Competent Authority Report

# DOCUMENT III-A

## Study Summaries - Active Substance

# DIDECYLDIMETHYLAMMONIUM CHLORIDE (PT 8)
# CAS 7173-51-5

## Section 1 Applicant and Company Information

| **Section 1**<br>**Annex Point IIA. 1** | | | Official use only |
|---|---|---|---|
| **1.1 Name and Address** | | | |
| 1.1.1 | Name and Address | 1) Lonza GmbH<br>Morianstrasse 32<br>DE-42041 Wuppertal<br>Germany<br>Tel: 00 49 202 245 38 0<br>Fax: 00 49 202 245 38 30<br>Email: [redacted]<br><br>2) Stepan Europe<br>Chemin Jongkind BP 127<br>38340 Voreppei<br>France<br>Tel: 0033 4 76505100<br>Fax: 0033 4 76505110<br>Email: [redacted]<br><br>3) McKenna, Long & Aldridge LLC<br>56, Rue des Colonies, Box 14<br>B-1000 Brussels<br>Belgium<br>Tel: (32-2) 278-1211<br>Fax: (32-2) 278-1200<br>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<br>DE-0845084 Burgkirchen<br>Germany<br><br>Tel: 0049 867970<br>Fax: 0049 86794545 | |
| 1.2.2 | 2nd Manufacturer | | |
| 1.2.2.1 | Name | Stepan Company | |
| 1.2.2.2 | Location | Chemin Jongkind BP 127<br>38340 Voreppe<br>France<br><br>Tel: 0033 4 76505100<br>Fax: 0033 4 76505110 | |
| 1.2.3 | 3rd Manufacturer | | |
| 1.2.3.1 | Name | Mason Chemical Company | |
| 1.2.3.2 | Location | 721 W. Algonquin Road<br>IL 60005 Arlington Heights | |

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| | USA<br>Tel: 001 847 290 1621<br>Fax: 001 847 290 1625 | |
| | **Evaluation by Competent Authorities** | |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** | |
| **Date** | 28/08/2008 | |
| **Materials and Methods** | | |
| **Results and discussion** | | |
| **Conclusion** | | |
| **Reliability** | | |
| **Acceptability** | | |

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| **Remarks** | 1.1.1 The contact information for the first and third joint Notifiers/Applicants should be updated as follows:<br>The e-mail address for Lonza GmbH should be: gisbert.mehring@lonza.com<br>The joint Notifier originally listed as "McKenna Long & Aldridge LLC," has changed:<br>Field Fisher Waterhouse LLP<br>Boulevard Brand Whitlock, 30<br>1200 Brussels<br>Belgium<br>Tel: (32-2) 278-1211<br>Fax: (32-2) 278-1200<br>Email: [redacted]<br><br>**Dec 2011**- Contact information in 1.1 should be updated as follows:<br>**1)** Lonza Cologne GmbH<br>Nattermannallee 1<br>DE-50829 Köln<br>Germany<br>Tel: 0049 221 99199262<br>Fax: 0049 221 99199263<br>Email: [redacted]m<br>**2)** Stepan Europe<br>Chemin Jongkind BP 127<br>38340 Voreppe<br>France<br>Phone: 0033 4 76505100<br>Fax: 0033 4 76505110<br>Email: [redacted]<br>**3)** Mason Europe Limited<br>c/o Technology Sciences (Europe) Ltd<br>Concordia House<br>St. James Business Park<br>Grimbald Crag Court<br>Knaresborough<br>North Yorkshire HG5 8QB<br>United Kingdom<br>Phone: 44 0 1423 799 634<br>Fax: 44 0 1423 797 804<br>Email: [redacted]<br><br>Also contact information in 1.2 should be updated as follows:<br>**1.2.1** Clariant GmbH (toll manufacturer for Lonza GmbH)<br>Werk Gendorf<br>DE-84504 Burgkirchen<br>Germany<br>Phone: 0049 867970<br>Fax: 0049 86794545<br>**1.2.3** Mason Chemical Company<br>721 W. Algonquin Road<br>Arlington Heights, IL 60005<br>USA<br>Phone: 001847 2901621<br>Fax: 001847 2901625<br><br>The following subsection should be also considered:<br>**1.3 Legal Representative**<br>Field Fisher Waterhouse LLP<br>Boulevard Louis Schmidt, 29<br>1040 Brussels<br>Belgium<br>Phone: (32 2) 742 7000<br>Fax: (32 2) 742 7100<br>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.*<br>*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<br>Annex Point IIA. 2 | | | Official use only |
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| **2.1** | **Common name proposed or accepted by ISO and synonyms** | Didecyldimethylammonium Chloride<br>DDAC<br>There are two dialkyldimethyl ammonium chlorides included in a category of quaternary ammonium biocides.<br><br>The category is comprised of the following substances:<br>Notified Substance / CAS RN<br>Didecyldimethylammonium Chloride / 7173-51-5<br>Di-$C_{8-10}$-dimethylammonium Chloride / 68424-95-3<br><br>Only **Didecyldimethylammonium Chloride (CAS RN 7173-51-5)** is included in this submission for Product Type 8 (Wood Preservatives).<br>[redacted]<br><br>Point of Clarification: Throughout this submission, Trade Names and Formulations were included in the "Synonyms" portion of the various documents. These Product names use CAS RN 7173-51-5 in their formulations. These names should not be confused with other chemical structural names for DDAC. | x |
| **2.2** | **Chemical (CAS) name** | 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride (for Product Type 8) | |
| **2.3** | **Manufacturer's development code number(s)** | [redacted] (for Product Type 8)<br>[redacted] (for Product Type 8) | |
| **2.4** | **CAS and EC numbers** | | |
| 2.4.1 | CAS number | 7173-51-5 (for Product Type 8) | |
| 2.4.2 | EC number | 230-525-2 (for Product Type 8) | |
| 2.4.3 | Other substance No. | None | |
| **2.5** | **Molecular and structural formula, molecular mass** | | |
| 2.5.1 | Molecular formula | $C_{22}$ $H_{48}$ N Cl (for Product Type 8) | |

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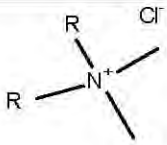
| 2.5.2 | Structural formula |  <br>$R = C_{10}H_{21}$<br>(for Product Type 8) | |
| 2.5.3 | Molecular mass | 362.1 g/mol (for Product Type 8) | |
| **2.6** | **Method of manufacture** | See Confidential Data | |
| 2.6.1 | Stability Information | DDAC is stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods. Shelf-life for salable products (ranging from approximately [redacted] active substance) is at least one year and often much longer. DDAC 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. D36). DDAC is also photolytically stable in the absence of a photosensitiser (see Section 7.1.1.1.2 (1), Ref. No. D37). DDAC is readily biodegradable and, therefore, the primary source of degradation at very low concentrations of DDAC is microbial (see Section 7.1.1.2.1 (1), Ref. No. D52). However, DDAC has disinfectant properties at concentrations of [redacted] and higher, 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. D14) provides analytical data showing concentrations of 0.1% and 0.6% to be stable for at least 14 days).<br><br>In conclusion, prolonged stability of aqueous, alcohol and alcohol/aqueous solutions of DDAC 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.<br><br>Table 2.6.1-1 provides prolonged stability of the primary DDAC test substance [redacted] used for mammalian toxicity testing. | |
| **2.7** | **Specification of purity** | [redacted]; Didecyldimethylammonium Chloride is not produced or sold as a solid material but always exists in process solvents (ethanol or isopropanol and/or water)<br><br>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 | |
| | | Impurities | |
| 2.8.1 | Common name and function | | x |
| 2.8.2 | IUPAC name | | |

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| 2.8.3 CAS No | | |
| 2.8.4 EC No.: EINECS | | |
| 2.8.5 Other | | |
| 2.8.6 Molecular formula | | |
| 2.8.7 Structural formula | | |
| 2.8.8 Molecular mass | | |
| 2.8.9 Concentration of the impurity or additive | | |
| **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 Didecyldimethylammonium 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. In addition, in the event of any spillage, all workers are fully decontaminated, while the area is fully cleaned and the waste is collected in labelled containers and disposed of by incineration. | |
| 2.10.1.2 Intended use(s) | Didecyldimethylammonium 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).<br><br>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 Didecyldimethylammonium 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 Didecyldimethylammonium Chloride (consumers are not involved in wood preservative 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.<br><br>The final version (June 2002) of Technical Notes for Guidance - Human Exposure to Biocidal Products (TNG) has been followed in conducting this assessment. | |

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| 2.10.1.2.2 Use process descriptions | **Occupational exposure:**<br><br>The biocidal product containing the active substance is used in two wood preservative treatment applications: dipping and vacuum pressure processes.<br><br>Dipping:<br><br>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 trapping and air emission control.<br><br>Vacuum pressure impregnation:<br><br>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.<br><br>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.<br><br>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, Didecyldimethylammonium Chloride. It is diluted 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 Didecyldimethylammonium Chloride concentration in both processes vary between 0.3% and 1.8%.<br><br>**Consumer exposure:**<br><br>Consumer exposure is restricted to handling of treated lumber in operations such as erecting fences. Consumers are not involved in the application stage. | |

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| | Exposure of humans to or via the environment has also been assessed. | |
| 2.10.1.2.3 Human (Occupational and consumer) exposure | The following are descriptions of main types of workers involved with occupational use of Didecyldimethylammonium Chloride as a wood preservative.<br><br>Mixing and loading stage:<br>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.<br>Other than incidental exposure in connecting and disconnecting transfer lines, exposure is not foreseen.<br><br>Application stage:<br>There are four main strata of workers that will be exposed to the wood preservative in the process plant. These are considered in Table 2.10.1.2.3-1:<br>The potential exposure route is inhaled and dermal<br>It is assumed that respiratory protective equipment is used only in event scenarios as the need to clear fallen wood within the treatment vessel<br><br>Frequency, duration and quantity:<br>Vacuum-pressure process: Daily use-cycle time 3 hours, 3 cycles per day<br>Dipping process: Up to 30 minutes immersion per batch.<br><br>Post-application:<br>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.<br><br>Consumer exposure:<br>The level of exposure is considered to be comparable to (or less than) occupation exposure to workers that handle treated wood after it is dry.<br><br>Exposure of humans to or via the environment has also been assessed. | |
| 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.<br><br>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. The processes involved have been subdivided into 8 different patterns of use to reflect the range of exposures that are possible.<br><br>As a worst case scenario, all calculations are based on the knowledge that the wood treatment solution employed contains 1.8% 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).<br><br>The following values are common to all use patterns:<br>Dermal exposure: Hands-only<br>Physical state of substance: Liquid | |

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| | Process temperature: 20°C<br>Aerosol formed: no<br>Inhalation of dust particles: No<br>In-vitro dermal absorption study through human skin: 2.92% in an aqueous formulation.<br><br>Worker use patterns are summarised in Table 2.10.1.2.4-1<br><br>**Substance properties: (as used in EUSES/EASE)**<br>Molecular weight: 362.08<br>Melting point: 188°C<br>Boiling point: 205°C<br>Vapour pressure at 25°C 2.3E-04 Pa<br>Octanol-water partition coefficient: 3.1<br>Water solubility: 5E+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.<br><br>EASE Model Predictions for Hands-Only Exposure to Didecyldimethylammonium Chloride in Wood Preservation Table 2.10.1.2.5-1<br><br>**Exposure of humans to or via the environment**<br><br>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).<br><br>Local total daily intake for humans:<br>Use pattern 1: 6.42E-05 mg/kg/d<br>Use pattern 2: 1.21E-06 mg/kg/d<br>Use pattern 3: 1.57E-03 mg/kg/d<br>Use pattern 4: 1.21E-06 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. | |
| 2.10.2.2 Intended uses(s) | Summarised below | |
| 2.10.2.2.1 Overview | An evaluation of the potential environmental effects of Didecyldimethylammonium 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.<br><br>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).<br>Use patterns 1-5 are addressed using the EUSES v.1.0 programme, with the following general values:<br>Molecular weight: 362.08 | |

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| | Melting point: 188°C<br>Vapour pressure: 2.3E-04 at 25°C<br>Partition coefficient (log Pow): 3.1 (QSAR, TGD, Part III, P. 548, reverse calculation from BCF value)<br>Water solubility: 5E+05 mg/l<br>High Production Volume Chemical<br>Volume of chemical imported to EU: Confidential (Reference A)<br>Industry category: 15/0 Others<br>Use category: 55/0 Others<br>Organic carbon-water partition coefficient: 1,599,564<br>Readily biodegradable, $t_{1/2}$ 11.2 days<br>Bioconcentration factor for fish: 81 l/kg<br><br>**Use pattern 1: Dipping/ immersion process:**<br>Application rate: 1.8 kg a.s./$m^3$ (worst case site-specific information)<br>Volume of wood treated per day: 2 $m^3$/day (worst-case site-specific information)<br>Total amount of a.s. processed per site per day: 3.6 kg<br>Number of emission days per year: 150 (worst-case site-specific information)<br>Total tonnage of a.s. processed per site per year: Confidential (Reference B) (worst case)<br>Total tonnage of a.s. used in region: Confidential (Reference C) (widespread use, 10% of tonnage used in default region)<br>Fraction of main local source: 3.375E-02 (worst case scenario: tonnage per site/regional tonnage)<br>Fraction of chemical used for application: 1 (worst case)<br>Fraction of chemical in formulation: 0.018 (concentration of a.s. in dipping solution)<br>Main category processing: Non-dispersive use<br>Default STP used<br><br>Fraction released to air: 1E-03 (ESD)<br>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)<br>Fraction released to surface water: 0 (ESD)<br>Fraction released to soil: 0 (ESD)<br><br>**Use pattern 2: Storage of wood treated by dipping/ immersion process:**<br>Leaching rate: 2.6% over 14 days (equivalent to 1.49E-04 kg a.s./$m^2$ over 14 days – see Section 2.10.2.2.4)<br>Effective surface area of treated wood, considered to be exposed to rain, per $m^2$ storage area: 11 $m^2/m^2$ (ESD)<br>Surface area of the storage place: 700 $m^2$ (ESD)<br>Total amount of a.s. leached from treated wood during storage per day: 1.15 kg (calculation from ESD)<br>Number of emission days per year: 10.7 (worst case, assumes that total amount leaching over 14 days leaches in 1 day)<br>Total tonnage (of a.s. on treated wood in storage in contact with water) used in region: 1Confidential (Reference D)<br>Fraction of main local source: 3.375E-02 (assumed that all wood treated in use pattern 1 would be stored at same site)<br>Fraction of chemical used for application: 1 (worst case) | |

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| Fraction of chemical in formulation: 0.018<br>Main category processing: Non-dispersive use<br>Default STP used.<br><br>Fraction released to air: 0 (ESD)<br>Fraction released to waste water: 0 (ESD)<br>Fraction released to surface water: 0.013 (ESD)<br>Fraction released to soil: 0.013 (ESD)<br><br>**Use pattern 3: Vacuum pressure process:**<br>Application rate: 1.8 kg a.s./$m^3$ (worst-case site-specific information)<br>Volume of wood treated per day: 50 $m^3$/day (worst-case site-specific information)<br>Total amount of a.s. processed per day: Confidential (Reference E)<br>Number of emission days per year: 150 (worst-case site-specific information)<br>Total tonnage of a.s. processed per site per year: Confidential (Reference F) (worst case)<br>Total tonnage of a.s. used in region: Confidential (Reference C) (widespread use, 10% of tonnage used in default region)<br>Thus, fraction of main local source: 0.84 (worst case scenario: tonnage per site/regional tonnage)<br>Fraction of chemical used for application: 1 (worst case)<br>Fraction of chemical in formulation: 3E-03 (concentration of a.s. in vacuum pressure solution)<br>Main category processing: Non-dispersive use<br>Default STP used<br><br>Fraction released to air: 1E-03 (ESD)<br>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)<br>Fraction released to surface water: 0<br>Fraction released to soil: 0<br><br>**Use pattern 4: Storage of wood treated by vacuum pressure process**<br>Leaching rate: 2.6% over 14 days (equivalent to 1.49E-04 kg a.s./$m^2$ over 14 days – see Section 2.10.2.2.4)<br>Effective surface area of treated wood, considered to be exposed to rain, per $m^2$ storage area: 11 $m^2/m^2$ (ESD)<br>Surface area of storage area: 525 $m^2$ (ESD)<br>Total amount of a.s. leached from treated wood over assessment period: 0.860 kg<br>Number of emission days per year: 10.7 (worst case, assumes that total amount leaching over 14 days leaches over 1 day)<br>Total tonnage of (of a.s. on treated wood in storage in contact with water) used in region: Confidential (Reference G)<br>Fraction of main local source: 0.84 (assumed that wood treated in use pattern 3 would be stored at same site)<br>Fraction of chemical used for application: 1 (worst case)<br>Fraction of chemical in formulation: 3E-03<br>Main category processing: Non-dispersive use<br>Default STP used<br><br>Fraction released to air: 0 | |

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| Fraction released to waste water: 0<br>Fraction released to surface water: 0.013 (ESD)<br>Fraction released to soil: 0.013 (ESD)<br><br>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).<br><br>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.<br>Thus, the appropriate Hazard Classes, as outlined in ESD, are Hazard Classes 1, 2, 3 and 4A. Didecyldimethylammonium 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.<br><br>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.<br><br>**Use pattern 5: Treated wood in service: Noise barrier (use class 3)**<br>Leaching rate: 2.6% over 14 days (equivalent to worst case value of 1.49E-04 kg a.s./$m^2$ over 14 days – see Section 2.10.2.2.4)<br>Leachable area of wood barrier: 3000 $m^2$ (ESD)<br>Amount of a.s. leached per barrier: 0.447 kg<br>Number of emission days per year: 10.7 (calculated, to take into account the leaching period of 14 days)<br>Maximum annual total tonnage of a.s. leached per noise barrier: 4.78 kg<br>Total tonnage of a.s. used in region: Confidential (Reference H) (widespread use, 10% of tonnage used in default region)<br>Fraction of main local source: 2.99E-04 (worst case scenario: tonnage per noise barrier/regional tonnage)<br>Fraction of chemical used for application: 1 (worst case)<br>Fraction of chemical in formulation: 0.018 (worst case)<br>Main category: private use<br>Default STP used<br><br>Fraction released to air: 0 (ESD)<br>Fraction released to waste water: 0.7 (ESD)<br>Fraction released to surface water: 0 (ESD)<br>Fraction released to soil: 0.3 (ESD) | |

| Section 2<br>Annex Point IIA. 2 | | Official use only |
|---|---|---|
| | **Use pattern 6: Treated wood in service: Fence (use class 3)**<br>Leaching rate: 2.6% over 14 days (equivalent to 1.49E-04 kg a.s./$m^2$ over 14 days – see Section 2.10.2.2.4)<br>Leachable area of wood fence: 2 $m^2$ (ESD)<br>Thus, amount of a.s. leached per fence: 2.98E-04 kg<br>Fraction released to soil: 1 (ESD)<br><br>**Use pattern 7: Treated wood in service: House (use class 3)**<br>Leaching rate: 2.6% over 14 days (equivalent to 1.49E-04 kg a.s./$m^2$ over 14 days – see Section 2.10.2.2.4)<br>Leachable area of wood house: 125 $m^2$ (ESD)<br>Amount of a.s. leached per house: 0.0186 kg (ESD)<br>Fraction released to soil: 1 (ESD)<br><br>**Use pattern 8: Treated wood in service: Transmission pole (use class 4A)**<br>Leaching rate: 2.6% over 14 days (equivalent to 1.49E-04 kg a.s./$m^2$ over 14 days – see Section 2.10.2.2.4)<br>Wood area above soil: 5.5 $m^2$ (ESD)<br>Wood area below soil: 1.6 $m^2$ (ESD)<br>Amount of a.s. leached per pole: 1.06E-03 kg<br>Fraction released to soil: 1 (ESD)<br><br>**Use pattern 9: Treated wood in service: Fence post (use class 4A)**<br>Leaching rate: 2.6% over 14 days (equivalent to 1.49E-04 kg a.s./$m^2$ over 14 days – see Section 2.10.2.2.4)<br>Wood area above soil: 0.8 $m^2$<br>Wood area below soil: 0.2 $m^2$<br>Amount of a.s. leached per post: 1.49E-04 kg<br>Fraction released to soil: 1 (ESD) | |
| 2.10.2.2.3 Predicted environmental concentrations | **Use Pattern 1:**<br>Aquatic environment:<br>Local PEC in surface water during emission episode: 1.36E-05 mg/l<br>Local PEC in sediment during emission episode: 0.474 mg/kg<br>PEC for micro-organisms in the STP: 2.1E-04 mg/l<br><br>Terrestrial environment:<br>Local PEC in pore water of agricultural soil: 3.11E-06 mg/l.<br>Local PEC in agric. soil (total) averaged over 30 days: 0.0878 mg/kg<br><br>Atmosphere:<br>Concentration in air during emission episode: 1E-06 mg/$m^3$<br>Annual average local PEC in air (total): 4.11E-07 mg/$m^3$<br><br>**Use Pattern 2: Storage of dipped/ immersed wood:**<br>Aquatic environment:<br>Local PEC in surface water during emission episode: 7.46E-06 mg/l<br>Local PEC in sediment during emission episode: 0.26 mg/kg<br>PEC for micro-organisms in the STP: 0 mg/l<br><br>Terrestrial environment:<br>Local PEC in pore water of agricultural soil: 3.63E-08 mg/l.<br>Local PEC in agric. soil (total) averaged over 30 days: 0.00103 mg/kg<br><br>Atmosphere:<br>Concentration in air during emission episode: 0 mg/$m^3$ | |

| Section 2<br>Annex Point IIA. 2 | Official use only |
|---|---|

Annual average local PEC in air (total): 8.09E-14 mg/m$^3$

**Use Pattern 3: Vacuum pressure application:**
Aquatic environment:
Local PEC in surface water during emission episode: 1.61E-04 mg/l
Local PEC in sediment during emission episode: 5.61 mg/kg
PEC for micro-organisms in the STP: 0.00523 mg/l

Terrestrial environment:
Local PEC in pore water of agricultural soil: 7.65E-05 mg/l.
Local PEC in agric. soil (total) averaged over 30 days: 2.16 mg/kg

Atmosphere:
Concentration in air during emission episode: 2.49E-05 mg/m$^3$
Annual average local PEC in air (total): 1.02E-05 mg/ m$^3$

**Use Pattern 4: Storage of vacuum-pressure-treated wood:**
Aquatic environment:
Local PEC in surface water during emission episode: 7.46E-06 mg/l
Local PEC in sediment during emission episode: 0.26 mg/kg
PEC for micro-organisms in the STP: 0 mg/l

Terrestrial environment:
Local PEC in pore water of agricultural soil: 3.63E-08 mg/l
Local PEC in agric. soil (total) averaged over 30 days: 0.00103 mg/kg

Atmosphere:
Concentration in air during emission episode: 0 mg/ m$^3$
Annual average local PEC in air (total): 8.09E-14 mg/ m$^3$

**Use Pattern 5: Treated wood in service: Noise barrier**
PEC for micro-organisms in the STP: 0.0122 mg/l (EUSES derived)

Amount of a.s. leached per barrier: 0.447 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

$Clocal_{soil,leach,time1}$ = 7.89E-06 $kg/kg_{wwt}$
Localised PEC in soil during emission episode: 7.89 mg/kg (ESD derived)

**Use Pattern 6: Treated wood in service: Fence**
Amount of a.s. leached per fence: 2.98E-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 (ESD)

$Clocal_{soil,leach,time1}$ = 1.75E-05 $kg/kg_{wwt}$
Localised PEC in soil during emission episode: 17.5 mg/kg

**Use Pattern 7: Treated wood in service: House**
Amount of a.s. leached per house: 0.0186 kg
(wet) Soil volume: 0.5 m$^3$
Bulk density of wet soil: 1700 $kg_{wwt}/m^3$
Fraction released to soil: 1 (ESD)

| Section 2<br>Annex Point IIA. 2 | | Official use only |
|---|---|---|
| | $Clocal_{soil,leach,time1}$ = 2.19E-05 $kg/kg_{wwt}$<br>Localised PEC in soil during emission episode: 21.9 mg/kg<br><br>**Use Pattern 8: Treated wood in service: Transmission pole**<br>Amount of a.s. leached per transmission pole: 1.06E-03 kg<br>(wet) Soil volume: 0.2 $m^3$<br>Bulk density of wet soil: 1700 $kg_{wwt}/m^3$<br>Fraction released to soil: 1 (ESD)<br><br>$Clocal_{soil,leach,time1}$ = 3.12E-06 $kg/kg_{wwt}$<br>Localised PEC in soil during emission episode: 3.12 mg/kg<br><br>**Use Pattern 9: Treated wood in service: Fence post**<br>Amount of a.s. leached per fence post: 1.49E-04 kg<br>(wet) Soil volume: 0.05 $m^3$<br>Bulk density of wet soil: 1700 $kg_{wwt}/m^3$<br>Fraction released to soil: 1 (ESD)<br><br>$Clocal_{soil,leach,time1}$ = 1.75E-06 $kg/kg_{wwt}$<br>Localised PEC in soil during emission episode: 1.75 mg/kg<br><br>**Non compartmental specific exposure relevant to the food chain (secondary poisoning):**<br><br>**Use Pattern 1:**<br>Concentration in fish from surface water for predators: 7.07E-04 mg/kg<br>Local concentration in earthworms from agricultural soil: 2.78E-04 mg/kg<br><br>**Use Pattern 2:**<br>Concentration in fish from surface water for predators: 6.05E-04 mg/kg<br>Local concentration in earthworms from agricultural soil: 2E-04 mg/kg<br><br>**Use Pattern 3:**<br>Concentration in fish from surface water for predators: 3.16E-03 mg/kg<br>Local concentration in earthworms from agricultural soil: 2.12E-03 mg/kg<br><br>**Use Pattern 4:**<br>Concentration in fish from surface water for predators: 6.05E-04 mg/kg<br>Local concentration in earthworms from agricultural soil: 2E-04 mg/kg | |
| 2.10.2.2.4 Determination of leaching rate | During a study to evaluate the leachability of Didecyldimethylammonium Chloride 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.<br><br>Assume 1 $m^3$ ≡ 1000 l<br>Thus,<br>1 $m^3$ ≡ 1000 x 1000 ml<br>1 $m^3$ = $1E^6$ ml<br><br>Volume of one wooden block = 6.9 ml<br>Number of wooden blocks/ $m^3$ = 1E+06/6.9 = 144927 blocks<br><br>Dimensions of wooden blocks = 19 mm x 19 mm x 19 mm (0.019 m x 0.019 m x 0.019 m)<br>Number of faces = 6 | |

| Section 2<br>Annex Point IIA. 2 | | Official use only |
|---|---|---|
| | Total surface area of a wooden block = 0.002166 $m^2$<br>Surface area of 1 $m^3$ blocks = 144927 x 0.002166 = 313.9 $m^2$<br><br>i) Use pattern 1: Dipping process (worst case)<br>Application rate = 1.8 kg a.s./$m^3$<br>Leaching rate = 2.6%<br><br>Thus leaching rate = 1.8 x 0.026 = 0.0468 kg/$m^3$<br>As 1 $m^3$ of wooden blocks is equivalent to 313.9 $m^2$<br>Thus, leaching rate = 1.49E-04 kg/$m^2$ over 14 days<br>ii) Use pattern 3: Vacuum process (worst case)<br>Application rate = 1.8 kg a.s./$m^3$<br>Leaching rate = 2.6%<br><br>Thus leaching rate = 1.8 x 0.026 = 0.0468 kg/$m^3$<br>As 1 $m^3$ of wooden blocks is equivalent to 313.9$m^2$<br>Thus, leaching rate = 1.49E-04 kg/$m^2$ over 14 days<br><br>Bestari, K. (2001) Determination of the Leachability of Bardac 2280 from treated wood. Study No 200-CT-WL-B22. Centre for Toxicology, University of Guelph, Guelph, Ontario N1 g 2W1, Canada (Unpublished)<br>[Ref No: D53 (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**<br>**Annex Point IIA. 2** | Official use only |
|---|---|
| **Remarks** | [redacted] |

| **Section 2**<br>**Annex Point IIA. 2** | Official use only |
|---|---|
| | **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.*<br>*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 – DDAC Lot #

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

| Name | A.S. in Solution % | Isopropanol % | Ethanol % | Water % |
|---|---|---|---|---|

[redacted]

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

[redacted]

[redacted]

[redacted]

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 | 1.8 |
| 3 | Non-dispersive | Yes | Intermittent | No | 1.8 |
| 4 | Non-dispersive | Yes | Extensive | No | 1.8 |
| 5 | Non-dispersive | Yes | Incidental | Yes | 1.8 |
| 6 | Non-dispersive | Yes | Intermittent | Yes | 1.8 |
| 7 | Non-dispersive | Yes | Extensive | Yes | 1.8 |
| 8 | Non-dispersive | No | Extensive | Yes | 1.8 |

Table 2.10.1.2.5-1 EASE Model Predictions for Hands-Only Exposure to Didecyldimethylammonium 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 | 0-0.3765 |
| 2 | 0 | 0 | 0-0.1 | 0-0.0271 |
| 3 | 0 | 0 | 0-0.1 | 0-0.0271 |
| 4 | 0 | 0 | 0-0.1 | 0-0.0271 |
| 5 | 0-0.1 | 0-6.307E-04 | 0-0.1 | 0-0.0271 |
| 6 | 0.1-1 | 6.307E-04 – 6.307E-03 | 0-0.1 | 0-0.0271 |
| 7 | 1-5 | 6.307E-03 – 0.0315 | 0-0.1 | 0-0.0271 |
| 8 | 1-5 | 6.307E-03 – 0.0315 | 0-0.1 | 0-0.0271 |

*Exposure is corrected from the reference figure given by the EASE software as only 25% of active substance is in the concentrate solution and 1.8% 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 not 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 |

| | | | |
|---|---|---|---|
| **Section 3.1.1 (1)**<br>**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)*<br>*If necessary, copy field and enter other reference(s).*<br>Schneider, S. (2000) Determination of the Melting Temperature of Dodigen 1881 AS (pure active substance of Bardac 22) in accordance with OECD-Guidline 102 and according to EEC-Guideline A.1. Report No. B 077/2000; for Clariant GmbH, Industriepark Hoechst, Frankfurt, Deutschland (sponsor); from Clariant GmbH – Werk Cassella-Offenbach, Analytische und Physikalische Abteilung, Frankfurt, Deutschland testing facility (unpublished).<br>Ref No.D47 (LON 3256) | |
| **1.2** | **Data protection** | Yes<br>*(indicate if data protection is claimed)* | |
| 1.2.1 | Data owner | *Give name of company*<br>The Dialkyl Project | |
| 1.2.2 | Criteria for data protection | *Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:*<br>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<br>Directive 92/69/EEC, Method A1; OECD Guideline No. 102<br>Year: 2000<br>*(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<br>*(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)* | |
| **2.3** | **Deviations** | No<br>*(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*<br>[redacted] | |

| | | | |
|---|---|---|---|
| **Section 3.1.1 (1)**<br>**Annex Point IIA 3.1.1** | | **Melting point** | |
| 3.1.2 | Specification | As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein.<br>[redacted]<br>Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5).<br>*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* | |
| 3.1.3 | Description | *If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)*<br>[redacted] | |
| 3.1.4 | Purity | [redacted] | |
| 3.1.5 | Stability | *Describe stability of test material*<br>The a.s., DDAC, 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 A1; OECD Guideline No. 102 | |
| | | **4. RESULTS** | |
| **4.1** | **Results** | Melting point: 188-205°C<br>Decomposition: at approximately 280°C | |
| | | **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.*<br>[redacted] | |
| **5.2** | **Results and discussion** | *Summarise relevant results; discuss dose-response relationship where relevant.*<br>[redacted] | |
| **5.3** | **Conclusion** | *Subsections for NOAEL, LOAEL etc. if appropriate*<br>[redacted] | |
| 5.3.1 | Reliability | *Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4*<br>[redacted] | |
| 5.3.2 | Deficiencies | [redacted] | |

| | | |
|---|---|---|
| **Section 3.1.1 (1)**<br>**Annex Point IIA 3.1.1** | **Melting point** | |
| | *(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 (SPECIFY)** | |
| **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.*<br>*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)<br>Annex Point IIA 3.1.2 | **Boiling point** | |
|---|---|---|
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA**<br><br>*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.*<br>*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** [ ]<br>**Limited exposure** [ ] | **Technically not feasible** [X] **Scientifically unjustified** [ ]<br>**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 accepable | |
| **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 3.1.1 | Bulk density/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).*<br>Schneider, S. (2000) Determination of the Density of Dodigen 1881 AS (pure active substance of Bardac 22) in accordance with OECD-Guideline 109 and according to EEC-Guideline A.3. Report No. B 079/2000; for Clariant GmbH, Industriepark Hoechst, Frankfurt, Deutschland (sponsor); from Clariant GmbH – Werk Cassella-Offenbach, Analytische und Physikalische Abteilung, Frankfurt, Deutschland testing facility (unpublished).<br>Ref No. D48 (LON 3257) | |
| **1.2 Data protection** | Yes<br>*(indicate if data protection is claimed)* | |
| 1.2.1 Data owner | *Give name of company*<br>The Dialkyl Project | |
| 1.2.2 Criteria for data protection | *Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:*<br>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<br>Directive 92/69/EEC, Method A3; OECD Guideline No. 109<br>Year: 2000<br>*(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<br>*(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed).* | |
| **2.3 Deviations** | No<br>*(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] | |

| Section 3.1.3(1) Annex point IIA 3.1.1 | | Bulk density/relative density | |
|---|---|---|---|
| 3.1.1 | Lot/Batch number | *List lot/batch number where relevant* [redacted] | |
| 3.1.2 | Specification | As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5). *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* | |
| 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., DDAC, 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 A3; OECD Guideline No. 109 | |
| | | **4. RESULTS** | |
| **4.1** | **Results** | Relative density: 0.902 @ 20°C | |
| | | **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** | *Subsections for NOAEL, LOAEL etc. if appropriate* [redacted] | |
| 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* | |

| | | |
|---|---|---|
| **Section 3.1.3(1)**<br>**Annex point IIA 3.1.1** | **Bulk density/relative density** | |
| | *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 (SPECIFY)** | |
| **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.*<br>*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)<br>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)*<br>*If necessary, copy field and enter other reference(s).*<br>Smeykal, H. (2000) Dodigen 1881 AS – DD 00/004; Vapour Pressure; 1st Original of 2; Report No. SI092-00; from Siemens Axiva GmbH & Co. KG, Frankfurt, Deutschland (unpublished).<br>Ref No. D49 (LON 3275) | |
| **1.2 Data protection** | Yes<br>*(indicate if data protection is claimed)* | |
| 1.2.1 Data owner | *Give name of company*<br>The Dialkyl Project | |
| 1.2.2 Criteria for data protection | *Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:*<br>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<br>Directive 92/69/EEC, Method A4<br>Year: 2000<br>*(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<br>*(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed).* | |
| **2.3 Deviations** | No<br>*(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*<br>[redacted] | |
| 3.1.2 Specification | As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. | |

| | | | |
|---|---|---|---|
| **Section 3.2(1)**<br>**Annex Point IIA 3.2** | | **Vapour pressure** | |
| | | [redacted]<br>Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5).<br>*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* | |
| 3.1.3 | Description | *If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)*<br>[redacted] | |
| 3.1.4 | Purity | [redacted] | |
| 3.1.5 | Stability | *Describe stability of test material*<br>The a.s., DDAC, 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 A4 | |
| | | **4. RESULTS** | |
| **4.1** | **Results** | Vapour pressure: 2.3E-06 hPa (2.3E-04 Pa) @ 50°C | |
| | | **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.*<br>[redacted] | |
| **5.2** | **Results and discussion** | *Summarise relevant results; discuss dose-response relationship where relevant.*<br>[redacted] | |
| **5.3** | **Conclusion** | *Subsections for NOAEL, LOAEL etc. if appropriate*<br>[redacted] | |
| 5.3.1 | Reliability | *Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4*<br>[redacted] | |
| 5.3.2 | Deficiencies | [redacted]<br>*(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)* | |

| Section 3.2(1)<br>Annex Point IIA 3.2 | Vapour pressure | |
|---|---|---|
| | **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 (SPECIFY) | |
| **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.*<br>*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<br>Annex Point IIA 3.2.1 | Henry's law constant | Official use only |
|---|---|---|
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA**<br><br>*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.*<br>*If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable* | |
| **Other existing data** [ X ]<br>**Limited exposure** [ ] | **Technically not feasible** [ ] **Scientifically unjustified** [ ]<br>**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** | | |

| Section 3.2.1<br>Annex Point IIA 3.2.1 | Henry's law constant | Official use only |
|---|---|---|
| | **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**<br>**Annex Point IIA. 3.3** | **Appearance** | Official use only |
|---|---|---|
| 3.3.1 Physical state | Solid | x |
| 3.3.2 Colour | Light-coloured | x |
| 3.3.3 Odour | Aromatic | x |

| Section 3.4 (1)<br>Annex Point IIA 3.4.1 | Absorption spectra (UV/Vis, IR, NMR) and mass spectrum, molar extinction at relevant wavelengths | |
|---|---|---|
| | 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)*<br>*If necessary, copy field and enter other reference(s).*<br>Petrovic P. (2000) Characterization of the Structure of Dodigen 1881 AS. Report No. B 085/2000; for Clariant GmbH, Industriepark Hoechst, Frankfurt, Deutschland (sponsor); from Clariant GmbH – Werk Cassella-Offenbach, Analytische und Physikalische Abteilung, Frankfurt, Deutschland testing facility (unpublished).<br>Ref No. D93 (LON 3278) | |
| 1.2 Data protection | Yes<br>*(indicate if data protection is claimed)* | |
| 1.2.1 Data owner | *Give name of company*<br>The Dialkyl Project | |
| 1.2.2 Criteria for data protection | Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:<br>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<br>Standard Operating Procedures of the testing facility<br>2000<br>*(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<br>(only where required) | Yes<br>(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed) | |
| 2.3 Deviations | *No*<br>(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] | |

| Section 3.4 (1)<br>Annex Point IIA 3.4.1 | | Absorption spectra (UV/Vis, IR, NMR) and mass spectrum, molar extinction at relevant wavelengths | |
|---|---|---|---|
| 3.1.1 | Lot/Batch number | *List lot/batch number where relevant*<br>[redacted] | |
| 3.1.2 | Specification | As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein.<br>[redacted]<br>Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5).<br>*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* | |
| 3.1.3 | Description | *If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution*<br>[redacted] | |
| 3.1.4 | Purity | *Give purity in g/kg, g/l, %w/w or % v/v active substance*<br>[redacted] | |
| 3.1.5 | Stability | *Describe stability of test material*<br>The a.s., DDAC, 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** | Standard Operating Procedures of the testing facility | |
| | | **4. RESULTS** | |
| **4.1** | **Results** | UV/VIS: The recorded UV/VIS spectra did not show any significant absorption due to lack of chromophores in the molecular structure of the test substance.<br>IR: The recorded IR spectrum does not show any absorption bands which are in disagreement with the proposed structure<br>NMR: Both $^{1}$H-NMR and $^{13}$C-NMR spectra of the test substance correspond with the proposed structure.<br>Mass spectrum: The obtained mass spectrum of the test substance shows a significant fragment at 310 m/e, which can be explained by a formal split off of methane from a quaternal amine ion. | |
| **4.2** | **Discussion** | The recorded spectra of the test substance correspond with the proposed structure. | |
| | | **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.*<br>[redacted] | |

| | | |
|---|---|---|
| **Section 3.4 (1)**<br>**Annex Point IIA 3.4.1** | **Absorption spectra (UV/Vis, IR, NMR) and mass spectrum, molar extinction at relevant wavelengths** | |
| | [redacted]. | |
| **5.2 Results and discussion** | *Summarise relevant results; discuss dose-response relationship where relevant.*<br>[redacted] | |
| **5.3 Conclusion** | [redacted]. | |
| 5.3.1 Reliability | *Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4*<br>[redacted] | |
| 5.3.2 Deficiencies | [redacted]<br>*(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 (SPECIFY)** | |
| **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.*<br>*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 3.5(1)<br>Annex Point IIA 3.5 | Solubility in water | |
|---|---|---|
| | **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)*<br>*If necessary, copy field and enter other reference(s).*<br>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. Report No. B 080/2000; for Clariant GmbH, Industriepark Hoechst, Frankfurt, Deutschland (sponsor); from Clariant GmbH – Werk Cassella-Offenbach, Analytische und Physikalische Abteilung, Frankfurt, Deutschland testing facility (unpublished).<br>Ref No. D51 (LON 3280) | |
| **1.2 Data protection** | Yes<br>*(indicate if data protection is claimed)* | |
| 1.2.1 Data owner | *Give name of company*<br>The Dialkyl Project | |
| 1.2.2 Criteria for data protection | *Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:*<br>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<br>Directive 84/449/EEC, Method A6<br>Year: 2000<br>*(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")* | x |
| **2.2 GLP (only where required)** | Yes<br>*(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed).* | |
| **2.3 Deviations** | No<br>*(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")* | x |
| | **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.* | |

| | | | |
|---|---|---|---|
| **Section 3.5(1)**<br>**Annex Point IIA 3.5** | | **Solubility in water** | |
| **3.1** | **Test material** | [redacted] | |
| 3.1.1 | Lot/Batch number | *List lot/batch number where relevant*<br>DD 00/004 | |
| 3.1.2 | Specification | As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein.<br>[redacted]<br>Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5).<br>*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* | |
| 3.1.3 | Description | *If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)*<br>[redacted] | |
| 3.1.4 | Purity | [redacted] | |
| 3.1.5 | Stability | *Describe stability of test material*<br>The a.s., DDAC, 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** | Due to the high solubility of the test substance, the flask method was adapted. 500 mg of the substance was weighed into 10 ml cylinders (graduated to 0.1 ml) and water added in small portions until full dissolving was visually achieved. The solution was brought to a temperature of 20 °C and the total volume of solution read from the graduation of the cylinder. pH dependency of water solubility was also measured. | |
| | | **4. RESULTS** | |
| **4.1** | **Results** | Water solubility: 500000 mg/l at 20 °C and at pH 2.2-9.2<br>pH ca 2.2 – 9.2 | |
| | | **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.*<br>[redacted] | |
| **5.2** | **Results and discussion** | *Summarise relevant results; discuss dose-response relationship where relevant.*<br>[redacted] | |

| | | |
|---|---|---|
| **Section 3.5(1)**<br>**Annex Point IIA 3.5** | **Solubility in water** | |
| **5.3 Conclusion** | *Subsections for NOAEL, LOAEL etc. if appropriate*<br>[redacted] | |
| 5.3.1 Reliability | *Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4*<br>[redacted] | |
| 5.3.2 Deficiencies | [redacted]<br>*(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** | [redacted] | |
| | **COMMENTS FROM OTHER MEMBER STATE (SPECIFY)** | |
| **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.*<br>*Discuss if deviating from view of rapporteur member state* | |
| **Results and discussion** | *Discuss if deviating from view of rapporteur member state* | |

| Section 3.5(1)<br>Annex Point IIA 3.5 | Solubility in water | |
|---|---|---|
| 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 3.6<br>Annex Point III-A.3.6 | Dissociation constant | |
|---|---|---|
| | JUSTIFICATION FOR NON-SUBMISSION OF DATA<br><br>*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.*<br>*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** [ ]<br>**Limited exposure** [ ] | **Technically not feasible** [ ] **Scientifically unjustified** [ X ]<br>**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] | |

| Section 3.6<br>Annex Point III-A.3.6 | Dissociation constant |
|---|---|
| **Evaluation of applicant's justification** | [redacted] |
| **Conclusion** | The Applicant justification is acceptable |
| **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 3.7 (1)<br>Annex Point IIA 3.7 | Solubility in organic solvents, including the effect of temperature on solubility | |
|---|---|---|
| | **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)*<br>*If necessary, copy field and enter other reference(s).*<br>Schneider, S. (2001) Determination of the Solubility of Dodigen 1881 AS [pure active substance of Bardac 22] in Organic Solvents. Report No. B 084/2000; for Clariant GmbH, Industriepark Hoechst, Frankfurt, Deutschland (sponsor); from AllessaChemie GmbH – Werk Cassella-Offenbach, Analytik, Frankfurt, Deutschland testing facility (unpublished).<br><br>Ref No. D101 (LON 3279) | |
| **1.2 Data protection** | Yes<br>*(indicate if data protection is claimed)* | |
| 1.2.1 Data owner | *Give name of company*<br>The Dialkyl Project | |
| 1.2.2 Criteria for data protection | *Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:*<br>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<br>Directive 94/37/EEC Annex 1, Section 2 & U.S. EPA, Subdivision D, Section 63-8<br>Year: 2001<br>*(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<br>*(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)* | |
| **2.3 Deviations** | No<br>*(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* | |

| Section 3.7 (1)<br>Annex Point IIA 3.7 | | Solubility in organic solvents, including the effect of temperature on solubility | |
|---|---|---|---|
| | | DD 00/004 | |
| 3.1.2 | Specification | As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein.<br>[redacted]<br>Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5).<br>*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* | |
| 3.1.3 | Description | *If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)*<br>[redacted] | |
| 3.1.4 | Purity | [redacted] | |
| 3.1.5 | Stability | *Describe stability of test material*<br>The a.s., DDAC, 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 94/37/EEC Annex 1, Section 2<br>U.S. EPA, Subdivision D, Section 63-8 | x |
| | | **4. RESULTS** | |
| **4.1** | **Results** | The results of the preliminary test indicated that the estimated solubility of the test substance is above 100 g/l solvent.<br>The results of the definitive test indicated that the estimated solubility of the test substance is above 600 g/l solvent.<br>Remarks:<br>The solvents used in the preliminary and definitive tests were acetone and methanol.<br>In all solutions, very small amounts of an insoluble crystalline impurity were observed. The crystals of this impurity remained undissolved even after large volumes of the related solvent had been added.<br>In a follow-up remark from the author of this study, it was noted that the observed crystals, or undissolved matter, were likely to be inorganic components such as NaCl (ash), which are known to be present in DDAC in an amount ≤ 1.5% w/w (see Section 2 of Annex IIA of Directive 98/8/EC, especially Section 2.8 therein). | |
| | | **5. APPLICANT'S SUMMARY AND CONCLUSION** | |

| Section 3.7 (1)<br>Annex Point IIA 3.7 | **Solubility in organic solvents, including the effect of temperature on solubility** | |
|---|---|---|
| **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.*<br>[redacted] | |
| **5.2 Results and discussion** | *Summarise relevant results; discuss dose-response relationship where relevant.*<br>[redacted] | |
| **5.3 Conclusion** | *Subsections for NOAEL, LOAEL etc. if appropriate*<br>[redacted] | |
| 5.3.1 Reliability | [redacted]<br>*1 Reliable without restriction; guideline study. Key study* | |
| 5.3.2 Deficiencies | [redacted]<br>(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] | |

| Section 3.7 (1)<br>Annex Point IIA 3.7 | **Solubility in organic solvents, including the effect of temperature on solubility** | |
|---|---|---|
| **Reliability** | [redacted] | |
| **Acceptability** | acceptable | |
| **Remarks** | [redacted] | |
| | **COMMENTS FROM OTHER MEMBER STATE (SPECIFY)** | |
| **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.*<br>*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 3.7(2) Annex Point IIA 3.7 | Solubility in organic solvents, including the effect of temperature on solubility | |
|---|---|---|
| | **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).*<br>Young, S. (2004) N,N-Didecyl-N,N-dimethylammonium Chloride (DDAC) Solubility in Octanol. Huntingdon Life Sciences, Huntingdon. Report No. DKG 011/033992 (unpublished)<br><br>Ref No. D92 (LON 3802) | |
| **1.2 Data protection** | Yes<br>*(indicate if data protection is claimed)* | |
| 1.2.1 Data owner | *Give name of company*<br>The Dialkyl Project | |
| 1.2.2 Criteria for data protection | *Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:*<br>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<br>Directive 92/69/EEC, Method A6<br>Year: 2004<br>*(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<br>*(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)* | |
| **2.3 Deviations** | No<br>*(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*<br>[redacted] | |
| 3.1.2 Specification | As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. | |

| Section 3.7(2) Annex Point IIA 3.7 | | Solubility in organic solvents, including the effect of temperature on solubility | |
|---|---|---|---|
| | | [redacted]<br>Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5).<br>*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* | |
| 3.1.3 | Description | If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)<br>[redacted] | |
| 3.1.4 | Purity | [redacted] | |
| 3.1.5 | Stability | *Describe stability of test material*<br>The a.s., DDAC, 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 A6, flask shake method to determine octanol solubility. | |
| | | **4. RESULTS** | |
| **4.1** | **Results** | The solubility of the test substance was found to be greater than 250 g/l at 20°C in octanol. | |
| | | **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.*<br>[redacted] | |
| **5.2** | **Results and discussion** | *Summarise relevant results; discuss dose-response relationship where relevant.*<br>[redacted] | x |

| | | |
|---|---|---|
| **Section 3.7(2)**<br>**Annex Point IIA 3.7** | **Solubility in organic solvents, including the effect of temperature on solubility** | |
| **5.3 Conclusion** | *Subsections for NOAEL, LOAEL etc. if appropriate*<br>[redacted] | |
| 5.3.1 Reliability | *Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4*<br>[redacted] | |
| 5.3.2 Deficiencies | [redacted]<br>*(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** | [redacted] | |
| | **COMMENTS FROM OTHER MEMBER STATE (SPECIFY)** | |
| **Date** | *Give date of the comments submitted* | |

| Section 3.7(2)<br>Annex Point IIA 3.7 | **Solubility in organic solvents, including the effect of temperature on solubility** | |
|---|---|---|
| **Materials and Methods** | *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*<br>*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* | |