Competent Authority Report

DOCUMENT III-A

Study Summaries - Active Substance

Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride (PT 8)
CAS 68424-85-1

Section 1 Applicant and Company Information

Section 1 **Annex Point IIA. 1**		Official use only
1.1 Name and Address		
1.1.1 Name and Address	1) Lonza GmbH Morianstrasse 32 DE-~~0~~42041 Wuppertal Germany Tel: 00 49 202 245 38 0 Fax: 00 49 202 245 38 30 Email: [redacted] 2) Stepan Europe Chemin Jongkind BP 127 38340 Voreppei France Tel: 0033 4 76505100 Fax: 0033 4 76505110 Email: [redacted] 3) McKenna, Long & Aldridge LLC 56, Rue des Colonies, Box 14 B-1000 Brussels Belgium Tel: (32-2) 278-1211 Fax: (32-2) 278-1200 Email: [redacted]	x
1.2 Active substance manufacturer		
1.2.1 1st Manufacturer		
1.2.1.1 Name	Clariant GmbH (toll manufacturer for Lonza GmbH)	
1.2.1.2 Location	Werk Gendorf DE-084504 Burgkirchen Germany Phone: 0049 867970 Fax: 0049 86794545	x
1.2.2 2nd Manufacturer		
1.2.2.1 Name	Cromogenia-Units S.A. (toll manufacturer for Lonza GmbH)	
1.2.2.2 Location	Faarell, 9 08014 Barcelona Spain Phone: +93 431 7700 Fax: +93 422 6014	
1.2.3 3rd Manufacturer		
1.2.3.1 Name	Stepan Company	
1.2.3.2 Location	Chemin Jongkind BP 127 38340 Voreppe France Phone: 00334 76505100	

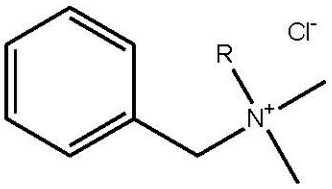
		Fax: 00334 76505110	
1.2.4	4th Manufacturer		
1.2.4.1	Name	Mason Chemical Company	
1.2.4.2	Location	721 W. Algonquin Road IL 60005 Arlington Heights USA Phone: 001847 2901621 Fax: 001847 2901625	
		Evaluation by Competent Authorities	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		31/07/2008	
Materials and Methods			
Results and discussion			
Conclusion			
Reliability			
Acceptability			

Remarks	1.1.1 The contact information for the first and third joint Notifiers/Applicants should be updated as follows: The e-mail address for Lonza GmbH should be: gisbert.mehring@lonza.com The joint Notifier originally listed as "McKenna Long & Aldridge LLC," has changed: Field Fisher Waterhouse LLP Boulevard Brand Whitlock, 30 1200 Brussels Belgium Tel: (32-2) 278-1211 Fax: (32-2) 278-1200 Email: [redacted] **Dec 2011**- Contact information in 1.1 should be updated as follows: **1)** Lonza Cologne GmbH Nattermannallee 1 DE-50829 Köln Germany Tel: 0049 221 99199262 Fax: 0049 221 99199263 Email: [redacted] **2)** Stepan Europe Chemin Jongkind BP 127 38340 Voreppe France Phone: 0033 4 76505100 Fax: 0033 4 76505110 Email: [redacted] **3)** Mason Europe Limited c/o Technology Sciences (Europe) Ltd Concordia House St. James Business Park Grimbald Crag Court Knaresborough North Yorkshire HG5 8QB United Kingdom Phone: 44 0 1423 799 634 Fax: 44 0 1423 797 804 Email: [redacted]

	Also contact information in 1.2 should be updated as follows: **1.2.1** Clariant GmbH (toll manufacturer for Lonza GmbH) Werk Gendorf DE-84504 Burgkirchen Germany Phone: 0049 867970 Fax: 0049 86794545 **1.2.2** Stepan Company Chemin Jongkind BP 127 38340 Voreppe France Phone: 00334 76505100 Fax: 00334 76505110 **1.2.3** Mason Chemical Company 721 W. Algonquin Road Arlington Heights, IL 60005 USA Phone: 001847 2901621 Fax: 001847 2901625 The following subsection should be also considered: **1.3 Legal Representative** Field Fisher Waterhouse LLP Boulevard Louis Schmidt, 29 1040 Brussels Belgium Phone: (32 2) 742 7000 Fax: (32 2) 742 7100 Email: [redacted]
	COMMENTS FROM
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Section 2 Identity

Section 2 Annex Point IIA. 2		Official use only
2.1 Common name proposed or accepted by ISO and synonyms	Alkyldimethylbenzylammonium Chloride ADBAC There are five alkyldimethylbenzyl and alkldiemthylethylbenzyl ammonium chlorides included in a category of benzyl substituted quaternary ammonium biocides. The category is comprised of the following substances: Notified Substance / CAS RN: **(C12-C16) Alkyldimethylbenzylammonium Chloride** — **68424-85-1**; (C12-C18) Alkyldimethylbenzylammonium Chloride — 68391-01-5; (C12-C14) Alkyldimethylbenzylammonium Chloride — 85409-22-9; (C12-C14) Alkyl Dimethyl Ethylbenzyl Ammonium Chloride — 85409-23-0; C(12-18) Alkyldimethylbenzylammonium Saccharinate — 68989-01-5 Only **C12-C16 ADBAC (CAS RN 68424-85-1)** is included in this submission for Product Type 8 (Wood Preservatives). [redacted] Point of Clarification: Throughout this submission, Trade Names and Formulations are included in the "Synonyms" portion of the various documents. These products use CAS RN 68424-85-1 in their formulations. These names should not be confused with other chemical structural names for ADBAC.	x
2.2 Chemical (CAS) name	Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chloride (for Product Type 8)	x
2.3 Manufacturer's development code number(s)	[redacted] for Product Type 8)	
2.4 CAS and EC numbers		
2.4.1 CAS number	68424-85-1 (for Product Type 8)	

Section 2 **Annex Point IIA. 2**			Official use only
2.4.2	EC number	270-325-2 (for Product Type 8)	
2.4.3	Other substance No.	None	
2.5	**Molecular and structural formula, molecular mass**		
2.5.1	Molecular formula	$C_9 H_{13} N Cl R$ where R = $C_{12} H_{25}$, $C_{14} H_{29}$ or $C_{16} H_{33}$ (for Product Type 8)	
2.5.2	Structural formula	 R = $C_{12}H_{25}$ $C_{14}H_{29}$ $C_{16}H_{33}$ (for Product Type 8)	
2.5.3	Molecular mass	340.0 – 396.1 g/mol (Avg. = 359.6 g/mol) (for Product Type 8)	
2.6	**Method of manufacture**	See Confidential Data	
2.6.1	Stability Information	ADBAC is stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods. Shelf-life for salable products (ranging from approximately [redacted] active substance) is at least one year and often much longer. ADBAC does not hydrolyze at a concentration of 10 ppm over a pH range of 5 to 9 (see Section 7.1.1.1.1 (1), Ref. No. A2). ADBAC is also photolytically stable (see Section 7.1.1.1.2 (1), Ref. No. A1). ADBAC is readily biodegradable and, therefore, the primary source of degradation at very low concentrations of ADBAC is microbial (see Section 7.1.1.2.1 (1), Ref. No. A88). However, ADBAC has disinfectant properties at concentrations of [redacted]r, thus preventing biodegradation in the test substances listed in Table 2.7-1. In addition, the subchronic dermal toxicity study in rats (see Section 6.4.2 (1), Ref. No. A18) provides analytical data showing more dilute concentrations of 0.1% and 0.6% to be stable for at least 14 days. In conclusion, prolonged stability of aqueous, alcohol and alcohol/aqueous solutions of ADBAC used for fate and toxicological testing is ensured since biodegradation, hydrolysis and photolysis do not occur at the concentrations of the test substances identified in Table 2.7-1. Table 2.6.1-1 provides prolonged stability data for the primary ADBAC test substance [redacted] used for mammalian toxicity testing.	
2.7	**Specification of purity**	[redacted] Alkyldimethylbenzylammonium Chloride is not produced or sold as a solid material but always exists in process solvents (ethanol or isopropanol and/or water).	x

Section 2 **Annex Point IIA. 2**		Official use only
	See Table 2.7-1 for information related to the test substances used for physical/chemical, fate and effects, and toxicity testing.	
2.8 Identity of impurities and additives	See Confidential Data	x
2.9 Origin of precursor(s) of the active substance	Synthesis	
2.10 Exposure data		
2.10.1 Human exposure		
2.10.1.1 Production	The production of Alkyldimethylbenzylammonium Chloride is carried out by fully trained personnel, wearing appropriate personal protective clothing. The appropriate environmental controls are in place to ensure that environmental and personal exposure is negligible.	
2.10.1.2 Intended use(s)	Alkyldimethylbenzylammonium Chloride is used for preventive protection of wood and constructional timbers in Hazard Classes 1 to 4A according to ISO draft standard (see Table 2.10.2.2.2-1). Intended uses are summarised below.	
2.10.1.2.1 Overview	The potential worker exposure from handling of cut lumber that has been treated with wood preservative containing Alkyldimethylbenzylammonium Chloride and to other workers involved in operation and maintenance of the site has been evaluated. It is considered that consumer exposure is also adequately assessed by the worker assessment as consumers are only exposed to articles treated with Alkyldimethylbenzylammonium Chloride (consumers are not involved in paint application processes). Hence consumer exposure will be comparable to (or lower than) "workers that handle treated wood after it is dry" class of occupational exposure. The final version (June 2002) of Technical Notes for Guidance - Human Exposure to Biocidal Products (TNG) has been followed in conducting this assessment.	
2.10.1.2.2 Use process descriptions	**Occupational exposure:** The biocidal product containing the active substance is used in two wood preservative treatment applications: dipping and vacuum pressure processes. Dipping: Dipping is a batch process with continuous treatment. A pack or single piece of wood is submerged into a dipping tank filled with a solution containing the wood preservative. Packs of wood are loaded on automatic equipment (e.g. hydraulic elevator) and lowered into a dipping tank. The period of time that the wood is submerged varies from a few minutes to an hour depending on anticipated use of the wood. At the end of treatment, the wood is held over the dipping vat for up to an hour to allow the excess preservative to drain. Drips are collected and recycled. The treated wood is then removed for storage. The dipping facilities are enclosed, and are equipped with vapour	

Section 2 Annex Point IIA. 2		Official use only
	trapping and air emission control. Vacuum pressure impregnation: Vacuum pressure is a process used to apply wood preservative by overcoming the resistance of the wood to deep penetration using pressure. The treatment is carried out in cylindrical airtight steel pressure/vacuum vessels. The operations are carried out on a cyclical basis. The untreated wood is loaded onto small rails or tramcars that are pushed into the cylinder using forklifts or other mechanical means. The cylinder door is sealed via a pressure tight door, either manually with bolts or hydraulically, and a vacuum applied to remove most of the air from the cylinder and the wood cells. The preservative solution is then pumped into the cylinder and the pressure raised. The total treatment time varies depending on species of wood and the commodity being treated, but in all instances the treating process remains a closed system. At the end of the treatment time, the pressure is released and the excess solution removed, typically by pumping and recycled. A final vacuum may be applied to remove excess preservative that would otherwise drip from the wood. The treated wood is then unloaded and stored. 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 Alkyldimethylbenzylammonium Chloride. It is diluted down to a suitable working strength with water. The degree of dilution varies depending on the wood species, type of wood product and anticipated use. The requirements for Alkyldimethylbenzylammonium Chloride concentration in both processes vary between 0.4% and 2%. **Consumer exposure:** Consumer exposure is restricted to handling of treated lumber in operations such as erecting fences. Consumers are not involved in the application stage. Exposure of humans to or via the environment has also been assessed.	

Section 2 **Annex Point IIA. 2**		Official use only
2.10.1.2.3 Human (Occupational and consumer) exposure	The following are descriptions of main types of workers involved with occupational use of Alkyldimethylbenzylammonium Chloride as a wood preservative. Mixing and loading stage: The active substance is supplied by tanker as a concentrate with approximately 1 delivery per week. It is delivered to the holding tank by transfer pipes and is a closed system. The concentrate is then diluted as appropriate in the process plant to give a solution to be use for preservation of the wood. All workers wear gloves, coveralls, and foot protection and are trained in the use of the equipment. Other than incidental exposure in connecting and disconnecting transfer lines, exposure is not foreseen. Application stage: There are four main strata of workers that may potentially be exposed to the wood preservative in the process plant. These are considered in Table 2.10.1.2.3-1: EASE Modelling of Worker Exposure: For purposes of modelling, the potential exposure routes are considered to be inhalation (model default) and skin contact. It is assumed that respiratory protective equipment is used only in event scenarios as the need to clear fallen wood within the treatment vessel Frequency, duration and quantity: Vacuum-pressure process: Daily use-cycle time 3 hours, 3 cycles per day Dipping process: Up to 30 minutes immersion per batch. Post-application: Professional post-application constitutes system maintenance and illustrated above. Non professional post application exposure is all regarded as secondary exposure through the use of preserved wood. Consumer exposure: The level of exposure is considered to be comparable to occupation exposure to workers that handle treated wood after it is dry. Exposure of humans to or via the environment has also been assessed.	

Section 2 **Annex Point IIA. 2**		Official use only
2.10.1.2.4 Exposure assessment	The model subdivides the wood treatment process into eight different patterns of use to reflect a broad range of exposure possibilities. In this instance, the EASE model (within the EUSES model) has been used to predict the workplace exposure from the use processes. This gives results of potential exposure assuming that no PPE is employed. In reality, PPE is worn, hence the estimates obtained are overestimates. As a worst case scenario, all calculations are based on the knowledge that the wood treatment solution employed contains 2% a.s. The neat concentrate of the substance (containing 25% a.s.) is only handled under closed conditions and so is modelled under Use Pattern 1 (see below for more details). The following values are common to all use patterns: Dermal exposure: Hands-only Physical state of substance: Liquid Process temperature: 20°C Aerosol formed: no Inhalation of dust particles: No In-vitro dermal absorption study through human skin: 2.92% in an aqueous formulation. Worker use patterns are summarised in Table 2.10.1.2.4-1 **Substance properties: (as used in EUSES/EASE)** Molecular weight: 304 Melting point: 150°C Vapour pressure at 25°C 1E-07 Pa Octanol-water partition coefficient: 3.06 (QSAR, TGD Part III pg 548, reverse calculation from BCF value) Water solubility: 4.31E+05 mg/l	
2.10.1.2.5 Predicted occupational exposure	The dermal and inhalation results from the EASE model for each use pattern are summarised below. EASE Model Predictions for Hands-Only Exposure to Alkyldimethylbenzylammonium Chloride in Wood Preservation Table 2.10.1.2.5-1 **Exposure of humans to or via the environment** This has been determined using the EUSES model for use patterns 1-4 (see Document III-A Section 2.10.2 for use pattern descriptions and details). Local total daily intake for humans: Use pattern 1: 2.81E-06 mg/kg/d Use pattern 2: 5.57E-07 mg/kg/d Use pattern 3: 5.68E-05 mg/kg/d Use pattern 4: 5.57E-07 mg/kg/d	X
2.10.2 Environmental exposure	*Headline only*	X
2.10.2.1 Production	As workers wear appropriate personal protective equipment and appropriate environmental controls are in place, it is estimated that exposure will be negligible.	

Section 2 **Annex Point IIA. 2**		Official use only
2.10.2.2 Intended uses(s)	Summarised below	
2.10.2.2.1 Overview	An evaluation of the potential environmental effects of Alkyldimethylbenzylammonium Chloride from the relevant stages of the wood preservative life-cycle, (product application, storage of treated wood prior to shipment, and treated wood-in-service) has been conducted. The EC recommended OECD Emission Scenario Document for Wood Preservatives (ESD) and EUSES model have been used to conduct this assessment.	
2.10.2.2.2 Use pattern exposure estimates	The biocidal product containing the active substance is used in two preventive treatment applications: drenching/dipping and vacuum pressure/pressure processing. These applications and their subsequent storage stages will be considered (use patterns 1-4). Use patterns 1-5 are addressed using the EUSES v.1.0 programme, with the following general values: Molecular weight: 304 Melting point: 150°C Vapour pressure: 1E-07 Pa at 25°C Partition coefficient (log Pow): 3.06 (QSAR, TGD, Part III, P. 548, reverse calculation from BCF value) Water solubility: 431,000 mg/l High Production Volume Chemical Volume of chemical imported to EU: CONFIDENTIAL (Reference A) Industry category: 15/0 Others Use category: 55/0 Others Organic carbon-water partition coefficient: Koc 6,171,657 Readily biodegradable Bioconcentration factor for fish: 79 l/kg **Use pattern 1: Dipping/immersion process:** Application rate: 2 kg a.s./m^3 (worst case site-specific information) Volume of wood treated per day: 2 m^3/day (worst-case site-specific information) Total amount of a.s. processed per site per day: 4 kg Number of emission days per year: 150 (worst-case site-specific information) Total tonnage of a.s. processed per site per year: CONFIDENTIAL (Reference B) kg (worst case) Total tonnage of a.s. used in region: CONFIDENTIAL (Reference C) kg (widespread use, 10% of tonnage used in default region) Fraction of main local source: 3.75E-02 (worst case scenario: tonnage per site/regional tonnage) Fraction of chemical used for application: 1 (worst case) Fraction of chemical in formulation: 0.02 (concentration of a.s. in dipping solution) Main category processing: Non-dispersive use Default STP used Fraction released to air: 1E-03 (ESD) Fraction released to waste water: 0.0015 (Worst case value including additional safety factor: based on USES 2.0 where predicted release from “salt impregnation” is 0.0001 and “drenching and dipping” is	

Section 2 Annex Point IIA. 2		Official use only
	0.0005) Fraction released to surface water: 0 (ESD) Fraction released to soil: 0 (ESD) **Use pattern 2: Storage of wood treated by dipping/immersion process:** Leaching rate: 2.6% over 14 days (equivalent to 1.66E-04 kg a.s./m^2 over 14 days – see Section 2.10.2.2.4) Effective surface area of treated wood, considered to be exposed to rain, per m^2 storage area: 11 m^2/m^2 (ESD) Surface area of the storage place: 700 m^2 (ESD) Total amount of a.s. leached from treated wood during storage per day: 1.28 kg (calculation from ESD) Number of emission days per year: 10.7 (worst case, assumes that total amount leaching over 14 days leaches in 1 day) Total tonnage (of a.s. on treated wood in storage in contact with water) used in region: CONFIDENTIAL (Reference D) kg Fraction of main local source: 3.75E-02 (assumed that all wood treated in use pattern 1 would be stored at same site) Fraction of chemical used for application: 1 (worst case) Fraction of chemical in formulation: 0.02 Main category processing: Non-dispersive use Default STP used. Fraction released to air: 0 (ESD) Fraction released to waste water: 0 (ESD) Fraction released to surface water: 0.013 (ESD) Fraction released to soil: 0.013 (ESD) **Use pattern 3: Vacuum pressure process:** Application rate: 2 kg a.s./m^3 (worst-case site-specific information) Volume of wood treated per day: 50 m^3/day (worst-case site-specific information) Total amount of a.s. processed per day: Confidential (Reference E) Number of emission days per year: 150 (worst-case site-specific information) Total tonnage of a.s. processed per site per year: CONFIDENTIAL (Reference F) kg (worst case) Total tonnage of a.s. used in region: CONFIDENTIAL (Reference C) kg (widespread use, 10% of tonnage used in default region) Thus, fraction of main local source: 0.9375 (worst case scenario: tonnage per site/regional tonnage) Fraction of chemical used for application: 1 (worst case) Fraction of chemical in formulation: 4E-03 (concentration of a.s. in vacuum pressure solution) Main category processing: Non-dispersive use Default STP used Fraction released to air: 1E-03 (ESD) Fraction released to waste water: 0.0015 (Worst case value including additional safety factor: based on USES 2.0 where predicted release from "salt impregnation" is 0.0001 and "drenching and dipping" is 0.0005) Fraction released to surface water: 0 Fraction released to soil: 0	

Section 2 Annex Point IIA. 2		Official use only
	Use pattern 4: Storage of wood treated by vacuum pressure process Leaching rate: 2.6% over 14 days (equivalent to 1.66E-04 kg a.s./m^2 over 14 days – see Section 2.10.2.2.4) Effective surface area of treated wood, considered to be exposed to rain, per m^2 storage area: 11 m^2/m^2 (ESD) Surface area of storage area: 525 m^2 (ESD) Total amount of a.s. leached from treated wood over assessment period: 0.959 kg Number of emission days per year: 10.7 (worst case, assumes that total amount leaching over 14 days leaches over 1 day) Total tonnage of (of a.s. on treated wood in storage in contact with water) used in region: CONFIDENTIAL (Reference G) kg Fraction of main local source: 0.9375 (assumed that wood treated in use pattern 3 would be stored at same site) Fraction of chemical used for application: 1 (worst case) Fraction of chemical in formulation: 4E-03 Main category processing: Non-dispersive use Default STP used Fraction released to air: 0 Fraction released to waste water: 0 Fraction released to surface water: 0.013 (ESD) Fraction released to soil: 0.013 (ESD) After treatment and storage, the finished wood is used in the following services: framing, roof timbers, exterior joinery, deck boards, fence posts. Appropriate examples have been modelled to assess the most significant potential environmental exposures (use patterns 5-9). Table 2.10.2.2.2-1 contains descriptions of wood preservative Hazard Classes according to the ISO draft standard "An international framework for classifying wood products durability based on use classes" with representative scenarios from the ESD. Thus, the appropriate Hazard Classes, as outlined in ESD, are Classes 1, 2, 3 and 4A. Alkyldimethylbenzylammonium Chloride is not used in applications falling under Hazard Classes 4B and 5. No scenarios have been proposed for Hazard Classes 1 and 2, and the emissions are considered to be negligible. Thus, the predicted environmental concentrations available for Hazard Classes 3 and 4A only are calculated. For use patterns 5-9, the primary receiving environmental compartment is soil, except for use pattern 5 where the receiving compartments are soil and the sewage treatment plant. Within the definitions of the ESD, the soil compartment for these use patterns is considered to be a localised area of soil, adjacent to the wooden structure under discussion. For the EUSES software model, however, the industrial soil compartment is considered to be a more widespread area in which the wooden structure is based. As such, the calculation of the predicted environmental concentrations for the soil compartment of each use pattern using EUSES is not considered to be valid and are calculated using the approach outlined in the ESD. **Use pattern 5: Treated wood in service: Noise barrier (use class 3)** Leaching rate: 2.6% over 14 days (equivalent to worst case value of 1.66E-04 kg a.s./m^2 over 14 days – see Section 2.10.2.2.4)	

Section 2 Annex Point IIA. 2		Official use only
	Leachable area of wood barrier: 3000 m^2 (ESD) Amount of a.s. leached per barrier: 0.498 kg Number of emission days per year: 10.7 (calculated, to take into account the leaching period of 14 days) Maximum annual total tonnage of a.s. leached per noise barrier: 5.33 kg Total tonnage of a.s. used in region: CONFIDENTIAL (Reference H) (widespread use, 10% of tonnage used in default region) Fraction of main local source: 3.33E-04 (worst case scenario: tonnage per noise barrier/regional tonnage) Fraction of chemical used for application: 1 (worst case) Fraction of chemical in formulation: 0.02 (worst case) Main category: private use Default STP used Fraction released to air: 0 (ESD) Fraction released to waste water: 0.7 (ESD) Fraction released to surface water: 0 (ESD) Fraction released to soil: 0.3 (ESD) **Use pattern 6: Treated wood in service: Fence (use class 3)** Leaching rate: 2.6% over 14 days (equivalent to 1.66E-04 kg a.s./m^2 over 14 days – see Section 2.10.2.2.4) Leachable area of wood fence: 2 m^2 (ESD) Thus, amount of a.s. leached per fence: 3.32E-04 kg Fraction released to soil: 1 (ESD) **Use pattern 7: Treated wood in service: House (use class 3)** Leaching rate: 2.6% over 14 days (equivalent to 1.66E-04 kg a.s./m^2 over 14 days – see Section 2.10.2.2.4) Leachable area of wood house: 125 m^2 (ESD) Amount of a.s. leached per house: 0.0208 kg (ESD) Fraction released to soil: 1 (ESD) **Use pattern 8: Treated wood in service: Transmission pole (use class 4A)** Leaching rate: 2.6% over 14 days (equivalent to 1.66E-04 kg a.s./m^2 over 14 days – see Section 2.10.2.2.4) Wood area above soil: 5.5 m^2 (ESD) Wood area below soil: 1.6 m^2 (ESD) Amount of a.s. leached per pole: 1.18E-03 kg Fraction released to soil: 1 (ESD) **Use pattern 9: Treated wood in service: Fence post (use class 4A)** Leaching rate: 2.6% over 14 days (equivalent to 1.66E-04 kg a.s./m^2 over 14 days – see Section 2.10.2.2.4) Wood area above soil: 0.8 m^2 Wood area below soil: 0.2 m^2 Amount of a.s. leached per post: 1.66E-04 kg Fraction released to soil: 1 (ESD)	
2.10.2.2.3 Predicted environmental concentrations	**Use Pattern 1:** Aquatic environment: Local PEC in surface water during emission episode: 5.76E-06 mg/l Local PEC in sediment during emission episode: 0.772 mg/kg PEC for micro-organisms in the STP: 2.38E-04 mg/l Terrestrial environment:	

Section 2 Annex Point IIA. 2		Official use only
	Local PEC in pore water of agricultural soil: 9.93E-07 mg/l. Local PEC in agric. soil (total) averaged over 30 days: 0.108 mg/kg Atmosphere: Concentration in air during emission episode: 1.11E-06 mg/m^3 Annual average local PEC in air (total): 4.57E-07 mg/m^3 **Use Pattern 2: Storage of dipped/immersed wood:** Aquatic environment: Local PEC in surface water during emission episode: 3.43E-06 mg/l Local PEC in sediment during emission episode: 0.461 mg/kg PEC for micro-organisms in the STP: 0 mg/l Terrestrial environment: Local PEC in pore water of agricultural soil: 5.83E-08 mg/l Local PEC in agric. soil (total) averaged over 30 days: 6.35E-03 mg/kg Atmosphere: Concentration in air during emission episode: 0 mg/m^3 Annual average local PEC in air (total): 1.3E-15 mg/m^3 **Use Pattern 3: Vacuum pressure application:** Aquatic environment: Local PEC in surface water during emission episode: 6.15E-05 mg/l Local PEC in sediment during emission episode: 8.25 mg/kg PEC for micro-organisms in the STP: 0.00595 mg/l Terrestrial environment: Local PEC in pore water of agricultural soil: 2.34E-05 mg/l. Local PEC in agric. soil (total) averaged over 30 days: 2.55 mg/kg Atmosphere: Concentration in air during emission episode: 2.78E-05 mg/m^3 Annual average local PEC in air (total): 1.14E-05 mg/m^3 **Use Pattern 4: Storage of vacuum-pressure-treated wood:** Aquatic environment: Local PEC in surface water during emission episode: 3.43E-06 mg/l Local PEC in sediment during emission episode: 0.461 mg/kg PEC for micro-organisms in the STP: 0 mg/l Terrestrial environment: Local PEC in pore water of agricultural soil: 5.83E-08 mg/l Local PEC in agric. soil (total) averaged over 30 days: 6.35E-03 mg/kg Atmosphere: Concentration in air during emission episode: 0 mg/m^3 Annual average local PEC in air (total): 1.3E-15 mg/m^3 **Use Pattern 5: Treated wood in service: Noise barrier** PEC for micro-organisms in the STP: 0.0138 mg/l (EUSES derived) Amount of a.s. leached per barrier: 0.498 kg (wet) Soil volume per m length: 10 m^3 Bulk density of wet soil: 1700 kg_{wwt}/m^3 Fraction released to soil: 0.3	

Section 2 Annex Point IIA. 2	Official use only

$Clocal_{soil,leach,time1}$ = 8.79E-06 kg/kg_{wwt}
Localised PEC in soil during emission episode: 8.79 mg/kg (ESD derived)

Use Pattern 6: Treated wood in service: Fence
Amount of a.s. leached per fence: 3.32E-04 kg
(wet) Soil volume per m length: 0.01 m^3
Bulk density of wet soil: 1700 kg_{wwt}/m^3
Fraction released to soil: 1

$Clocal_{soil,leach,time1}$ = 1.95E-05 kg/kg_{wwt}
Localised PEC in soil during emission episode: 19.5 mg/kg

Use Pattern 7: Treated wood in service: House
Amount of a.s. leached per house: 0.0208 kg
(wet) Soil volume: 0.5 m^3
Bulk density of wet soil: 1700 kg_{wwt}/m^3
Fraction released to soil: 1

$Clocal_{soil,leach,time1}$ = 2.45E-05 kg/kg_{wwt}
Localised PEC in soil during emission episode: 24.5 mg/kg
Use Pattern 8: Treated wood in service: Transmission pole
Amount of a.s. leached per transmission pole: 1.18E-03 kg
(wet) Soil volume: 0.2 m^3
Bulk density of wet soil: 1700 kg_{wwt}/m^3
Fraction released to soil: 1

$Clocal_{soil,leach,time1}$ = 3.47E-06 kg/kg_{wwt}
Localised PEC in soil during emission episode: 3.47 mg/kg

Use Pattern 9: Treated wood in service: Fence post
Amount of a.s. leached per fence post: 1.66E-04 kg
(wet) Soil volume: 0.05 m^3
Bulk density of wet soil: 1700 kg_{wwt}/m^3
Fraction released to soil: 1

$Clocal_{soil,leach,time1}$ = 1.95E-06 kg/kg_{wwt}
Localised PEC in soil during emission episode: 1.95 mg/kg

Non compartmental specific exposure relevant to the food chain (secondary poisoning):

Use Pattern 1:
Concentration in fish from surface water for predators: 3.09E-04 mg/kg
Local concentration in earthworms from agricultural soil: 4.35E-04 mg/kg

Use Pattern 2:
Concentration in fish from surface water for predators: 2.71E-04 mg/kg
Local concentration in earthworms from agricultural soil: 4.14E-04 mg/kg

Use Pattern 3:
Concentration in fish from surface water for predators: 1.21E-03 mg/kg
Local concentration in earthworms from agricultural soil: 9.5E-04 mg/kg

Section 2 Annex Point IIA. 2		Official use only
	Use Pattern 4: Concentration in fish from surface water for predators: 2.71E-04 mg/kg Local concentration in earthworms from agricultural soil: 4.14E-04 mg/kg	
2.10.2.2.4 Determination of leaching rate	During a study to evaluate the leachability of a structural analogue (Didecyldimethylammonium Chloride) active substance from treated wood, it was determined that (at an application concentration of 3.5 kg a.s./m^3) 2.6% leached over 14 days. [redacted] Assume 1 m^3 ≡ 1000 l Thus, 1 m^3 ≡ 1000 x 1000 ml 1 m^3 = 1E+06 ml Volume of one wooden block = 6.9 ml. Number of wooden blocks/m^3 = 1E+06/6.9 = 144927 blocks Dimensions of wooden blocks = 19 mm x 19 mm x 19 mm (0.019 m x 0.019 m x 0.019 m) Number of faces = 6 Total surface area of a wooden block = 0.002166 m^2 Surface area of 1 m^3 blocks = 144927 x 0.002166 = 313.9 m^2 i) Use pattern 1: Dipping process Application rate = 2.0 kg a.s./m^3 Leaching rate = 2.6% Thus leaching rate = 2.0 x 0.026 = 0.052 kg/m^3 As 1 m^3 of wooden blocks is equivalent to 313.9 m^2 Thus, leaching rate ≡ 1.66E-04 kg/m^2 over 14 days ii) Use pattern 3: Vacuum process Application rate = 2.0 kg a.s./m^3 Leaching rate = 2.6%	

Section 2 Annex Point IIA. 2		Official use only
	Thus leaching rate = 2.0 x 0.026 = 0.052 kg/m^3 As 1 m^3 of wooden blocks is equivalent to 313.9 m^2 Thus, leaching rate ≡ 1.66E-04 kg/m^2 over 14 days Bestari, K. (2001) Determination of the leachability of Bardac 2280 from Treated Wood. Study No. 2000-CT-WL-B22. Centre for Toxicology, University of Guelph, Guelph, Ontario, N1 g 2W1, Canada. (Unpublished) [Ref No: A103 (LON 3815)]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	18/04/2006	
Materials and Methods		
Results and discussion		
Conclusion	The submitted data are acceptable	
Reliability	0	
Acceptability	acceptable	

Section 2 **Annex Point IIA. 2**	Official use only
Remarks	[redacted]
	COMMENTS FROM
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 2.6.1-1: Stability Analysis Data – ADBAC Lot # [redacted] -

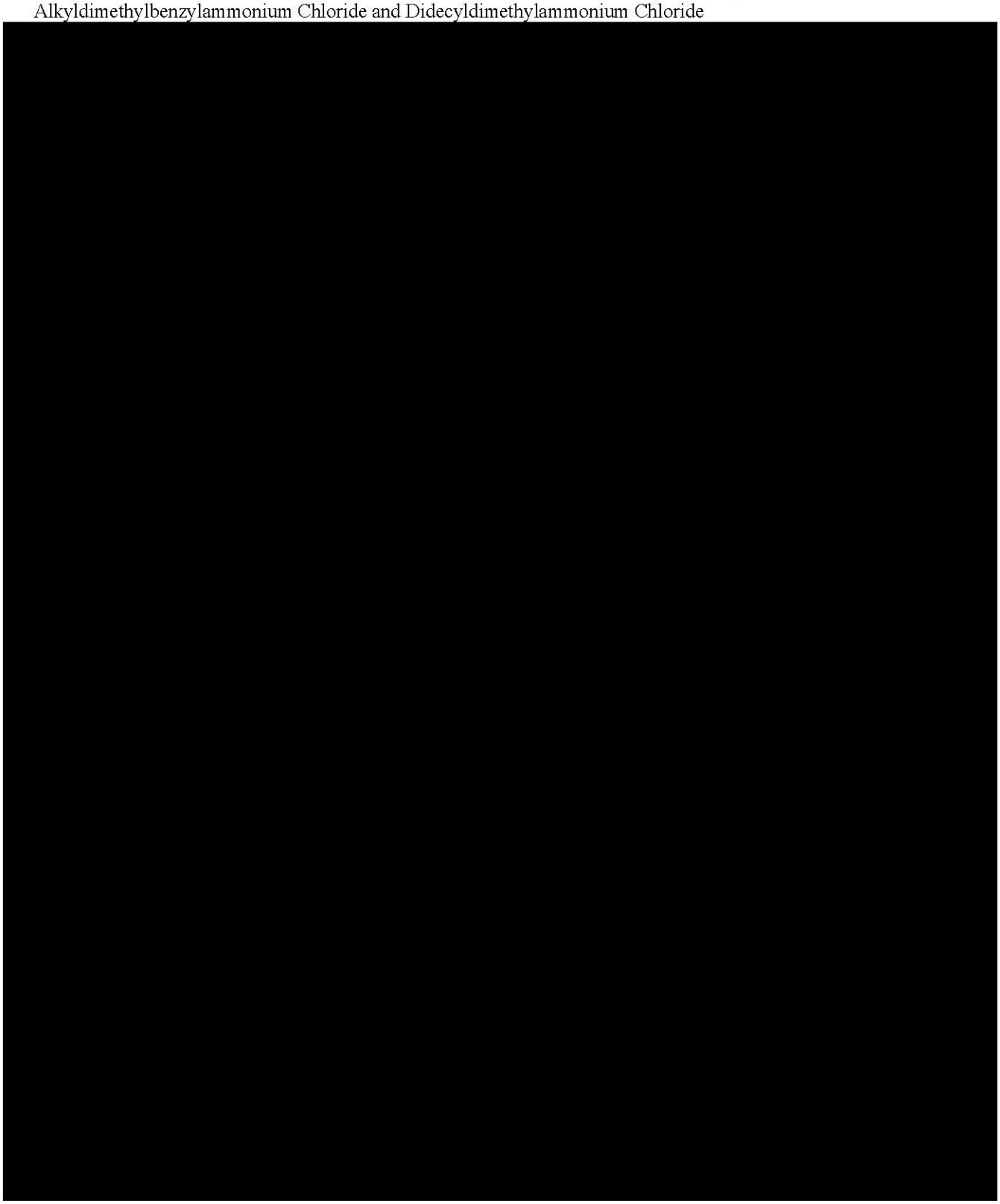
[redacted]

Table 2.7-1: Test Substances used for Physical/Chemical, Fate and Effects, and Toxicity Testing.

Name	A.S. in solution	Alcohol	Water
[redacted]	[redacted]		

- Not applicable
[a] Typical production material after removal of process solvent; purity determined by titration
[b] Active substance is Alkyl(C_{12}-C_{18})dimethylbenzylammonium Chloride
[c] Active substance is Alkyl(coco) dimethylbenzylammonium Chloride; coco (coconut oil) contains C_8-C_{18} chains with a predominance (>75%) of C_{12} –C_{16}
[d] Note: Active substance is Didecyldimethylammonium Chloride – used for Read-Across Studies

Table 2.7-2: Comparison of Physical/Chemical Properties, Fate and Effects and Toxicity Data for Alkyldimethylbenzylammonium Chloride and Didecyldimethylammonium Chloride



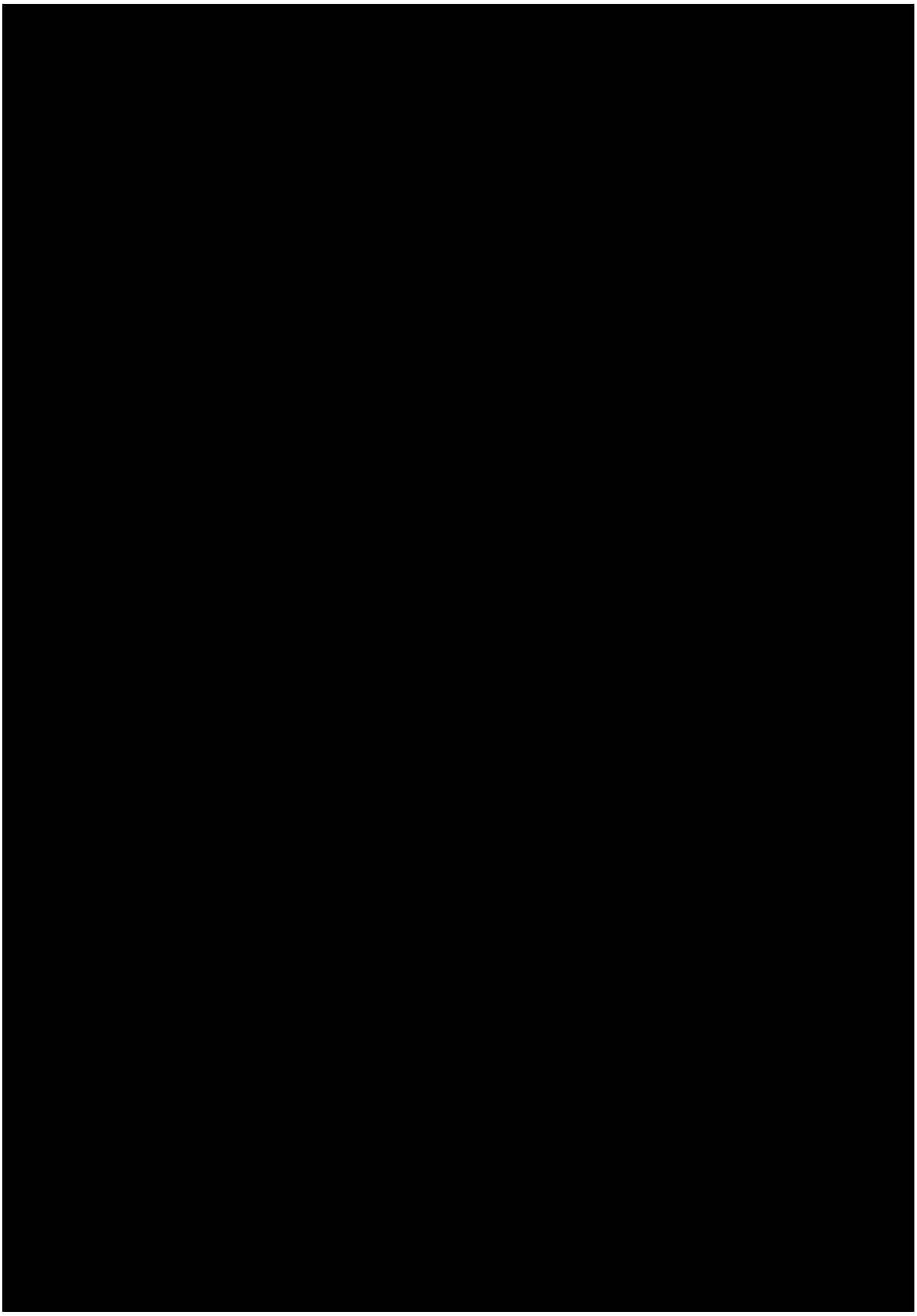


Table 2.8-1 Identity of impurities and additives

See Confidential Data

Table 2.10.1.2.3-1

Worker strata	Type of worker	Job description
Workers that handle wet treated lumber	Diptank/vacuum process operator	Operates system (i.e. on control Panel)
	Grader*	Grades wet treated lumber by hand
	Piler*	Pulls wet treated lumber off the conveyer and piles it to the side
	Sorter operator	Operates the automated sorting system
	Tray attendant	Ensures conveyer not jamming
Workers that handle treated wood after it is dry	Bander operator*	Attaches bands around lumber and packages the loads
	Stenciller*	Sprays paint number and logos on stacked lumber
	Tallyman*	Staples information sheet onto wood
	Trimmer*	Most lumber untreated, however some treated lumber is returned to be trimmed
	Packager*	Operates automated packaging machine that moves lumber into place. May cover loads with white packaging material
	Papercapper*	Staples paper and caps onto stacked dry treated lumber
Maintenance workers of equipment	Chemical operator*	Maintains chemical supply balance, and equipment including greasing door seals etc
	Millwright*	Repairs all conveyor chains and keeps operation of the mill running
	Cleanup-crew*	General cleanup of the mill facilities, often done at weekends
Forklift operators	Forklift driver*	Drives dry treated lumber to yard

The workers marked with * come into direct contact with the treated lumber or sawdust sludge.

Table 2.10.1.2.4-1

Use pattern	Pattern of control	LEV in operation	Dermal contact level	Directly handled	Max. a.s. conc (%)
1	Closed	Yes	Incidental	No	25
2	Non-dispersive	Yes	Incidental	No	2
3	Non-dispersive	Yes	Intermittent	No	2
4	Non-dispersive	Yes	Extensive	No	2
5	Non-dispersive	Yes	Incidental	Yes	2
6	Non-dispersive	Yes	Intermittent	Yes	2
7	Non-dispersive	Yes	Extensive	Yes	2
8	Non-dispersive	No	Extensive	Yes	2

Table 2.10.1.2.5-1 EASE Model Predictions for Hands-Only Exposure to Alkyldimethylbenzylammonium Chloride in Wood Preservation

Use Process	Dermal Exposure		Inhalation Exposure	
	dermal weight of a.s. on the skin of workers $mg/cm^2/d$	potential dermal uptake for workers* mg/kg/d	vapour concentration in air for workers ppm	vapour concentration in air for workers* mg/m^3
1	0	0	0-0.1	0-0.316
2	0	0	0-0.1	0-0.0253
3	0	0	0-0.1	0-0.0253
4	0	0	0-0.1	0-0.0253
5	0-0.1	0 - 7.008E-04	0-0.1	0-0.0253
6	0.1-1	7.008E-04 – 7.008E-03	0-0.1	0-0.0253
7	1-5	7.008E-03 – 0.03504	0-0.1	0-0.0253
8	1-5	7.008E-03 – 0.03504	0-0.1	0-0.0253

*Exposure is corrected from the reference figure given by the EASE software as only 25% of active substance is in the concentrate solution and 2% active substance is in the solution used to treat the wood directly. A correction is also applied for the maximum absorption of 2.92%.

Table 2.10.2.2.2-1 contains descriptions of wood preservative Hazard Classes according to the ISO draft standard "An international framework for classifying wood products durability based on use classes" with representative scenarios from the ESD.

Class	Service conditions		Description	Typical uses
1	Interior, dry		Situation in which wood or wood-based product is under cover, fully protected from the weather and not exposed to wetting.	Framing, roof timbers
2	Interior, damp		Situation in which wood or wood-based product is under cover, fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting.	Framing, roof timbers
3	A	Protected exterior	Situation in which wood or wood product is not covered and no in contact with the ground. It is either continually exposed to the weather or is protected from the weather but subject to frequent wetting.	Exterior joinery
3	B	Unprotected exterior		Deck boards
4	A	In-ground	Situation in which wood or wood product is permanently in contact with the ground or fresh water and thus is permanently exposed to wetting.	Fence posts
4	B	In-ground, severe, fresh water		Cooling tower
5	Marine		Situation in which wood or wood-based product is permanently exposed to salt water.	Piles

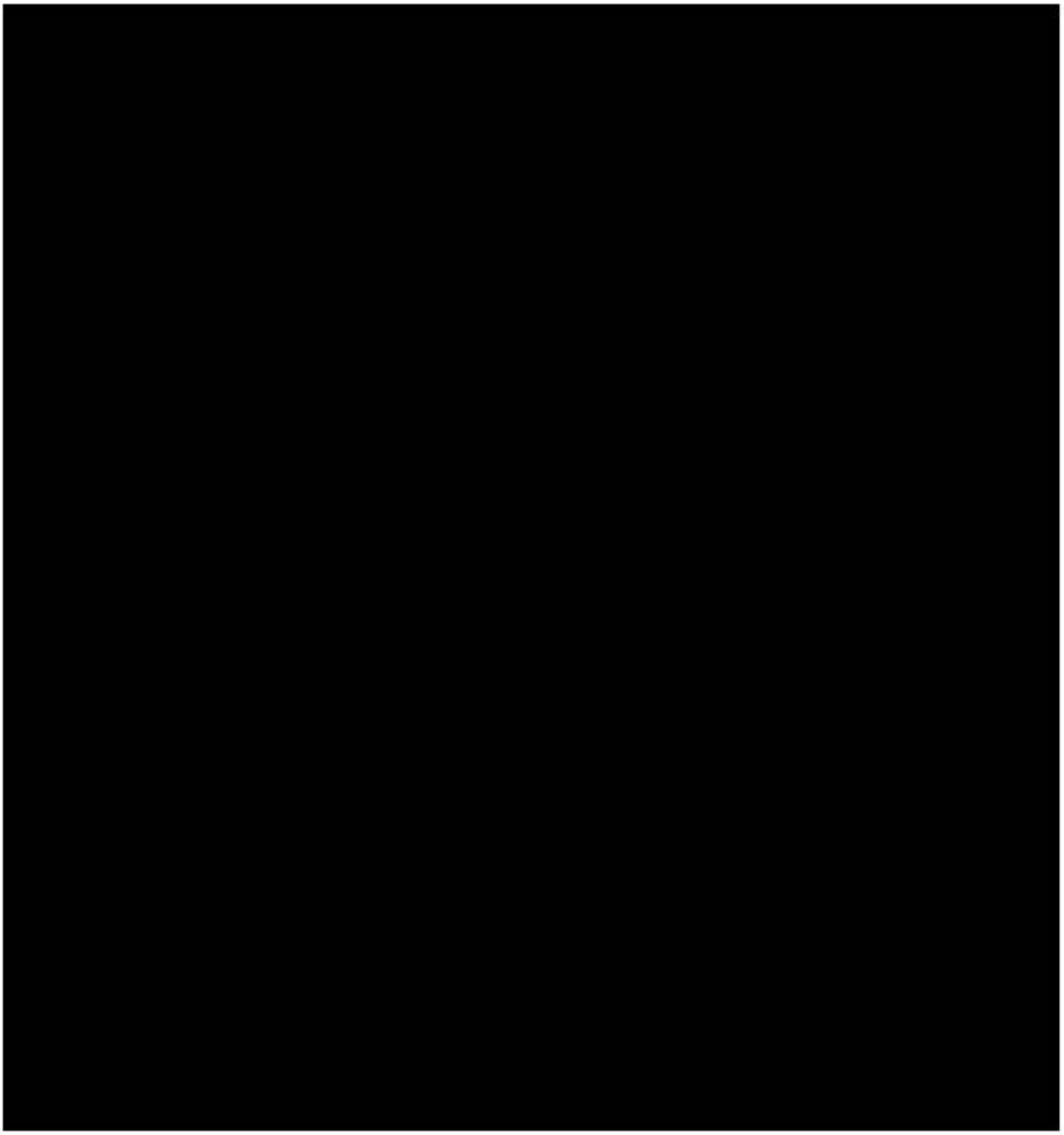
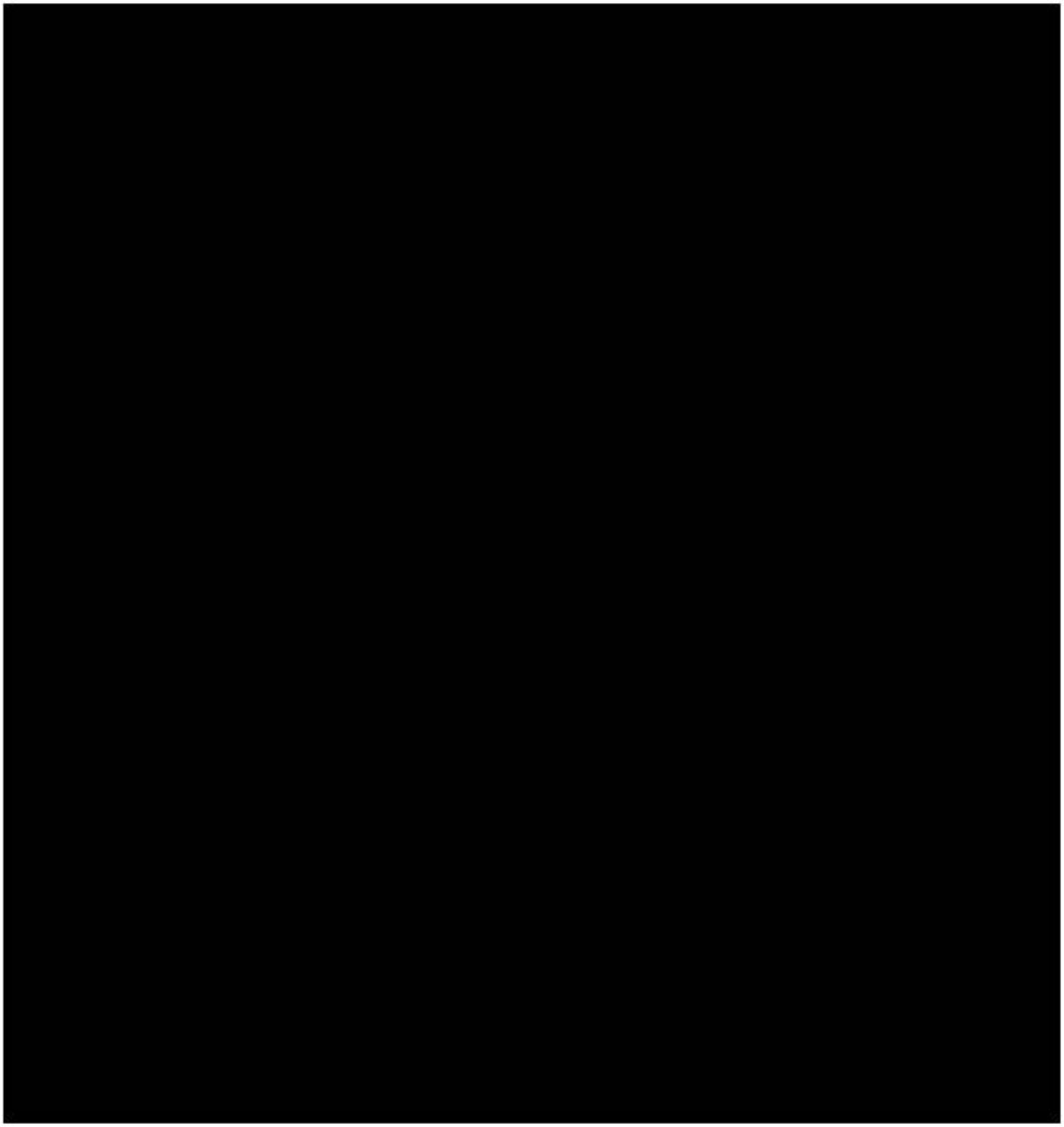


Figure 2.6-1: Typical Certificate of Analysis for Alkylbenzylamine.



Section 3.1.1 (1) **Annex Point IIA 3.1.1**	**Melting point**	
	1. REFERENCE	Official use only
1.1 Reference	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages)* *If necessary, copy field and enter other reference(s).* Fischer, A. (2001) Determination of the melting point of Barquat MB AS in accordance with OECD-Guideline 102. Clariant GmbH, Frankfurt, Germany. Unpublished report no. B 013/2001 (unpublished) [Ref No: A39 (LON 3391)]	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* ADBAC Issues Steering Committee	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD Guideline No. 102 Year: 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	[redacted]	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 3.1.1 (1) **Annex Point IIA 3.1.1**	**Melting point**	
3.1.2 Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* As given in section II of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted]. Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1).	
3.1.3 Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution* [redacted]	
3.1.4 Purity	*Give purity in g/kg, g/l, %w/w or % v/v active substance* [redacted]	
3.1.5 Stability	*Describe stability of test material* The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2 Method	OECD Guideline No. 102; Differential Scanning Calorimetry	
	4. RESULTS	
4.1 Results	Ambiguous, at ca 150°C.	
4.2 Discussion	The substance did not melt. With increasing temperature the substance softens and becomes less viscous and clear. Upon cooling for 12 to 24 hours at room temperature the substance reverts to its original state.	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* [redacted]	
5.3 Conclusion	The test substance does not possess a melting point as it does not melt.	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4*	

Section 3.1.1 (1) **Annex Point IIA 3.1.1**	**Melting point**	
	[redacted]	
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

Section 3.1.2(1) Annex Point IIA 3.1.2	**Boiling point**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [X] **Scientifically unjustified** [ ] **Other justification** [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	The applicant justification is accepted	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 3.1.3(1) Annex Point IIA 3.1.3	Relative density	
	1. REFERENCE	Official use only
1.1 Reference	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages)* *If necessary, copy field and enter other reference(s).* Fischer, A. (2001) Determination of the Relative Density of Barquat MB AS in accordance with OECD-Guideline 109. Clariant GmbH, Frankfurt, Germany. Unpublished report no. B 011/2001 (unpublished). [Ref No: A40 (LON 3380)]	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* ADBAC Issues Steering Committee	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD Guideline No. 109 Year: 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy).*	
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed).*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	[redacted]	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 3.1.3(1) **Annex Point IIA 3.1.3**	**Relative density**	
3.1.2 Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* As given in section II of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1).	
3.1.3 Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	*Describe stability of test material* The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2 Method	OECD Guideline No. 109	
	4. RESULTS	
4.1 Results	Relative density: 0.96 @ 20°C	
4.2 Discussion		
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	The test substance has a relative density of 0.96 @ 20°C	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	acceptable
Remarks	
	COMMENTS FROM OTHER MEMBER STATE
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

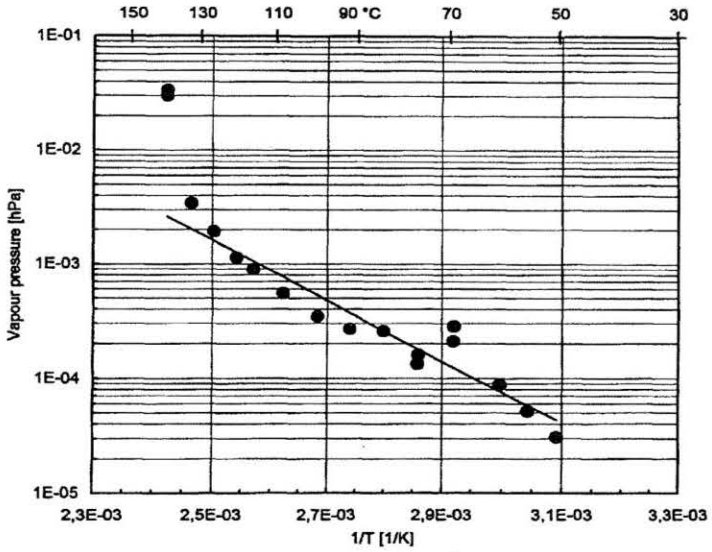
Section 3.2(1) Annex Point IIA 3.2	**Vapour pressure**	
	1. REFERENCE	Official use only
1.1 Reference	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages) If necessary, copy field and enter other reference(s).* Franke, J. Barquat MB AS, KP01/03 (2001) – Vapour Pressure. Siemens Axiva GmbH & Co. KG for Clariant GmbH, Frankfurt, Germany. Unpublished report no. 20010308.01 (unpublished). [Ref No: A41 (LON 3385)]	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* ADBAC Issues Steering Committee	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes Directive 92/69/EEC, Method A4 Year: 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	[redacted]	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 3.2(1) Annex Point IIA 3.2	**Vapour pressure**	
3.1.2 Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] ADBAC sample prepared by removal of process solvents (water and alcohol) from a typical production process. Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1).	
3.1.3 Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	*Describe stability of test material* The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2 Method	Directive 92/69/EEC, Method A.4; Vapour pressure balance (effusion method)	
	4. RESULTS	
4.1 Results	Vapour pressure: < 1E-03 Pa @ 50°C	x
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* [redacted]	

Section 3.2(1) Annex Point IIA 3.2	**Vapour pressure**	
	[redacted]	
5.3 Conclusion	The test substance has a low vapour pressure. Vapour pressure of the test substance at 20, 25 and 50 °C was calculated to be 6.03E-06, 8.57E-06 and 4.22E-05 hPa (6.03E-04, 8.57E-04 and 4.22E-03 Pa), respectively.	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	

Section 3.2(1) Annex Point IIA 3.2	Vapour pressure	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

Figure 3.2(1)-1: Regression of measured vapour pressure values for extrapolation of vapour pressure at 20, 25 and 50°C.



Section 3.2.1 Annex Point IIA 3.2.1	Henry's law constant	Official use only
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	
Other existing data [X] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	

Section 3.2.1 Annex Point IIA 3.2.1	Henry's law constant	Official use only
Conclusion	The applicant justification is accepted	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 3.3 **Annex Point IIA. 3.3**	**Appearance**	Official use only
3.3.1 Physical state	Solid @ 20°C and 101.3 kPa	
3.3.2 Colour	Light beige @ 20°C and 101.3 kPa	
3.3.3 Odour	Not specified	