonium chloride (ADBAC) to *Daphnia magna*. Battelle Columbus Operations, Columbus, OH, USA. Study No.SC890056 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.4.3.5.1– Effects	England, D.C. and T. Leak	1995	Chronic toxicity of sediment-incorporated ADBAC to *Chironomus tentans*.	Yes	ADBAC ISC

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on sediment dwelling organisms (*Chironomus tentans*)			ABC Laboratories, Inc., Columbia, MO, USA. Report No. 41004 GLP Unpublished		
Doc IIIA 7.4.3.5.2 -- Aquatic plant toxicity	Desjardins, D., J.A. McGregor and H.O. Krueger.	2005	A 7-Day Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC; 40% C12, 50% C14, 10% C16; CAS RN 68424-85-1) with Duckweed (*Lemna gibba* G3). Wildlife International, Ltd. Study No. 350A-105. GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.5.1.1 – Inhibition to microbiological activity	de Vette, H.Q.M., Hanstveit, R. and J.A. Schoonmade	2001	The assessment of the ecological effects of alkyldimethylbenzylammonium chloride (Guidelines OPPTS 850.5100 Soil Microbial Community Test, OECD 216 and OECD 217 and CTB Section H.4.1). TNO Chemistry, Delft, The Netherlands. Report No. V99.1170 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.5.1.2 – Acute toxicity test to earthworms	Rodgers, M.H.	2004	N-Alkyl (C12-16)-N,N-dimethyl-Nbenzylammonium chloride (ADBAC): Acute toxicity (LC_{50}) to the earthworm. Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England. Report No. ADB/023 033976 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.5.1.3 – Acute toxicity to plants	Gray, J.	2004	N-Alkyl(C12-C16)-N,N-dimethyl-Nbenzylammonium chloride (ADBAC): Acute toxicity to terrestrial plants. Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England. Study No. ADB/024 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.5.3.1.1 – Acute oral toxicity (Bobwhite quail)	Campbell, S.M. and M. Jaber	1993	An acute oral toxicity study with alkyl dimethyl benzyl ammonium chloride (ADBAC) in the northern bobwhite quail. Wildlife International Ltd., Easton, MD, USA.	Yes	ADBAC ISC

Section No. / Reference No.	**Author**	**Year**	**Title** **Source (where different from company)** **Report No.** **GLP** **(Un)Published** *Non-Key Studies are italicized.*	**Data Protection Claimed (Yes/No)**	**Owner**
			Project No. 289-109 GLP Unpublished		
Doc IIIA 7.5.3.1.2(1) – Short-term toxicity	Gallagher, S.P., Martin, K.H. and J.B. Beavers	2005	A dietary LC_{50} study with alkyl dimethyl benzyl ammonium chloride (ADBAC; 40% C12, 50% C14, 10% C16; CAS RN 68424-85-1) in the northern bobwhite. Wildlife International Ltd., Easton, MD, USA. Project No. 350-101 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 7.5.3.1.2(2) – Short-term toxicity	Gallagher, S.P., Martin, K.H. and J.B. Beavers	2005	A dietary LC_{50} study with alkyl dimethyl benzyl ammonium chloride (ADBAC; 40% C12, 50% C14, 10% C16; CAS RN 68424-85-1) in the mallard. Wildlife International Ltd., Easton, MD, USA. Project No. 350-102 GLP Unpublished	Yes	ADBAC ISC
Doc IIIA 2.10.2.2.4 – Determination of leaching rate	*Bestari, K.*	*2001*	*Determination of the leachability of Bardac 2280 from treated wood.* *Centre for Toxicology, University of Guelph, Guelph, Ontario, Canada.* *Study No. 2000-CT-WL-B22* *GLP* *Unpublished*	*Yes*	*ADBAC ISC*
Doc IIIA 5.1.3.2 – Efficacy tests with single active substance formulation (ADBAC) against insects	*Linfield, W.M.*	*1969*	*Chapter 2,"Straight-Chain Alkylammonium Compounds. In E. Jungermann (Ed.), "Cationic Surfactants".* *Marcel Dekker, New York, N.Y.pp 9-70.* *GLP Status: not applicable* *Published*	*No*	*n/a*
Doc IIIA 5.1.3.2 – Efficacy tests with single active substance formulation (ADBAC) against insects	*Preston, A.F., P.J. Walcheski, P.A. McKaig and D.D. Nicholas*	*1987*	*Recent research on alkylammonium compounds in the U.S.* *Proc. Am. Wood Pres. Assn. 83, 331-347.* *GLP status: not applicable* *Published*	*No*	*n/a*

Section No. / Reference No.	Author	Year	Title Source (where different from company) Report No. GLP (Un)Published *Non-Key Studies are italicized.*	Data Protection Claimed (Yes/No)	Owner
Doc IIIA 5.1.3.2 – Efficacy tests with single active substance formulation (ADBAC) against insects	*Wazny, J. and R. Rudniewski*	*1997*	*Fungitoxic effect of the quaternary ammonium compounds wood preservatives against Basidiomycetes by using agar-plate and agar-block methods.* *International Research Group on Wood Preservation.* *Document No. IRG/WP/96-30118.* *GLP status: not applicable* *Published*	*No*	*n/a*
Doc IIIA 5.1.3.2 – Efficacy tests with single active substance formulation (ADBAC) against insects	*Tang, H. and J.N. Ruddick*	*1994*	*Evaluating the potential of amine chemicals for use as wood protecting agents. Part 1: Investigation of cation component of quaternary ammonium compounds.* *International Research Group on Wood Preservation* *Document No. IRG WP 94-30049.* *GLP status: not applicable* *Published*	*No*	*n/a*
Doc IIIA 5.1.3.2 – Efficacy tests with single active substance formulation (ADBAC) against insects	*Tsunoda, K.*	*1990*	*Effect of alkyl chain length on the fungicidal efficacy of benzalkonium chlorides.* *J. Antibact. Antifung. Agents 18(4), 185-189.* *GLP status: not applicable* *Published*	*No*	*n/a*
Doc IIIA (new submission 2013 March)	Veliath-Houston, L.	2013	Maquat MC1412-50% and Maquat BPD-50: Batch Analyses of Alkyl(C_{12-16}) dimethylbenzyl-ammonium Chloride Manufacturing Use Concentrates. Eurofins/Product Safety Laboratories, Dayton, NJ, USA. Study No. 35788 GLP Unpublished	Yes	Mason Chemical Company (Mason Europe Limited)
Doc IIIA (new submission 2013 March)	Veliath-Houston, L.	2013	BTC 835 and BTC 50E: Batch Analyses of Alkyl(C_{12-16}) dimethylbenzylammonium Chloride Manufacturing Use Concentrates. Eurofins/Product Safety Laboratories, Dayton, NJ, USA. Study No. 35824 GLP Unpublished	Yes	Stepan Company (Stepan Europe)

Section No. / Reference No.	Author	Year	Title Source (where different from company) Report No. GLP (Un)Published *Non-Key Studies are italicized.*	Data Protection Claimed (Yes/No)	Owner
Doc IIIA (new submission 2013 March)	Veliath-Houston, L.	2013	Barquat MB-50: Batch Analyses of Alkyl(C_{12-16}) dimethylbenzyl-ammonium Chloride Manufacturing Use Concentrates. Eurofins/Product Safety Laboratories, Dayton, NJ, USA. Study No. 35846 GLP Unpublished	Yes	Lonza Inc. (Lonza GmbH)

n/a = not applicable

Document IIIB

Section No. / Reference No.	Author	Year	Title Source (where different from company) Report No. GLP (Un)Published *Non-Key Studies are italicized.*	Data Protection Claimed (Yes/ No)	Owner
Doc IIIB 3.5(1) – Acidity/alkalinity and if necessary pH value (1% in water)	Sydney, P.	2006	BQ-25: Physicochemical properties. Huntingdon Life Sciences Ltd., Hungtingdon, Cambdridgeshire, England. Report No. ADB0031/062228 GLP Unpublished	Yes	ADBAC ISC
Doc IIIB 3.6(1) – Relative Density	Sydney, P.	2006	BQ-25: Physicochemical properties. Huntingdon Life Sciences Ltd., Hungtingdon, Cambdridgeshire, England. Report No. ADB0031/062228 GLP Unpublished	Yes	ADBAC ISC
Doc IIIB 3.8(1) – Technical characteristics of the biocidal product: Persistent foaming	Sydney, P.	2006	BQ-25: Physicochemical properties. Huntingdon Life Sciences Ltd., Hungtingdon, Cambdridgeshire, England. Report No. ADB0031/062228 GLP Unpublished	Yes	ADBAC ISC
Doc IIIB 3.10.2(1) – Viscosity	Sydney, P.	2006	BQ-25: Physicochemical properties. Huntingdon Life Sciences Ltd., Hungtingdon, Cambdridgeshire, England. Report No. ADB0031/062228 GLP Unpublished	Yes	ADBAC ISC
Doc IIIB 5.10.2 – Efficacy data	*Tang, H. and J.N. Ruddick*	*1994*	*Evaluating the potential of amine chemicals for use as wood protecting agents. Part 1: Investigation of cation component of quaternary ammonium compounds.* *International Research Group on Wood Preservation* *Document No. IRG WP 94-30049.* *GLP status: not applicable* *Published*	*No*	*n/a*

Section No. / Reference No.	**Author**	**Year**	**Title** **Source (where different from company)** **Report No.** **GLP** **(Un)Published** *Non-Key Studies are italicized.*	**Data Protection Claimed (Yes/ No)**	**Owner**
Doc IIIB 5.10.2 – Efficacy data	*Tsunoda, K.*	*1990*	*Effect of alkyl chain length on the fungicidal efficacy of benzalkonium chlorides.* *J. Antibact. Antifung. Agents 18(4), 185-189* *GLP status: not applicable* *Published*	*No*	*n/a*
Doc IIIB 5.10.2 – Efficacy data	*Tsunoda, K. and K. Nishimoto*	*1987*	*Effectiveness of alkylammonium compounds as above-ground wood preservatives.* *Mokuzai Gakkaishi, 33 (7), 589-595* *GLP status: not applicable* *Published*	*No*	*n/a*
Doc IIIB 5.10.2 – Efficacy data	*Tsunoda, K. and K. Nishimoto*	*1983*	*Fungicidal and termicidal effectiveness of alkylammonium compounds.* *International Research Group on Wood Preservation* *Document No. IRG WP 3232.* *GLP status: not applicable* *Published*	*No*	*n/a*

n/a = not applicable

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
IIA2.02 IIB7.2.1 IIB7.2.1 IIIA5.3 IIIB5.10.2 IIIB5.10.2	Akamatsu, T, et al.	1996	An assessment of the antimicrobial activity of commercially available disinfectants, Biocontrol Science 1:(1) 25-32, Not GLP, Published	No	Public data
App.6.1g IIIB8 IIIB9	Akzo Nobel Surface Chemistry AB	2005	Safety data sheet BKC-50 AkzoNobel – The Netherlands, Not GLP, Published	No	Akzo Nobel Surface Chemistry AB
IIA1.4.2 IIA1.4.3 IIB6.4 IIIB4.1	Akzo Nobel Surface Chemistry AB	1995	Determination of the activity in fatty quaternary ammonium salts, Akzo Nobel -The Netherlands, Report No.: VE/2.007, Not GLP, Published	No	Akzo Nobel Surface Chemistry AB
IIA1.4.2 IIB6.4	Akzo Nobel Surface Chemistry AB	1995	Determination of water in fatty quaternary ammonium salts, Akzo Nobel - The Netherlands, Report No.: VE/2.006, Not GLP, Published	No	Akzo Nobel Surface Chemistry AB
IIA1.4.2	Akzo Nobel Surface Chemistry AB	1997	Determination of sodium chloride in fatty quaternary ammonium salts, Akzo Nobel - The Netherlands, Report No.: VE2.019, Not GLP, Published	No	Akzo Nobel Surface Chemistry AB
IIA1.4.2	Akzo Nobel Surface Chemistry AB	1998	Determination of free amine and amine hydrochloride in fatty quaternary ammonium salts, Akzo Nobel – The Netherlands, Report No.: VV/2.002, Not GLP, Published	No	Akzo Nobel Surface Chemistry AB
IIA2.2 IIB7.2	Akzo Nobel Surface Chemistry AB	2004	Literature search efficacy BKC Akzo Nobel Surface Chemistry AB, Not GLP, Unpublished	Yes	EQC
App.6.1g IIIA8 IIIA9	Akzo Nobel Surface Chemistry AB	2005	SDS Arquad MCB-50EP Akzo Nobel Surface Chemistry AB, Not GLP, Published	No	Akzo Nobel Surface Chemistry AB

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IIA3.10 IIIA6.12	Alexander, BR	2003	Medical data for BKC, Thor Specialties UK Ltd., Not GLP, Unpublished	Yes	Thor Special-ties UK Ltd
IIA2.2 IIB7.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Angele, MH	1975	Surface activity, microbial activity, and use of selected tetraalkylnitrogen compounds, Seifen, Oele, Fette, Wachse (1975), 101(10), 273-7, Not GLP, Published	No	Public data
IIA1.4.4 IIIA4.3	Anonymous	2006	Appendix "Determination of Alkyldimethylbenzylammoniu m chloride in the dietary admixtures" from two reports (Chevalier, G, Report 22525 TSR, pages 147-157, Oct 2002 and Guillaumat, P-O, Report 26146 TCC, pages 139-146, Feb. 2006) Centre International de Toxicologie, (CIT) – France, GLP, Unpublished	Yes	EQC
IIA3.1 IIIA6.2 IIIB6.4	Appelqvist, T	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. Centre International de Toxicologie (CIT) - France, Report No.: 25629 PAR, GLP, Unpublished	Yes	EQC
IIA3.5 IIA3.7 IIIA6.5 IIIA6.7	Appelqvist, T	2007	BKC Combined toxicity/carcinogenicity study by dietary admixture in rats. Centre International de Toxicologie (CIT) - France, Report No.: 25627 TCR, GLP, Unpublished	Yes	EQC
IIA3.4	Basketter, DA, et al.	1996	The local lymph node assay: A viable alternative to currently accepted skin sensitization tests, Food Chem. Toxicol 34:985-997, Not GLP, Published	No	Public data
IIA3.4	Basketter,	1998	Strategies for identifying false positive responses in	No	Public data

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
	DA, et al.		predictive skin sensitization tests, Food Chem. Toxicol 36:327-333, Not GLP, Published		
IIA1.3 IIIA3.9 IIIA7.4.2 IIIA7.5.5.1	Bergström, PO	1993	Determination of the partition coefficient, Pow, between 1-Octanol and water for cocoalkyldimethylbenzylammonium chloride – QKKBCl, Analyscentrum Berol Nobel - Sweden, Report No.: 93 AC 0012, GLP, Unpublished	Yes	EQC
IIB8.2 IIB8.2.5 IIIB6.6 IIIB6.6	Bergström, P-O	1996	Determination of Querton 210Cl on stainless steel surfaces, Report number 96 AC 206, Not GLP, Unpublished	Yes	EQC
IIA3.10	Bernstein, JA, et al.	1994	A combined respiratory and cutaneous hypersensitivity syndrome induced by work exposure to quaternary amines, J Allergy Clin Immunol 2:(1) 257-259, Not GLP, Published	No	Public data
IIA3.2 IIA3.3.1 IIA3.5 IIA3.6.1 IIA3.7 IIA3.8.1 IIA3.8.2 IIA3.10 IIIA6.1.2 IIIA6.4.2 IIIB6.1.2	BIBRA	1989	BIBRA Toxicity Profile - Benzalkonium chloride BIBRA Toxicology International, Report No.: CC/Sl/May 1988 (g)/P. 309/(28)/T.1722/ACN 14353, Not GLP, Published	No	Public data
IIIA5.7.1 IIIB5.11.2	Bjorland, J, et al.	2005	Widespread distribution of disinfectant resistance genes among staphylococci of bovine and caprine origin in Norway, J Clin Microbiol 43:(9) 4363-4368, Not GLP, Published	No	Public data
IIA3.1	Blank, LH, et al.	1964	Penetration of Cationic surfactants into skin, J Invest Dermatol 42:363-366, Not GLP,	No	Public data

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			Published		
IIA3.1	Bleau, G	1983	Recherche du benzalkonium dans le sang de femmes utilisant le tampon pharmatex, Referenced in CIR, Not GLP, Published	No	Public data
IIA2.4 IIB7.4 IIIA6.10	Block, SS	1991	Disinfectants and antiseptics. A. By chemical type, Disinfection, Sterilization, and Preservation, 4th ed. Lea & Febiger, Philidelphia - London. pp. 250-255, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Blow, DP	1986	The International Research Group on Wood Preservation, Working Group II, Fundamentals of Testing; Alkyl dimethyl benzyl ammonium chloride: toxicity to Coniophora puteana when formulated in water and organic solvent Fosroc Ltd., Marlow, Bucks, England, IRG, IRG Document No: IRG/WP 2250, a986, Not GLP, Published	No	Public data
IIB6.3 IIIB3.8.6	Bodsch, J.	2008	Alkyldimethylbenzylammonium chloride (BKC) Persistent Foaming, Dr. Noack Laboratorien - Gemany, report no.: CF0111871 Not GLP, Unpublished	Yes	EQC
IIB6.3 IIIB3.8.6	Bodsch, J.	2012	Alkyldimethylbenzylammonium chloride (BKC) Surface Tension incl. Determination of CMC (Critical Micelle Concentration), amendment 1 Dr. U. Noack Laboratorien - Germany, Report No.: 060220AH/CPT106972, GLP, Unpublished	Yes	EQC
IIA3.1	Bogs, U and Lohse, E	1971	Zur verteilung von Invertseifen im Körper von Säugetieren. [On the Distribution of Cationic Surface-Active Agents in the	No	Public data

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			Body of mammals], Arch Toxikol. 28:(1) 68-71, Not GLP, Published		
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Borgmann-Strahsen, R	2009	Biocidal activity of Arquad MCB-50 under clean conditions and Staphylococcus aureus, AkzoNobel – The Netherlands, Not GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Borgmann-Strahsen, R	2009	Biocidal activity of Arquad MCB-50 under dirty conditions and Staphylococcus aureus, AkzoNobel – The Netherlands, Not GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Borgmann-Strahsen, R	2009	Biocidal activity of Arquad MCB-50 under clean conditions and Pseudomonas aeruginosa, AkzoNobel – The Netherlands, Not GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Borgmann-Strahsen, R	2009	Biocidal activity of Arquad MCB-50 under dirty conditions and Pseudomonas aeruginosa, AkzoNobel – The Netherlands, Not GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Borgmann-Strahsen, R	2009	Biocidal activity of Arquad MCB-50 under clean conditions and Enterococcus hirae, AkzoNobel – The Netherlands, Not GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Borgmann-Strahsen, R	2009	Biocidal activity of Arquad MCB-50 under clean conditions and Escherichia coli, AkzoNobel – The Netherlands, Not GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Borgmann-Strahsen, R	2009	Biocidal activity of Arquad MCB-50 under clean conditions and Candida albicans, AkzoNobel – The Netherlands, Not GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2	Borgmann-Strahsen, R	2009	Biocidal activity of Arquad MCB-50 under dirty conditions	Yes	EQC

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IIIA5.3 IIIB5.10.2			and Candida albicans, AkzoNobel – The Netherlands, Not GLP, Unpublished		
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Borgmann-Strahsen, R	2009	Biocidal activity of Arquad MCB-50 under clean conditions and Aspergillus niger, AkzoNobel – The Netherlands, Not GLP, Unpublished	Yes	EQC
IIIA5.7.1 IIIB5.11.2	Braoudaki, M and Hilton, AC	2004	Adaptive resistance to biocides in Salmonella enterica and Escherichia coli O157 and cross- resistance to antimicrobial agents, J Clin Microbiol 42:(1) 73-78, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Bravery, AF and Carey, JK	1985	Some data on the activity of alternative fungicides for wood preservation, IRG, IRG Document No: IRG/WP 3333, Not GLP, Published	No	Public data
IIA1.3 IIIA3.2.1 IIIA3.9.1 IIIA3.7	Brekelmans M,	2012	Determination of physic-chemical properties of C12-16 alkyldimethylbenzylammoniu m chloride (BKC), Notox bv - The Netherlands, Notox project 495713 GLP Unpublished	Yes	EQC
IIA1.3 IIIA3.2	Brekelmans M,	2012	Determination of vapour pressure of C12-16 BKC by isothermal thermogravimethry, Notox bv - The Netherlands, Notox project 499392, GLP, Unpublished	Yes	EQC
IIA1.3 IIIA3.2	Brekelmans M,	2013	Determination of vapour pressure of C12-16 BKC by isothermal thermogravimethry (amendment 1), Notox bv - The Netherlands, Notox project 499392, GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2.1 IIIA5.3	Brown, J, et al.	1991	Development of a mini-block test method for the rapid evaluation of preservative	No	Public data

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IIIB5.10.2			performance against Basidiomycte fungi, IRG - 22nd Annual Meeting of The International Research Group on Wood Preservation, Working group II: Fundamentals of Testing 12, Not GLP, Published		
IIA3.10	Burge, PS and Richardson, MN	1994	Occupational asthma due to indirect exposure to lauryl dimethyl benzyl ammonium chloride used in a floor cleaner, Thorax. 49:(8) 842-843, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Butcher, JA	1979	Testing new preservatives for protection of wood exposed in aboveground situations, Material und Organismen 14:(1) 43-53, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Butcher, JA	1980	Current status of AAC preservatives in New Zealand IRG - Paper prepared for the 11th Meeting of The International Research Group on Wood Preservation, Working group III: Preservations and Methods of Treatment 9, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Butcher, JA	1985	Benzalkonium chloride (an AAC preservative): Criteria for approval, performance in service, and implications for the future, IRG - Paper prepared for the 16th Annual meeting of The International Research Group on Wood Preservation - Working group III: Preservations and Methods of Treatment 12, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Butcher, JA and Greaves, H	1982	AAC preservatives: IRG - Recent New Zealand and Australian experience, Paper prepared for the 13th Annual Meeting of The International Research Group on Wood Preservation,	No	Public data

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			Working group III: Preservations and Methods of Treatment 8, Not GLP, Published		
IIA2.2 IIB7.2 IIIA5.3	Butcher, JA, et al.	1977	Comparison of a quaternary ammonium compound and copper-chrome-arsenate as wood preservatives, Forrest Products Journal 27:(7) 22-25, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	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, Not GLP, Published	No	Public data
IIA3.8.1	Buttar, HP	1985	Embryotoxicity of benzalkonium chloride in vaginally treated rats, J.Appl.Toxicol. 5:(6) 398-401, Not GLP, Published	No	Public data
IIIA5.7.1 IIIB5.11.2	Chaplin, CE	1952	Bacterial resistance to quaternary ammonium disinfectants, J Bacteriol 63:(4) 453-458, Not GLP, Published	No	Public data
IIB8.1	Chemical Specialties Inc.	2003	Treated wood fact sheet 2003, issue 04/03, Not GLP, Published	No	Public data
IIA3.1 IIA3.5 IIIA6.4.1.1	Chevalier, G	2002	Alkyldimethylbenzylammonium chloride 13 week dietary study in rats. Centre International de Toxicologie (CIT) - France, Report No.: 22525 TSR, GLP, Unpublished	Yes	EQC
IIA3.3.1 IIA3.3.2 IIA3.5 IIA3.10 IIIA6.4.3	CIR	1989	Final Report on the Safety Assessment of Benzalkonium Chloride, JACT 8:(4) 589-625, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1	Cross, DJ	1979	Alkylammonium compounds as insecticidal wood	No	Public data

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
IIIA5.3 IIIB5.10.2			preservatives, Material und Organismen 14:(2) 105-116, Not GLP, Published		
IIB7.2	CTGB	2008	Authorisation of Plant Protection Products and Biocides, http://www.ctgb.nl/ Not GLP, Published	No	Public data
IIA1 IIA3.1 IIA3.2 IIA3.5 IIA3.7 IIA3.9 IIA3.10 IIIA2.1	Cutler, RA and Drobeck, HP	1970	Toxicology of cationic surfactants, Cationic surfactants 4 (Chap. 15):527-616, Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIB7.2.1 IIB7.2.1 IIB7.2.1 IIIA5.3 IIIB5.10.2	Daoud, NN, et al.	1983	Antimicrobial activity and physicochemical properties of some alkyldimethylbenzyl-ammonium chlorides, Microbios (1983), 37(148), 73-85, Not GLP, Published	No	Public data
IIA3.6.1 IIIA6.6.3	Davis, PB	1987	Investigation into the possible induction of point mutation at the HGPRT locus of Chinese hamster ovary cells by Arquad DMMCB-50, TNO Division of Technology for Society - The Netherlands, Report No.: R 86/152, GLP, Unpublished	Yes	EQC
IIA1.4.2	Den Hartog, I	2003	Overview of results of 5-batch analysis for BKC, Akzo Nobel Surface Chemistry, Not GLP, Unpublished	Yes	EQC
IIB6.0 IIIB5.10.1	Den Hartog, I	2007	Label BKC-50, Akzo Nobel Surface Chemistry AB, Not GLP, Unpublished	No	EQC
IIA4.2.1.1 IIIA7.4.1.1 IIIA7.4.3	Dömmrose, AM	1987	Investigation of the lethal effects of the test sample Arquad B-50 to rainbow trout, Natec Institute für naturwissenschaftlich-technische Dienste GmbH,	Yes	EQC

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			Germany, Report No.: NA 86 9835/2, GLP, Unpublished		
IIA2.2 IIB7.2.1 IIB8.2.5 IIIA5.3 IIIB5.10.2 IIIB6.6	Dyer, DL, et al.	1998	Testing a new alcohol-free hand sanitizer to combat infection, AORN J 68:(2) 239-241, 243-234, 247-251 Not GLP, Published	No	Public data
IIIB6.5	EMEA	1998	2-Aminoethanol - Summary report, EMEA, Report No.: EMEA/MRL/331/97, Not GLP, Published	No	Public data
IIA1.3 IIIA3.2 IIIA6.1.3 IIIA6.4.3	EpiWin v3.20	2008	Estimations/calculations on C12-16-BKC, Akzo Nobel Surface Chemistry AB, Not GLP, Unpublished	No	Public data
IIIB6.05	ESIS	2000	IUCLID data set 2-aminoethanol, ESIS - European Chemicals Bureau - Year 2000 CD-ROM edition, Not GLP, Published	No	Public data
IIA3.8.2 IIIA6.8.2	Foulon, O	2008	BKC - Two-generation study (reproduction and fertility effects) by dietary admixture in rats, Centre International de Toxicologie (CIT) - France, Report No.: 26149 RSR, GLP, Unpublished	Yes	EQC
IIA3.10	Fuchs, T, et al.	1993	Benzalkoniumchlorid - relevantes Kontaktallergen oder Irritans? Ergebnisse einer Multicenter-Studie der Deutschen Kontaktallergiegruppe, Hautarzt 44:(11) 699-702, Not GLP, Published	No	Public data
IIA3.10	Gall, H	1979	Toxisches Kontaktekzem auf die quaternäre Ammoniumverbindung Benzalkoniumchlorid, Derm Beruf Umwelt 27:(5)	No	Public data

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			139-140, Not GLP, Published		
IIA3.5	Gaou, I	2004	BKC - Two-phase dose-range-finding toxicity study by oral route (dietary admixture) in Beagle dogs, Centre International de Toxicologie (CIT) - France, Report No.: 26144 TCC, GLP, Unpublished	Yes	EQC
IIA3.5	Gaou, I	2006	BKC - 4 week preliminary toxicity study by oral route (dietary admixture) in Beagle dogs, Centre International de Toxicologie (CIT) - France, Report No.: 26145 TSC, GLP, Unpublished	Yes	EQC
IIA3.8.1 IIIA6.8.1	Gaoua, W	2005	BKC, Prenatal developmental toxicity by oral route (gavage) in rabbits, Centre International de Toxicologie (CIT) - France, Report No.: 26148 RSL, GLP, Unpublished	Yes	EQC
IIA4.2.1.5 IIIA7.4.1.4	Geerts, R and Van Ginkel, CG	2004	Toxicity of BKC to activated sludge, Akzo Nobel - The Netherlands, Report No.: CER F04001 T 03018, GLP, Unpublished	Yes	EQC
IIA4.1.1.3.1 IIIA7.2.3.1 IIIA7.2.3.2 IIIB7.5	Geffke, T	1999	Preventol R50 - Adsorption / Desorption using a Batch Equilibrium Method, Dr. U. Noack-Laboratorien - Germany, Report No.: CAD61831, GLP, Unpublished	Yes	EQC
IIA1.4.1 IIA1.4.4 IIIA4.2a IIIA4.2c	Geffke, T	2007	Alkyldimethylbenzylammonium chloride (BKC) Residue Analytical Method for Determination in tap water, surface water and soil, Dr. U. Noack-Laboratorien - Germany, Report No.: CRA106972, GLP, Unpublished	Yes	EQC

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IIA4.1.1.2.1 IIIA3.10 IIIA7.1.1.1.1	Geurts, MGJ, et al.	1996	Hydrolysis as a function of pH of Arquad DMMCB-50, Akzo Nobel - The Netherlands, Report No.: RGL F96083, GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2.1 IIB7.2.1 IIIA5.3 IIIB5.10.2	Gloor, M, et al.	1980	Antibacterial and antimycotic effect of quaternary ammonium compounds, Fette, Seifen, Anstrichmittel (1980), 82(3), 124-7, Not GLP, Published	No	Public data
IIA1.4.1 IIA1.4.1 IIIA4.1 IIIA4.1	Goller S	2008	Alkyldimethylbenzylammonium chloride (BKC) - Quantification of the By-products Dr. U. Noack-Laboratorien, Germany, Report No.: 071220AH-CBP10697, GLP, Unpublished	Yes	EQC
IIA3.1	Green, K and Chapman, JG	1986	Benzalkonium Chloride kinetics in young and adult albino and pigmented rabbit eyes, J. Toxicol.-Cut. and Ocular Toxicol. 5:(2) 133-142, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIB7.2.1 IIIA5.3 IIIB5.10.2	Gueller, S, et al.	1988	Didecyldimethylammonium chloride - a modern biocide, Seifen, Oele, Fette, Wachse (1988), 114(5), 169-73, Not GLP, Published	No	Public data
IIA3.5 IIIA6.4.1.2	Guillaumat, P-O	2006	BKC - 13-Week toxicity study by oral route (dietary admixture) in Beagle dogs. Centre International de Toxicologie (CIT) - France, Report No.: 26146 TCC, GLP, Unpublished	Yes	EQC
IIA3.1 IIIA6.2 IIIA6.4.2 IIIB6.4	Hallifax, D	1991	E0206 (Benzalkonium chloride): adsorption and excretion study in the rat after topical application, Life Science Research Ltd. England, Report No.: 91/AWL019/0333, GLP, Unpublished	Yes	EQC

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IIA2.2 IIB7.0.1 IIIA5.3 IIIB5.10.2	Hedley, M., et al.	1995	Report prepared for the 26th Annual meeting of The International Research Group on Wood Preservation. Section 3; Wood Protecting chemicals: Field tests of preservative-treated radiata pine in Japan, IRG, IRG Document No: IRG/WP 95-30083, 1995 4 Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Hegarty, B	1988	Neue Erkentnisse über den echten Hausschwamm Serpula lacrymans, Sonderdruck aus Holz-Zentralblatt, Stuttgart 114 Jahrgang 114:(46), Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.3 IIIB5.10.2	Hilmes, W, et al.	2001	Membrane active biocides-safe but effective, Seife, Oele, Fette, Wachse, 127, Jahrgang 8-2001, Not GLP, Published	No	Public data
IIA2.7 IIB7.5 IIIA5.7.1 IIIB5.11.2	Hingst, V, et al.	1995	[Epidemiology of microbial resistance to biocides] Zentralbl Hyg Umweltmed, 197:(1-3) 232-251, Not GLP, Published	No	Public data
IIA1 IIIA2.1	Houthoff, E	2004	Dossier approach for Benzalkonium chloride (BKC), European Quats Consortium, Not GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2.1 IIB7.2.1 IIB7.2.1 IIIA5.3 IIIB5.10.2	Huang, J-C, et al.	1998	Comparison of fungicidal effects of commercial disinfectants at concentrations suggested for practical use, Biocontrol Science (1998), 3(2), 105-108, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIB7.2.1 IIIA5.3 IIIB5.10.2	Hueck, HJ, et al.	1966	Bacteriostatic, fungistatic, and algistatic activity of fatty nitrogen compounds, Applied Microbiology 14:(3) 308-319, Not GLP, Published	No	Public data
App.6.1g	Huntsman Surface	2005	SDS Empigen BAC50, Huntsman,	No	Huntsman Surface Sciences

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IIIA9	Sciences Europe		Not GLP, Published		Europe
IIB8.1 IIIB5B.3	ICBO	1999	Acceptance criteria for ACQ wood preservative treatment, ICBO Evaluation Service, Report No.: AC7 Not GLP, Published	No	Public data
IIB8.1	ICBO	2001	Acceptance criteria for wood preservative treatment for 'decking use only', ICBO Evaluation Service, Report No.: AC186, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIB7.2.1 IIIA5.3 IIIB5.10.2	Jerchel, D	1947	Invert soaps and tetrazolium salts, Fiat Rev. German Sci. Biochemistry (1947) - Volume Date 1939-1946, (Pt. I); 59-65, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Johansson, P	1999	Field trials with Wood Preservatives for Class AB, Progress report no1. Results after 3 years' exposure, Nordic Wood Report No.: SP - Report 1999:27E, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIB7.2.1 IIIA5.3 IIIB5.10.2	Johnson, ML, et al.	2003	Fungicidal effects of chemical disinfectants, UV light, desiccation and heat on the amphibian chytrid Batrachochytrium dendrobatidis, Diseases of Aquatic Organisms 57:(3) 255-260, Not GLP, Published	No	Public data
IIA3.2 IIIA6.1.1 IIIB6.1.1	Jones, J and Collier, TA	1986	Arquad B-50: OECD 401 Acute oral toxicity in the rat, Safepharm Laboratories Ltd., England, Report No.: 106/2, GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2.1 IIB7.2.1 IIIA5.3 IIIB5.10.2	Jono, K, et al.	1986	Effect of alkyl chain length of benzalkonium chloride on the bactericidal activity and binding to organic materials, Chemical & Pharmaceutical	No	Public data

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			Bulletin (1986), 34(10), 4215-24, Not GLP, Published		
IIA4.1.2 IIIA7.4.2 IIIA7.4.3	Kappeler, TU	1982	Aquatic toxicity of distearyldimethylammonium chloride (DSDMAC), Tenside Detergents 19:(3) 169-176, Not GLP, Published	No	Public data
IIA2.7 IIB7.5 IIB7.5 IIIA5.7.1 IIIB5.11.2 IIIB5.11.2	Kaulfers, PM	1995	[Epidemiology and reasons for microbial resistance to biocides], Zentralbl Hyg Umweltmed 197:(1-3) 252-259 Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIB7.2.1 IIIA5.3 IIIB5.10.2	Kihara, K, et al.	1997	Existence of an optimal concentration for bactericidal activity of quaternary ammonium compounds, Biocontrol Science 2:(2) 61-66, Not GLP, Published	No	Public data
IIIA7.4.2 IIIA7.4.3	Knezovich, JP and Inouye, LS	1993	The influence of sediment and colloidal material on the bioavailability of a quaternary ammonium surfactant, Ecotoxicol Environ Saf 26:(3) 253-264, Not GLP, Published	No	Public data
IIB8.3.1	KNMI	2004	http://www.knmi.nl/product 13 Februari, 2004 Not GLP, Published	No	Public data
IIB6.3 IIIB3.10.2	Krack, M.	2008	Arquad MCB-SOEP - Kinematic viscosity OECD 114, Siemens Prozess-Sicherheit, Germany, Report no.: 20080203.01, GLP, Unpublished	Yes	EQC
IIA4.2.1.4 IIIA7.4.1.3 IIIA7.4.3	Kroon, AGM, et al.	1996	Toxicity fo Arquad DMMCB-50 to the freshwater alga Selenatrum capricornutum, Akzo Nobel - The Netherlands, Report No.: RGL F96072, GLP, Unpublished	Yes	EQC
IIA1.4.2	Lange, J	2005	Comparative Study on the	Yes	EQC

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			Identity of Arquad MCB-50, Acticide BAC 50M, EMPIGEN BAC 50 Five Batch Analysis, Dr. U. Noack-Laboratorien - Germany Report no.: CFB102822, GLP, Unpublished		
IIB6.3 IIB6.3 IIIB3.1 IIIB3.5 IIIB3.7.1	Lange, J	2007	Alkyldimethylbenzylammonium chloride (BKC) Accelerated Storage Procedure, Dr. U. Noack-Laboratorien - Germany Report No.: CPL111871, GLP, Unpublished	Yes	EQC
IIA1.3 IIIA3.8	Lange, J	2007	Alkyldimethylbenzylammonium chloride (BKC) Stability in Organic Solvents, Dr. U. Noack-Laboratorien - Germany Report No.: CSS106972, GLP, Unpublished	Yes	EQC
IIA1.4.1 IIIA4.1	Lange, J	2011	BKC (lyophilised Arquad® MCB-50EP) Determination of the Content of the Active Ingredients and Relevant Impurities, Dr. U. Noack-Laboratorien - Germany, Report number: CBG14241/101025AH, GLP, Unpublished	Yes	EQC
IIA1.4.1 IIA1.4.4 IIIA4.2a IIIA4.2b IIIA4.2c	Lange, J	2012	BKC (lyophilised Arquad MCB-50EP) Residue Analytical Method for the Determination in Ground, Surface, Tap Water and Soil, (+ ammendment1) Dr. U. Noack-Laboratorien – Germany, Report number CRA14241 / 101025AH GLP, Unpublished	Yes	EQC
IIA1.4.2	Lange, J	2014	5 batch analysis AkzoNobel Surface Chemistry AB, Dr. U. Noack-Laboratorien – Germany Report number: CFB15698 130731AH GLP Unpublished	Yes	Akzo Nobel Surface Chemistry AB
IIA1.4.2	Lange, J	2014	5 batch analysis Thor Specialties Ltd - UK,	Yes	Thor Specialties Ltd

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			Dr. U. Noack-Laboratorien – Germany Report number: CFB15711 130731AH GLP Unpublished		
IIA1.4.2	Lange, J	2014	5 batch analysis Thor Specialties Ltd - ES, Dr. U. Noack-Laboratorien – Germany Report number: CFB15684 130731AH GLP Unpublished	Yes	Thor Specialties Ltd
IIA1.4.2	Lange, J	2014	5 batch analysis Huntsman Surface sciences, Dr. U. Noack-Laboratorien – Germany Report number: CFB15707 130731AH GLP Unpublished	Yes	Huntsman Surface sciences
IIIA5.7.1 IIIB5.11.2	Langsrud, S and Sundheim, G	1997	Factors contributing to the survival of poultry associated Pseudomonas spp. exposed to a quaternary ammonium compound, J Appl Microbiol 82:(6) 705-712, Not GLP, Published	No	Public data
IIA2.2 IIA2.7 IIB7.2.1 IIIA5.3 IIIA5.7.1 IIIB5.10.2 IIIB5.11.2	Langsrud, S, et al.	2003	Intrinsic and acquired resistance to quaternary ammonium compounds in food-related Pseudomonas spp, Journal of Applied Microbiology (2003), 95(4), 874-882, Not GLP, Published	No	Public data
IIA4.1.2 IIIA7.4.2 IIIA7.4.3	Lewis, MA and Wee, VT	1983	Aquatic safety assessment for cationic surfactants, Environmental Toxicology and Chemistry 2:(1) 105-118, Not GLP, Published	No	Public data
IIA3.3.1 IIIA6.1.2 IIIA6.1.4 IIIB6.1.2 IIIB6.2	Liggett, MP and Seaber, JA	1982	Irritant effects of Arquad B-50 PCT on rabbit skin, Huntingdon Research Centre Ltd. - England, Report No.: 8289D/AKZ 131/SE, 25, GLP, Unpublished	Yes	EQC

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IIA3.3.1 IIIA6.1.4 IIIB6.2	Liggett, MP and Seaber, JA	1982	Irritant effects of Empigen BAC on rabbit skin, Huntingdon Research Centre Ltd. - England, Report No.: 8287D/AKZ 131/SE, GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	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, Not GLP, Published	No	Public data
IIA1.4.2	Löfgren, L, et al.	2003	UV, IR, NMR analysis of Empigen BAC 50, Acticide Bac 50M and Arquad MCB-50, Akzo Nobel - Sweden, Report No.: ANL 03014, Not GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2.1 IIIA5.3 IIIA5.7.1 IIIB5.10.2 IIIB5.11.2	Lunden, J, et al.	2003	Adaptive and cross-adaptive responses of persistent and non-persistent Listeria monocytogenes strains to disinfectants, International Journal of Food Microbiology (2003); 82(3); 265-272, Not GLP, Published	No	Public data
IIA3.10 IIIA6.12	Maatman, LHM	2003	Medical data BKC Akzo Nobel – The Netherlands, Not GLP, Unpublished	Yes	Akzo Nobel Surface Chemistry AB
IIA4.2.1.3 IIIA7.4.3 IIIA7.4.3.4	Mark, UE, et al.	1995	Chronic toxicity of Arquad DMMCB-50 to Daphnia magna Akzo Nobel - The Netherlands, Report No.: RGL F95035, GLP, Unpublished	Yes	EQC
IIA2.7 IIB7.5 IIIA5.7.1 IIIB5.11.2	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, Not GLP,	No	Public data

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IIA2.7 IIB7.5 IIB7.5 IIB7.5 IIB7.5 IIIA5.7.1 IIIB5.11.2	McDonnell, G and Russell, AD	1999	Antiseptics and disinfectants: activity, action, and resistance, Clin Microbiol Rev 12:(1) 147-179, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Moll, H	1943	Invert soaps - Pharmazeutische Zentralhalle fuer Deutschland (1943) – 84 (No. 4;No. 5); 37-44;49-52, Not GLP, Published	No	Public data
IIA1.3 IIIA3.11	Möller, DM	2007	Alkyldimethylbenzylammonium chloride (BKC) Auto-flammability A.16 (Solids - determination of relative self-ignition temperature), Siemens AG Prozess-Sicherheit, Frankfurt am Main - Germany, Report No.: 20070082.02, GLP, Unpublished	Yes	EQC
IIA1.3 IIA1.3 IIIA3.1.1 IIIA3.1.2 IIIA3.10	Möller, DM	2007	Alkyldimethylbenzylammonium chloride (BKC) Thermal stability (OECD 113), Siemens AG Prozess-Sicherheit, Frankfurt am Main - Germany, Report No.: 20070082.01, GLP, Unpublished	Yes	EQC
IIA1.3 IIIA3.1.1 IIIA3.1.2 IIIA3.10	Moller, M	2012	Determination of physico-chemical properties Thermal Stability (OECD 113) Melting Point (EC A.1., OECD 102), Boiling Point (EC A.2., OECD 103), consilab Gesellschaft für Anlagensicherheit mbH Industriepark Höchst, G 830/840, 65926 Frankfurt am Main, Germany, Report number: CSL-11-0356.01, GLP Unpublished	Yes	EQC
IIB8.2 IIIB6.6 IIIB6.6	Montfoort, J, et al.	1996	The use of disinfectants in livestock farming, RIVM Rapport 679102033, Not GLP, Published	No	Public data

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IIB6.3 IIIB3.6	Mulder, RJ	1996	Certificate of Analysis: oscillerende dichtheidsmeter Arquad DMMCB-50 Akzo Nobel - The Netherlands, Report No.: 0169507931900, Not GLP, Unpublished	Yes	EQC
IIA4.2.3.2 IIIA7.5.1.2 IIIB7.8.4	Noack, M	1999	Earthworm (Eisena fetida), acute toxicity test in artificial soil, Dr. U. Noack-Laboratorium für angewandte biologie - Germany, Report No.: D RRA61831, GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Norton, J	2002	The Protection of Plywood with Benzalkonium Chloride (BAC) Wood Preservative, IRG, IRG Document No: IRG/WP 02-40219, Not GLP, Published	No	Public data
IIB8.1	NTR Nordic Wood Preservative Council	2005	Wood preservatives approved by the Nordic Wood Preservation Council, NTR Nordic Wood Preservative Council, Publication No.: 72, Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Ntsama-Essomba, C, et al.	1997	Resistance of Escherichia coli growing as biofilms to disinfectants, Veterinary Research (1997), 28(4), 353-363, Not GLP, Published	No	Public data
IIIA3.9 IIIA7.4.2 IIIA7.5.5.1	O, B. H.	1996	Log Po/w of Arquad 2.10 and Arquad DMMCB - calculation results outlined according to EC regulations, Akzo Nobel - The Netherlands, Report No.: ACRD 968-095, Not GLP, Unpublished	Yes	EQC
IIB8.3	OECD	2003	OECD series on emission scenario documents, number 2 - Emission scenario document for wood preservatives, OECD, Not GLP,	No	Public data

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IIA3.8.1	Palmer, AK, et al.	1983	Absence of embryotoxic effects in rats with three quarternary ammonium compounds (cationic surfactants), Toxicology 26:(3-4) 313-315, Not GLP, Published	No	Public data
IIA1 IIIA2.1 IIIA7.1.2.2.1	Patrauchan, MA and Oriel, PJ	2003	Degradation of benzyldimethylalkylammonium chloride by Aeromonas hydrophila sp. K, J Appl Microbiol 94:(2) 266-272, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIB7.2.1 IIIA5.3 IIIB5.10.2	Peters, J and Spicher, G	1998	Model tests for the efficacy of disinfectants on surfaces. Part 4. Dependence of test results on the amount of contamination and the kind of active substance, Zentralblatt fuer Hygiene und Umweltmedizin (1998), 201(4-5), 311-323 Not GLP, Published	No	Public data
IIA1.4.1 IIIA4.1	Petrovic P	2011	Determination of Sodium Content in BCK (=lyophilised Arquad MCB-50 EP) by ICP-OES, ALLESSACHEMIE GMBH, Report number: B 010/2011 / VP 010/2011, GLP Unpublished	Yes	EQC
IIA1.4.2	Petrovic P	2014	Determination of Sodium content in 5batch analysis of Arquad MCB-50 ALLESSACHEMIE GMBH, Report number: VP043-2014, GLP, Unpublished	Yes	AkzoNobel Surface Chemistry AB
IIA1.4.2	Petrovic P	2014	Determination of Sodium content in 5batch analysis of Acticide BAC 50 M UK, ALLESSACHEMIE GMBH, Report number: VP045-2014, GLP Unpublished	Yes	Thor Specialties UK Ltd
IIA1.4.2	Petrovic P	2014	Determination of Sodium content in 5batch analysis of Acticide BAC 50 M ES,	Yes	Thor Specialties UK Ltd

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			ALLESSACHEMIE GMBH, Report numberVP044-2014, GLP Unpublished		
IIA1.4.2	Petrovic P	2014	Determination of Sodium content in 5batch analysis of Empigen BAC 50 ALLESSACHEMIE GMBH, Report number: VP046-2014, GLP Unpublished	Yes	Huntsman Surface Sciences
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Plackett, DV	1984	The preliminary evaluation of selected sulfonium salts for use in wood preservation, IRG, IRG Document No: IRG/WP 3278, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Plackett, DV, et al.	1985	Exterior weathering trials on radiata pine roofing shingles, IRG, IRG Document No: IRG/WP 3240, Not GLP, Published	No	Public data
IIB8.2 IIIB6.6	Preller, EA and Schipper, HJ	1999	Respiratory and dermal exposure to disinfectants: a study in slaughterhouses and the meat processing industry TNO Nutrition and Food Research - The Netherlands, Report No.: V98.1306, Not GLP, Published	No	Public data
IIA3.10	Preller, L, et al.	1996	Disinfectant use as a risk factor for atopic sensitization and symptoms consistent with asthma: an epidemiological study, Eur Respir J. 9:(7) 1407-1413, Not GLP, Published	No	Public data
IIA2.2 IIB7.2. IIIA5.3 IIIB5.10.2	Renner, P and Peters, J	1999	Resistance of enterococci to heat and chemical agents, Zentralblatt fuer Hygiene und Umweltmedizin (1999), 202(1), 41-50 Not GLP, Published	No	Public data
IIB8.3	RIVM	2003	Pearl 2.0 RIVM, Alterra, Not GLP,	No	Public data

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			Published		
IIA1.3 IIA1.4.1 IIIA3.4.2 IIIA3.4.3 IIIA3.4.4 IIIA3.10	Roos, M	2007	Characterization of the Molecular Structure of BKC (freeze dried), AllessaChemie GmbH, Germany, Report No.: B 056/2006, GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Ruddick, JNR	1984	The influence of staining fungi on the decay resistance of wood treated with alkylammonium compounds, IRG, IRG Document No: IRG/WP 3308, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIB7.2.1 IIIA5.3 IIIB5.10.2	Sagaster, HR and Roebisch, G	1987	Bacteriostatic activity of a series of cation-active surfactants in Staphylococcus aureus, Zeitschrift fuer die Gesamte Hygiene und Ihre Grenzgebiete (1987), 33(5), 269-70, Not GLP, Published	No	Public data
IIIA5.7.1 IIIB5.11.2	Sakagami, Y, et al.	1989	Mechanism of resistance to benzalkonium chloride by Pseudomonas aeruginosa, Applied and Environmental Microbiology 55:(8) 2036-2040, Not GLP, Published	No	Public data
IIA3.4	Schallreuter, KU, et al.	1986	Induction of Contact Dermatitis in Guinea Pigs by Quaternary Ammonium Compounds: The Mechanism of Antigen Formation, Environmental Health Perspectives 70:229-237, Not GLP, Published	No	Public data
IIA4.1.1.3.2 IIB8.3.1	Schoknecht, U, et al.	2002	Biozidemissionen aus materialien Bundesanstalt für Materialforschung und –prüfung, BAM, Not GLP, Published	No	Public data
IIA1.3	Schulze, M	2007	Alkyldimethylbenzylammoniu	Yes	EQC

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IIIA3.3			m chloride (BKC) Appearance: Physical State, Colour and Odour, Dr. U. Noack-Laboratorien - Germany, Report No.: 060220AH/CAP106971, GLP, Unpublished		
IIA1.4.1 IIIA4.1	Schulze, M	2007	Alkyldimethylbenzylammoniu m chloride (BKC) Determination of Identity and Purity before and after dehydration Dr. U. Noack-Laboratorien - Germany, Report No.: 060220AH/CGB106971, GLP, Unpublished	Yes	EQC
IIA1.3 IIIA3.1.3	Schulze, M	2007	Alkyldimethylbenzylammoniu m chloride (BKC) Determination of the Density, Dr. U. Noack Laboratorien - Germany, Report No.: 060220AH/CPD106971, GLP, Unpublished	Yes	EQC
IIA1.3 IIIA3.11	Schulze, M	2007	Alkyldimethylbenzylammoniu m chloride (BKC) Flammability of Solids, Dr. U. Noack Laboratorien - Germany, Report No.: 060220AH/CPE10697, GLP, Unpublished	Yes	EQC
IIA1.3 IIIA3.7	Schulze, M	2007	Alkyldimethylbenzylammoniu m chloride (BKC) Solubility in Organic Solvents (Modified Flask Method), Dr. U. Noack-Laboratorien - Report No.: CLF106974, GLP, Unpublished	Yes	EQC
IIA1.3 IIIA3.15	Schulze, M	2007	Alkyldimethylbenzylammoniu m chloride (BKC) Statement on Explosive Properties, Dr.Noack Lab oratorien - Gemany, Report no.: CEP10697N, GLP, Unpublished	Yes	EQC
IIA1.3	Schulze, M	2007	Alkyldimethylbenzylammoniu	Yes	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
IIB6.3 IIIA3.16 IIIB3.3			m chloride (BKC) Statement on Oxidising Propertie,s Dr.Noack Laboratorien - Gemany, Report no.: CES10697N, GLP, Unpublished		
IIA1.3 IIB6.3 IIIA3.13 IIIB3.10.1	Schulze, M	2007	Alkyldimethylbenzylammoniu m chloride (BKC) Surface Tension incl. Determination of CMC (Critical Micelle Concentration), Dr. U. Noack Laboratorien - Germany, Report No.: 060220AH/CPT106972, GLP, Unpublished	Yes	EQC
IIA1.3 IIA1.4.1 IIA4.1.1.2.2 IIB6.3 IIIA3.4.1 IIIA7.1.1.1.2 IIIA7.3.1 IIIB3.7.2	Schulze, M	2007	Alkyldimethylbenzylammoniu m chloride (BKC) UV-VIS Absorption Spectra, Dr. U. Noack Laboratorien - Germany, Report No.: 060220AH/CPU106971, GLP, Unpublished	Yes	EQC
IIA1.3 IIB6.3 IIIA3.5 IIIB3.5	Schulze, M	2007	Alkyldimethylbenzylammoniu m chloride (BKC) Water Solubility (Modified Flask Method), Dr. U. Noack Laboratorien - Germany, Report No.: 060220AH/CWF106971, GLP, Unpublished	Yes	EQC
IIB6.3 IIIB3.2 IIIB3.4	Schuurman, P	1996	Physico-chemical properties of Arquad DMMCB-50, Akzo Nobel - The Netherlands, Report No.: ACRD 960-0407, Not GLP, Unpublished	Yes	EQC
IIA4.2.3.4 IIIA7.5.1.3	Servajean, E	2004	Laboratory assessment of the side effects of BKC on plant growth, Phytosafe - France, Report No.: 03-99-036-ES, GLP, Unpublished	Yes	EQC
IIIA5.7.1 IIIB5.11.2	Shimp, RJ, et al.	1989	Adaptation to a quaternary ammonium surfactant by suspended microbial communities in a model	No	Public data

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			stream, Environmental Toxicology and Chemistry 8:(8) 723-730, Not GLP, Published		
IIA3.7	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, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Stepanovic, S, et al.	1996	Comparative examination of three test methods for evaluation of efficacy of disinfectants against Listeria monocytogenes, Mediterranean Congress of Chemotherapy; 10th; Antalya, Turk., Oct. 20-25; 1996; 421-425, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Stephenso n, RA	1990	Optimisation of the Performence of Quaternary Ammonium Compounds, Industrial applications of surfactants II. 235-275, Not GLP, Published	No	Public data
IIIA5.7.1 IIIB5.11.2	Sundheim, G, et al.	1992	Resistance of meat associated staphylococci to a quaternary ammonium compound, Food Microbiology 9:161-167, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Sundman, CE	1984	Tests with ammoniacal copper and alkyl ammonium compounds as wood preservative, IRG, Report No.: IRG-WP 84-3299, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Takahashi, M, et al.	1990	Evaluation of termiticides in field trials, IRG, IRG Document No: IRG/WP 3633, Not GLP, Published	No	Public data
IIB6.3	Ter Haar, J	2000	UN classified products filled	Yes	EQC

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IIIA3.17 IIIB3.7.3			into plastic drums (25l, 60l, 210l) Akzo Nobel - The Netherlands, Report No.: 00-125-JtH, Not GLP, Unpublished		
IIA4.2.1.2 IIIA7.4.1.2 IIIA7.4.3	Thiébaud, H	1999	Noramium DA 50 - Toxicité aigué vis-à-vis des daphnies, Elf Atochem S.A., Centre d'application de Levallois, Report No.: 3768/97/A, GLP, Unpublished	Yes	EQC
IIA3.4 IIIA6.1.5 IIIB6.3	Thomas, MB	1974	Querton 2.10Cl and Querton KKBCl: Draize skin tests, Repeated insult skin tests, Guinea pig maximisation tests, LD50 determination, Consultox Laboratories Ltd., England, Report No.: CL74: 75: 1025, Not GLP, Unpublished	Yes	EQC
IIIA9	Thor Specialties UK Ltd	2001	SDS Acticide DDQ 50, Thor Specialities UK Ltd, September 16, 2001 Not GLP, Published	No	Thor Specialties UK Ltd
App.6.1g	Thor Specialties UK Ltd	2005	SDS Acticide Bac 50 M Thor Specialities UK Ltd, Not GLP, Published	No	Thor Specialties UK Ltd
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Tillot, RJ and Coggins, CR	1981	Non-arsenical waterborne preservatives - A review of performance and properties, BWPA annual convention 32-48 Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Tomlinson, E, et al.	1977	Effect of colloidal association on the measured activity of alkylbenzyldimethylammoniu m chlorides against Pseudomonas aeruginosa, Journal of Medicinal Chemistry (1977), 20(10), 1277-82, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Tsunoda, K	1990	Effect of alkyl chain length on the fungicidal efficacy of benzalkonium chlorides, Bokin Bobai 18:(4) 185-189, Not GLP, Published	No	Public data

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IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Tsunoda, K and Nishimoto, K	1983	Fungicidal and termiticidal effectiveness of alkylammonium compounds, IRG, IRG Document No: IRG/WP 3232, Not GLP, Published	No	Public data
IIA3.10	Van Berkel, M and De Wolff, FA	1988	Survival after acute benzalkonium chloride poisoning, Human Toxicol 7:191-193, Not GLP, Published	No	Public data
App.6.7 IIA2.2	Van de Knaap, D	2003	Literature search for BKC, Akzo Nobel - The Netherlands, Not GLP, Unpublished	No	Public data
App.6.7 IIA2.2 IIB7.2	Van de Knaap, D	2004	Literature search for BKC and wood Akzo Nobel – The Netherlands, Not GLP, Unpublished	No	Public data
App.6.7 IIA2.2 IIB7.2	Van de Knaap, D	2004	Literature search for wood and EN 113 results, Akzo Nobel – The Netherlands, Not GLP, Unpublished	No	Public data
IIA3.10	Van de Sandt, JJM, et al.	1993	Skin Organ Culture as an Alternative to In Vivo Dermatotoxicity Testing, ATLA 21:443-444, Not GLP, Published	No	Public data
IIA4.2.3.3	Van der Linde, D	2003	An artificial sediment test using the nematode Caenorhabditis elegans, Akzo Nobel - The Netherlands Report no.: CER F00, Not GLP, Unpublished	Yes	EQC
IIA1 IIIA2.1 IIIA7.1.2 IIIA7.1.2.2.1	Van Ginkel, CG	2004	Biodegradation of Cationic Surfactants; An Environmental Perspective. Chapter 25, Handbook of Detergents Part B Environmental Impact 523-549, Not GLP, Published	No	Public data
IIA4.1.1.1.1 IIIA7.1.2.1.	Van Ginkel, CG and	2007	Determination of the degradation of BKC in a simulation test of an activated	Yes	EQC

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1	Geerts, R		sludge plant treating domestic wastewater, Akzo Nobel - The Netherlands, Report number: ECRA F07015 T 07002 CAS, GLP, Unpublished		
IIA4..1.1.2 IIIA7.2.1	Van Ginkel, CG and Pomper, MA	1994	A comparison of the biodegradability of Arquad 2.10-50 and Arquad DMMCB-50 Akzo Nobel - The Netherlands, Report No.: CRL F 94023, Not GLP, Unpublished	Yes	EQC
IIA4.1.1.1.1 IIIA7. IIIA7.1.1.2.1 IIIA7.1.1.2.2 IIIA7.1.1.2.3 IIIA7.1.2.1.2 IIIA7.1.2.2.1 IIIA7.1.2.2.2 IIIA7.3.1	Van Ginkel, CG and Stroo, CA	1992	Biodegradability of Arquad DMMCB-50 in closed bottle test Akzo Nobel - The Netherlands, Report No.: CRL F92075, GLP, Unpublished	Yes	EQC
IIA4.2.3.1 IIIA7.5.1.1	Van Ginkel, CG and Van der Togt, B	2004	Toxicity of BKC to soil microorganisms: Nitrogen transformation inhibition test, Akzo Nobel - The Netherlands, Report No.: CER F04012, GLP, Unpublished	Yes	EQC
App.6.7 IIA2.2 IIB7.2	Van Puijenbroek, R and den Hartog, I	2006	Literature searches for efficacy data of BKC for BPD Product Types 8, 2, 3 and 4, Akzo Nobel - The Netherlands, Report number: CAP-MAS M06077, Not GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Wakeling, RN	1991	A comparison of soft rot, white rot and brown rot in CCA, CCP, CCF, CCB, TCMTB and benzalkonium chloride treated Pinus radiata IUFRO stakes, after 9-15 years exposure at five test sites in New Zealand, IRG, Report No.: IRG/WP 1485, Not GLP,	No	Public data

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			Published		
IIA2.2 IIB7.11 IIB7.2.1 IIIA5.3 IIIB5.10.2	Wallhäuser, KH	1995	Praxis der Sterilisation Disinfection – Konservierung, Not GLP, Published	No	Public data
IIA3.6.1 IIIA6.6.2	Wilmer, J and De Vogel, N	1986	Chromosome analysis of Chinese hamster ovary cells treated in vitro with Arquad DMMCB- 50, TNO CIVO Institutes - The Netherlands, Report No.: V86.351/260493, GLP, Unpublished	Yes	EQC
IIA3.6.1 IIIA6.6.1	Wilmer, JWGM	1986	Examination of Arquad DMMCB-50 for mutagenic activity in the Ames test, TNO Toxicology Division - The Netherlands, Report No.: V 86.165/260064, GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Wong, MH	1990	Studies on fungi isolated from Eucalyptus fibers, Microbios 64:(258) 19-29, Not GLP, Published	No	Public data
IIA2.2 IIB7.2.1 IIIA5.3 IIIB5.10.2	Zhou, F, et al.	2004	Synthesis and antimicrobial characteristics of novel biocides, 1,1'-(decanedioyl)bis(4- methyl-4-alkylpiperazinium) iodides with a gemini structure, Biocontrol Science (2004), 9(3), 61-67, Not GLP, Published	No	Public data