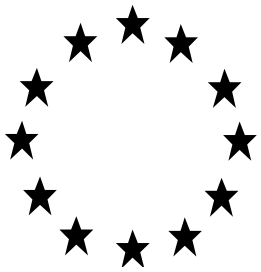
Directive 98/8/EC concerning the placing biocidal products on the market

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

Assessment Report



Didecyldimethylammonium 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 didecyldimethylammonium chloride (DDAC, CAS no. 7173-51-5) 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.

DDAC was notified as an existing active substance separately by Lonza AG & Stepan Europe & Mason Europe Ltd (US ISC) and by Akzo Nobel 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 didecyldimethylammonium 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 applicant. The Rapporteur Member State accepted the dossiers as complete for the purpose of the evaluation on 28th September 2004.

As regards the 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 20th September 2007. The competent authority report included a recommendation for the inclusion of didecyldimethylammonium chloride in 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.

On the basis of the final competent authority report, the Commission proposed the inclusion of

[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

didecyldimethylammonium chloride in 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 and Thor (European Quat Consortium, EQC), on 25th January 2005 the evaluation was suspended. After a meeting with EQC 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. A further revision of the dossier was presented by the Applicant on 14th March 2008, following a meeting on 13th December 2007, where the identity of the active substance was discussed again (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 didecyldimethylammonium 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 didecyldimethylammonium 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 didecyldimethylammonium 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 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

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

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

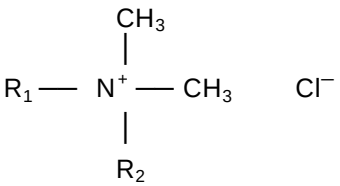
The data submitted by the two Applicants for the evaluation and approval of didecyldimethylammonium chloride (DDAC, CAS no. 7173-51-5) are reported in the following chapters. In particular, Lonza AG & Stepan Europe & Mason Europe Ltd (members of the 'ADBAC and DDAC Issues Steering Committee') and Akzo Nobel & 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

Didecyldimethylammonium chloride (DDAC) is not manufactured solvent-free, but in process solvents as technical concentrate (in water or water/alcohol).

CAS-No.	7173-51-5
EINECS-No.	230-525-2
Other No.	612-131-00-6 (Annex I Index number)
IUPAC Name	N,N-Didecyl-N,N-dimethylammonium chloride
CAS Name	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride
Molecular formula	$C_{22}H_{48}N.Cl$
Structural formula	 where $R_1 = R_2 = C_{10}H_{21}$
Molecular weight	362.1 g/mol
Purity	>87.0% w/w (dry weight) for **US ISC** >97.9% w/w (dry weight) for **EQC**

DDAC 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	BC-25
Manufacturers development code number	None assigned
Active substance	Didecyldimethylammonium chloride
Content of the a.s. [g/kg]	250
Function	Fungicide, insecticide
Physical state of preparation	Liquid
Nature of preparation	Water-based concentrate (SL)

EQC

Trade name	DDAC-50
Manufacture's development code number	None assigned
Active substance	Didecyldimethylammonium chloride
Content of the a.s. [g/kg]	500
Function	Fungicide/fungistatic
Physical state of preparation	Liquid
Nature of preparation	Solvent-based concentrate

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

DDAC 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 DDAC technical concentrate (in water/isopropanol and water, respectively).

DDAC is a white/slight yellowish solid, with hygroscopic behaviour and aromatic/moderate mushroom-like odour. Its relative density D_4^{20} is ≈ 0.9. DDAC is thermally stable, non-volatile and highly soluble in water. Water solubility was found to be independent of temperature and pH. DDAC is fully ionized in water.

The partition coefficient n-octanol/water is not determinable by the use of the shake-flask method, since DDAC is a surfactant. The HPLC method is not applicable either, due to the absence of suitable calibration compounds and to the interaction of DDAC 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} =0.38, *log* K_{ow} =-0.41 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 DDAC molecular structure. As for the UV/VIS spectra, no absorption is observed above 290 nm under the investigated conditions (neutral/acidic/basic medium).

DDAC does not show explosive or oxidising properties. DDAC is not classified as a flammable solid, either.

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

DDAC-50 (representative product for EQC) is a solvent-based concentrate which is not expected to have explosive or oxidising properties. Auto-ignition temperature is 260°C, whereas flash point is 26°C (thus requiring the classification of the product as Flam. Liq. 3 according to CLP).

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 Dialkyldimethyl Ammonium Chlorides") for the determination of DDAC, impurities and process solvents in commercially available technical concentrate

Bardac 22 (nominal DDAC content: 50% w/w) was submitted by the Applicant, superseding those in Doc. IIIA under Sections 4.1(1), (2) and (3). Results are summarized in Section 4.1(4)(a) in Doc. IIIA and Section 4.1(4)(b)-(c) in the Annex of „Confidential data". Further, additional validation data/information were submitted by US ISC post Annex I inclusion of DDAC under BPD. It can be concluded that valid analytical methods are available for DDAC, its impurities and process solvents in 50% w/w DDAC-based technical concentrates.
A five-batch analysis per member of the consortium was also submitted by US ISC post Annex I inclusion of DDAC under BPD, to support/confirm the set reference specification (dry weight). 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, so each source of the US ISC covered by five-batch analysis can be considered as a reference source.

EQC: A new study report for the identification/quantification of DDAC and its impurities in the technical material obtained by lyophilisation of a sample of a water-based technical concentrate (Arquad 2.10-40) 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 DDAC technical material.
In order to set the reference specification, a five-batch analysis of the active substance as manufactured (technical concentrate) was submitted by either member of EQC, i.e. Akzo Nobel and 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 both sources. Therefore, both sources 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 BC-25 and DDAC-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 DDAC-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 DDAC-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 either US ISC and EQC for the determination of residues in soil and water, which are necessary for post-authorization control and monitoring, support the residue definition (DDAC).

US ISC: LC-MS methods for the analysis of DDAC residues in soil and water (drinking, ground and surface water) down to 0.01 mg/kg and 0.1 µg/L, respectively, were available in the original dossier. Only one mass fragment 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 DDAC 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. Post Annex I inclusion of DDAC under BPD, US ISC submitted new analytical methods for residues in soil and water in order to fulfil the requirement.

An analytical method by LC-MS/MS on a C18 reversed-phase column for the determination of DDAC residues in two soil types (sandy loam and clay) down to 0.01 mg/kg is now available. The method is highly specific (LC-MS/MS, with two ion transitions validated), linear over the range 0.002−0.1 mg DDAC/kg soil, accurate (with mean recovery rate at LOQ and 10xLOQ in the acceptable range 70−120%) and precise (%$RSD_{n=5}$ ≤20% for either fortification level). The LOQ (as the lowest fortification level successfully validated) complies with the relevant PNEC (i.e. LOQ<$PNEC_{soil}$ =1.58 mg/kg dw soil).

An analytical method by LC-MS/MS on a C18 reversed-phase column for the determination of DDAC residues in drinking, ground and surface water down to 0.1 µg/L is also now available. The method is highly specific (LC-MS/MS, with two ion transitions validated), linear over the range 0.02−1.0 µg DDAC/L in matrix, accurate (with mean recovery rate at LOQ and 10xLOQ in the acceptable range 70−120%) and precise (%$RSD_{n=5}$ ≤20% for either fortification level). Ground- and drinking-water: the LOQ (as the lowest fortification level successfully validated) complies with the EU drinking water limit based on DWD (0.1 µg/L).
Surface water: the LOQ (as the lowest fortification level successfully validated) complies with the $PNEC_{water}$ (1.1 µg/L)

EQC: An analytical method by RP-HPLC/MS-MS which enables the analysis of DDAC in soil down to a level of 0.05 mg/kg was available in the original dossier. The method was fully validated for one MS/MS transition but, according to the *Additional guidance on the TNsG on Data Requirements for Analytical Methods,* HPLC-MS/MS methods are regarded as highly specific only when two ion transitions have been validated. Therefore, additional validation on a second MS/MS transition was requested.

In 2014 a new RP-HPLC/MS-MS analytical method which enables the analysis of DDAC in soil down to a level of 0.02 mg/kg was submitted. The method is highly specific (LC-MS/MS, with two ion transitions validated), linear over the range 0.004−0.16 mg DDAC/kg soil, accurate (with mean recovery rate at LOQ and 10xLOQ in the acceptable range 70−120%) and precise (%$RSD_{n=5}$ ≤20% for either fortification level). The LOQ (as the lowest fortification level successfully validated) complies with the relevant PNEC (i.e. LOQ<$PNEC_{soil}$ =1.58 mg/kg dw soil).

RP-HPLC/MS-MS analytical method for the analysis of DDAC in surface water down to a level of 0.1 µg/L was available in the original dossier. The method was deemed adequately accurate and precise based on results for one MS/MS transition. Anyway, according to the *Additional guidance on the TNsG on Data Requirements for Analytical Methods*, HPLC-MS/MS methods are regarded as highly specific only when two ion transitions have been validated. Therefore, additional validation on a second MS/MS transition was requested.
In 2014 a new RP-HPLC/MS-MS analytical method which enables the analysis of DDAC in surface water down to a level of 0.04 µg/L was submitted. The method is highly specific (LC-MS/MS, with two ion transitions validated), linear over the range 0.02−0.8 µg DDAC/L surface water, accurate (with mean recovery rate at LOQ and 10xLOQ in the acceptable range 70−120%) and precise (%$RSD_{n=5}$ ≤20% for either fortification level). The LOQ (as the lowest fortification level successfully validated) complies with the relevant PNEC (i.e. LOQ<$PNEC_{water}$ =1.1 µg/L).
An analytical method by LC-MS/MS for the determination of DDAC residues in ground water down to a level of 0.1 µg/L is also available. The method is highly specific (LC-MS/MS, with two ion transitions validated), linear over the range 0.06−6.0 µg DDAC/L in ground water, accurate (with mean recovery rate at LOQ and 10xLOQ in the acceptable range 70−120%) and precise (%$RSD_{n=5}$ ≤20% for either fortification level). The LOQ (as the lowest fortification level successfully validated) complies with the EU drinking water limit of 0.1 µg DDAC/L.

2.1.2. Intended Uses and Efficacy

PT 8, Wood Preservative

DDAC is a wood preservative used for the preventive protection of wood and constructional timbers in Hazard Classes from 1 to 4A against wood destroying organisms and wood discolouring moulds and fungi.

Mode of action

DDAC is a cationic surfactant type active substance. 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

Biocidal product BC-25 **(US ISC)** is a wood preservative with preventive efficacy against wood-destroying fungi basidiomycetes, insects and soft rot fungi. It 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 in water. In practice it is always used in formulations in combination with other active substances. The use concentration depends on the type of application technique, use class required and on additional formulation components. The requirements for the final concentration of DDAC vary between 0.3% and 1.8%. The application rate of DDAC in wood is 1.8 kg/m^3. Number and timing of applications depends on application technique, wood species, moisture and hazard class.

Biocidal product DDAC-50 **(EQC)** is a wood preservative for temporary and permanent protection against fungi. The method of application is by dipping in dipping bath and spraying in a closed tunnel. According to the information provided by the Applicant, both the application processes are intended for professional users in industrial settings only. Concerning 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. DDAC-50 is typically diluted with water to 5-15% active substance. The proposed retention is 0.8-3.2 kg a.s./m^3, corresponding to 8-32 g a.s./m^2.

Organisms 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 moulds

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 DDAC-resistance in the field of wood protection exist. On the other hand, DDAC acts as a wood preservative, which works by preventing the 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 demonstrates that the active substance has a sufficient level of efficacy against the target organism(s) and the evaluation of the summary data provided in support of the efficacy of the accompanying products, 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

DDAC is currently classified according to Annex I of Council Directive 67/548/EC (with amendments and adaptations) and according to Regulation (EC) No 1272/2008 (CLP Reg.).

Current Classification and Labelling of DDAC as in Directive 67/548/EEC

Classification	
Class of danger	Xn; R22 C; R34
R phrases	R22 Harmful if swallowed R34 Causes burns
S phrases	S2 Keep out of the reach of children S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice S36/37/39 Wear suitable protective clothing, gloves and eye/face protection S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

Current classification and labelling of DDAC according to Annex VI as in Reg. (EC) No 1272/2008 (CLP Reg.)

Classification	
Hazard Class and Category	Acute toxicity (oral), Hazard Category 4 Skin Corrosion Hazard Category 1B_
Hazard Statement Codes	H302 H314
Labelling	
GHS Pictogram	GHS05, GHS07
Signal Word	Danger
Hazard Statement	H302:Harmful if swallowed H314: Causes severe skin burns and eye damage

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

Proposed Classification and Labelling of DDAC based on Regulation EC 1272/2008

Classification	
Hazard Class and Category	Acute toxicity (oral), Hazard Category 3 Skin Corrosion Hazard Category 1B_ Aquatic Acute 1_ Aquatic Chronic 2_
Hazard Statement Codes	H301 H314 H400 H411
Labelling	
GHS Pictogram	GHS05, GHS06, GHS09
Signal Word	Danger
Hazard Statement	H301:Toxic if swallowed H314: Causes severe skin burns and eye damage H400: Very toxic to aquatic life H411: Toxic to aquatic life with long lasting effects

M Factor	M factor=10 (Acute)

US ISC

Proposed Classification and labelling of product BC-25 based on Reg. EC 1272/2008

Classification	
Hazard Class and Category	Acute toxicity (oral), Hazard Category 2 Skin Corrosion Hazard Category 1B Aquatic Acute 1 Aquatic Chronic 2_
Hazard Statement Codes	H302 H314 H400 H411
Labelling	
GHS Pictogram	GHS05,GHS09
Signal Word	Danger
Hazard Statement	H302:Harmful if swallowed H314: Causes severe skin burns and eye damage H411: 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)

EQC

Proposed Classification and labelling of DDAC 50 based on Reg. EC 1272/2008

Classification	
Hazard Class and Category	Flam. Liq. 3 Acute Tox 4 Skin Corr. 1B STO SE 3 Aquatic Acute 1
Hazard Statement Codes	H226 H302 H314 H336 H400
Labelling	
GHS Pictogram	GHS02, GHS05, GHS09
Signal Word	Danger
Hazard Statement	H226: Flammable liquid and vapour H302: Harmful if swallowed H314: Causes severe skin burns and eye damage H336: May cause drowsiness or dizziness H400: Very toxic to aquatic life
Precautionary statements	P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking P233: Keep container tightly closed P261: Avoid breathing dust/fume/gas/mist/vapours/ spray. 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): Remove/Take off immediately all contaminated clothing. Rinse skin with/shower 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

Didecyldimethylammonium chloride (DDAC, CAS no. 7173-51-5) is highly ionic and, therefore, it is expected not to be readily absorbed from the gastrointestinal tract or skin. As indicated in a toxicokinetics study on rats, the majority (>90%) of orally administered DDAC is excreted, very likely unabsorbed, via the faeces. Based on data on urine excretion (≈3%) and tissue residues (<1%), and on the 90% recovery of radioactivity obtained in the available toxicokinetic study, it is expected that DDAC oral absorption is limited to ≈10% at non corrosive concentration) **(US ISC)**. The same conclusion could obtained analysing another study indicating that the vast majority (86-96%) of the oral dose was excreted in the faeces as unabsorbed material (only up to 2.57% of the oral dose was eliminated in the bile in a 24-hour period). Based on the urinary mean value (3-4%) and biliary excretion values (2.6%), as well as on the absence of residues in the carcass, as measured at 168 h, the actual absorbed fraction was within a range of 5-10% of the orally administered dose **(EQC)**.

The majority of DDAC metabolism, accounting for 40% of total administered dose is expected to be carried out by intestinal flora giving rise to hydroxylation products in the alkyl chain, none of them exceeding 10% **(US ISC)**. The low amount of radioactivity excreted in the urine consists of 20% of parent compound, whereas approximately 24% accounted for conjugated metabolites. No further attempts were made to identify the DDAC metabolites **(EQC)**.

The active substance does not show any bioaccumulation potential **(US ISC; EQC)**.

About 0.1% of a DDAC dose delivered as aqueous solution penetrated human skin in vitro in 24 h; mean total absorbable DDAC was 9.41% (rounded to 10% at non corrosive concentration), including the radioactivity present in the dermis and epidermis at the dose site **(US ISC)**. The available data do not allow a clear quantification of DDAC percutaneous absorption, although they indicate that there are not marked differences between the oral and the dermal bioavailability. Therefore, it is expected that DDAC dermal absorption is limited to ≈10% at non corrosive concentration (as maximum value) **(EQC)**.

The lowest determined oral LD_{50} for DDAC is in the range 238-264 mg/kg bw mg/kg **(US ISC-EQC, respectively)**. 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.

The rabbit acute dermal LD_{50} of DDAC is 3342 mg/kg. and no classification is required for the dermal route (LD_{50} = 3342mg/kg bw) **(US ISC)**. Literature values of dermal LD50s >2000 mg/kg also indicate that DDAC should not be classified for acute dermal toxicity **(EQC)**.

Inhalation of DDAC is not considered a potential route of exposure based on scenarios and vapour pressure $2.3x10^{-4}$ Pa at 50ºC **(US ISC)**. Inhalation toxicity study was considered unnecessary, since the active substance is not volatile, (vapour pressure < 1×10^{-2} Pa at 20°C) and only spraying with big, not inhaled, droplets with MMAD > 40 µm is recommended; in addition no inhalation testing is allowed with corrosive chemicals **(EQC)**.

DDAC is 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, DDAC is not expected to be a respiratory sensitizer **(US ISC; EQC)**.

From a two-week skin irritation study in rats, a NOAEC of 0.6% active substance in water at

2.0 mL/kg body weight per day after a 5 day application and a NOAEC of 0.3% active substance in water at 2.0 mL/kg body weight per day after 2-week application can be derived **(US ISC; EQC)**.

2.2.1.2. Effects assessment

As with acute exposure, DDAC repeated intake results in death in rodents at a concentration that affects the gastrointestinal mucosa or microflora or in unspecific toxicity with the major effects likely associated to the concentration dependent cytotoxicity, irritation and corrosivity at the site of contact. Indeed, the effects on which the NOEL derivation could have been based, independently on the species tested, were 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 NOAELs were 107-134 mg/kg/day in male and female mice and 61-74 mg/kg/day in male and female rats mainly based on aspecific effects, such as decreased body weights, considered to be secondary to local effects on gut mucosa and intestinal microflora. No organ specific toxicity was evidenced. With both rodent species high mortality (80% and 96% of treated rats and mice) occurred in animals given DDAC fortified diets at the highest dose tested; death was attributed to gastrointestinal alterations resulting in dehydration and wasting. The exposure to the immediately lower dose caused only minimal body weight effects (10-15% decrease). The steepness of the dose-response curve (from no effects to high % mortality caused by 3-fold higher dose) is also indicative of the mechanism of action through irritation/corrosive properties of DDAC **(US ISC)**.

A 90-days repeated dose oral toxicity study in rats resulted in a NOAEL of 46 mg a.s./kg bw/day, whereas the dietary administration of DDAC to dogs resulted in a NOEL of 15 mg/kg bw/day (the highest dose tested). Preliminary range finding studies indicated that immediately higher doses corresponded to decreased body weights associated to decreased food intake **(EQC)**.

In a 1-year oral gavage study in dogs with DDAC, the two highest doses (10 and 20 mg/kg/day) resulted in g.i.-related complications including emesis and abnormal faeces. The clinical signs observed in all the animals treated at 10 mg/kg/d (emesis, salivation, soft/loose faeces) persisted for the entire study duration; taking into account that the treatment dosage is reached with 2 different administrations within the day (lowering the entity of the bolus dose achievable with a single administration-possibly giving rise to more severe effects) this dosage cannot be considered as the NOAEL derived from the study. The NO(A)EL should be fixed equal to 3 mg/kg/d, related to local effects on gut mucosa. The clinical signs reported at 10 mg/kg/d, on which the NOAEL derivation is based, are consistent with the irritation/corrosive properties of the test item: only a small amount of DDAC becomes systemically available, without giving rise to any significant systemic effects. The systemic effects (10-15% decrease in body weight), were seen at 20/30 mg/kg/d, although secondary to effects in the gut. In this context, the AEL cannot be regarded as a "true" systemic threshold and therefore, at WGII2015 it has been agreed that the AEL approach should not to be performed. Consequently, only a qualitative local risk assessment (including exposure assessment) have to be considered from the use of DDAC **(US ISC)**.

In a 90-day subchronic dermal study, no effects were seen at the highest dose that could be applied without excessive skin irritation. Therefore the systemic NOAEL was 12 mg/kg/d (highest dose tested) and the local NOAEL was 2 mg/kg/d **(US ISC)**.

No dermal repeated toxicity study has been carried out. However, regarding systemic effects the oral NOAEL can be considered has a worst case, due to the available information on dermal absorption and the mechanism of action of the a.s. No studies have been provided to derive a NO(A)EC for skin corrosion after repeated exposure **(EQC)**.

Inhalation repeated toxicity study was considered unnecessary, since the active substance is not volatile, (vapour pressure < 1 x 10^{-2} Pa at 20°C) and only spraying with big, not inhaled, droplets with MMAD > 40 µm is recommended; in addition no inhalation testing is allowed with corrosive chemicals **(US ISC; EQC)**.

The NOAELs for non neoplastic effects after chronic dietary DDAC administration were 32-41 mg/kg/day for rats and 76 − 93 mg/kg/day for mice. NOAELs values derivation was mainly based on unspecific effects, such as decreased body weights, considered to be secondary to local effects on gut mucosa and intestinal microflora. No organ specific toxicity was evidenced. In line with the fact that the main outcome directly derives from the irritative/corrosive properties of the active substance, the subchronic and chronic NOAELs are similar in rodents, and little difference is expected between the 2 exposure scenario **(US ISC)**.

After chronic exposure of rats to DDAC, the NOAEL for non neoplastic effects was 600 ppm, equivalent to a range of 27.3-33.8 mg DDAC/kg bw/day, based on the effects observed at 1200 ppm, that is decreased body weight (up to −26%) and body weight gains in females and non-neoplastic histopathological findings in the mesenteric lymph nodes and Peyer's patches (consistent with the continued irritant action of the test item) **(EQC)**.

DDAC displayed no genotoxic activity in the three mutagenicity tests required for the authorisation of Biocidal Products: in-vitro gene mutation assay in S. typhimurium (Ames test), in vitro chromosomal aberrations assay in CHO cells and CHO/HGPRT forward mutation assay **(US ISC; EQC)**.

Moreover, no clastogenic activity was observed in chromosomal aberration test in rat bone marrow in vivo. Therefore DDAC can be considered not genotoxic **(US ISC)**.

No neoplastic lesions were found that were considered treatment related and therefore DDAC was not found to be carcinogenic under the conditions of the available study **(US ISC; EQC)**.

DDAC does not affect reproduction or development at doses that are not toxic to the mother. The NOAEL from maternal toxicity in the reproductive toxicity study was 1 mg/kg/d **(US ISC)**.

A rabbit prenatal developmental toxicity study showed high maternal toxicity with abortions at top dose (32 mg/kg bw); at mid-dose (12 mg/kg bw) signs of maternal distress were observed without any litter effect. Thus, the maternal NOAEL was 4 mg/kg bw, whereas the developmental NOAEL was 12 mg/kg (EQC).

A full OECD 416 compliant two-generation reproduction study in rats has been completed, with dietary administration of DDAC of 203, 608 and 1620 mg/kg food corresponding to actual dose levels of ≥ 10, ≥ 30 and ≥ 52 mg/kg bw. At top dose, cortical adrenal hypertrophy in F0 females as well as lower weight gain and higher spleen weights in F1 were present. No reproductive effects were observed. The NOEL for systemic toxicity was 608 mg/kg food (≥ 32 mg/kg bw/d). This study therefore did not indicate concern for toxicity to reproduction **(EQC)**.

The lack of any structural similarity to known neurotoxins or of any alert for neurotoxic effects shown by quaternary ammonium chemicals in general together with no indication of neurotoxic effects in any of the performed toxicological studies support the conclusion that DDAC has no neurotoxic potential **(US ISC; EQC)**.

Medical data

No specific observations or sensitivity/allergenicity or any medical information have been reported **(US ISC; 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 **(US ISC)** or 2-6% propan-2-ol in water **(EQC)**. The degree of dilution varies depending on the wood species, type of wood product and anticipated use. Therefore the a.s. concentrations in the processes vary between 0.3% and 15%.

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

DDAC 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.

DDAC 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 DDAC-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	0.0555	0.0044	0.032
APPLICATION PHASE (Vacuum Pressure treatment): Handling Model1	0.069	0.008	0.024

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

The local irritant effect of the DDAC 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 1.8 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	1.8
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	2.88
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 = 2.88 mg

Concentration in the mouth = F/(G x H) = 1.92 mg/mL = 1920 mg/kg

Local dose expressed as percentage of active substance = 0.192 %

EQC

DDAC 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.

DDAC 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 DDAC-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	Inhalation exposure
	mg/cm^2	mg/cm^2	mg/m^3
MIXING&LOADING Riskofderm Connecting lines	0.00055	-	-
APPLICATION PHASE (Automated dipping treatment): Handling Model1	0.46	0.091	-
Spraying in a closed tunnel: Dipping and Deluge	0.33	0.057	0.15

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

The local irritant effect of DDAC 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) = 2.13 mg/mL = 2133 mg/kg

Local dose expressed as percentage of active substance = 0.213%

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% DDAC).

Local NOAEC derivation – Dermal route

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

In the skin irritation study the treated body surface has not been well defined and therefore, the assumption of 10% coverage of the animal body could be made based on the guideline recommendations. According to the TGD, the total surface body of rat (male and female) is 400 cm^2 and the mean body weight is 300g. Assuming that 10% of the body surface has been exposed to the test substance, the resulting exposed area is of 40 cm^2.

For the characterization of the risk due to the local dermal effects a NO(A)EC (expressed in mg/cm^2) has to be derived following the formula below:

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

NOAEC = (0.3 kg x 6 mg/kg bw/day) / 40 cm^2 = 0.045 mg/cm^2

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

Local NOAEC derivation – Oral route

For local effects an oral NOAEL has been set at 3 mg/kg bw/d from a 1-year oral gavage study in dogs. This NOAEL is particularly relevant since from the same study it was possible to differentiate a NOAEL for local effects on the g.i. mucosa (3 mg/kg bw/d) on the basis of emesis present at the higher dose (10 mg/kg bw/d), which was on the other hand considered as a systemic NOAEL, based on decrease body weight at the immediately higher dose. For the purpose of a semi-quantitative risk assessment, the NOAEL value of 3 mg/kg bw/d (1-year oral gavage toxicity study) in dogs has to be used for the oral NOAEC derivation rather than the NOAEL from the reproductive toxicity studies on rats. This taking into consideration that also in the DDACarbonate CAR it is stated that "(…) dogs appear to be more sensitive to the adverse effects of repeated oral exposure to DDAC than rats and mice and toxicity occurs at lower doses in gavage studies compared to dietary studies (…)" (Draft Final CAR – Doc.I, p.11/59).

In the oral NOAEC derivation it was considered as follows: a fixed dose volume of 10 mL/kg dose, a body weight of 10 kg for dos. Therefore, using the NOAEL of 3 mg/kg bw/d as point of departure, the oral NOAEC results to be of 0.3 mg/mL equivalent to a NOAEC of 0.03%.

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

Exposure and risk from use of the product

For local dermal effects, the NOAEC expressed in terms of % should be compared with the in-use concentration of the active substance in the representative products. In this regards, the formulations BC-25 (US ISC) and DDAC-50 (EQC) contain 25% and 50% of DDAC, respectively. On the other hand, the in-use concentrations of DDAC in the representative products range from 0.3% to 15% (*i.e.*, from 0.3% to 1.8% and 15% for the formulations BC-25 and DDAC-50, respectively). Therefore, being the concentrations of the DDAC solutions applied equal or higher than the (marginal) NOAEC of 0.3% DDAC 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 DDAC. The conclusion from the semi-quantitative risk assessment due to the corrosive properties of DDAC is that PPE are per definition required when applying DDAC.

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 concentrations range from 0.192% DDAC (1.92 mg/mL) to 0.213% DDAC (2.13 mg/mL) depending on the biocidal products applied (*i.e.*, BC-25 or DDAC-50).

Being the oral NOAEC of 0.03% less than the local concentrations, a potential risk is still highlighted for children chewing and sucking timber treated cut-off.

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

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

Therefore, based on the above discussion, it is considered inappropriate to use an AEL approach for DDAC and similar quaternary amines, because there is no true systemic toxicity. DDAC, 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.

<u>Conclusion</u>

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."

Biocidal Product

US ISC

An in vitro dermal absorption study showed that less than 0.1% DDAC fully penetrate human skin in 24 h; considering also epidermis and dermis material at the dose site, receptor fluid and rinse receptor fluid, 9.41% of total absorption can be assumed.

An acute oral toxicity study has been performed on 5% aqueous dilutions of DDAC resulting in an LD_{50} = 238 mg/kg and leading to the classification Xn, R22 being applied. According to the provisions of directive 1999/45/EC, this product is also classified as Xn, R22 (trigger concentration is ≥25%).

An acute dermal toxicity study has been performed on an 80% solution of DDAC resulting in an LD_{50} = 3342 mg/kg. According to the provisions of directive 1999/45/EC this product is also not classified for dermal toxicity.

This product contains 25% DDAC in water and no other components. DDAC is not volatile as the vapour pressure is 2.3E-04 Pa at 50°C. Therefore there is no concern for inhalation exposure.

Skin and eye irritation studies have been performed on an 80% dilution of DDAC, which lead to the classification as corrosive, R34 being applied. According to the provisions of directive 1999/45/EC, this product is also classified as C, R34 (trigger concentration is ≥10%).

An aqueous dilution of DDAC, at a higher concentration than BC-25, did not show any sensitizing potential.

EQC

The biocidal product DDAC-50 contains 50% DDAC; 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 on Arquad 2.10-50 (containing 50% DDAC as DDAC-50 and having the same composition) resulted in an LD_{50} = 658 mg/kg bw (combined sex) and 527 mg/kg bw (in females) leading to the classification Harmful if swallowed, Xn, R22.

The dermal LD_{50} value for Arquad 2.10-50 is > 2000 mg/kg bw and, according to EU regulation, the product has not to be classified for this end-point. DDAC is not volatile as the vapour pressure is < 1 x 10^{-2} Pa at 20°C. The industrial production and formulation does not lead to aerosol formation. In case of spraying, only spraying with big droplets (> 40 µm) is recommended. Therefore there is no concern for inhalation exposure. In addition, according to the TGD, inhalation toxicity must not be studied for preparations classified as corrosive, as indicated for the test item by results of the skin irritation study.

A skin irritation study has been performed on a formulation similar to DDAC-50 (i.e. Querton 2.10Cl-80, containing 80% DDAC in 15% propan-2-ol and 5% water), which is considered valid for DDAC-50, being the active substance content higher; therefore testing Querton 2.10Cl-80 represents a worst case. Results lead to the classification as corrosive, R34 ('Causes burns') being applied. On this basis it was ethically unjustified to test DDAC-50 for eye irritation.

DDAC-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 results of the ready biodegradability test showed that at test termination (28 days), 93.3% of the radioactivity was evolved as $^{14}CO_2$, 1.32% was recovered in the extracts and 3.28% remained in the solid. In the abiotic sample 92.22% of the radioactivity was recovered in the extracts and 1.5% remained in the solid. Didecyldimethylammonium chloride (DDAC, CAS no. 7173-51-5) is biodegraded in aerobic conditions **(US ISC)**.

Due to the fact that DDAC was readily biodegradable, field studies on accumulation in the sediment, aerobic degradation studies in soil, field soil dissipation and accumulation studies were not needed. However a biodegradation study in two water/sediment systems has been performed and showed that the substance easily migrates from the aqueous phase to the sediment phase and is also easily adsorbed to sediments (high K_{oc}). The study has a reliability indicator of 3, is not considered a key study, it has been used in support of the risk assessment. The degradation in the sediment phase did not increase very much after the first month and the DT_{50} of the total system was not reached within the 120 days test duration.

A study to measure biodegradation in seawater was not conducted as DDAC used as a wood preservative will not be released to the marine environment in considerable amounts.

The results of the ready biodegradability show that 69% of DDAC was degraded after 28 days in the Closed Bottle Test **(EQC)**. The reference substance, sodium benzoate, was degraded 80% after 14 days. The 10% degradation level was reached around day 2 and the 60% degradation level around day 18; the 10-day window criteria was not met (10-60% estimated over 14 days, the 14-d window acceptable for Closed Bottle Test was not met) and the sludge had been pre-adapted. DDAC is removed from wastewater at very high percentages (>99.99%) in the continuous activated sludge test (OECD 303A). DDAC will biodegrade almost completely (<0.024% removed via sorption in OECD 303A test) in conventional biological wastewater treatment plants.

The test substance can be considered as 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).

DDAC is ready biodegradable.

Abiotic Degradation

DDAC was hydrolytically stable during the 30-day hydrolysis study at pH 5, 7 or 9 at 25°C.

DDAC 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 The half-life of the test compound was determined to be 227 days with

7% degradation after 30 days.

The test substance was stable and not subject to photodegradation on soil. Extractable residues decreased from 90.5% to 80.8% (exposed) and 81.1% (non-exposed). Soil bound residues increased from 9.48% to 25.2% (exposed) and 20.9% (non-exposed). 73.8 to 74% of activity was recovered in the extractable bound residues. Half-lives were calculated as t1/2 = 132 days (exposed) and t1/2 = 169 days (non-exposed). Rate constants were calculated as 5.26 E-03/days (exposed) and 4.11E-03/days (non-exposed) **(US ISC)**.

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. At pH 9, a 15.6% and 9.94% hydrolysis was observed. An increase of test substance was observed at pH 9. The reason for the observed increase could not be clarified. 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 = 0.346 days (8.314 hours), assuming 24 hour according to TGD (2003) chapter 2.3.6.3.

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

DDAC is found to be photolytically stable in the absence of a photosensitiser. The mean atmospheric half life of DDAC is 0.346 days (8.314 hours), assuming 24 hour according to TGD (2003).

Distribution

DDAC can be considered as immobile in four soil/sediment types with the adsorption (Ka) and mobility (Ka_{oc}) coefficients of Ka=1.095 and Ka_{oc}=437805 for sand, Ka=8179 and Ka_{oc}=908757 for sandy loam, Ka=32.791 and Ka_{oc}=1599564 for silty clay loam, and Ka=30851 and Ka_{oc}=1469081 for silt loam. The desorption (Kd) and mobility (Kd_{oc}) coefficients are following reported: Kd=591 and Kd_{oc}=236473 for sand, Kd=2074 and Kd_{oc}=230498 for sandy loam, Kd=8309 and Kd_{oc}=405328 for silty clay loam, and Kd=7714 and Kd_{oc}=367334 for silt loam.

It is well known that because of their positive charge, the cationic surfactants adsorb strongly to the negatively charged surfaces of sludge, soil and sediments. The average K_{oc} is 1.10 10^6 **(US ISC)**.

DDAC can be considered as immobile in five soil types. The adsorption mobility (Ka_{oc}) coefficients are in the range 40339 to 280547 L/kg. The desorption mobility (Kd_{oc}) coefficients are in the range 53883 L/kg to 232426 L/kg. In the following table the K_{oc} values are summarised:

Soil type	Ka [L/kg]	Ka_{oc} [L/kg]	Kd [L/kg]	Kd_{oc} [L/kg]
clay	9230	280547	3718	113009
silt loam	2868	120000	4237	177280
loam	1456	43855	2117	63765
silt	2188	160882	3161	232426
loamy sand	1787	40339	2387	53883

The 1/n values indicate that a non-linear relationship exists between the concentrations in soil and the concentrations the water. DDAC adsorbs strongly onto soil and does not desorb very easily for all soil types.

It is well known that, because of their positive charge, cationic surfactants adsorb strongly to the negatively charged surfaces of sludge, soil and sediments. The average K_{oc} is 129125 L/kg. **(EQC)**.

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

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 562314 L/Kg.

Mobility

DDAC adsorbs strongly onto soil, therefore the leachate from wood into soil will be adsorbed immediately and will not desorb very easily.

The results of this study indicated that DDAC had little or no potential for mobility in soil and should not pose an environmental risk for contamination of ground water. Therefore, mobility-lysimeter studies were not justified.

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

DDAC had little or no potential for mobility in soil and should not pose an environmental risk for contamination of ground water.

Bioaccumulation

DDAC is ready biodegradable in water, it adsorbsorbs strongly onto soil, and it is considered as immobile in soil/sediment.

A *log* $K_{ow} \approx 0$ could be roughly obtained from solubility in n-octanol and water, anyhow *log* K_{ow} is not a reliable predictor of bioaccumulation of surfactants.

The bioconcentration potential of DDAC in fish was investigated in a flow through test with bluegill (28 d exposure + 18 d depuration) **(included in the US ISC dossier)**. Based on the measured ^{14}C residues, the steady-state BCF (whole fish) was 81 L/kg.

No data are available on the BCF earthworm and calculation according to TGD (eq. 82d) is not applicable to ionic substances, therefore bioaccumulation by terrestrial organisms cannot be estimated with the data available. Nevertheless, a sensitivity analysis carried out by the eCA indicated that a very high (unrealistic) $BCF_{earthworm}$ would be needed in order to conclude unacceptable risk of secondary poisoning of birds and mammals ($PEC_{oral\ predator} > PNEC_{oral\ predator}$) via the terrestrial food chain.

From the information available, it can be concluded that DDAC has a low potential for bioaccumulation.

Leaching study

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 **(US ISC)**. 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 second leaching study was BAM study (Schoknecht, 2002). In this study the leaching is determined on the basis of continuous exposure to water **(EQC)**.

For leaching of DDAC from wood, the results of C_{12-16}-BKC are used because no data for DDAC are available. From another leaching test (Stevens M & Eetvelde van G, 1994) it can be concluded that the amount leaching from wood is approximately the same for C_{12-16}-BKC as for DDAC. Wood was treated with active ingredient for 30 minutes by vacuum pressure and the amount that leached from the wood was determined after 88 hours. For Arquad 2.10 (DDAC) 0.66% had leached from the wood, for Arquad DMMCB (C_{12-16}-BKC) the percentage was 0.74. The test method was different from the method used in Schoknecht (2002), but since both substances were treated the same way in this test, the results for both compounds are comparable and can be extrapolated to the test performed by Schoknecht. C_{12-16}-BKC leaches slightly more than DDAC and therefore the results of the leaching test of C_{12-16}-BKC presented below are overestimating the leaching of DDAC and can be considered a worst case scenario.

DDAC 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 Q*Leach have been calculated according to the Appendices I and II of the OECD ESD, the EXCEL file containing the calculation of Q*Leach for the DDAC leaching study has been reported in the Doc IIB Annex I – Flux calculations_DDAC, the same approach has been accepted for other QUATs already discussed at TM level.

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 similar, the values provided in the first study have been used in the calculation of Predicted Environmental Concentrations (PECs). In conclusion, due to the fact that the first leaching study (US ISC) was conduct on DDAC whilst the second one (EQC) was conduct on C_{12-16}-BKC, the eCA used the results of the first leaching study (US ISC).

2.2.2.2 Effects assessment

Aquatic compartment

The toxicity of DDAC to aquatic organisms is documented by short- and long-term studies with fresh water species belonging to three trophic levels.

The results of short-term toxicity studies indicate that DDAC is very toxic to fish, *Daphnia magna* and algae.

The acute toxicity of DDAC to fish has been evaluated in several tests conducted with different species, the 96h LC_{50} ranging from 0.19 to 1.0 mg a.s./L. The lowest endpoint among the fully reliable data is retrieved for Fathead minnow (most sensitive species) with a LC_{50} = 0.19 mg a.s./L **(US ISC)**. Data of chronic toxicity to fish are available from one early life stage test with *Brachydanio rerio*, which provided a NOEC = 0.0322 mg a.s./L **(US ISC)**.

For *Daphnia magna*, a valid acute toxicity study provided a 48h-EC_{50} = 0.062 mg a.s./L **(US ISC)**. A lower endpoint was retrieved from another study submitted by **EQC** (48h-EC_{50} = 0.029 mg a.s./L), but this was rated as supportive information because the lack of chemical analysis of test concentrations. The 48h-EC_{50} = 0.062 mg a.s./L is selected for DDAC because of the higher reliability, even if it provides a higher value. This approach was agreed at WGII 2015.

The chronic toxicity to *Daphnia magna* was tested in two reproduction studies, providing a 21d NOEC = 0.010 mg/L **(US ISC)** and 21d NOEC = 0.021 mg/L **(EQC)**. Since both tests were conducted with the same method and both data are fully reliable, the geomean of the two endpoints was calculated for DDAC giving a 21d NOEC = 0.014 mg/L.

As for algae, toxicity data are available from a 96 hours study in the US ISC dossier (rated 1, measured concentrations). The results, expressed in terms of initial measured concentrations, are 96h E_rC_{50} = 0.026 mg/L, 72h/96h NOE_rC and 96h E_rC_{10}=0.014 mg/L. Based on mean measured concentrations, the 96h E_rC_{50} = 0.021 mg a.s./L and 96h NOE_rC = 0.011 mg/L (the E_rC_{10} was not calculated). From a second test with green algae (**EQC**, rated 2) a 72h E_rC_{50} = 0.062 mg a.s./L, 72h NOE_rC = 0.013 and 72h E_rC_{10} = 0.024 were obtained. Data are expressed as nominal concentration, but the stability of the test substance (measured in extra vessels without algae) was established only in the two higher concentrations out of the three analysed. The results of the 96h study, besides being more reliable, also provided the lower values and then therefore they are selected for DDAC.

From the comparison of acute and chronic data, it appears that the chronic toxicity of DDAC is < 10 times higher than the acute toxicity. A low acute-to-chronic ratio is indicative of a non-specific mode of action and is consistent with the toxicity mechanism of cationic surfactants (physical binding to respiratory membranes).

CONCLUSION on Aquatic Compartment - Water compartment:

The PNEC water for DDAC is derived based on the lowest of the three chronic data available for the three trophic levels, i.e. the algae 96h NOE_rC = 0.011 mg a.s./L (mean measured concentrations) **(US ISC)**, applying an AF of 10, hence:

PNEC water = 0.011 mg a.s./L / 10 = 0.0011 mg a.s./L

STP compartment

The effects of DDAC on the respiration of activated sewage sludge have been investigated in two studies of 3 hours duration, giving an EC_{50} = 11.03 mg a.s./L **(US ISC)** and EC_{50} = 17.9 mg a.s./L (EQC), respectively. The EC_{10} was calculated only in the second test **(EQC)**, giving EC_{10} =5.95 mg a.s./L.

The two studies are carried out according to the same guideline (OECD 209) and both are rated 1, hence it is considered acceptable to calculate a geometric mean of their results: geomean EC_{50} = 14.03 mg a.s./L **(US ISC, EQC)**.

CONCLUSION on Aquatic Compartment - STP compartment:

The PNEC for micro-organism is derived from the geomean EC_{50} = 14.03 mg a.s./L **(US ISC, EQC)** and the application of an AF of 100:

$PNEC_{micro\text{-}organisms}$ = 14.03 mg a.s./L / 100 **= 0.14 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 of10 to derive the PNEC for microorganisms in STP. At product authorization stage, in order to use the (geomean) EC_{10} as the endpoint to derive the PNEC, the missing EC_{10} from the first study US ISC should be calculated statistically. This approach is consistent with the conclusion reached at WGII2015 for another "back-log" multiple dossier for another QUAT (Coco Alkyltrimethylammonium Chloride).

Sediment Compartment

Toxicity data on sediment dwelling organisms come from one chronic sediment-spiked test with *Chironomus tentans*, which gave a 28 d NOEC of 530 mg a.s./kg dw (equivalent to 356.16 mg/kg wwt) submitted in the US ISC dossier. It should be noted that in this test midge larvae were fed with fresh food and Chironomus is not a true endobenthic ingester, hence the toxicity of DDAC, because of its high adsorption potential, might have been underestimated.

CONCLUSION on Aquatic Compartment - Sediment compartment:

The issue of the reliability of the available toxicity endpoint obtained was discussed at WGII2015 for other "back-log" multiple dossiers relative to other adosorptive QUATs, for which a study with analogous test desing was submitted. It was concluded to base, at present, the $PNEC_{sediment}$ on the study with Chironumus using an AF of 100. However, at the renewal stage, either the validity of this study should be verified or the equilibrium partitioning method (EPM) should be applied in addition, and the lowest endpoint should then be used for the assessment of risk to sediment dwelling organisms. Consistenly, in the present assessment, the $PNEC_{sediment}$ is calculated applying an assessment factor of 100 to the NOEC = 530 mg a.s./kg dw **(US ISC)**, therefore:

$PNEC_{sediment}$ = (530 mg a.s./kg dw / 100) = **5.30 mg a.s./kg dwt**

$PNEC_{sediment}$ = (356.16 mg/kg wwt / 100) = **3.56 mg a.s./kg wwt**

Terrestrial Compartment

Soil organisms

Acute toxicity tests have been conducted on soil dwelling invertebrates and terrestrial plants, while the results of chronic tests have been submitted for soil dwelling invertebrates and soil micro-organisms.

For terrestrial invertebrates (earthworms, *E. foetida*), the toxicity of DDAC was investigated in one acute test (14d LC_{50} = >1000 mg/kg dw, artificial soil) **(US ISC)**, and one chronic test (56d NOEC= 125 mg a.i./kg dw, natural soil) submitted in the EQC dossier. Hence both these endpoints are selected for the hazard evaluation of DDAC.

The effects on nitrogen transformation activity of soil micro-organisms has been investigated in two 28d studies **(US ISC, EQC)**, while the effects on carbon mineralization has been investigated only in one of the studies submitted **(US ISC)**. The two studies have been performed have been rated as fully reliable, nevertheless they provide quite different results. The US ISC study resulted in a 28d EC_{10} >1000 mg/kg dw and 28d EC_{50} >1000 mg/kg dw for both carbon and nitrogen mineralization tested in two soils (sandy loam and low humic content sand) while the EQC study provided, for nitrogen transformation inhibition tested in one natural soil, a 28d EC_{50} = 135.6 mg a.i./kg dw soil (120 mg a.s./kg wwt soil) and 28d EC_{10} = 79.1 mg a.s. /kg dw soil (70 mg a.s./kg ww soil). Hence these latter enpoints **(EQC)**, representing the lowest value, are taken into account for DDAC. These data on nitrogen mineralization would cover also the effects on carbon mineralization.

The acute effects of DDAC on plants were evaluated in two "Seedling emergence and seedling

growth" tests, which used various species. In the first test **(US ISC)**, conducted with mustard (*Brassica alba*), mung bean (*Phaseolus aureus*) and wheat (*Triticum aestivum*) in garden soil, the lowest EC_{50} = 283 mg a.s./kg dw was calculated for mustard. In the second test **(EQC)** *Triticum aestivum*, *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*: 11 mg/kg dw soil (tested in sand) and 148 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. The results obtained in test with silica sand are considered unrealistic worst case, then 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 *T. pratense* with an EC_{50} = 148 mg/kg dw soil (EQC), which is the endpoint to be taken into account.

CONCLUSION on Soil organisms:

The available data show that the soil characteristic can strongly influence the toxicity of DDAC to soil organisms. 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), DDAC is expected to sorb to different negatively charged surfaces, therefore normalization based on organic matter is considered not appropriate.

Based on acute data there are no indication that plants is the most sensitive taxon, hence the PNEC soil is based on the lowest value between the two chronic data available (microorgansims and earthworms), i.e. 28d EC_{10} = 79.1 mg a.s. /kg dw soil (microorganisms) to which an application factor of 50 is applied:

$PNEC_{soil}$ = 79.1 mg a.s. /kg dw soil / 50 = **1.58 mg a.s. /kg dw soil**

$PNEC_{soil}$ = 70.0 mg a.s. /kg ww soil / 50 = **1.4 mg a.s. /kg ww soil**

Birds

The acute toxicity of DDAC to birds has been measured in one study with northern bobwhite quail submitted in the **US ISC dossier**, which provided a LD_{50} = 229 mg/kg bw. In two short term dietary toxicity tests conducted with northern bobwhite and mallard duck **(US ISC)**, the lowest endpoint was retrieved for this latter species as 5d LC_{50} > 1633 mg/kg. This estimate represents the concentration, corrected to take into account the observed food avoidance, at which no mortality was recorded; therefore it is still a conservative estimate of the short-term toxicity to birds.

CONCLUSION on birds:

A factor of 3000 was appied to the 5d LC_{50} > 1633 mg/kg in order to derive the PNEC:

$PNEC_{birds}$ = 1633 mg a.s./kg food / 3000 **= 0.54 mg/kg food**

Mammals

From the several long-term dietary studies with mammals available, the relevant lowest enpoint (expressed in terms of mg of a.s. per kg food) is NOEC = 486 mg/kg food (corresponding to 15-18 mg/kg bw), retrieved from a 90 days oral repeated dose study with dog **(EQC)**. This endpoint also provides a PNEC lower than the PNEC that would be calculated

using endpoints from other tests of longer duration conducted with other species.

CONCLUSION on mammals:

The $PNEC_{oral,\ predator}$ is derived applying an assessment factor of 90 to the 90d NOEC = 486 mg/kg food (dog):

$PNEC_{oral,\ predator}$ = 486 mg/kg food /90 = **5.4 mg a.i./kg food**

2.2.2.1 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

DDAC is hydrolytically stable over an environmentally relevant pH range of 5-9.

DDAC was found to be photolytically stable in the absence of a photosensitiser.

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

Therefore **P criterion is not fulfilled**.

B criterion: BCF in aquatic species > 2000

From a bioconcentration study with *Lepomis macrochirus*, submitted in the US ISC dossier, the whole body BCF resulted as 81 L/kg. In addition, the toxicokinetic study with mammals indicates that the dermal and gastrointestinal absorption of DDAC is limited (at most 10%) and excretion is rapid. It can be concluded that the **B criterion is not fulfilled.**

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

The results of an ELS test with fish provides a 34d NOEC = 0.032 mg a.s./L **(US ISC)**. The long term toxicity of DDAC to *Daphnia magna* can be expressed as 21d NOEC = 0.014 mg/L (geomean of two studies from **US ISC** and **EQC**). From the most reliable study with algae, a 96h NOE_rC = 0.011 mg a.s./L **(US ISC)** is retrieved, which represents the lowest endpoint for the long-term toxicity to aquatic organisms.

The substance is classified in according to DSD: Xn; R22 C; R34 N; R50 (Cn ≥ 2.5%)

The substance is classified in according to CLP: Dgr; GHS05; GHS06; GHS09; H301; H314; H400 (M factor=10)

As regard to CMR properties no classification is required.

From the information available it is concluded that DDAC **does not fulfil the T criterion**, although it is highlighted that the toxicity endpoint practically coincides with the trigger.

CONCLUSION on PBT assessment:

The active substance DDAC 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 DDAC was discussed at technical meeting level (TMIII2009).

DDAC 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:

- DDAC is not persistent (readily biodegradable);

- DDAC 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 0.367 d and 0.346 d for **US ISC** and **EQC**, respectively).

2.2.2.2 Exposure assessment

Aquatic Compartment Exposure assessment

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 (During WG−II-2015, the K_{oc} of DDAC was discussed in the frame of two other QUATs. The Environment Working Group was not able to agree on the K_{oc} to be used for the risk assessment and it was agreed to initiate an ad-hoc follow up. It was also decided that the agreed K_{oc} should also be included in the list of endpoint for DDAC, depending on the ad-hoc follow up conclusion.

US ISC		**Local PEC**
Scenario 1: Dipping treatment during application		
PEClocalwater STP		0.0079 mg/L
PEClocalsed STP		189.5 mg/kgwwt
PECmicroorganism STP		0.21 mg/L
Scenario 2: Dipping treatment during storage		
PEClocalwater run-off		2.3×10^{-3} mg/L
PEClocalsed run-off		51 mg/kgwwt
Scenario 3: Vacuum pressure treatment during application		
PEClocalwater STP		0.0024 mg/L
PEClocalsed STP		56.3 mg/kgwwt
PECmicroorganism STP		0.06 mg/L
Scenario 4: Vacuum pressure treatment during storage		
PEClocalwater		1.7×10^{-3} mg/L
PEClocalsed		40.8 mg/kgwwt
***Scenario 5: Bridge over pond**		
PEClocalwater	Time1	0.09 mg/L
	Time2	0.00006 mg/L
PEClocalsed	Time1	2152 mg/kgwwt
	Time2	1.4 mg/kgwwt
Scenario 6: Noise Barrier		
PEClocalwater STP	Time1	0.0025 mg/L
	Time2	0.00002 mg/L
PEClocalsed STP	Time1	60 mg/kgwwt
	Time2	0.5 mg/kgwwt
PEC_{STP}	Time1	0.02 mg/L
PEC_{STP}	Time2	0.00017 mg/L

*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). PECs values are summarised in the following table:

EQC		**Local PEC**
Scenario 1: Dipping treatment during application		
PEClocalwater STP		0.0008 mg/L
PEClocalsed STP		2.2 mg/kgwwt
PECmicroorganism STP		0.45 mg/L
Scenario 2: Dipping treatment during storage		
PEClocalwater run-off		2.4 x 10^{-3} mg/L
PEClocalsed run-off		6.7 mg/kgwwt
***Scenario 5: Bridge over pond**		
PEClocalwater	Time1	0.09 mg/L
	Time2	0.00096 mg/L
PEClocalsed	Time1	253 mg/kgwwt
	Time2	2.7 mg/kgwwt
Scenario 6: Noise Barrier		
PEClocalwater STP	Time1	0.0014 mg/L
	Time2	0.000028 mg/L
PEClocalsed STP	Time1	3.9 mg/kgwwt
	Time2	0.08 mg/kgwwt
PEC_{STP}	Time1	0.014 mg/L
PEC_{STP}	Time2	0.00028 mg/L

*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.

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 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

* the equations available in the OECD ESD document (Chapter 7, Removal processes in the receiving compartment, p.115).

Atmospheric Compartment Exposure assessment

In the following table, the PEC values calculated are reported.

	Local PEC (OECD ESD)
Scenario 1: Dipping application	
Annual average local PEC in air	3.98×10^{-5} mg/m^3
Scenario3: Vacuum pressure application:	
Annual average local PEC in air	1.2×10^{-5} mg/m^3

2.2.2.3 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 F water is 0.2 %, and different K_{oc} values (

Note: During WG-II-2015, the K_{oc} of DDAC was discussed in the frame of two other QUATs. The Environment Working Group was not able to agree on the K_{oc} to be used for the risk assessment and it was agreed to initiate an ad-hoc follow up. It was also decided that the agreed K_{oc} should also be included in the list of endpoint for DDAC, depending on the ad-hoc follow up conclusion

The decision on which K_{oc} to use has no influence on the outcome of the evaluation.

Scenario		PEC/PNEC values		
		Water compartment	**Sediment compartment**	**Sewage treatment plant**
Use scenario 1 (dipping treatment during application)		**7.2**	**35.7**	**1.5**
Use scenario 2 (dipping treatment during storage)		**2.1**	**9.6**	-
Use scenario 3 (Vacuum pressure treatment during application)		**2.2**	**10.6**	0.42
Use scenario 4 (Vacuum pressure treatment during storage)		**1.5**	**7.7**	-
Use scenario 6 Noise Barrier	TIME 1	**2.3**	**11.3**	0.14
	TIME 2	0.02	0.09	1.2×10^{-3}

The PEC/PNEC ratios for the water and sediment compartments in the use 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 sewage treatment plant.

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

Surface water	**PEC mg/L**	**PNEC mg/L**	**PEC/PNEC**
Application + daily storage	0.042	0.0011	**38.2**
Noise Barrier TIME1	0.0014		**1.3**
Noise Barrier TIME2	0.000021		0.02
Sediment	**PEC mg/kg wwt**	**PNEC mg/kg wwt**	**PEC/PNEC * 10**
Application + daily storage	114	5.3	**21.5**
Noise Barrier TIME1	3.9		0.74
Noise Barrier TIME2	0.06		0.01
STP	**PEC mg/L**	**PNEC mg/L**	**PEC/PNEC**
Application	0.45	0.14	**3.2**

The PEC/PNEC ratios for the water and sediment compartments for dipping treatment during application and storage are above 1.

The PEC/PNEC ratio for the water compartment in the in-service scenarios is higher than 1 at Time1 for Noise barrier, while at Time2 no unacceptable risk is found.

The PEC/PNEC ratio for the sediment in the in-service scenarios does not indicate unacceptable risk.

For the use scenario 1, the PEC/PNEC value is higher than the trigger value of 1 also for the sewage treatment plant.

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	**2.1**
	After 15 years	**3.9**
Scenario 4: Storage of vacuum-pressure-treated wood:	After 30 days	**2.1**
	After 20 years	**5.1**
Scenario 6: Treated wood in service: Noise barrier	After 30 days	0.9
	After 20 years	**1.8**
Scenario 7: Treated wood in service: Fence	After 30 days	**1.9**
	After 20 years	**4.0**
Scenario 8: Treated wood in service: House	After 30 days	**2.2**
	After 20 years	**4.8**
Scenario 9: Treated wood in service: Transmission pole	After 30 days	0.3
	After 20 years	0.7
Scenario 10: Treated wood in service: Fence post	After 30 days	0.3
	After 20 years	0.6

For scenarios 2 and 4 the PEC/PNEC values are higher than 1 showing unacceptable risk for the terrestrial compartment. Therefore, all timber treated by dipping and vacuum pressure

applications should be stored on impermeable hard standing surfaces to prevent direct losses to soil and allow losses to be collected for re-use or disposal.

For scenarios 6, 7, and 8 the PEC/PNEC values are higher than 1 except for noise barrier TIME 1 is round 1.

For scenario 9 and 10 the PEC/PNEC values are higher than 1 in the short-term whilst the long-term use does not pose any risk.

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. A safe use of the product can also be 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 more than 500 g/L. A safe use has been identified for UC 1, UC 2 and UC 4A.

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	PEC µg/L	Limit value µg/L
Scenario 2: Storage of dipped/ immersed wood	0.23	0.1
Scenario 4: Storage of vacuum-pressure-treated wood	0.23	
Scenario 6: Treated wood in service: Noise barrier	0.09	
Scenario 7: Treated wood in service: Fence	0.19	
Scenario 8: Treated wood in service: House	0.23	
Scenario 9: Treated wood in service: Transmission pole	0.03	
Scenario 10: Treated wood in service: Fence post	0.03	

In scenarios 2 and 4 the trigger value of 0.1 µg/L is slightly exceeded by the PECgw, indicating a potential 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.

Also in scenarios 7 and 8 the limit value is slightly exceeded, indicating a potential risk for groundwater. The treated wood is not placed on the market until it is dry. Consequently, exposure following release to groundwater from the treated wet surfaces is considered to be an unlikely to occur. However, for in-service use of treated wood, mitigation measures are proposed which would restrict the use of the DDAC containing wood preservative products in UC 3. Safe uses are identified in UC 1, 2 and 4A.

Environmental risk in the atmosphere

For the atmosphere compartment no PNEC values are available. However, for all scenarios, the 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 ($\leq 1 \times 10^{-4}$) suggesting that there is no concern for this compartment. In addition, on the basis of abiotic effects, atmospheric half life is 8.314 hours (calculated using the Atmospheric Oxidation Program (AOPWIN)), DDAC 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
Use scenario 1 (dipping treatment during application)	0.648/5.4 = 0.120	0.648/0.54 = **1.20**
Use scenario 2 (dipping treatment during storage)	0.186/5.4 = 0.034	0.186/0.54 = 0.34
Use scenario 3 (Vacuum pressure treatment during application)	0.194/5.4 = 0.036	0.194/0.54 = 0.36
Use scenario 4 (Vacuum pressure treatment during storage)	0.138/5.4 = 0.026	0.138/0.54 = 0.26

The PEC/PNEC value for scenario 1 for fish-eating birds is above the trigger value of 1. This ratio has been derived from a very worst-case NOEC, applying a factor of 3000. Therefore, this ratio can likely overestimate the real risk coming from this scenario.

For all other scenario, PEC/PNEC values are below 1, indicating that there is no concern with regard to non-compartment specific effects relevant to the food chain (secondary poisoning via aquatic food chain).

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

US ISC

Not applicable. The representative product BC-25 is a water-based concentrate, which is not expected to pose any physical hazard.

EQC

Due to a measured flash point of 26°C, the representative product DDAC-50 is classified as Flam. Liq. 3 according to CLP. The risk posed by such physical hazard can be considered negligible provided that the recommended methods and precautions concerning handling, use, storage, transport or fire (as under Sec. 8 of Doc. IIIB) are adopted.

2.2.3 Assessment of endocrine disruptor properties

CONCLUSIONs for US ISC & EQC

Based on available experimental results, there is no indication that DDAC affects the endocrine system. Structural characteristics and SAR do not hint to possible effects of DDAC 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 didecyldimethylammonium chloride 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. Didecyldimethylammonium chloride is proposed to be included in Annex I of the Directive provided that data/information required by RMS under chapter 3.4 are submitted by the Applicant.

The overall conclusion from the human health evaluation of didecyldimethylammonium chloride, for use in product type 8 (wood preservatives) is that the active substance in biocidal products containing 1.8% w/w didecyldimethylammonium chloride 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 population. 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 1.8% w/w didecyldimethylammonium chloride. Therefore, wood preservatives containing didecyldimethylammonium chloride at 1.8% 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 Fence and House scenarios the PEC/PNEC values are higher than 1, for Noise barrier the PEC/PNEC value for is quite below for the short-term use whilst the PEC/PNEC values are higher than 1 for long term use. Therefore the product should not be used in Use Class 3. For UC 4A (Transmission Pole and Fence Post) the PEC/PNEC values are below 1, thus no unacceptable risk has been identified.

For the groundwater compartment, unacceptable risks have been identified following storage on site and for treated wood in service. For the storage scenarios presenting a concern risk reduction measure is proposed in order to prevent losses which would be collected for re-use or disposal. For treated wood in service, mitigation measures are proposed which would restrict the use of the DDAC containing wood preservative products in UC 3.

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

3.1. Proposed Decision regarding Inclusion in Annex I

The Italian CA recommends that didecyldimethylammonium chloride 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: Didecyldimethylammonium chloride

IUPAC name: N,N-Didecyl-N,N-dimethylammonium Chloride

CAS No.: 7173-51-5

EC No.: 230-525-2

Minimum degree of purity of the active substance:

The active substance as manufactured shall have a minimum purity of 87% (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.

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

Products containing didecyldimethylammonium chloride 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 1.8% active substance. Therefore any deviation from the value of 1.8% 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.

3.3. Requirement for further information

There is no need of further studies/information.

3.4. Updating this Assessment Report

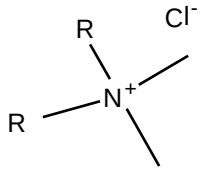
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of didecyldimethylammonium chloride 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 didecyldimethylammonium chloride (DDAC).

Appendix I: Combined List of endpoints

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

Active substance (ISO Name)	Not available Given in EINECS as didecyldimethylammonium chloride
Product-type	P8

Identity

Chemical name (IUPAC)	N,N-Didecyl-N,N-dimethylammonium Chloride
Chemical name (CA)	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride
CAS No	7173-51-5
EC No	230-525-2
Other substance No.	612-131-00-6 (Annex I Index number)
Minimum purity of the active substance as manufactured (g/kg or g/l)	**US ISC** 870 g/kg (dry weight) **EQC** 979 g/kg (dry weight)
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	$C_{22}H_{48}N.Cl$
Molecular mass	362.1 g/mol
Structural formula	 R = $C_{10}H_{21}$

Physical and chemical properties

Melting point (state purity)	**US ISC** The melting range is from 188 to 205°C (98.2%) **EQC** The melting range is from 94 to 100°C (88.2%)
Boiling point (state purity)	**US ISC** The substance decomposes before boiling (98.2%) **EQC** The substance decomposes under boiling (88.2%)
Thermal stability / Temperature of decomposition	**US ISC** ca. 280°C (98.2%) **EQC** > 180°C (88.2%)
Appearance (state purity)	**US ISC** Light-coloured solid with aromatic odour (98.2%) **EQC** Clump building powder with hygroscopic behaviour. White/slight yellowish colour. Moderate mushroom-like odour (95.0%)
Relative density (state purity)	**US ISC** D_4^{20} =0.902 (98.2%) **EQC** D_4^{20} = 0.8651 (95.0%)
Surface tension (state temperature and concentration of the test solution)	**US ISC** 27.0 mN/m at 20°C (test solution: 1 g/l aqueous solution) **EQC** 25.82 mN/m at 20 ± 0.5 °C (test solution: 1.0 g/l aqueous solution) CMC: 0.65 g/l at 20 ± 0.5 °C
Vapour pressure (in Pa, state temperature)	**US ISC** 5.9E-06 Pa @ 20°C (extrapolated) 1.1E-05 Pa @ 25°C (extrapolated) 2.3E-04 Pa @ 50°C (extrapolated) **EQC** < 1.5E-3 Pa @ 20°C (extrapolated) < 5.8E-3 Pa @ 25°C (extrapolated)
Henry's law constant (Pa m^3 mol^{-1})	**US ISC** 4.27E-09 Pa m^3 mol^{-1} @ 20°C **EQC** < 8.4E-7 Pa m^3 mol^{-1} @ 20°C

Solubility in water (g/l or mg/l, state temperature)	**US ISC** pH 2.2: 500 g/l at 20 °C pH 9.2: 500 g/l at 20 °C **EQC** 645 g/l in doubled distilled water at 20.0 ± 0.5°C 625 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** acetone: > 600 g/l @ 20ºC methanol: > 600 g/l @ 20ºC n-octanol: > 250 g/l @ 20ºC **EQC** isopropanol: 942 g/l @ 10°C 906 g/l @ 20°C 953 g/l @ 30°C n-octanol: 269 g/l @ 20°C
Stability in organic solvents used in biocidal products including relevant breakdown products	**US ISC** ethanol: Stable < 5% loss for 14 days at 55°C isopropanol: Stable < 5% loss for 14 days at 55°C **EQC** After 14 days at 54 ± 2 °C, DDAC is concluded to be stable in isopropanol (also confirmed by the accelerated storage stability test on the isopropanol-based biocidal product DDAC-50).
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_{fish} available) **EQC** -0.41 @ 20°C (calculated from individual solubilities in n-octanol and water)
Dissociation constant	Not applicable. DDAC 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 DDAC. No maxima determined due to lack of chromophores in the molecular structure **EQC** No absorption above 290 nm in the neutral, acidic and basic media
Photostability (DT_{50}) (aqueous, sunlight, state pH)	**US ISC** ca. 0% after 30 days (direct) ca. 7% after 30 days (indirect) **EQC** Not applicable: no absorption above 290 nm in UV spectrum **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** stable **(US ISC)**
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not applicable
Flammability or flash point	Not flammable
Explosive properties	Not explosive
Oxidising properties	Not oxidising
Auto-ignition or relative self ignition temperature	**US ISC** Relative self-ignition temperature of 195°C **EQC** No self-ignition observed up to 403°C

Classification and proposed labelling (US ISC and EQC)

	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 H301; H314
with regard to environmental hazards	GHS09 H400 (M factor=10) **H411**

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/MS-MS [parent ion (m/z): 326; daughter ions (m/z): 186, 57]
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 and HPLC/UV for process solvents

Analytical methods for residues

Soil (principle of method and LOQ)	**US ISC** Extraction with propan-2-ol:water: hydrochloric acid (90:10:0.1, v/v/v) containing 0.01M ammonium formate prior to dilution with water:hydrochloric acid (100:0.1, v/v) containing 0.01 M ammonium formate. Analysis by RP-HPLC/MS-MS [parent ion (m/z): 326; daughter ions (m/z): 186, 43]. LOQ = 0.01 mg/kg (sandy loam and clay) **EQC** Extraction with acetonitrile containing 1% TFA. After sonication and centrifugation, dilution (factor 2) with water containing 1% TFA. Analysis by RP-HPLC/MS-MS [parent ion (m/z): 326; daughter ions (m/z): 186, 57]. LOQ = 0.02 mg/kg
Air (principle of method and LOQ)	Not required. The a.s. is non-volatile nor expected to occur in air (representative products BC-25 and DDAC-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)	**US ISC** Dilution (factor 2) with propan-2-ol:water:hydrochloric acid (90:10:0.2, v/v/v) containing ammonium formate (0.02 M). Analysis by RP-HPLC/MS-MS [parent ion (m/z): 326; daughter ions (m/z): 186, 43]. LOQ = 0.1 µg/L (ground, drinking and surface water) **EQC** Samples over SPE cartridges. After drying, elution with 5 mL of acetonitrile. Dilution of 0.6 mL of the solution with 0.4 mL of water. Analysis by RP-HPLC/MS-MS [parent ion (m/z): 326.; daughter ions (m/z): 186, 57]. LOQ = 0.1 µg/L (ground and drinking water) Enrichment over SPE cartridges. Elution with acetonitrile and dilution (factor 2) with water containing 02% TFA. Analysis by RP-HPLC/MS-MS [parent ion (m/z): 326; daughter ions (m/z): 186, 57]. LOQ = 0.04 µg/L (surface water)
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 DDAC-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 DDAC-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 DDAC-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 DDAC-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 (≈3%) and tissue residues (<1%), and on the 90% recovery of radioactivity in faeces as unabsorbed material DDAC oral absorption is limited to 10% at non-corrosive concentrations. **EQC** Based on the urinary excretion (3-4%), biliary excretion values (2.6%), the absence of residues in the carcass, and 85-90% recovery of radioactivity in faeces as unabsorbed material the actual absorbed fraction is approximately10% of the orally administered dose, at non-corrosive concentrations.
Rate and extent of dermal absorption*:	**US ISC** About 0.1% of a DDAC dose delivered as aqueous solution fully penetrated human skin in vitro in 24 h; including the radioactivity present in the dermis and epidermis at the dose site mean total absorbable DDAC was 9.41% (rounded to 10%) at non-corrosive concentrations. **EQC** No possible to quantify DDAC in the available study; indication of similarity between oral and the dermal bioavailability. It is estimated as a worst case that DDAC dermal absorption is limited to ≈10% at non-corrosive concentrations.
Distribution:	**US ISC** Mainly in the g.i. tract, tissue residues (<1%). **EQC** Radioactivity mainly detected in the g.i. tract, and at a much lower level in the liver and in the kidney. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Mainly detected in the g.i. tract, and at a much lower level in the liver and in the kidney. No detectable residues at 168 h **(US ISC; EQC)**

Potential for accumulation:	**US ISC** None. Tissue residues (<1%) **EQC** None. No residues in the carcass **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** None **(US ISC; EQC)**
Rate and extent of excretion:	**US ISC** The majority (>90%) of orally administered DDAC is excreted, very likely unabsorbed, via the faeces. Urine excretion ≈3% in 24-48 hours **EQC** The vast majority (86-96%) of the oral dose was excreted in the faeces as unabsorbed material. Urinary excretion was 3-4% and biliary excretion 2.6%, in a 24-hour period. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Around 90% of the oral dose was excreted in the faeces as unabsorbed material. Urinary excretion was 3-4% and biliary excretion 2.6% within 24 hours **(US ISC; EQC)**
Toxicologically significant metabolite(s)	**US ISC** None. The majority of DDAC metabolism is expected to be carried out by intestinal flora giving rise to hydroxylation products in the alkyl chain, none of them exceeding 10% **EQC** None. Conjugated metabolites were detected in the urine **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** None. The majority of DDAC metabolism is expected to be carried out by intestinal flora forming hydroxylation products in the alkyl chain, none of them exceeding 10%. In addition conjugated metabolites were excreted in urines **(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** 238 mg/kg **EQC** 264 mg/kg bw **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** The lowest value is 238 mg/kg **(US ISC)**
Rat LD_{50} dermal	**US ISC** 3342 mg/kg **EQC** No test available. Literature data : >2000 mg/kg **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 3342 mg/kg **(US ISC)**
Rat LC_{50} inhalation	**US ISC** No test available. Not allowed since DDAC is corrosive **EQC** No test available. Not necessary since the active substance is not volatile, (vapour pressure < 1 x 10^{-2} Pa at 20°C) and only spraying with big, not inhaled, droplets with MMAD > 40 µm is recommended. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Test unnecessary: DDAC is not volatile, (vapour pressure < 1 x 10^{-2} Pa at 20°C and 2.3x10-4 Pa at 50ºC); only spraying with big, not inhaled, droplets with MMAD > 40 µm is recommended; testing is not allowed with corrosive chemicals **(US ISC; EQC)**

Skin corrosion/irritation	**US ISC** Corrosive **EQC** Corrosive **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Corrosive **(US ISC; EQC)**

Eye irritation	**US ISC** Corrosive **EQC** Corrosive **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Corrosive **(US ISC; EQC)**
Respiratory tract irritation	**US ISC** No data available. Expected to be irritant/corrosive **EQC** No data available. Expected to be irritant/corrosive **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No data available. Expected to be irritant/corrosive
Skin sensitisation (test method used and result)	**US ISC** Not a skin sensitiser (Magnusson and Kligman procedure - OECD Guideline 406) **EQC** Not a skin sensitiser (Magnusson and Kligman procedure - OECD Guideline 406) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Not a skin sensitiser (Magnusson and Kligman procedure - OECD Guideline 406) **(US ISC; EQC)**
Respiratory sensitisation (test method used and result)	**US ISC** No data available. Expected to be not a respiratory sensitizer. **EQC** No data available. Expected to be not a respiratory sensitizer. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No data available. Expected to be not a respiratory sensitizer

Repeated dose toxicity

Short term

Species / target / critical effect	**US ISC** No study available **EQC** Rat/gi tract/ irritation corrosivity leading to body weight reduction. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Rat/gi tract/ irritation corrosivity leading to body weight reduction. **(EQC)**
Relevant oral NOAEL / LOAEL	**US ISC** None **EQC** None. The only availbale study is by gavage in rat /28-day/ NOAEL = 2.5 mg/kg/day: not relevant **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Data available only via gavage, which is not an appropriate route of exposure for NOAEL derivation.
Relevant dermal NOAEL / LOAEL	**US ISC** Local effects NOAEC=0.6% DDAC in water at 2 mL/kg bw per day (5 day application) Local effects NOAEC =0.3% DDAC in water at 2 mL/kg bw per day (2-week application). **EQC** No study available. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Local effects NOAEC =0.6% DDAC in water at 2 mL/kg bw per day (5 day application) **(US ISC)** Local effects NOAEC =0.3% DDAC in water at 2 mL/kg bw per day (2-week application). **(US ISC)**
Relevant inhalation NOAEL / LOAEL	**US ISC** No study available. Not necessary. **EQC** No study available. Not necessary. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No study available. Not necessary.

Subchronic

Species/ target / critical effect	**US ISC** Rat and dog/gi tract/ irritation corrosivity leading to body weight reduction. **EQC** Rat and dog/gi tract/ irritation corrosivity leading to body weight reduction. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Rat and dog/gi tract/ irritation corrosivity leading to body weight reduction **(US ISC; EQC)**
Relevant oral NOAEL / LOAEL	**US ISC** 1 year dog: NOAEL for local effects: 3 mg/kg/d NOAEL for systemic effects: 10 mg/kg/d **EQC** 90 days dog: NOAEL for systemic effects: 15 mg/kg/d **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** NOAEL for local effects: 3 mg/kg/d **(US ISC)** NOAEL for systemic effects: 10 mg/kg/d **(US ISC)**
Relevant dermal NOAEL / LOAEL	**US ISC** 90-day rat Systemic NOAEL = 12 mg/kg /d (highest dose tested) Local effects NOAEL = 2 mg/kg/d. **EQC** None **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Systemic NOAEL = 12 mg/kg /d (highest dose tested) **(US ISC)** Local effects NOAEL = 2 mg/kg/d. **(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.

Long term

Species/ target / critical effect	**US ISC** Rat/mice /gi tract/ irritation corrosivity leading to body weight reduction. **EQC** Rat/mice /gi tract/ irritation corrosivity leading to body weight reduction. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Rat and mice/gi tract/ irritation corrosivity leading to body weight reduction **(US ISC; EQC)**
Relevant oral NOAEL / LOAEL	**US ISC** 2 year Rat: Non neoplastic effects lowest NOAEL: 32 mg/kg/day **EQC** 2 year Rat: Non neoplastic effects lowest NOAEL: 27 mg/kg/day **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Non neoplastic effects NOAEL: 27 mg/kg/day **(EQC)**
Relevant dermal NOAEL / LOAEL	**US ISC** No study available. Not necessary. **EQC** No study available. Not necessary. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No study available. Not necessary.

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.

Genotoxicity

US ISC

In vitro:

Ames test – negative (with and without metabolic activation)

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

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

In vivo:

Chromosomal aberration test in rat bone marrow – negative.

EQC

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:

DDAC can be considered not genotoxic based on:

In vitro Ames test with and without metabolic activation **(US ISC)**

In vitro chromosomal aberration test with and without metabolic activation with OECD 473 **(EQC)**

In vitro mammalian cell gene mutation assay with and without metabolic activation with OECD 476 **(EQC)**

In vivo chromosomal aberration test in rat bone marrow **(US ISC)**

Carcinogenicity

Species/type of tumour

US ISC

Rat/none

Mouse/none

EQC

Rat/none

CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:

DDAC was not found to be carcinogenic **(US ISC; EQC)**

Relevant NOAEL/LOAEL	**US ISC** None **EQC** None **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Rat study **(US ISC; EQC)** Mouse study **(US ISC)**

Reproductive toxicity

Developmental toxicity

Species/ Developmental target / critical effect	**US ISC** 1) Rat / NOAEL / maternal toxicity 2) Rabbit / NOAEL /maternal toxicity **EQC** Rabbit/ maternal toxicity (cases of discoloured urine, splayed legs) / severe toxicity with abortion at top dose level (32 mg/kg) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No specific concern for developmental toxicity; prenatal effects only seen as unspecific consequence of maternal distress **(US ISC or EQC)**
Relevant maternal NOAEL	**US ISC** 1) 0.8 mg/kg bw/day 2) 1.0 mg/kg bw/day **EQC** 4 mg/kg bw
Relevant developmental NOAEL	**US ISC** 1)≥ 16.2 mg/kg bw/day 2) ≥ 3 mg/kg bw/day **EQC** 12 mg/kg bw **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Prenatal toxicity only seen in rabbits, clearly secondary to maternal effects: NOAEL 12 mg/kg bw **(EQC)** Lowest NOAEL for maternal toxicity (local effects) in rats, not considered relevant for systemic toxicity: 0.8 mg/kg bw **(US ISC)**

Fertility

Species/critical effect	**US ISC** Rat /NOEL/reduced body weight and food consumption in parental and F1-F2 animals **EQC** Rat/ two-generation/ systemic toxicity Cortical adrenal hypertrophy in F0 females; lower weight gain and increased spleen weight in F1 **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Available studies do not indicate any specific potential for reproductive toxicity. Observed effects concern solely general toxicity **(US ISC; EQC)**
Relevant parental NOAEL	**US ISC** 750 mg/kg food (≥ 31 mg/kg bw/day) **EQC** 608 mg/kg food, corresponding to ≥ 30 mg/kg bw
Relevant offspring NOAEL	**US ISC** 750 mg/kg food (≥ 31 mg/kg bw/day) **EQC** 608 mg/kg food, corresponding to ≥ 30 mg/kg bw
Relevant fertility NOAEL	**US ISC** ≥ 750 mg/kg food (≥ 31 mg/kg bw/day) **EQC** > 608 mg/kg food, corresponding to ≥ 30 mg/kg bw **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** No specific potential for reproductive toxicity, overall NOAEL (parental effects) at least 31 mg/kgbw/d (608mg/kg feed) **(EQC)**

Neurotoxicity

Species/ target/critical effect	**US ISC** No study available. Not necessary. **EQC** No study available. Not necessary. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No study available. Not necessary. (No structural similarity to known neurotoxin; no alert for neurotoxic effects; no sign of neurotoxicity found in sub-chronic/chronic study)

Developmental Neurotoxicity

Species/ target/critical effect	**US ISC** n.a. **EQC** n.a.

Immunotoxicity

Species/ target/critical effect	**US ISC** No study available. Not necessary. **EQC** No study available. Not necessary. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** No study available. Not necessary.

Developmental Immunotoxicity

Species/ target/critical effect	**US ISC** n.a. **EQC** n.a.

Other toxicological studies

US ISC

No other study available.

EQC

No other study available.

CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:

No study available. Not necessary.

Medical data

US ISC

No medical reports on the manufacturing personnel have been submitted.

EQC

No study available. Statements from medical doctors from different production locations indicate that during production no problems are found which can be related to exposure to DDAC.

CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:

No specific observations or sensitivity/allergenicity or any medical information have been reported **(US ISC; EQC)**

Summary for Local effects

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

Summary for systemic effects

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

[4] If residues in food or feed.

Dermal absorption

Study (*in vitro/vivo*), species tested	**US ISC** In vitro study on Human dermatomed skin membranes **EQC** In vivo study on rats (some cross-contamination due to grooming and possible concomitant oral exposure-quantification not possible)
Formulation (formulation type and including concentration(s) tested, vehicle)	**US ISC** 1. 1.85% (w/v) DDAC in water 2. NP-1 formulation 1.85% (w/v) DDAC plus components other than water (not specified) **EQC** 1.5 and 15 mg/kg (40% DDAC in water)
Dermal absorption values	**US ISC** 1. 10% (for water dilutions only) 2. 17.8% (for non water dilutions formulations) **EQC** 10% (as for the oral route) is taken as worst case approach.

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 relevant
General public	Not relevant
Exposure via residue in food	n.a.

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** >30 days at 25°C **EQC** Stable **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** stable **(US ISC; EQC)**
pH 5	**US ISC** >30 days at 25°C **EQC** n.a **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** stable **(US ISC; EQC)**
pH 9	**US ISC** >30 days at 25°C **EQC** cannot be considered stable. The results show a 15.6% and 9.94% hydrolysis in the first and second series of data, respectively, in five days **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** stable **(US ISC)**
Other pH:	**US ISC** n.a. **EQC** stable pH = 4 **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** stable **(EQC)**
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	**US ISC** ca. 0% after 30 days (direct) ca. 7% after 30 days (indirect) **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** Not used in seawater **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** A biodegradation study in two water/sediment systems has been performed and showed that the substance easily migrates from the aqueous phase to the sediment phase and is also easily adsorbed to sediments (high K_{oc}). The degradation in the sediment phase did not increase very much after the first month and the DT_{50} of the total system was not reached within the 120 days test duration * **EQC** DDAC will adsorb to any negatively charged surface and then become immobile **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** DDAC will adsorb to any negatively charged surface and then become immobile **(US ISC; EQC)**
Distribution in water / sediment systems (metabolites)	**US ISC** n.a. **EQC** No metabolites of concern formed **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** no metabolites **(EQC)**

*Amount of ^{14}C-DDAC as mean percentageof the recovered radioactivity in the TNO and Kromme Rijn water/sediment system.

	Days									
	0	**1**	**2**	**7**	**14**	**28**	**42**	**56**	**84**	**120**
TNO	97.9	93.9	91.7	91.3	77.4	69.2	70.6	67.8	76.1	69.5
Kromme Rijn	97.0	94.5	94.5	87.0	68.8	54.3	57.9	54.8	64.7	54.4

Route and rate of degradation in soil

Mineralization (aerobic)	**US ISC** n.a. **EQC** No test provided that shows complete mineralization **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** - **EQC** -
DT_{90f}:	**US ISC** - **EQC** -
Anaerobic degradation	**US ISC** n.a. **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Soil photolysis	**US ISC** Stable, not subject to photogradation in soil **EQC** n.a. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** stable **(US ISC)**
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** Not measured **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** 1095 L/kg, 591 L/kg (sand) 8179 L/kg, 2074 L/kg (sandy loam) 32791 L/kg, 8309 L/kg (silty clay loam) 30851 L/kg,7714 L/kg (silt loam) **EQC** 9230 L/kg, 4718 L/kg (Clay) 2868 L/kg, 4237 L/kg (Silt loam) 1456 L/kg, 2117 L/kg (Loam) 2188 L/kg, 3161 L/kg (Silt) 1787 L/kg, 2387 L/kg (Loamy sand)
Ka_{oc} , Kd_{oc}	**US ISC** 437805 L/kg, 236473 L/kg (sand) 908757 L/kg, 230498 L/kg (sandy loam) 1599564 L/kg, 405328 L/kg (silty clay loam) 1469081 L/kg, 367334 L/kg (silt loam) K_{oc} mean: 1103801 L/kg **EQC** 280547 L/kg, 113009 L/kg (Clay) 120000 L/kg, 177280 L/kg (Silt loam) 43855 L/kg, 63765 L/kg (Loam) 160882 L/kg, 232426 L/kg (Silt) 40339 L/kg, 53883 L/kg (Loamy sand) K_{oc} mean: 186687 L/kg
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 562314 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** Not specified **EQC** no adsorption above 290 nm in UV spectrum **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** not specified
Photo-oxidative degradation in air	**US ISC** Latitude: ..... Season: ..... DT_{50} ..... **EQC** Latitude: ..... Season: ..... DT_{50} ..... **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** n.a.
Volatilization	**US ISC** Not volatile [vapour pressure 2.3 E^{-06} hPa (2.3 x 10^{-4} Pa) at 50°C] **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** monitoring study for several municipal STPs STP effectively removes 98.5% of the active ingredients from the waste water **EQC** monitoring study for several municipal STPs STP effectively removes 98.5% of the active ingredients from the waste water **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** STP effectively removes 98.5% of the active ingredients from the waste water **(US ISC; EQC)**
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** Fathead minnow *(Pimephales promelas)*	96h	Mortality	LC_{50} = 0.19 mg a.s./L
EQC Zebra fish (*Brachydanio rerio*)	96h	Mortality	Only supportive information available **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** LC_{50} = 0.19 mg a.s./L **(US ISC)**
Chronic toxicity **US ISC** Zebra fish (*Brachydanio rerio*)	34d	Growth	NOEC = 0.0322 mg a.s./L EC_{10} = not available
EQC			No data available **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** NOEC = 0.0322 mg a.s./L **(US ISC)**

Invertebrates			
Acute toxicity **US ISC** *Daphnia magna*	48h	Immobilization	EC_{50} = 0.062 mg a.s./L
EQC *Daphnia magna*	48h	Immobilization	Only supportive information available **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** EC_{50} = 0.062 mg a.s./L **(US ISC)**
Chronic toxiciy (aquatic) **US ISC** *Daphnia magna*	21d	Reproduction/survival	$NOEC_{survival}$ = 0.010 mg a.s./L (measured) EC_{10} = not available
EQC *Daphnia magna*	21d	Reproduction/survival	NOEC = 0.021 mg a.s./L (measured) EC_{10} = not available **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 21d NOEC= 0.014 mg a.s./L (geomean value from **US ISC** and **EQC**)

Chronic toxicity(sediment) **US ISC** *Chironomus tentans*	28d	Mortality and growth	NOEC = 530 mg a.s./kg dw (equivalent to 356.16 mg/kg wwt)
EQC			No data available **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** NOEC = 530 mg a.s./kg dw (equivalent to 356.16 mg/kg wwt) **(US ISC)**

Algae			
US ISC *Pseudokirchneriella subcapitata (ex Selenastrum capricornutum)*	96h	Biomass production and cell density	Based on initial measured conc: 72h E_rC_{50} = 0.015 mg a.s./L 96h E_rC_{50} = 0.026 mg a.s./L; 72h E_rC_{10} = 0.015 mg a.s./L 96h NOE_rC and E_rC_{10} = 0.014 mg a.s./L Based on mean measured conc.: 72h E_rC_{10} = not available 96h E_rC_{50} = 0.021 mg a.s./L 72h EC_{10} = not available 96h EC_{10} = not calculated 96h NOE_rC = 0.011 mg a.s./L
EQC *Pseudokirchneriella subcapitata*	72 h	Inhibition of growth rate	Based on nominal conc. (only partly confirmed): 72h E_rC_{50} = 0.062 mg a.s./L 72h NOE_rC = 0.013 mg a.s./L 72h E_rC_{10}= 0.024 mg a.s./L **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** 96h E_rC_{50} = 0.021 mg a.s./L 96h NOE_rC = 0.011 mg a.s./L (mean measured conc.) **(US ISC)**

Microorganisms			
US ISC			
Activated sewage sludge	3h	Respiration inhibition	EC_{50} = 11.0 mg a.s./L $NOEC/EC_{10}$ = not calculated
EQC			
Activated sludge	3h	Respiration inhibition	EC_{50} = 17.9 mg a.s./L (nominal conc.) NOEC = 4.0 mg a.i./L EC_{10} =5.95 mg a.i./L **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** 21d NOEC= 3h EC_{50} = 14.3 mg a.s./L (geomean value from **(US ISC and EQC)**

Effects on earthworms or other soil non-target organisms

Acute toxicity to to earthworms (*Eisenia foetida)*	**US ISC** 14d LC_{50} > 1000 mg a.s./kg dw, in artificial soil **EQC** No data available **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** 14d LC_{50} > 1000 mg a.s./kg dw, in artificial soil **(US ISC)**
Acute toxicity to plants	**US ISC** EC_{50} = 283 mg a.s./kg dw soil (EC_{50} =281 mg/kg ww soil) (garden soil; mustard, most sensitive plant, nominal) . **EQC** EC_{50} = 148 mg a.s./kg dw (131 mg a.s./kg ww) (natural soil; *T. pratense*, most sensitive plant; nominal - partial recovery) EC_{50} = 11 mg/kg dw soil (9.7 mg a.s./kg ww) (sand; *T. pratense*, most sensitive plant; nominal - partial recovery) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** EC_{50} = 148 mg a.s./kg dw soil **(EQC)**. Data for natural soil are more realistic. *T. pretense* most sensitive species tested in natural soil.
Reproductive toxicity to earthworms (*Eisenia foetida)*	**US ISC** No data available **EQC** 56d NOEC= 125 mg a.s./kg dw soil (nominal. natural soil) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** 56d NOEC= 125 mg a.s./kg dw soil (nominal. natural soil) **(EQC)**

Effects on soil micro-organisms

Nitrogen mineralization	**US ISC** 28d EC_{50} > 1000 mg a.s./kg dw (nominal) 28d EC_{10} > 1000 mg a.s./kg dw (nominal) **EQC** 28d EC_{50} = 135.6 mg a.i./kg dw soil (120 mg a.s./kg wwt soil) 28d EC_{10} = 79.1 mg a.s. /kg dw soil(70 mg a.s./kg ww soil) (measured in stock solution) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** 28d EC_{50} = 135.6 mg a.i./kg dw soil (120 mg a.s./kg wwt soil) 28d EC_{10} = 79.1 mg a.s. /kg dw soil(70 mg a.s./kg ww soil) (measured in stock solution) **(EQC)**
Carbon mineralization	**USISC** EC_{50} > 1000 mg a.s./kg **EQC** No data available – not required **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** Data on nitrogen mineralization **(EQC)** would cover this point.

Effects on terrestrial vertebrates

Acute toxicity to mammals	**US ISC** Rat LD_{50} oral = 238 mg/kg bw **EQC** Rat LD_{50} oral = 329 mg a.s./kg bw (combined sexes) 264 mg a.s./kg bw (F) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** The lowest value is 238 mg/kg **(US ISC)**

Repeated dose toxicity to mammals	**US ISC** NOEC = 500 mg a.s./kg food (18 months, mouse) **EQC** NOEC = 486 mg a.s./kg food (90d, dog) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION:** NOEC = 486 mg a.s./kg food (90d, dog) **(EQC)**
Acute toxicity to birds	**US ISC** Northern bobwhite quail LD_{50} = 229 mg a.s./kg bw **EQC** No data available. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** Northern bobwhite quail LD_{50} = 229 mg a.s./kg bw **(US ISC)**
Dietary toxicity to birds	**USISC** Mallard duck LC_{50} = >1633 mg a.s./kg a.s. food **EQC** No data available. **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** Mallard duck LC_{50} = >1633 mg a.s./kg a.s. food **(US ISC)**
Reproductive toxicity to birds	**US ISC** Not available **EQC** No data available.

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** Measured $BCF_{fish\ whole\ body}$ = 81 L/kg **EQC** $BCF_{fish\ whole\ body}$ = 81 L/kg (blue gill) (letter of access to US ISC's study) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** Measured $BCF_{fish\ whole\ body}$ = 81 L/kg **(US ISC)**
Depuration time (DT_{50})	**US ISC** 7-14d whole body **EQC** 7-14d whole body (letter of access to US ISC's study) **CONCLUSION TO BE TAKEN INTO ACCOUNT AT PRODUCT AUTHORIZATION** 7-14d whole body **(US ISC)**
Depuration time (DT_{90})	**US ISC** No data available **EQC** No data available
Level of metabolites (%) in organisms accounting for > 10 % of residues	**US ISC** No data available **EQC** No data available

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: DDAC is a cationic surfactant and its interaction, with phospholipid-bilayer structures, severely alters the cell wall permeability. Under PT 8 (wood preservative), DDAC acts as a fungistatic and as an insecticide, by control of wood destroying basidiomycetes, soft rot fungi and insects. The representative product BC-25 is an aqueous solution containing 25% DDAC. Objects to be protected: Wood and constructional timbers USERS: industrial/professional	BC-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 PT 8	25% DDAC	Dipping and vacuum pressure processes	Number and timing of applications depends on application technique, wood species, moisture and hazard class.	--	-- The requirements for DDAC concentration in both processes vary between 0.3% and 1.8%.	--	-- An uptake of approximately 1.8 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. BC-25 prevents the development of wood discolouring organisms by contact, controls the mycelial growth of wood destroying basodiomycetes and prevents attack by insects.

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	g a.s./L min max	water L/m^2 min max	g a.s./m^2 min max	
CLAIM: Under PT 8 (wood preservative), DDAC acts as a fungicidal/fungistatic by temporary and permanent protection against fungi. Objects to be protected: Wood USERS: industrial/professional	DDAC-50	*Brown-rot White-rot Gloephyllum trabeum Coniophora putena Poria placenta, Serpula lacrymans Coriolus versicolor Donkioporia expansa, Sapstain White mycelium etc.*	solvent-based concentrate under PT 8	50% DDAC	Automated dipping process and in spraying application in closed tunnel	Dipping time can vary due to several circumstances like for instance: type of wood, temperature, humidity of the wood. It is important to check if the proposed retention is achieved, to determine the exact dipping time needed for a specific case.	--	-- The product is typically applied at in use concentration of 5-15% DDAC	--	0.8 – 3.2 kg a.s./m^3, corresponding to 8 – 32 g a.s./m^2	From practical experiences with standalone-biocides in this field of application it is known that a local formation of "resistant" strains at the application site may occur. For this reason DDAC or other biocides are normally not used as unique biocide in formulations.

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 III 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 3.1.1 – Melting point	Schneider, S.	2000	Determination of the melting temperature of Dodigen 1881 AS (pure active substance of Bardac 22) in accordance with OECD-Guideline 102 and according to EEC Guideline A.1. Clariant GmbH - Werk Cassella-Offenbach, Analytische und Physikalische Abteilung, Frankfurt, Germany. Report No. B 077/2000 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 3.1.3 – Density	Schneider, S.	2000	Determination of the density of Dodigen 1881 AS (pure active substance of Bardac22) in accordance with OECD-Guideline 109 and according to EEC-Guideline A.3. Clariant GmbH - Werk Cassella-Offenbach, Analytische und Physikalische Abteilung, Frankfurt, Germany. Report No. B 079/2000 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 3.2 – Vapor pressure	Smeykal, H.	2000	Dodigen 1881 AS - DD 00/004: Vapour pressure. Siemens Axiva GmbH & Co. KG, Frankfurt, Germany. Report No. SI092-00 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 3.4.1 – UV/VIS 3.4.2 – IR 3.4.3 – NMR 3.4.4 – MS	Petrovic P.	2000	Characterization of the structure of Dodigen 1881AS. Clariant GmbH - Werk Cassella-Offenbach, Analytische und Physikalische Abteilung, Frankfurt,	Yes	DDAC 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**
			Germany. Report No. B 085/2000 GLP Unpublished		
Doc IIIA 3.5 – Solubility in water	Schneider, S.	2000	Determination of the water solubility of Dodigen 1881 AS (pure active substance of Bardac 22) in accordance with EEC-Guideline A.6. Clariant GmbH – Werk Cassella-Offenbach, Analytische und Physikalische Abteilung, Frankfurt, Germany. Report No. B 080/2000 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 3.7(1) – Solubility in organic solvents	Schneider, S.	2001	Determination of the solubility of Dodigen 1881 AS [pure active substance of Bardac22] in organic solvents. AllessaChemie GmbH - Werk Cassella-Offenbach, Analytik, Frankfurt, Germany. Report No. B 084/2000 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 3.7(2) – Solubility in organic solvents	Young S.	2004	N,N-Didecyl-N,N-dimethylammonium chloride (DDAC): Solubility in octanol. Huntingdon Life Sciences, Huntingdon, Cambridgeshire, England. Report No. DKG/011033992 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 3.8 – Stability in organic solvents	Young S.	2004	N,N-Didecyl-N,N-dimethylammonium chloride(DDAC): Stability in ethanol and isopropanol. Huntingdon Life Sciences, Huntingdon, Cambridgeshire, England. Report No. DKG/012 042290 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 3.9 – Partition coefficient	Nixon, W.B.	1998	DDAC octanol/water partition coefficient test.	Yes	DDAC 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**
			Letter report dated August 14, 1998. Wildlife International, Ltd., Easton, MD, USA. GLP status: not applicable Unpublished		
Doc IIIA 3.9 – Partition coefficient	Young, S.	2004	N,N-Didecyl-N,N-dimethylammonium chloride (DDAC): Solubility in octanol. Huntingdon Life Sciences, Huntingdon, Cambridgeshire, England. Report No. DKG/011033992 GLP Unpublished [REPORT FILED UNDER ENDPOINT 3.7]	Yes	DDAC ISC
Doc IIIA 3.10 – Thermal stability	Keipert, W.	2001	Determination of the thermal stability and stability in air of Dodigen 1881 AS (Bardac 22 AS) in accordance with OECD- Guideline 113. AllessaChemie GmbH – Werk Cassella-Offenbach, Analytik, Frankfurt, Germany. Report No. B 012/2001 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 3.11(1) – Flammability (solids) & Autoflammability	Keipert, W.	2001	Determination of the relative self ignition temperature of Dodigen 1881 AS (Bardac 22 AS) in accordance with EEC-Guideline A.16. AllessaChemie GmbH – Werk Cassella-Offenbach, Analytik, Frankfurt, Germany. Report No. B 022/2001 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 3.11(2) – Flammability (solids) & Autoflammability	Keipert, W.	2001	Determination of the flammability of Dodigen 1881 AS (Bardac 22 AS) in accordance with EEC-Guideline A.10. AllessaChemie GmbH - Werk Cassella-Offenbach, Analytik, Frankfurt, Germany. Report No. B 021/2001	Yes	DDAC 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 3.13 – Surface tension	Schneider, S.	2001	Determination of the surface tension of an aqueous solution of Dodigen 1881 AS (Bardac 22 AS) in accordance with OECD-Guideline 115. AllessaChemie GmbH, Analytik, Frankfurt, Germany. Report No. B 023/2001 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 3.14 – Viscosity	Keipert, W.	2003	Determination of the viscosity of Bardac 22/Dodigen 1881 in accordance with OECD-Guideline 114. AllessaChemie GmbH, Analytik, Frankfurt, Germany. Report No. B 019/2003 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 3.15(1) – Explosive properties	Keipert, W.	2001	Determination of the explosive properties of Dodigen 1881 AS (Bardac 22 AS) in accordance with EEC Guideline A.14. AllessaChemie GmbH - Werk Cassella-Offenbach, Analytik, Frankfurt, Germany. Report No. B 024/2001 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 3.15(2) – Explosive properties	Tremain, S.P.	2002	Didecyl dimethylammonium chloride (DDAC): Determination of explosive and oxidising properties, expert statement. Safepharm Laboratories Ltd., Shardlow, Derbyshire, England. SPL Project No. 102/438 GLP status: not applicable Unpublished	Yes	DDAC ISC
Doc IIIA 3.16 – Oxidising properties	Tremain, S.P.	2002	Didecyl dimethylammonium chloride (DDAC): Determination of explosive and oxidising properties, expert statement. Safepharm Laboratories Ltd.,	Yes	DDAC 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
			Shardlow, Derbyshire, England. SPL Project No. 102/438 GLP status: not applicable Unpublished [REPORT FILED UNDER ENDPOINT 3.15]		
Doc IIIA 4.1(1) – Analytical methods for purity/impurity	Sloan, R.	1994	Bardac 2280 - Characterization of the test substance. Lonza Inc, Research and Development Annondale, NJ, USA. Report No. 94-013 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 4.1(2) – Analytical methods for purity/impurity	Young, S.	2003	Didecyldimethylammonium chloride (DDAC; CAS RN 7173-51-5): Screening by ion chromatography. Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England. Study No. DKG/010 Non-GLP (screening study) Unpublished	Yes	DDAC ISC
Doc IIIA 4.1(3) – Analytical methods for purity/impurity (new submission)	Kurz M. and Ranft V.	2007	Determination of quaternary ammonium compounds and related quaternary impurities by HPLC-ELSD. Lonza AG, Basel, Switzerland Study No.CSPE-44/BS-07-70. Non-GLP (ISO-9001 compliant) Unpublished	Yes	DDAC ISC
Doc IIIA 4.1(4) – Analytical methods for purity/impurity (new submission 2013 August)	Veliath-Houston, L.	2013	Methods Validation for the Characterization of Didecyldimethylammonium Chloride. Product Safety Labs, Dayton, NJ, USA Study No. 35657 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 4.2 (a) (1)– Analytical methods for determination of residues in soil	Brewin, S.	2003	Didecyldimethylammonium chloride (DDAC; CAS RN 7173-51-5): Validation of methodology for the determination of residues in soil. Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire,	Yes	DDAC 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**
			England Report No. ADB/014 033180 GLP Unpublished		
Doc IIIA 4.2 (a) (2) – Analytical methods for determination of residues in soil (new submission 2013 October)	Miller, C	2013	N,N-didecyl-N,N-dimethylammonium chloride (DDAC): Validation of an analytical method for the determination of residues in soil. Huntingdon Life Sciences, Ltd., Huntingdon, Cambridgeshire, England Study No. ADB0095 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 4.2 (c) (1)– Analytical methods for determination of residues in water	Brewin, S.	2003	Didecyldimethylammonium chloride (DDAC; CAS RN 7173-51-5): Validation of methodology for the determination of residues in drinking, ground and surface water Huntingdon Life Sciences, Ltd., Huntingdon, Cambridgeshire, England Report No. ADB/015 033168 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 4.2 (c) (2)– Analytical methods for determination of residues in water (new submission 2013 October)	Miller C.	2013	N,N-didecyl-N,N-dimethylammonium chloride (DDAC): Validation of an analytical method for the determination of residues in ground water, drinking water and surface water. Huntingdon Life Sciences, Ltd., Huntingdon, Cambridgeshire, England Project No. ADB0094 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 5.3.1 – Effects on Target Organisms	Archer, K., Nicholas, D.D. and T.P. Schultz	1995	Screening of wood preservatives: Comparison of the soil block, agar block and agar plate tests. Forest Prod. J. 45(1): 86-89 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
	Archer, K., Nicholas, D.D. and T.P. Schultz	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 L.J. Cookson	1993	A comparison of *Coniophora olivacea* and *Coniophora puteana* test strains. International Research Group on Wood Preservation. Document No. IRG/WP/20004. GLP status: not applicable Published	no	n/a
	Wazny, J. and L.J. Cookson	1994	Comparison of the agar block and soil block methods used for evaluation of fungitoxic value of QAC and CCA wood preservatives. International Research Group on Wood Preservation Document No. IRG/WP/20039. GLP status: not applicable Published	no	n/a
Doc IIIA 6.1.1 – Acute oral toxicity	Morris, T.D.	1992	Acute oral toxicity in rats – Median lethal dosage determination with didecyldimethylammonium chloride (DDAC). Hill Top Biolabs, Inc., Miamiville, Ohio, USA. Study No. 91-8114-21(A) GLP Unpublished	Yes	DDAC ISC
Doc IIIA *6.1.1 – Acute oral toxicity*	*Ullmann, L. and Sacher, R.*	*1983*	*Acute oral toxicity study (LD50) with P 0151 in rats.* *Research & Consulting Company AG, Itingen, Switzerland.* *Project No. 021532* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA 6.1.2 – Acute dermal toxicity	Siglin, J.C.	1987	Acute dermal toxicity study in rabbits LD50 test (EPA) with DMD10AC.	Yes	DDAC 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
			Springborn Institute for Bioresearch, Inc., Spencerville, OH, USA. Study No. 3165.1.2C GLP Unpublished		
Doc IIIA *6.1.2 – Acute dermal toxicity*	*Nitka S.*	*1980*	*An acute dermal LD50 study in albino rabbits.* *Consumer Product Testing, Fairfield, NJ, USA.* *Report No 8044-10* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA 6.1.4(1) – Skin irritation	Jones, J.R. and T.A. Collier	1986	P0151: OECD 404 Acute dermal irritation/corrosion test in the rabbit. Safepharm Laboratories Ltd., Derbyshire, England. Project No. 102/1 GLP Unpublished	Yes	DDAC ISC
Doc IIIA *6.1.4 – Skin irritation*	*Allan, D.J.*	*1995*	*P4289: Acute dermal irritation test in rabbits.* *Safepharm Laboratories Ltd., Derbyshire, England.* *Project No. 102/1908* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA *6.1.4 – Skin irritation*	*Morris, T.D.*	*1991*	*Primary skin irritation study in rabbits with didecyldimethylammoniumchloride (DDAC).* *Hilltop Biolabs, Inc., Miamiville, OH, USA.* *Study No. 91-8114-2 (B)* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA 6.1.4(2) – Eye irritation	Morris, T.D.	1991	Primary eye irritation study in rabbits with didecyldimethylammonium chloride (DDAC). Hill Top Biolabs, Inc., Cincinnati, OH, USA. Study No. 91-8114-21 GLP	Yes	DDAC 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**
			Unpublished		
Doc IIIA 6.1.5(1) – Skin sensitisation	Clement, C.	1992	BARDAC-22: Test to evaluate the sensitizing potential by topical applications in the guinea pig. Hazleton-Institute Français de Toxicologie, L'Arbresle, France. Report No. 704323 RE GLP Unpublished	Yes	DDAC ISC
Doc IIIA 6.1.5(2) – Skin sensitisation	Kukulinski, M.	2003	Skin sensitization study of Maquat 4480-E, Batch #30717J5, OPPTS 870.2600. Tox Monitor Laboratories, Inc., Oak Park, IL, USA. Project No. 03-092-5 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 6.1.5(3) – Skin sensitisation	Merkel, D.J.	2004	Bardac 2280: Dermal sensitization test in guinea pigs (Buehler method). Product Safety Laboratories, Dayton, NJ, USA. Study No. 15512 GLP Unpublished	Yes	DDAC ISC
Doc IIIA *6.1.5 – Skin sensitisation*	*Morris T.D.*	*1991*	*Photoallergy study in guinea pigs with didecyldimethylammoniumchloride (DDAC).* *Hill Top Biolabs, Cincinnati, OH , USA.* *Study No. 91-8114-21(D)* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA 6.2(1) – Metabolism in mammals (toxicokinetics; dermal absorption)	Roper, C.S.	2001	The *in vitro* percutaneous absorption of [14C]-didecyldimethylammonium chloride (DDAC) through human skin. Inveresk Research, Tranent, Scotland.	Yes	DDAC ISC

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			Report No. 19128 GLP Unpublished		
Doc IIIA 6.2(2) – Metabolism in mammals (toxicokinetics; dermal absorption)	Selim, S.	1989	Absorption, distribution, metabolism and excretion studies of didecyldimethylammoniumchloride (DDAC) in the rat. Biological Test Center, Irvine, CA, USA. Study No. P01421 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 6.4.1(1) – Subchronic oral toxicity (rat)	Van Miller, J.P.	1988	Ninety-day dietary subchronic oral toxicity study with didecyldimethylammoniumchloride in rats. Union Carbide, Bushy Run Research Center, Export, PA, USA. Report No. 51-506 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 6.4.1(2) – Subchronic oral toxicity (dog)	Osheroff, M.R	1990	Subchronic oral toxicity study of didecyldimethylammonium chloride in dogs. Hazelton Laboratories America, Inc., Vienna, VA, USA. Study No. 2545-100 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 6.4.1(3) – Subchronic oral toxicity (mouse)	Van Miller, J.P.	1988	Subchronic dietary dose range finding study with didecyldimethylammonium chloride in mice. Union Carbide, Bushy Run Research Center, Export, PA, USA. Report No. 51-507 GLP Unpublished	Yes	DDAC ISC
Doc IIIA *6.4.1 – Subchronic oral toxicity*	*Cox, G.E. and Bailey, D.*	*1975*	*90-Day feeding study in dogs with a quaternary ammonium sanitizer BARDAC-22.* *Food and Drug Research Laboratories, Inc., Waverly, NY, USA.*	*Yes*	*DDAC 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**
			Laboratory No. 2224a *Non-GLP* *Unpublished*		
Doc IIIA 6.4.2 – Subchronic dermal toxicity test (rat)	Gill, M.W. and J.P. Van Miller	1988	Ninety-day subchronic dermal toxicity study with didecyldimethylammonium chloride in rats. Union Carbide, Bushy Run Research Center, Export, PA, USA. Project No. 51-554 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 6.5(1) – Chronic toxicity (dog)	Schulze, G.E.	1991	Chronic oral toxicity study of didecyldimethylammoniumchloride in dogs. Hazelton Washington, Inc., Vienna, VA, USA. Study No. 2545-102 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 6.5(2) – Chronic toxicity (rat)	Gill, M.W., Chun, J.S. and C.L. Wagner	1991	Chronic dietary toxicity/oncogenicity study with didecyldimethylammonium chloride in rats. Union Carbide, Bushy Run Research Center, Export, PA, USA. Report No. 53-566 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 6.6.1 – *In vitro* gene mutation study in bacteria	Thompson, P.W.	2001	LZ1043 (Didecyldimethylammonium chloride): Reverse mutation assay "Ames Test" using *Salmonella typhimurium*. Safepharm Laboratories Ltd., Derby, England. Project No. 102/368 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 6.6.2 – *In vitro* cytogenicity study in mammalian cells	Holmstrom, M., Leftwich, D.J. and I.A. Leddy	1986	PO151: Chromosomal aberrations assay with Chinese hamster ovary cells *in vitro*. Inveresk Research International, Musselburgh, Scotland. Report No. 4236	Yes	DDAC ISC

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			GLP Unpublished		
Doc IIIA 6.6.3 – *In vitro* gene mutation assay in mammalian cells	Young, R.R.	1988	Mutagenicity test on didecyldimethylammoniumchloride (DDAC) in the CHO/HGPRT forward mutation assay. Hazleton Laboratories America, Inc., Kensington, MD, USA. Report No. 10141-0-435 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 6.6.4 – *In vivo* Mutagenicity (conditional)	Allen, J.A., Proudlock R.J. and P.C. Brooker	1987	Analysis of metaphase chromosomes obtained from bone marrow of rats treated with P0151 (Bardac 22). Report No. LZA 24/8761. Huntingdon Research Centre, Ltd., Huntingdon, England. GLP Unpublished	Yes	DDAC ISC
Doc IIIA 6.6.5 – *In vivo* Mutagenicity(conditional)	Cifone, M.A.	1988	Mutagenicity test on didecyldimethyl – ammoniumchloride (DDAC) in the rat primary hepatocyte unscheduled DNA synthesis assay. Hazleton Laboratories America, Inc., Kensington, MD, USA. Study No. 10141-0-447 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 6.7(1) – Carcinogenicity (mouse)	Gill, M.W., Hermansky, S.J. and C.L. Wagner	1991	Chronic dietary oncogenicity study with didecyldimethylammonium chloride in mice. Union Carbide, Bushy Run Research Center, Export, PA, USA. Report No. 53-528 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 6.7(2) – Carcinogenicity (rat)	Gill, M.W., Chun, J.S. and C.L. Wagner	1991	Chronic dietary toxicity/oncogenicity study with didecyldimethylammonium chloride in rats. Union Carbide, Bushy Run Research Center, Export, PA, USA. Report No. 53-566	Yes	DDAC 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 [REPORT FILED UNDER 6.5]		
Doc IIIA 6.8.1(1) – Teratogenicity, rat	Neeper-Bradley, T.L.	1991	Developmental toxicity evaluation of didecyldimethylammoniumchloride administered by gavage to CD® (Sprague-Dawley) rats. Union Carbide, Bushy Run Research Center, Export, PA, USA. Project No: 53-534 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 6.8.1(2) – Teratogenicity, rabbit	Tyl, R.W.	1989	Developmental toxicity study of didecyldimethylammoniumchloride administered by gavage to New Zealand white rabbits. Union Carbide, Bushy Run Research Center, Export, PA, USA. Project No. 51-590 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 6.8.2 – Two generation reproduction study	Neeper-Bradley, T. L.	1991	Two-generation reproduction study in Sprague-Dawley (CD) rats with didecyldimethylammonium chloride administered in the diet. Union Carbide, Bushy Run Research Center, Export, PA, USA. Report No. 52-648 GLP Unpublished	Yes	DDAC ISC
Doc IIIA *6.11 – Studies on other routes of administration (parenteral routes) – Acute* *IV study in rats*	*Duprey, L.P. and J.O. Hoppe*	*1967*	*TS 19: Toxicity and irritation studies on quarternary ammonium compounds.* *Sterling Winthrop Research Institute, Renssalaer, NY, USA.* *Non-GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA 7.1.1.1.1 – Hydrolysis	Dykes, J. and M. Fennessey	1989	Hydrolysis of didecyldimethylammoniumchloride (DDAC) as a function of pH at 25°C. ABC Laboratories Inc., Columbia, MO, USA. Report No. 37004 GLP	Yes	DDAC ISC

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			Unpublished		
Doc IIIA 7.1.1.1.2 – Phototransformation in water	Dykes, J. and M. Fennessey	1989	Determination of the photolysis rate of didecyldimethylammoniumchloride (DDAC) in pH 7 buffered solution at 25°C. ABC Laboratories Inc., Columbia, MO, USA. Report No. 37005 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.1.1.2.1(1) – Ready Biodegradability	Downing, J.L.	1993	Aerobic aquatic biodegradation of didecyldimethylammonium chloride using a shake flask test system. ABC Laboratories, Inc., Environmental Fate and Assessment Division, Columbia, MO, USA. Report No. 40687 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.1.1.2.1(2) – Ready biodegradability	Schaefer E.C.	1996	Aerobic aquatic biodegradation test with didecyldimethylammoniumchloride (DDAC) and a bentonite clay: DDAC complex conducted with natural sediment and site water. Wildlife International Ltd., Easton, MD, USA. Project No. 434E-101 Non-GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.1.1.2.1(3) – Ready biodegradability	Hirschen, D.M., Ziemer, M. and D. Seifert	1998	Bardac 22: DOC die-away test OECD 301 A with pre-adapted inoculum. Clariant GmbH, Frankfurt, Germany. Report No. D0094-1 Non-GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.1.1.2.1(4) – Ready biodegradability	Bazzon, M and F. Deschamps	2002	Biotic degradation biodegradability evaluation on aqueous medium ultimate aerobia of the referenced compounds, CATIGENE T 50. INERIS, Vert-lepetit, France. Study No. 506223 Non-GLP (Study conducted under the principles of GLP but not in full compliance – well documented	Yes	DDAC ISC

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			study) Unpublished		
Doc IIIA 7.1.1.2.1(5) – Ready biodegradability	Fiebig, S.	2006	Dodigen 1881: Ready Biodegradability: Modified Sturm Test. Dr. U. Noack-Laboratorien, Germany. Study No. AST97952 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.1.1.2.2 – Inherent biodegradability	Hirschen, D.M., Ziemer, M. and D. Seifert	1998	Bardac 22: DOC die-away test OECD 301 A with pre-adapted inoculum. Clariant GmbH, Frankfurt, Germany. Report No. D0094-1 GLP Unpublished [REPORT FILED UNDER ENDPOINT 7.1.1.2.1]	Yes	DDAC ISC
Doc IIIA 7.1.2.1.1 – Aerobic biodegradation	Schaefer, E.C.	2001	didecyldimethylammonium chloride (DDAC): Dieaway in activated sludge. Wildlife International, Inc., Easton, MA, USA. Project No. 289E-112 GLP Unpublished	Yes	DDAC ISC
Doc IIIA Other Non-Key Biodegradability Reports Included in this Submission	*Bücking H. -W.*	*1989*	*Prüfung des biologischen Abbaus von BARDAC 22 im OECD-Confirmatory-Test.* *Hoechst, Frankfurt, Germany.* *Report No. 95/89(B)* *GLP* *Unpublished*	*Yes*	*DDAC 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
	Cranor, W.	*1991*	*Anaerobic aquatic metabolism of 14CDidecyldimethylammoniumchloride (14C-DDAC).* *ABC Laboratories, Inc., Columbia, MO, USA.* *Report No. 37007* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
	Cranor, W.	*1991*	*Aerobic aquatic metabolism of 14CDidecyldimethylammoniumchloride (14C-DDAC).* *ABC Laboratories, Inc., Columbia, MO, USA.* *Report No. 37008* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
	Cranor, W.	*1991*	*Aerobic soil metabolism of 14C - didecyldimethylammonium chloride (14C-DDAC).* *ABC Laboratories, Columbia, MO, USA.* *Report No. 37006* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
	Todt K.	*1991*	*Abbau von Didecydimethylammoniumchlorid im Boden unter Praxisbedingungen.* *NATEC, Hamburg, Deutschland.* *Abschlußbericht NA 91 9601* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA 7.1.2.2.2(1) Water/sediment degradation study	*de Vette, H.Q.M., van Asten, J.G. and A.O. Hanstveit*	*2000*	*A water/sediment study of didecyldimethylammonium chloride (DDAC) using [14C]-DDAC.* *TNO Nutrition and Food Research, Delft, The Netherlands.* *Study No. IMW-99-9048-01* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA 7.2.2.4 – Other soil degradation studies	Schmidt, J.	1992	Determination of the photolysis rate of didecyldimethylammonium chloride on the surface of soil. ABC Laboratories, Columbia, MO,	Yes	DDAC ISC

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			USA. Report No. 39505 GLP Unpublished		
Doc IIIA 7.2.3.1 – Adsorption and desorption	Daly, D.	1989	Soil/sediment adsorption-desorption of 14C - Didecyldimethylammoniumchloride(DDAC). Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, USA Report No. 37009 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.4.1.1(1) – Acute toxicity to fish (*Oncorhynchus kisutch*)	LeLievre, M.K.	1990	Evaluation of didecyldimethylammonium chloride (DDAC) in a static acute toxicity test with Coho salmon, *Oncorhynchus kisutch*. Springborn Laboratories, Inc., Wareham, MA, USA. SLI Report No. 90-4-3290 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.4.1.1(2) – Acute toxicity to fish (*Lepomis macrochirus*)	LeLievre, M.K.	1990	Evaluation of Didecyldimethylammonium chloride (DDAC) in a static acute toxicity test with bluegill sunfish, *Lepomis macrochirus*. Springborn Laboratories, Inc., Wareham, MA, USA. SLI Report No. 89-10-3111 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.4.1.1(3) – Acute toxicity to fish *(Pimephales promelas)*	Putt, A.E.	1994	Didecyldimethylammoniumchloride (DDAC): Static acute toxicity to fathead minnow (*Pimephales promelas*) with and without the presence of humic acid. Springborn Laboratories, Inc., Wareham, MA, USA. Report No. 94-1-5122 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.4.1.1(4) –	Swigert, J.P.,	1995	An evaluation of	Yes	DDAC ISC

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Acute toxicity to fish (*Pimephales promelas*)	Graves, W.C. and M.A. Mank		didecyldimethylammoniumchloride (DDAC) in a 96-hour flowthrough acute toxicity study with the fathead minnow (*Pimephales promelas*). Wildlife International Ltd., Easton, MD, USA. Project No. 289A-124 GLP status: no data provided Unpublished		
Doc IIIA 7.4.1.1(5) – Acute toxicity to fish (*Oncorhynchus mykiss*)	Swigert, J.P., Graves, W.C. and M.A. Mank	1995	An evaluation of didecyldimethylammonium chloride (DDAC) in a 96-hour flowthrough acute toxicity study with the rainbow trout (*Oncorhynchus mykiss*). Wildlife International Ltd., Easton, MD, USA. Project No. 289A-125 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.4.1.1 – Acute toxicity to fish (Cyprinodon variegatus)	*Collins, M.K.*	*1994*	*Didecyldimethylammonium-chloride (DDAC): Evaluation in a static acute toxicity test with sheepshead minnow (Cyprinodon variegatus).* *Springborn Laboratories, Inc., Wareham, MA, USA.* *SLI Report No. 93-6-4833* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA 7.4.1.1 – Acute toxicity to fish (Acipenser transmontanus)	*Miller, J.L.*	*1997*	*Evaluation of Bardac 2280 in a static-renewal acute toxicity test with juvenile white sturgeon, (Acipenser transmontanus).* *Aqua-Science Environmental Toxicology Specialists, Davis, CA, USA.* *Non-GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA 7.4.1.1 – Acute toxicity to fish (Oncorhynchus mykiss)	*Luy, T. and S. Frances*	*1971*	*Report on fish (rainbow trout) toxicity testing using BARDAC 22.* *Wells Laboratories, Inc., Jersey City, NJ, USA.* *Study No. D-7381* *Non-GLP* *Unpublished*	*Yes*	*DDAC ISC*

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Doc IIIA 7.4.1.1 – Acute toxicity to fish (Poecilia reticulata)	*Adema, D.M.M.*	*1978*	*The acute toxicity of Barquat MB 50, Barquat 4250 and Bardac 22 to young guppies.* *Centraal Laboratorium TNO, Delft, The Netherlands.* *Report No. CL 78/34* *Non-GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA 7.4.1.1 – Acute toxicity to fish (Acipenser transmontanus) in the presence of Fraser River sediment	*Miller, J.L.*	*1997*	*Evaluation of Bardac 2280 in a static-renewal acute toxicity test with juvenile white sturgeon (Acipenser transmontanus), in the presence of Fraser River sediment.* *Aqua-Science, Davis, CA, USA.* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA 7.4.1.1 – Acute toxicity to fish (Oncorhynchus mykiss)	*Swigert, J.P., Graves, W.C. and M.A. Mank*	*1995*	*Evaluation of a Bentonite clay:didecyldimethylammoniumchloride (DDAC) complex in a 96-hour static acute toxicity study with the rainbow trout (Oncorhynchus mykiss).* *Wildlife Internationl, Ltd., Easton, MD, USA.* *Project No. 289A-121* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA 7.4.1.2(1) – Acute toxicity to invertebrates (*Daphnia magna*)	LeLievre, M.K.	1990	Evaluation of didecyldimethylammonium chloride (DDAC) in a static acute toxicity test with daphnids, *Daphnia magna*. Springborn Laboratories, Inc., Wareham, MA, USA. Report No. 89-10-3112 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.4.1.2(2) – Acute toxicity to invertebrates (*Daphnia magna*)	Swigert, J.P., Graves, W.C. and M.A. Mank	1995	An evaluation of didecyldimethylammoniumchloride (DDAC) in a 48-hour flowthrough acute toxicity study with the cladoceran (*Daphnia magna*). Wildlife International Ltd., Easton, MD, USA. Project No. 289A-122 Non-GLP	Yes	DDAC ISC

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			Unpublished		
Doc IIIA *7.4.1.2 – Acute toxicity to invertebrates (Mysidopsis bahia)*	*LeLievre, M.K.*	*1990*	*Evaluation of didecyldimethylammonium chloride (DDAC) in a static acute toxicity test with mysid shrimp, Mysidopsis bahia.* *Springborn Laboratories, Inc., Wareham, MA, USA.* *Report No. 90-2-3233* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA *7.4.1.2 – Acute toxicity to invertebrates (Crassostrea virginica)*	*Dionne, E.*	*1994*	*Didecyldimethylammoniumchloride (DDAC): Evaluation in a static (recirculated) acute toxicity test with Eastern oysters (Crassostrea virginica) using [14C]-DDAC.* *Springborn Laboratories, Inc., Environmental Sciences Division, Wareham, MA, USA.* *Report No: 93-12-5079* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA *7.4.1.2 – Acute toxicity to invertebrates (Crassostrea virginica)*	*Dionne, E.*	*1994*	*Didecyldimethylammoniumchloride (DDAC): Evaluation in a static (recirculated) acute toxicity test with Eastern oysters (Crassostrea virginica) using [14C]-DDAC.* *Springborn Laboratories, Inc., Environmental Sciences Division, Wareham, MA, USA.* *Report No. 93-6-4854* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA 7.4.1.3(1) – Growth inhibition test on algae (*Selenastrum capricornutum*)	Desjardins, D., Kendall, T.Z., Van Hoven, R.L. and H.O. Krueger	2003	Bardac 2280: A 96-hour toxicity test with the freshwater alga (*Selenastrum capricornutum*). Wildlife International, Ltd., Easton, MD, USA. Project No. 289A-152 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.4.1.3(2) – Growth inhibition test on algae *(Scenedesmus*	Scheerbaum, D.	1998	Bardac 22: Alga, growth inhibition test (72hr). Dr.U.Noack-Laboratorium fur Angewandte Biologie, Sarstedt,	Yes	DDAC 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**
subspicatus)			Germany. Study No. SS061301 GLP Unpublished		
Doc IIIA 7.4.1.3(3) – Growth inhibition test on algae (Selenastrum capricornutum) in Natural Surface Water	Desjardins, D., Kendall, T.Z., Van Hoven, R.L. and H.O. Krueger	2003	Bardac 2280: A 96-hour toxicity test with the freshwater alga (Selenastrum capricornutum) using natural surface water. Wildlife International, Ltd., Easton, MD, USA. Project No. 289A-153 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.4.1.4 – Inhibition to microbiological activity	Mead, C.	2001	LZ1043 (Didecyldimethylammounium chloride): Assessment of the inhibitory effect on the respiration of activated sewage sludge. Safepharm Laboratories Ltd., Derby, England. Project No. 102-369 GLP Unpublished	Yes	DDAC ISC
Doc IIIA *7.4.1.4 – Inhibition to microbiological activity*	*Vonk, J.W.*	*1989*	*Biodegradability of Bardac-22.* *Netherlands Organization for Applied Scientific Research, TNO Division of Technology for Society, Delft, The Netherlands.* *Report No. R89/252* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA 7.4.2 – Bioconcentration (*Lepomis machrochirus*)	Fackler, P.H.	1990	Bioconcentration and elimination of 14Cresidues by bluegill (*Lepomis machrochirus*) exposed to didecyldimethylammonium chloride (DDAC). Springborn Laboratories, Inc., Wareham, MA, USA. Report No. 89-7-3043 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.4.3.2 – Reproduction and growth in fish	Hooftman, R.N., de Vette, H.Q.M. and B. Borst	2001	Early life stage test under intermittent flow-through conditions with didecyldimethylammounium chloride and the fish species,	Yes	DDAC 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**
(*Brachydanio rerio*)			*Brachydanio rerio* (OECD Guideline No. 210). TNO Chemistry, Delft, The Netherlands. Report No. V99.1173 GLP Unpublished		
Doc IIIA 7.4.3.4 – Reproduction and growth in invertebrates (*Daphnia magna*)	Hooftman, R.N. and H.Q.M. de Vette	2001	Intermittent flowthrough reproduction test with didecyldimethylammonium chloride and *Daphnia magna*. TNO Nutrition and Food Research, Department of Environmental Toxicology, Delft, The Netherlands. Report No. V99.1171 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.4.3.4 – Reproduction and growth in invertebrates (Daphnia magna)	*Jonas, W.*	*1992*	*Bardac 2270: Reproduktionstest an Daphnia magna.* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA 7.4.3.5.1 – Effects on sediment dwelling organisms (*Chironomus tentans*)	England, D.C. and T. Leak	1995	Chronic toxicity of sedimentincorporated didecyldimethylammoniumchloride (DDAC) to *Chironomus tentans*. ABC Laboratories, Columbia, MO, USA. Report No. 41005 GLP Unpublished	Yes	DDAC ISC
DDAC IIIA 7.5.1.1 – Inhibition to microbiological activity	DeVette, H.Q.M., Hanstveit, R. and J.A. Schoonmade	2001	The assessment of the ecological effects of didecyldimethylammounium 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. Study No. IMW-99-9048-05 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.5.1.2(1) – Acute toxicity to earthworms	Henzen, L.	1999	The acute toxicity of DDAC to the worm species *Eisenia fetida* in a 14-day test (OECD Guideline No. 207).	Yes	DDAC 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
			TNO Nutrition and Food Research Institute, Delft, The Netherlands. Report No. V99.160 GLP Unpublished		
Doc IIIA 7.5.1.2(2) – Acute toxicity 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, Huntingdon, Cambridgeshire, England. Report No. ADB/023 033976 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.5.1.3 – Acute toxicity to plants	Gray, J.	2004	N,N-Didecyl-N,N-dimethylammonium chloride (DDAC): Acute toxicity to terrestrial plants. Huntingdon Life Sciences, Huntingdon, Cambridgeshire, England. Study No. DKG/014 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.5.3.1.1 – Acute oral toxicity (Bobwhite Quail)	Campbell, S., Hoxter, K.A. and G.J. Smith	1991	Didecyldimethylammonium chloride: An acute oral toxicity study with the northern bobwhite. Wildlife International Ltd., Easton, MD, USA. Project No. 289-103A GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.5.3.1.2(1) – Short-term toxicity (Bobwhite Quail)	Long, R.D., Hoxter, K.A. and G.J. Smith	1991	Didecyldimethylammonium chloride: A dietary LC_{50} Study with the northern bobwhite. Wildlife International Ltd., Easton, MD, USA. Project No. 289-101 GLP Unpublished	Yes	DDAC ISC
Doc IIIA 7.5.3.1.2(2) – Short-term toxicity (Mallard duck)	Long, R.D., Hoxter, K.A. and G.J. Smith	1991	Didecyldimethylammoniumchloride: A dietary LC_{50} study with the mallard. Wildlife International Ltd., Easton,	Yes	DDAC 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
			MD, USA. Project No. 289-102 GLP Unpublished		
Doc IIIA (new submission 2013 August)	Zehr, P.S.	2013	Maquat 4450-E: Batch Analyses of a Didecyldimethylammonium Chloride Manufacturing Use Concentrate. Product Safety Labs, Dayton, NJ, USA Study No. 35814 GLP Unpublished	Yes	Mason Chemical Company (Mason Europe Limited)
Doc IIIA (new submission 2013 August)	Zehr, P.S.	2013	BTC 1010: Batch Analyses of a Didecyldimethylammonium Chloride Manufacturing Use Concentrate. Product Safety Labs, Dayton, NJ, USA Study No. 35847 GLP Unpublished	Yes	Stepan Company (Stepan Europe)
Doc IIIA (new submission 2013 August)	Zehr, P.S.	2013	Bardac 22: Batch Analyses of a Didecyldimethylammonium Chloride Manufacturing Use Concentrate. Product Safety Labs, Dayton, NJ, USA Study No. 35825 GLP Unpublished	Yes	Lonza Inc. (Lonza GmbH)

n/a = not applicable

Non-Key reports and supporting references included in this submission

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 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. 200-CT-WL-B22* *GLP* *Unpublished*	*Yes*	*DDAC ISC*
Doc IIIA 5.4.1.2 – Efficacy tests with single active substance formulation (DDAC) against insects	*Ruddick, J.N.R.*	*1984*	*Appendix C – Alkylammonium compounds as wood preservatives.* *Proc. Am. Wood. Pres. Assn. 80, 191-204. and* *Appendix D – Field testing of alkylammonium wood preservatives, pp. 206-210.* *GLP status: not applicable* *Published*	*No*	*n/a*
Doc IIIA 5.4.1.2 – Efficacy tests with single active substance formulation (DDAC) against insects	*Archer, K., Nicholas, D.D. and T.P. Schultz*	*1995*	*Screening of wood preservatives: Comparison of the soil block, agar block and agar plate tests.* *Forest Prod. J. 45(1): 86-89.* *GLP status: not applicable* *Published*	*No*	*n/a*
Doc IIIA 5.4.1.2 – Efficacy tests with single active substance formulation (DDAC) against insects	*Creffield, J.W.*	*1993*	*A study on the effectiveness of DDAC to protect wood from attack by termites.* *IRG Document No. IRG/WP/93-30009.* *GLP status: not applicable* *Published*	*No*	*n/a*
Doc IIIA 5.4.1.2 – Efficacy tests with single active substance formulation (DDAC) against insects	*Graf, E.*	*1987*	*Determination of the protective effectiveness of Bardac 22 against wood destroying basidiomycetes after leaching procedure.* *Swiss Federal Laboratories for Materials Testing and Research, EMPA St. Gallen, Switzerland.* *Report No. 2311491* *GLP Status: Undetermined* *Unpublished* *English translation of the German original test report (Bestimmung der Wirksamkeitsgrenze von Bardac 22 gegen holzzerstörende Basidiomyceten) attached as Annex.*	*Yes*	*DDAC 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
Doc IIIA 5.4.1.2 – Efficacy tests with single active substance formulation (DDAC) 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 5.4.1.2 – Efficacy tests with single active substance formulation (DDAC) against insects	*Molnar, S., Dickinson, D.J. and R.J. Murphy*	*1996*	*Accelerated testing for out-of-ground contact using natural biological preconditioning.* *International Research Group on Wood Preservation* *Document No. IRG/WP 96-20088.* *GLP Status: not applicable* *Published*	*No*	*n/a*
Doc IIIA 5.4.1.2 – Efficacy tests with single active substance formulation (DDAC) against insects	*Molnar, S., Dickinson, D.J. and R.J. Murphy*	*1997a*	*Accelerated testing for out-of-ground contact using natural biological preconditioning.* *International Research Group on Wood Preservation* *Document No. IRG/WP 97-20108.* *GLP Status: not applicable* *Published*	*No*	*n/a*
Doc IIIA 5.4.1.2 – Efficacy tests with single active substance formulation (DDAC) against insects	*Molnar, S., Dickinson, D.J. and R.J. Murphy*	*1997b*	*Microbial ecology of treated lap-joints at Hilo, Hawaii for 24 months.* *International Research Group on Wood Preservation Document* *No. IRG/WP 97-20107.* *GLP Status: not applicable* *Published*	*No*	*n/a*
Doc IIIA 5.4.1.2 – Efficacy tests with single active substance formulation (DDAC) against insects	*Preston, A.F., McKaig, P.A. and P.J. Walcheski*	*1986*	*Termite resistance of treated wood in an above ground field test.* *International Research Group on Wood Preservation* *Document No. IRG/WP 1300.* *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 5.4.1.2 – Efficacy tests with single active substance formulation (DDAC) against insects	*Preston, A.F., Walcheski, P.J., McKaig, P.A. 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*
Doc IIIA 5.4.1.2 – Efficacy tests with single active substance formulation (DDAC) against insects	*Walker, L.E.*	*1999*	*Waterproofing and preservative compounds and preparation thereo. U.S. Patent 5,855,817; and Walker L.E.* *(1998) Waterproofing and preservative composition for wood. U.S. Patent 5,833,741.* *GLP Status: not applicable* *Published*	*No*	*n/a*
Doc IIIA 5.4.1.2 – Efficacy tests with single active substance formulation (DDAC) against insects	*Wazny, J. and L.J. Cookson*	*1993*	*A comparison of Coniophora olivacea and Coniophora puteana test strains.* *International* *Research Group on Wood Preservation* *Document No. IRG/WP/20004.* *GLP Status: not applicable* *Published*	*No*	*n/a*
Doc IIIA 5.4.1.2 – Efficacy tests with single active substance formulation (DDAC) against insects	*Wazny, J. and L.J. Cookson*	*1994*	*Comparison of the agar block and soil block methods used for evaluation of fungitoxic value of QAC and CCA wood preservatives.* *International Research Group on Wood Preservation* *Document No. IRG/WP/20039.* *GLP Status: not applicable* *Published*	*No*	*n/a*
Doc IIIA 5.4.1.2 – Efficacy tests with single active substance formulation (DDAC) against insects	*Zahora, A., Jin, L., Cui, F., Walcheski, P. and K. Archer*	*2000*	*E-mail communication of June 9, 2000 and attached memo to AWPA Formosan Subterranean Task Force.*	*No*	*n/a*

n/a = not applicable

Document III B

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	BC-25: Physicochemical proerties. Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England. Report No. DKG0018/062229 GLP Unpublished	Yes	DDAC ISC
Doc IIIB 3.6(1) – Relative Density	Sydney, P.	2006	BC-25: Physicochemical proerties. Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England. Report No. DKG0018/062229 GLP Unpublished	Yes	DDAC ISC
Doc IIIB 3.8(1) – Technical characteristics of the biocidal product: Persistent foaming	Sydney, P.	2006	BC-25: Physicochemical proerties. Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England. Report No. DKG0018/062229 GLP Unpublished	Yes	DDAC ISC
Doc IIIB 3.10.2(1) – Viscosity	Sydney, P.	2006	BC-25: Physicochemical proerties. Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England. Report No. DKG0018/062229 GLP Unpublished	Yes	DDAC ISC
Doc IIIB 5.10.2.3 – Efficacy field tests with multiple active substances formulation (including DDAC)	Archer, K., Nicholas, D.D. and T.P. Schultz	1995	Screening of wood preservatives: Comparison of the soil block, agar block and agar plate tests. Forest Prod. J. 45(1): 86-89. GLP Status: not applicable Published	No	n/a
Doc IIIB 5.10.2.3 – Efficacy field tests with multiple active substances formulation (including DDAC)	Moffat, A.R.	1994	A determination of the toxic level of ACQ2100 wood preservative for the powder post borer Lyctus brunneus (Stephens). International Research Group on Wood Preservation Document No. IRG/WP 94-20029. 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 5.10.2.3 – Efficacy field tests with multiple active substances formulation (including DDAC)	Molnar, S., Dickinson, D.J. and R.J. Murphy	1996	Accelerated testing for out-of-ground contact using natural biological preconditioning. International Research Group on Wood Preservation Document No. IRG/WP 96-20088. GLP Status: not applicable Published	No	n/a
Doc IIIB 5.10.2.3 – Efficacy field tests with multiple active substances formulation (including DDAC)	Molnar, S., Dickinson, D.J. and R.J. Murphy	1997	Accelerated testing for out-of-ground contact using natural biological preconditioning. International Research Group on Wood Preservation Document No. IRG/WP 97-20108. GLP Status: not applicable Published	No	n/a
Doc IIIB 5.10.2.3 – Efficacy field tests with multiple active substances formulation (including DDAC)	Molnar, S., Dickinson, D.J. and R.J. Murphy	1997	Microbial ecology of treated lap-joints at Hilo, Hawaii for 24 months. International Research Group on Wood Preservation Document No. IRG/WP 97-20107.	No	n/a
Doc IIIB 5.10.2.3 – Efficacy field tests with multiple active substances formulation (including DDAC)	Preston, A.F., Walcheski, P.J., McKaig, P.A. and D.D. Nicholas	1987	Recent research on alkylammonium compounds in the U.S. Proc. Am. Wood Pres. Assn. 83: 331-347. Published	No	n/a
Doc IIIB 5.10.2.3 – Efficacy field tests with multiple active substances formulation (including DDAC)	Zahora, A., Jin, L., Cui, F., Walcheski, P. and K. Archer	2000	E-mail communication of June 9, 2000 and attached memo to AWPA Formosan Subterranean Task Force.	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 (Yes/No)	Owner
IIA1.4.2 IIA1.4.3 IIB6.4.1 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 IIA1.4.3 IIB6.4.1 IIIB4.1	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 IIA1.4.3 IIB6.4.1 IIIB4.1	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 IIA1.4.3 IIB6.4.1 IIIB4.1	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
IIA1.4.2 IIA1.4.3 IIB6.4.1 IIIB4.1	Akzo Nobel Surface Chemistry AB	1999	Determination of 2-propanol in fatty quaternary ammonium salts, Akzo Nobel - The Netherlands, Report No.: CG2.025, Not GLP Published	No	Akzo Nobel Surface Chemistry AB
App.6.1g IIIA8 IIIA9 IIIB9	Akzo Nobel Surface Chemistry AB	2003	SDS Arquad 2.10-50 Akzo Nobel Surface Chemistry AB, Not GLP, Published	No	Akzo Nobel Surface Chemistry AB
IIA2.2	Akzo Nobel Surface Chemistry AB	2004	Literature search efficacy DDAC, Akzo Nobel – The Netherlands, Not GLP, Unpublished	No	Public data
App.6.1g IIIB8	Akzo Nobel Surface Chemistry AB	2005	SDS DDAC-50 Akzo Nobel Surface Chemistry AB, Product code D3376A, Not GLP, Published	No	EQC
IIA3.10 IIIA6.12.1	Alexander, BR	2003	Medical data for DDAC Thor Specialties UK Ltd, Not GLP, Unpublished	Yes	Thor Specialties UK Ltd

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data protection (Yes/No)	Owner
IIA2.2 IIB7.2 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
IIA3.1 IIIA6.2 IIIB6.4	Appelqvist, T	2005	[14C] DDAC - Pharmacokinetics, tissue distribution and mass balance of radioactivity following single dermal application and single and repeated oral gavage administration to Sprague dawley rats, Centre International de Toxicologie (CIT), France, Report No.: 25629 PAR, GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Archer, K, et al.	1995	Screening of wood preservatives: Comparison of the soil-block, agar-block, and agar-plate tests, Forest Products Journal 45:(1) 86-89, Not GLP, Published	No	Public data
IIA1.3	Armak Chemicals	1985	Physical & chemical characteristics, Armak Chemicals - Bulletin 85-52, Not GLP Published	No	Akzo Nobel Surface Chemistry AB
IIA1.3 IIIA3.9 IIIA7.4.2 IIIA7.5.5	Bergström, PO	1993	Determination of the partition coefficient, Pow, between 1-Octanol and water for dicecyldimethylammonium chloride, Q2.10Cl Analyscentrum Berol Nobel, Sweden, Report No.: 93 AC 0012, Not GLP, Unpublished	Yes	EQC
IIB8.2 IIIB6.6	Bergström, P-O	1996	Determination of Querton 210Cl on stainless steel surfaces. Analyscentrum Berol Nobel, Sweden, Report No.:96 AC 206 Not GLP, Unpublished	Yes	EQC
IIA3.5	BIBRA	1990	Toxicity profile Didecyldimethylammonium chloride, BIBRA, Not GLP, Published	No	Public data
IIIA5.7.1 IIIB5.11.2	Bjorland, J, et al.	2005	Widespread distribution of disinfectant resistance genes	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 (Yes/No)	Owner
			among staphylococci of bovine and caprine origin in Norway, J Clin Microbiol 43:(9) 4363-4368, Not GLP, Published		
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
IIB6.3 IIIB3.8.6	Bodsch J	2008	Didecyldimethylammonium chloride (DDAC) Persistent Foaming, Dr.Noack Lab., Gemany, Report no.: CF0112181, GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Borgmann-Strahsen, R	2009	Biocidal activity of Arquad 2.10-50 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 2.10-50 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 2.10-50 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 2.10-50 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 2.10-50 under clean conditions and Escherichia coli, AkzoNobel – The Netherlands,	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 (Yes/No)	Owner
			Not GLP, Unpublished		
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Borgmann-Strahsen, R	2009	Biocidal activity of Arquad 2.10-50 under clean conditions and Candida albicans, 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 2.10-50 under dirty conditions and Candida albicans, 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 2.10-50 under clean conditions and Aspergillus niger, AkzoNobel – The Netherlands, Not GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Borgmann-Strahsen, R	2009	Biocidal activity of 2-propanol under clean conditions-Aspergillus, AkzoNobel – The Netherlands, Not GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Borgmann-Strahsen, R	2009	Biocidal activity of 2-propanol under clean conditions-Candida albicans, AkzoNobel – The Netherlands, Not GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Borgmann-Strahsen, R	2009	Biocidal activity of 2-propanol under clean conditions-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 2-propanol under clean conditions-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 2-propanol under clean conditions-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 2-propanol under clean conditions-Staphylococcus aureus, AkzoNobel – The Netherlands, Not GLP, Unpublished	Yes	EQC
IIA3.1	Bosshard, E and Schlatter, C,	1982	Technical Documentation: Skin penetration and	No	Public data

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			gastrointestinal absorption of [3H] Didecyl-demethyl-ammonium iodide in rats, Institute of Toxicology, Switzerland Not GLP, Published		
IIA1.3 IIIA3.2.1 IIIA3.7 IIIA3.8 IIIA3.9.1	Brekelmans M	2012	Determination of physic-chemical properties of didecyldimethyl-ammonium chloride (DDAC), Notox bv, The Netherlands, Notox Project number: 495712, GLP, Unpublished	Yes	EQC
IIA1.3 IIIA3.2	Brekelmans M	2012	Determination of vapour pressure of DDAC by isothermal thermogravimethry, Notox bv, The Netherlands, Notox project: 499391, GLP, Unpublished	Yes	EQC
IIA1.3 IIIA3.2	Brekelmans M	2014	Determination of vapour pressure of DDAC by isothermal thermogravimethry - report amendment 1, Notox bv, The Netherlands, Notox project: 499391, GLP, Unpublished	Yes	EQC
IIA3.1 IIIA6.2 IIIA6.4.2 IIIB6.4	Bosshard, E and Schlatter, C	1982	Technical Documentation: Skin penetration and gastrointestinal absorption of [3H] Didecyl-dimethyl-ammonium iodide in rats, Institute of Toxicology - Switzerland, Not GLP, Published	No	Public data
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 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
IIA2.2 IIB7.2 IIIA5.3	Butcher, JA, et al.	1979	Potential of unmodified and copper-modified alkylammonium compounds	No	Public data

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IIIB5.10.2			as groundline preservatives, New Zealand Journal of Forestry Science 9:(3) 348-358, Not GLP, Published		
IIA1.4.1 IIA1.4.4 IIIA4.2a IIIA4.2c	Buttler	2014	DDAC (Arquad 2.10-40) Residue Analytical Method for the Determination in Soil and Surface Water, Dr U Noack-Laboratorien,, Report no: CRA15753 / 130731AH GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Cassens, DL and Eslyn, WE	1981	Fungicides to prevent sapstain and mold on hardwood lumber, Forest Products Journal 31:(9) 39-42, 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 IIIB5.3	Chemical Specialties Inc.	2003	Treated wood fact sheet 2003, issue 04/03, Chemical Specialties Inc., Not GLP, Published	No	Public data
IIA3.8.1	Chevalier, G	2003	DDAC Escalating dose range-finding study with DDAC by oral route (gavage) in non pregnant rabbit (Synopsis), Centre International de Toxicologie (CIT) - France, Report No.: 26747 TSL, 18 Nov 2003 GLP, Unpublished	Yes	EQC
IIA1.4.1 IIA1.4.4 IIIA4.3 IIIA6.15	Chevalier, G	2004	Appendix 3 "Determination of ARQUAD 2.10-40 in the dietary admixtures" from: DDAC 13 week dietary toxicity study in rats, Centre International de Toxicologie (CIT) - France, Report No.: 22525 TSR, pages 109-119, GLP, Unpublished	Yes	EQC
IIA3.1 IIA3.5 IIIA6.4.1,1	Chevalier, G	2004	DDAC 13 week dietary toxicity study in rats, Centre International de Toxicologie (CIT) - France, Report No.: 24602 TCR, GLP,	Yes	EQC

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			Unpublished		
IIA3.8.1 IIIA6.8.1	Chevalier, G	2005	DDAC Preliminary study of prenatal developmental toxicity by oral route (gavage) in rabbits. Centre International de Toxicologie (CIT) - France, Report No.: 26153 RSL, GLP, Unpublished	Yes	EQC
IIA3.8.1 IIIA6.8.1	Chevalier, G	2005	Prenatal developmental toxicity study by oral route (gavage) in rabbits, Centre International de Toxicologie (CIT) - France, Report No.: 26154 RSL, GLP, Unpublished	Yes	EQC
IIA3.5 IIIA6.4.1.2	Chevalier, G	2006	DDAC, 13 week toxicity study by oral route (dietary admixture) in Beagle dogs Centre International de Toxicologie (CIT) - France, Report No.: 26152 TSC, GLP, Unpublished	Yes	EQC
IIA3.5 IIA3.7 IIIA6.5 IIIA6.7	Chevalier, G	2008	DDAC Combined chronic toxicity / Carcinogenicity, via oral route in rats (Sprague Dawley), Centre International de Toxicologie (CIT) - France, Report No.: 25630 TCR, GLP, Unpublished	Yes	EQC
IIA3.8.2 IIIA6.8.2	Chevalier, G	2008	DDAC Two-generation study (reproduction and fertility effects) by dietary admixture in rats, Centre International de Toxicologie (CIT) - France, Report No.: 26155 RSR, GLP, Unpublished	Yes	EQC
IIB8.1 IIIB5.3	College Toelating Bestrijdingsmiddelen	2005	Bijlage I bij toelating van het middel Permawood A, Toelatingsnummer 12642 N - Wageningen, Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Creffield, JW	1993	A study on the effectiveness of DDAC to protect wood from attack of termites, IRG, Not GLP, Published	No	Public data
IIB7.2 IIB7.2 IIB7.2 IIIB5.3	CTGB	2008	Authorisation of Plant Protection Products and Biocides, http://www.ctgb.nl/,	No	Public data

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IIIB5.3 IIIB5.10.2			Not GLP, Published		
IIA1 IIA3.2 IIA3.3.2 IIA3.9 IIA3.10 IIIA1 IIIA6.1.4 IIIA6.12.6 IIIB6.2	Cutler, RA and Drobeck, HP	1970	Toxicology of cationic surfactants, Cationic surfactants 4 (Chap. 15):527-616, Not GLP, Published	No	Public data
IIA3.2 IIIA6.1.1 IIIB6.1.1	Daamen, PAM	1990	Assessment of acute oral toxicity with Arquad 2.10-50 in the rat RCC Notox - The Netherlands, Report No.: 031477, GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	De Groot, RC, et al.	1992	Alternative species and preservatives for wood roofing: laboratory decay studies, Forest Products Journal 42:(11-12) 57-60, Not GLP, Published	No	Public data
IIA3.10 IIIA6.12.6	Dejobert, Y, et al.	1997	Contact dermatitis from didecyldimethylammonium chloride and bis-(aminopropyl)-lauryl amine in a detergent-disinfectant used in hospital, Contact Dermatitis 37:(2) 95-96, Not GLP, Published	No	Public data
IIA1.4.2	Den Hartog, I	2003	Overview of results of 5-batch analysis for DDAC, Akzo Nobel Surface Chemistry AB, Not GLP, Unpublished	Yes	EQC
IIB6 IIB8.3 IIIB5.10.1	Den Hartog, I	2004	Label DDAC-50, Akzo Nobel Surface Chemistry AB, Not GLP, Published	No	EQC
IIA1.3	Dery, M,	1996	Quaternairy ammonium compounds, Kirk Othmer, Encyclopedia of Chemical Technology., 20:p:739-776, Not GLP, Published	No	Public data
IIA4.2.1.2 IIIA7.4.1.2 IIIA7.4.3.1 IIIA7.4.3.2 IIIA7.4.3.3.1	Douglas, MT and Handley, JW	1988	The acute toxicity of Querton 210CL-50 to Dahpnia magna, Huntingdon Research Ltd. - England, Report No.: KND 38/881224	Yes	EQC

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IIIA7.4.3.3.2			GLP, Unpublished		
IIA2.2 IIB7.2 IIIA5.37 IIIB5.10.2	Drysdale, JA and Preston, AF	1982	Laboratory screening trials with chemicals for the protection of green timber against fungi, New Zealand Journal of Forestry Science 12:(3) 457-466, Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Dubois, J	1999	Variation in Canadian bleustain fungi, IRG, IRG Document No: IRG/WP 99-10303, Not GLP, Published	No	Public data
IIB8.2 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
IIB7.2 IIIB5.10.2	Elsmore, R	1986	Biocidal control of Legionellae Israel Journal of Medical Sciences (1986), 22(9), 647-54 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	Unanimous	2008	Estimations/calculations on C10-DDAC (CAS 7173-51-5) EpiWin v3.201 Not GLP, Unpublished	No	Public data
IIIB6.5	ESIS	2000	IUCLID data set 2-aminoethanol ESIS - European Chemicals Bureau, Year 2000 CD-ROM edition, Not GLP, Published	No	Public data
IIA3.5 IIIA6.4.1.2	Gaou, I	2007	DDAC, 4 week preliminary toxicity study by oral route (dietary admixture) in Beagle dogs Centre International de Toxicologie (CIT) - France, Report No.: 26151 TSC, GLP, Unpublished	Yes	EQC

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IIA1.4.1 IIA4.1.1.3.1 IIIA7.1.1.1.2 IIIA7.2.3.1 IIIA7.2.3.2 IIIB7.5	Geffke, T	2002	Didecyldimethylammonium chloride (DDAC) - Adsorption-desorption using a Batch Equilibrium Method Dr U Noack-Laboratorien - Germany, Report No.: CAD84871, GLP, Unpublished	Yes	EQC
IIA1.4.1 IIA1.4.4 IIIA4.2a IIIA4.2c	Geffke, T	2007	Didecyldimethylammonium chloride (DDAC) Residue Analytical Method for Determination in tap water, surface water and soil Dr.U. Noack-Laboratorien, Germany, Report No.: CRA10693, GLP, Unpublished	Yes	EQC
IIA4.1.1.2.1 IIIA3.10 IIIA7.1.1.1.1	Geurts, MGJ and Van Wijk, RJ	1997	Hydrolysis as a function of pH of Arquad 2.10-50 Akzo Nobel - The Netherlands, Report No.: RGL F97052, GLP, Unpublished	Yes	EQC
IIA1.4.1 IIA1.4.1 IIIA4.1 IIIA4.1	Goller S	2008	Didecyldimethylammonium chloride (DDAC) - Quantification of the By-products, Dr. U. Noack-Laboratorien - Germany, Report No.: 071220AH-CBP10693, GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIB7.2 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
IIA3.3.1 IIIA6.1.4 IIIB6.2	Guest, RL	1987	Querton 2.10Cl-80: Acute dermal irritation / corrosion test in rabbit, Safepharm Laboratories Ltd - England, Report No.: 116/26, GLP, Unpublished	Yes	EQC
IIA3.6.1 IIIA6.6.3	Haddouk, H	2002	In vitro mammalian cell gene mutation test in L5178Y TK+/- mouse lymphoma cells, Centre International de Toxicologie (CIT) - France, Report No.: 22502 MLY, GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2	Hedley, M, et al.	1982	Evaluation of alkylammonium compounds for use as low	No	Public data

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IIIA5.3 IIIB5.10.2			toxicity wood preservatives in Japan, Wood Research 68:37-46, Not GLP, Published		
IIA2.2 IIB7.2 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 Document No: IRG/WP 95-30083, Not GLP, Published	No	Public data
IIA3.1 IIA3.2 IIA3.4 IIA3.5 IIA3.6.1 IIA3.7 IIA3.8.1 IIA3.8.2 IIA3.10	Henderson, ND	1992	A review of the environmental impact and toxic effects of DDAC, BC Environment Canada, 0-7726-1614-0, Not GLP, Published	No	Public data
IIA2.2 IIB7.2 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
IIA1.4.4 IIIA4.2	Holzer S,	2011	DDAC (lyophilised Arquad 2.10-40) Residue Analytical Method for the Determination in Ground Water, Dr. U. Noack Laboratorien - Germany, Report number: CRA14063 / 101025AH, GLP, Unpublished	Yes	EQC
IIA1 IIIA1	Houthoff, E	2004	Dossier approach for Dialkyldimethyl ammonium compounds (DDAC), European Quats Consortium, Not GLP, Unpublished	No	EQC
IIA2.2 IIB7.2 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,	No	Public data

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IIB8.1 IIIB5.3	ICBO	1999	Acceptance criteria for ACQ wood preservative treatment, ICBO Evaluation Service, Report No.: AC78, Not GLP, Published	No	Public data
IIB8.1 IIIB5.3	ICBO	2001	Acceptance criteria for wood preservative treatment for 'decking use only', ICBO Evaluation Service, Report No.: AC186, Not GLP, Published	No	Public data
IIA3.6.1	Inoue, K, et al.	1980	Studies of in vitro cell transformation and mutagenicity by surfactants and other compounds, Fd Cosmet Toxcol 18:289-296, Not GLP, Published	No	Public data
IIA3.1	Isomaa, B	1975	Absorption, Distribution and excretion of [14C]CTAB, a Quaternary Ammonium Surfactant, in the rat, Fd Cosmet Toxicol 13:231-237, Not GLP, Published	No	Public data
IIB7.2 IIIB5.10.2	Jin, L and Preston, AF	1993	Deplation of preservatives from treated wood: results from laboratory, fungus cellar and field tests, Cannes Conferences, Report No.: IRG/WP93-50001-007, Not GLP, Published	No	Public data
IIA2.2 IIB7.2 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
IIA4.1.3 IIIA7.4.2 IIIA7.4.3.1 IIIA7.4.3.3.1 IIIA7.4.3.3.2	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 IIIA5.7.1 IIIB5.11.2	Kaulfers, PM	1995	Epidemiology and reasons for microbial resistance to biocides, Zentralbl Hyg Umweltmed	No	Public data

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			197:(1-3) 252-259, Not GLP, Published		
IIA2.2 IIB7.2 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
IIB8.3	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 2.10-50 - Kinematic viscosity OECD 114 Siemens Prozess-Sicherheit, Germany, Report no.: 20080202.01, GLP, Unpublished	Yes	EQC
IIA4.2.1.4 IIIA7.4.1.3 IIIA7.4.3.1/01 IIIA7.4.3.2/01 IIIA7.4.3.3.1/01 IIIA7.4.3.3.2/01	Kroon, AGM	1994	Toxicity of Arquad 2.10 to fresh water alga Selenatrum caprinutum Akzo Nobel The Netherlands, Report No.: CRL F94189, Not GLP, Unpublished	Yes	EQC
IIA1.4.2	Lange, J	2005	Comparative Study on the Identity of Arquad 2.10-50 and Acticide DDQ 50 Five Batch Analysis, Dr U. Noack-Laboratorien - Germany, Report No.: CFB103131, GLP, Unpublished	Yes	EQC
IIA1.4.2	Lange J	2014	DDAC - 5 batch analysis - Acticide DDAQ 50, Dr U. Noack-Laboratorien - Germany, Report number: CFB15689 130731AH, GLP, Unpublished	Yes	Thor Specialties UK Ltd
IIA1.4.2	Lange J	2014	DDAC - 5 batch analysis - Arquad 210-50, Dr U. Noack-Laboratorien - Germany, Report number: CFB15647 130731AH, GLP, Unpublished	Yes	Akzo Nobel Surface Chemistry AB
IIB6.3 IIIB3.1 IIIB3.7.1	Lange, J	2007	Didecyldimethylammonium chloride (DDAC) Accelerated Storage Procedure Dr. U. Noack-Laboratorien - Germany, Report No.:	Yes	EQC

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			060220AH/CPL112181, GLP, Unpublished		
IIA1.4.1 IIIA4.1	Lange, J	2007	Didecyldimethylammonium chloride (DDAC) Determination of Identity and Purity before and after dehydration, Dr. U. Noack-Laboratorien - Germany, Report No.: 060220AH/CGB106931, GLP, Unpublished	Yes	EQC
IIA1.3 IIIA3.8	Lange, J	2007	Didecyldimethylammonium chloride (DDAC) Stability in Organic Solvents, Dr. U. Noack-Laboratorien - Germany, Report No.: CSS106932, GLP, Unpublished	Yes	EQC
IIA1.4.1 IIIA4.1	Lange, J	2011	DDAC (lyophilised Arquad 2.10-40) Determination of the Content of the Active Ingredients and Relevant Impurities, Dr. U. Noack Laboratorien - Germany, Report number CBG14063 / 101025AH, GLP, Unpublished	Yes	EQC
IIA1.4.1 IIIA4.1	Lange, J	2014	lyophilised product of Arquad 2.10-40 Determination of the Content of the Active Ingredients and Relevant Impurities, Dr. U. Noack Laboratorien - Germany, Report number CGB15929 / 130731AH, GLP, Published	Yes	EQC
IIA1.4.1 IIA1.4.4 IIIA4.2a IIIA4.2c	Lange, J	2014	residue analytical method for the determination in soil and surface water, Dr. U. Noack Laboratorien - Germany, Report number CRA15753/1307321AH, GLP, Unpublished	Yes	EQC
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,	No	Public data

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			Not GLP, Published		
IIA2.2 IIA2.7 IIB7.2 IIIA5.3 IIIA5.7.1 IIIB5.10.2	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
IIB7.2 IIB8.1 IIIB5.3 IIIB5.10.2	Lebow, S	2004	Alternatives to Chromated Copper Arsenate (CCA) for Residential Construction, Environmental Impacts of Preservative-Treated Wood Conference, Not GLP, Published	No	Public data
IIA4.1.3 IIIA7.4.2 IIIA7.4.3.1 IIIA7.4.3.2 IIIA7.4.3.3.1 IIIA7.4.3.3.2	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
IIA2.2 IIB7.2 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, Patent US4.,585,795 Not GLP, Published	No	Public data
IIA1.4.2 IIA4.1.1.2.2 IIB6.3 IIIB3.7.2	Löfgren, L, et al.	2003	MS analysis of Arquad 2.10-50, Akzo Nobel – Sweden, Report No.: ANL 03023, Not GLP, Unpublished	Yes	EQC
IIA1.4.2 IIA4.1.1.2.2 IIB6.3 IIIB3.7.2	Löfgren, L, et al.	2003	UV IR and NMR analysis of Acticide DDQ50 and Arquad 2.10-50, Akzo Nobel - Sweden, Report No.: ANL 03015, Not GLP, Unpublished	Yes	EQC
IIA3.5	Lortie, A	2004	DDAC- Two-phase dose-range-finding toxicity study by oral route (dietary admixture) in Beagle dogs, Centre International de Toxicologie (CIT) - France Report No.: 26150 TSC, GLP, Unpublished	Yes	EQC

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IIIA5.7.1 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 IIIA6.12.1	Lundgren, U	2003	Medical Data for employees working with DDAC at Akzo Nobel Surface ChemistryAB – Stockvik Sweden, Akzo Nobel Surface Chemistry AB - Sweden, Not GLP, Unpublished	Yes	Akzo Nobel Surface Chemistry AB
IIA4.2.1.1 IIIA7.4.1.1 IIIA7.4.3.1 IIIA7.4.3.2 IIIA7.4.3.3.1 IIIA7.4.3.3.2	Mark, U and Hantink-de Rooij, EE	1990	Acute toxicity of Arquad 2.10-50 to fish, Akzo Nobel - The Netherlands, Report No.: CRL P90078, 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, Published	No	Public data
IIA2.7 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 IIIA5.3 IIIB5.10.2	McKaig, PA	1985	The International Research Group on Wood Preservation. Working Group II; Fundamentals of Testing. Factors affecting decay rates in a fungus cellar, IRG, IRG Document No: IRG/WP 2242, 1985, Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIB7.2 IIIA5.3 IIIB5.10.2	Mein, I, et al.	1997	Acid food industry sanitizer composition, containing a biocidal surfactant, Wo 9742818, Not GLP, Published	No	Public data
IIA1.3 IIIA3.11	Möller, DM	2007	Didecyldimethylammonium chloride (DDAC) Auto-flammability A.16 (Solids -	Yes	EQC

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			determination of relative self-ignition temperature), Siemens AG Prozess-Sicherheit, Frankfurt am Main, Germany, Report No.: 20070081.02, GLP, Unpublished		
IIA1.3 IIIA3.1.1 IIIA3.1.2 IIIA3.10	Möller, DM	2007	Didecyldimethylammonium chloride (DDAC) Thermal stability (OECD 113), Siemens AG Prozess-Sicherheit, Frankfurt am Main, Germany, Report No.: 20070081.01, GLP, Unpublished	Yes	EQC
IIA1.3 IIIA3.1.1 IIIA3.1.2 IIIA3.10	Moller M	2011	Determination of physico-chemical properties, Thermal Stability (OECD 113), Melting Point (EC A.1., OECD 102), Boiling Point (EC A.2., OECD 103), consilab, Frankfurt am Main, Germany, Report number: CSL-11-0356, GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Molnar, S, et al.	1996	Accelerated testing for out of ground contact using natural biological preconditioning, IRG, IRG Document No: IRG/WP 96-20088, Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Molnar, S, et al.	1996	Microbial ecology of treated lap-joints exposed at Hilo, Hawaii for 12 months, IRG, IRG Document No: IRG/WP 96-20089, Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Molnar, S, et al.	1997	Accelerated testing for out of ground contact using natural biological preconditioning: Part 2, IRG, IRG Document No: IRG/WP 97-20108, Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Molnar, S, et al.	1997	Microbial ecology of treated Lap-joints exposed at Hilo, Hawaii for 24 months IRG, IRG Document No: IRG/WP 97-20107, Not GLP, Published	No	Public data

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IIB8.2 IIIB6.6	Montfoort, J, et al.	1996	The use of disinfectants in livestock farming, RIVM Rapport 679102033 Not GLP, Published	No	Public data
IIB6.3 IIIB3.6	Mulder, RJ	1996	Certificate of Analysis: oscillerende dichtheidsmeter Arquad 2.10-50, Akzo Nobel - The Netherlands, Report No.: FP 95159, Not GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Nagano, Y	2001	Fungus cellar testing as an evaluation method for performance of treated timber in ground contact, IRG, IRG Document No: IRG/WP 01-20227, Not GLP, Published	No	Public data
IIA2.26 IIB7.2 IIIA5.3 IIIB5.10.2	Nicholas, DD and Preston, AF	1980	Evaluation of alkyl ammonium compounds as potential wood preservatives, Annual Meeting of the American Wood-Preservers' Association 76:13-21, Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIB7.2 IIIA5.3 IIIB5.10.2	Nishihara, T, et al.	1998	Neutralizing effect of sodium laurate on the bactericidal action of a quaternary ammonium disinfectant against Staphylococcus aureus, Biocontrol Science 3:(1) 1-5, Not GLP, Published	No	Public data
IIB8.1 IIIB5.3	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
IIA1.3 IIIA3.9 IIIA7.4.2 IIIA7.5.5	O, BH.	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
IIA1.3 IIB6.3 IIIB3.10.1	O, BH.	1996	Surface tension according to EC guidelines Akzo Nobel - The Netherlands, Report No.: FL 7657, Not GLP, Unpublished	Yes	EQC
IIB8.3	OECD	2003	OECD series on emission scenario documents, number 2 - Emission scenario	No	Public data

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			document for wood preservatives OECD, Not GLP, Published		
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
IIA3.2 IIIA6.1.2 IIIB6.1.2	Pels Rijcken, WR	1996	Assessment of acue dermal toxicity with Arquad 2.10-50 in the rat, Notox - The Netherlands, report no.: 177345, GLP, Unpublished	Yes	EQC
IIA3.4 IIIA6.1.5 IIIB6.3	Pels Rijcken, WR	1996	Assessment of contact hypersensitivity to Arquad 2.10-50 in the albino guinea pig, (Buehler test), Notox - The Netherlands, Report No.: 161753, GLP, Unpublished	Yes	EQC
IIA1.3 IIB6.3 IIIB3.2 IIIB3.4.1 IIIB3.4.2	Peters, B and Haisma, L	1996	Physico-chemical properties of Arquad 2.10-50, Akzo Nobel - The Netherlands, Report No.: ACRD 960-0230, Not GLP, Unpublished	Yes	EQC
IIA1.4.1 IIIA4.1	Petrovic P	2011	Determination of Sodium Content in DDAC (=lyophilised Arquad 2.10-40) by ICP-OES, AllessaChemie GmbH, Report number: B 001/2011 / VP 001/2011, GLP, Unpublished	Yes	EQC
IIA1.4.2	Petrovic P	2014	DDAC - 5batch analysis NaCl - Arquad 210-50, Allessa GmbH – Germany, VP041-2014, GLP Unpublished	Yes	Akzo Nobel Surface Chemistry AB
IIA1.4.2	Petrovic P	2014	DDAC - 5batch analysis NaCl - Acticide DDQ50, VP042-2014, Allessa GmbH - Germany GLP. Unpublished	Yes	Thor Specialties UK Ltd
IIB6.3 IIIB3.9	Porter, MR	1991	Cationics. Chapter 8. Handbook of Surfactants. 179-188, Not GLP, Published	No	Public data
IIB8.2	Preller, EA and Schipper, HJ	1999	Respiratory and dermal exposure to disinfectants: a	No	Public data

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IIIB6.6			study in slaughterhouses and the meat processing industry TNO Nutrition and Food Research - The Netherlands, Report No.: V98.1306, Not GLP, Published		
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Preston, AF	1983	Dialkyldimethylammonium halides as wood preservatives, JAOCS, J. Am. Oil Chem. Soc. 60:(3) 567-570, Not GLP, Published	No	Public data
IIA2.26 IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Preston, AF and Chittenden, CM	1982	Alkylammonium compounds as above-ground wood preservatives, New Zealand Journal of Forestry Science 12:(1) 102-106 Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Preston, AF and Nicholas, DD	1982	Efficacy of a series of alkylammonium compounds against wood decay fungi and termites, Wood and Fiber 14:(1) 37-42, Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Preston, AF, et al.	1983	The use of laboratory, fungus cellar and field tests in the development of wood preservatives, Annual Meeting of the American Wood-Preservers' Association 79:207-212, Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Preston, AF, et al.	1987	Recent research on alkylammonium compounds in the US, Annual Meeting Am. Wood-preserv. Assoc. 331-348 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, Published	No	Public data
IIA1.4.1 IIIA3.4.2 IIIA3.4.3 IIIA3.4.4 IIIA3.10	Roos, M	2007	Characterization of the Molecular Structure of DDAC (freeze dried), AllessaChemie GmbH, Germany,	Yes	EQC

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			Report No.: B 012/2007, GLP, Unpublished		
IIIA5.07.1 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
IIA4.2.1.4 IIIA7.4.1.3 IIIA7.4.3.1 IIIA7.4.3.2 IIIA7.4.3.3.1 IIIA7.4.3.3.2	Scheerbaum D	2011	Arquad 2.10-40 Alga, Growth Inhibition Test with Pseudokirchneriella subcapitata, 72 h., Dr. U. Noack Laboratorien - Germany, Report number: SPO14062 / 101025AH, GLP, Unpublished	Yes	EQC
IIA3.6.1 IIIA6.6.1	Scheres, HME	1990	Evaluation of mutagenic activity of Arquad 2.10-50 in Ames Salmonella/microsome test (with independent repeat), RCC Notox - The Netherlands, Report No.: 031466, GLP, Unpublished	Yes	EQC
IIA4.1.1.3.2 IIB8.03	Schoknecht, U, et al.	2002	Biozidemissionen aus materialien, Bundesanstalt für Materialforschung und -prüfung (BAM), Not GLP, Published	No	Public data
IIA1.3 IIIA3.3	Schulze, M	2007	Didecyldimethylammonium chloride (DDAC) Appearance: Physical State, Colour and Odour, Dr. U. Noack-Laboratorien - Germany, Report No.: 060220AH/CAP106931, GLP, Unpublished	Yes	EQC
IIA1.3 IIIA3.1.3	Schulze, M	2007	Didecyldimethylammonium chloride (DDAC) Determination of the Density, Dr. U. Noack Laboratorien - Germany, Report No.: 060220AH/CPD106931, GLP, Unpublished	Yes	EQC
IIA1.3 IIIA3.11	Schulze, M	2007	Didecyldimethylammonium chloride (DDAC) Flammability of Solids, Dr. U. Noack Laboratorien -	Yes	EQC

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			Germany, Report No.: 060220AH/CPE106931, GLP, Unpublished		
IIA1.3 IIIA3.7	Schulze, M	2007	Didecyldimethylammonium chloride (DDAC) Solubility in Organic Solvents (Modified Flask Method), Dr. U. Noack-Laboratorien - Report No.: 060220AH/CLF106933, GLP, Unpublished	Yes	EQC
IIA1.3 IIB6.3 IIIA3.15 IIIB3.3	Schulze, M	2007	Didecyldimethylammonium chloride (DDAC) Statement on Explosive Properties, Dr.Noack Laboratorien. - Gemany, report no.: CEP10693N, GLP, Unpublished	Yes	EQC
IIA1.3 IIB6.3 IIIA3.16 IIIB3.3	Schulze, M	2007	Didecyldimethylammonium chloride (DDAC) Statement on Oxidising Properties, Dr.Noack Laboratorien - Gemany, report no.: CES10693N, GLP, Unpublished	Yes	EQC
IIA1.3 IIIA3.13	Schulze, M	2007	Didecyldimethylammonium chloride (DDAC) Surface Tension incl. Determination of CMC (Critical Micelle Concentration), Dr. U. Noack Laboratorien - Germany, Report No.: 060220AH/CPT106931, GLP, Unpublished	Yes	EQC
IIA1.3 IIA1.4.1 IIIA3.4.1 IIIA7.1.1.1.2 IIIA7.3.1 IIIA7.3.2	Schulze, M	2007	Didecyldimethylammonium chloride (DDAC) UV-VIS Absorption Spectra Dr. U. Noack Laboratorien - Germany, Report No.: 060220AH/CPU106932, GLP, Unpublished	Yes	EQC
IIA1.3 IIB6.3 IIIA3.5 IIIB3.5	Schulze, M	2007	Didecyldimethylammonium chloride (DDAC) Water Solubility (Modified Flask Method), Dr. U. Noack Laboratorien - Germany, Report No.: 060220AH/CWF106932, GLP, Unpublished	Yes	EQC

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IIA4.2.3.4 IIIA7.5.1.3	Servajean, E	2004	Laboratory assessment of the side effects of DDAC on plant growth, Phytosafe - France, Report No.: 03-99-035-ES, GLP, Unpublished	Yes	EQC
App.6.1h	Shell Chemicals	2003	SDS Isopropylalcohol Shell Chemicals, Not GLP, Published	No	Shell Chemicals
IIIA5.7.1 IIIB5.11.2	Shimp, RJ, et al.	1989	Adaptation to a quaternary ammonium surfactant by suspended microbial communities in a model stream, Environmental Toxicology and Chemistry 8:(8) 723-730, Not GLP, Published	No	Public data
IIA3.1 IIA3.5	Smith, C, et al.	1989	Twenty-eight day oral toxicity study in rats with Querton 210Cl-50, Huntingdon Research Centre Ltd. - England, Report No.: KND 39/89556, GLP, Unpublished	Yes	EQC
IIB7.2 IIIB5.10.2	Solo-Gabriele, H, et al.	2000	Alternative chemicals and improved disposal-end management practices for CCA-treated wood, Florida center for solid and hazardous waste management, Report No.: #00-03, Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIIA5.30 IIIB5.10.2	Stephenson, RA	1990	Optimisation of the Performence of Quaternary Ammonium Compounds, Industrial applications of surfactants II. 235-275, Not GLP, Published	No	Public data
IIA4.1.1.3.2	Stevens, M and Van Eetvelde, G	1994	Leaching of active ingredients from timber treated with different Akzo formulations, University of Gent - Belgium, Report No.: HT94-MI01, Not GLP, Unpublished	Yes	EQC
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	Takahashi, M, et al.	1990	Evaluation of termiticides in field trials,	No	Public data

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IIIA5.3 IIIB5.10.2			IRG, IRG Document No: IRG/WP 3633, Not GLP, Published		
IIB7.2 IIIB5.10.2	Tascioglu, C, et al.	2005	Adsorption of ACQ and Cu MEA wood preservatives in red pine, IRG, IRG Document No.: IRG/WP 05-30374, Not GLP, Published	No	Public data
IIB6.3 IIIA3.17 IIIB3.7.3	Ter Haar, J	2000	UN classified products filled into plastic drums (25l, 60l, 210l), Akzo Nobel - The Netherlands, Report No.: 00-125-JtH, Not GLP, Unpublished	Yes	EQC
IIA4.2.3.3 IIIA7.4.3.5.1 IIIA7.5.2.1	Thomas, P and Velthoven, K,	2005	Toxicity of DDAC in Caenorhabditis elegans growth inhibition test (Personal communication), Akzo Nobel – The Netherlands, Not GLP Unpublished	Yes	EQC
IIA4.0.1.3 IIIA7.4.3.1 IIIA7.4.3.2 IIIA7.4.3.3.1 IIIA7.4.3.3.2 IIIA7.4.3.4	Thomas, PC, et al.	2004	Chronic toxicity to Daphnia Magna in a 21-day reproduction test under semi-static conditions, Akzo Nobel - The Netherlands, Report No.: CER F04010 GLP, Unpublished	Yes	EQC
App.6.1g IIIA9 IIIB9	Thor Specialties UK Ltd	2001	SDS Acticide DDQ 50 Thor Specialities UK Ltd, Not GLP, Published	No	Thor Specialties UK Ltd
IIA1.4.2 IIA1.4.3 IIB6.4.1 IIIB4.1	Thor Specialties UK Ltd	1998	Determination of amine and amine hydrochloride percent, Thor Specialities Ltd., England, Report No.: QTF 03, Not GLP Published	No	Thor Specialties UK Ltd
IIA1.4.2 IIA1.4.3 IIB6.4.1 IIIB4.1	Thor Specialties UK Ltd	2001	Determination of purity using cationic activity test (Epton test), THOR Specialities Ltd., England, Report No.: QTF 04, Not GLP, Published	No	Thor Specialties UK Ltd
IIA1.4.2 IIA1.4.3 IIB6.4.1 IIIB4.1	Thor Specialties UK Ltd	2003	GCMS-determination of octanol, decanol and dodecanol in quats, Thor Specialities Ltd., England Report No.: QTF 01, Not GLP,	No	Thor Specialties UK Ltd

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			Published		
IIA1.4.2 IIA1.4.3 IIB6.4.1 IIIB4.1	Thor Specialties UK Ltd	2004	Method summary for sodium in surfactant, Warwick analytical services Ltd, England, Report No.: WAS 1950, Not GLP, Published	No	Thor Specialties UK Ltd
IIA2.2 IIB7.2 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 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
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Tsunoda, K and Nishimoto, K	1987	Effectiveness of alkylammonium compounds as above-ground wood preservatives, Mokuzai Gakkaishi 33:(7) 589-59,5 Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Tsunoda, K and Nishimoto, K	1987	Fungicidal effectiveness of amended alkylammonium compound, IRG, IRG Document No: IRG/WP 3421, Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIB7.2 IIIA5.3 IIIB5.10.2	Tuncan, EU	1993	Effect of cold temperature on germicidal efficacy of quaternary ammonium compound, iodophor, and chlorine on Listeria, Journal of Food Protection (1993), 56(12), 1029-33, Not GLP, Published	No	Public data
IIB7.2 IIIB5.10.2	UK - Health and Safety Executive	2008	Approved products http://www.hse.gov.uk/biocides/ Not GLP, Published	No	Public data
App.6.7 IIA2.22	Van de Knaap, D	2003	Literature search for DDAC Akzo Nobel - The Netherlands, Not GLP, Unpublished	No	Public data
App.6.7 IIA2.2	Van de Knaap, D	2004	Literature search for DDAC and wood Akzo Nobel – The	No	Public data

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			Netherlands, Not GLP, Unpublished		
App.6.7 IIA2.2	Van de Knaap, D	2004	Literature search for wood and EN 113 results Akzo Nobel – The Netherlands, Not GLP, Unpublished	No	Public data
IIA3.6.1 IIIA6.06.2	Van de Waart, EJ	1996	Evaluation of the ability of Arquad 2.10-50 to induce chromosome aberration in cultured peripheral human lymphocytes (with independent repeat), Notox - The Netherlands, Report No.: 161764, GLP, Unpublished	Yes	EQC
IIA4.2.3.3 IIIA7.4.3.5.1 IIIA7.5.2.1	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 IIIA1	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
IIIA7.1.2.1.1	Van Ginkel, CG and Geerts, R	2007	Determination of the degradation of DDAC in a simulation test of an activated sludge plant treating domestic wastewater, Akzo Nobel - The Netherlands, ECRA F07016 T 07003 CAS, GLP, Unpublished	Yes	EQC
IIA4.1.1.1.2 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 IIA4.1.1.2.2 IIA4.2.3.1 IIIA7.1.1.1.2 IIIA7.1.1.2.1 IIIA7.1.1.2.2 IIIA7.1.1.2.3 IIIA7.1.2.1.2	Van Ginkel, CG and Pomper, MA	1996	Biodegradability of Arquad 2.10-50 in closed bottle test Akzo Nobel - The Netherlands, Report No.: CRL F96008, GLP, Unpublished	Yes	EQC

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IIIA7.1.2.2.1 IIIA7.1.2.2.2 IIIA7.2.2.1 IIIA7.3.1 IIIA7.3.2 IIIA7.4.1.4					
IIIA7.5.1.1	Van Ginkel, CG and Van der Togt, B	2004	Toxicity of DDAC to soil microorganisms: Nitrogen transformation inhibition test, Akzo Nobel - The Netherlands, Report No.: CER F04013, 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 DDAC for BPD Product Types 8, 2, 3 and 4, Akzo Nobel - The Netherlands, CAP-MAS M06079, Not GLP, Unpublished	Yes	EQC
IIA2.2 IIB7.2 IIB7.2 IIIA5.3 IIIB5.10.2	Wallhäuser, KH	1995	Praxis der Sterilisation Disinfection - Konservierung Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Walsh, SE, et al.	2003	Activity and mechanisms of action of selected biocidal agents on Gram-positive and -negative bacteria, J.Appl.Microbiol. 94:240-247, Not GLP, Published	No	Public data
IIA2.2 IIB7.2 IIIA5.3 IIIB5.10.2	Wazny, J and Cookson, LJ	1994	Comparison of the agar-block and soil-block methods used for evaluation of fungitoxic value of QAC and CCA wood preservatives, IRG, IRG Document No: IRG/WP 94-20039, Not GLP, Published	No	Public data
IIIB5.3	Western Wood Preservers Institute	2002	Treated wood news - Introduction to AWPA's use category system Treated wood news, Summer 2002 Not GLP, Published	No	Public data
IIA4.2.3.2 IIIA7.5.1.2	Winkelmann, G.	2008	Arquad 2.10-40 - Earthworm (Eisenia fetida), Effects on Reproduction in Natural Soil (LUFA 2.2), Dr. U. Noack-Laboratorium - Germany, Report No.: 071109AG/RRR11186, GLP, Unpublished	Yes	EQC