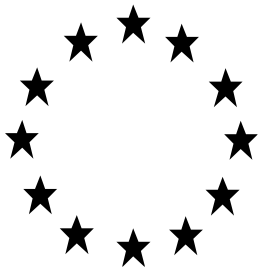
Competent Authority Report



DOCUMENT III-A

Study Summaries Active Substance

Section 1-5

Rapporteur Member State: Italy

December 2012

SECTION 1

APPLICANT

Section 1 Applicant and Company Information

Section 1 **Annex Point IIA. 1**			Official use only
1.1 Name and Address			
1.1.1	Name	Lonza GmbH	
1.1.2	Address	Morianstrasse 32 DE-42041 Wuppertal Germany [redacted]	
1.2 Active substance manufacturer			
1.2.1	1st Manufacturer		
1.2.1.1	Name	[redacted]	
1.2.1.2	Location	[redacted]	
		Evaluation by Competent Authorities	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	
Materials and methods			
Conclusion		[redacted]	
Reliability		[redacted]	
Acceptability		Acceptable	
Remarks			
		COMMENTS FROM ...	
Date		*Give date of comments submitted*	
Results and discussion		*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*	
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*	
Remarks			

SECTION 2

IDENTITY

Section 2 Identity

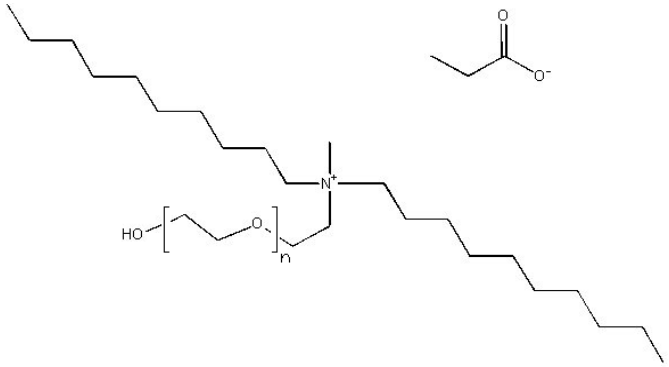
Section 2 Annex Point IIA. 2		Official use only
2.1 Common name proposed or accepted by ISO and synonyms	Didecylmethylpoly(oxyethyl)ammonium Propionate As this AS is a polymer, no EINECS/ELINCS name is available. For some of the endpoints addressed in Sections 6 and 7, tests have been conducted on the chemical and structural analog, Didecyldimethyl-ammonium Chloride. Data on identity of Didecyldimethylammonium Chloride are enclosed as Section 2A. A justification for read across of Didecylmethyl-poly(oxyethyl)-ammonium Propionate with data of Didecyldimethylammonium- Chloride is presented in ANNEX 2.1-1 and is enclosed before Sections 6 and 7, respectively, to allow for individual assessment of these Sections. Refer to Table 2.1-1 for synonyms of Didecylmethyl-poly(oxyethyl)-ammonium Propionate and also for information related to test substance used for testing.	

Table 2.1-1 Synonyms of N,N-Didecyl-N-methyl-poly(oxyetyl)ammonium Propionate and other test substances used in tests

Name	Active substance	Purity a.s. %	Ethane 1,2-diol, homo-polymer %	Ethane 1,2-diol %	Water %
BARDAP 26	Didecylmethylpoly(oxyethyl)-ammonium propionate	nom 70 (69–73)	nom 18 (15-21)	nom 10 (8-12)	max.5
Bardap 26 AS	Didecylmethylpoly(oxyethyl)-ammonium propionate	91.5-93.5	1.8	9.3	0.02
DMPAP (internal abbreviation for Didecymethylpoly-(oxyethyl)-ammonium-propionate)	Didecylmethylpoly(oxyethyl)-ammonium propionate	Various			
[redacted] (synonym of toll manufacturer for Bardap 26)	Didecylmethylpoly(oxyethyl)-ammonium propionate	70	18	10	max.5
[redacted] (internal company code of toll manufacturer)	Didecylmethylpoly(oxyethyl)-ammonium propionate	70	18	10	max.5
[redacted] (internal substance name of toll manufacturer)	Didecylmethylpoly(oxyethyl)-ammonium propionate	93.5			

X

2.2 Chemical name	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	X

Section 2 **Annex Point IIA. 2**			Official use only
		IUPAC name: .alpha.-[2-(Didecylmethylammonio)ethyl]-.omega.-hydroxy-poly(oxy-1,2-ethanediyl) propionate CAS INDEX name: Poly(oxy-1,2-ethanediyl), .alpha.-[2-(didecylmethylammonio)ethyl]-.omega.-hydroxy-, propanoate	
2.3	**Manufacturer's development code number(s)**	[redacted]	
2.4	**CAS and EC numbers**		
2.4.1	CAS number	94667-33-1	
2.4.2	EC number	None assigned	
2.4.3	Other substance No.	None assigned	
2.5	**Molecular and structural formula, molecular mass**		
2.5.1	Molecular formula	$C_{26}H_{55}NO_3(C_2H_4O)_n$ where n = 0 – 3	
2.5.2	Structural formula	 n = 0-3	
2.5.3	Molecular mass	MW used: C=12.011; H=1.00794; N=14.0067; O=15.999	>X

No. of oxyethyl moieties (1)	MW	Relative % distribution	MW individual
Monomer (1)	429.726	0.84	360.970
Dimer (2)	473.779	0.15	71.067
Trimer (3)	517.832	<0.01	5.178
Tetramer (4)	561.885	<0.001	0.562
		MW TOTAL:	**437.777**

2.6	**Method of**	This information is considered commercially sensitive. Please, refer, to the	

Section 2 **Annex Point IIA. 2**		Official use only
manufacture	*Confidential Annex.*	
2.6.1 Stability Information	Didecylmethylpoly (oxyethyl) ammonium Propionate is stable in aqueous, solutions for extended periods. Shelf-life for salable products (ranging from approximately [redacted] active substance) is at least two years and often much longer. Didecylmethylpoly (oxyethyl) ammonium Propionate does not hydrolyse at a concentration of 4g/L over a pH range of 4 to 9 (see Section 7.1.1.1.1). Further on, the structural analog Didecyl dimethylammonium Chloride is photolytically stable, a chemical property generally observed for quaternary ammonium compounds. Didecylmethylpoly (oxyethyl) ammonium Propionate is inherently biodegradable and, therefore, the primary source of degradation at very low concentrations of Didecylmethylpoly (oxyethyl) ammonium Propionate is microbial. However, Didecylmethylpoly (oxyethyl) ammonium Propionate has disinfectant properties at concentrations of 0.01% and higher, thus preventing biodegradation in the test substances listed in Table 2.1-1. In conclusion, prolonged stability of aqueous solutions of Didecylmethylpoly (oxyethyl) ammonium Propionate 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 2.1-1 (above). Table 2.6.1-1 provides prolonged stability of Didecylmethylpoly (oxyethyl) ammonium Propionate used for mammalian toxicity, fate and ecotoxicity toxicity testing.	
	Table 2.6.1-1: Stability of technical Didecylmethylpoly (oxyethyl) ammonium Propionate (Bardap 26) over a two year period [redacted] Conclusion: BARDAP 26 is stable over a period of two years under mentioned storage conditions.	
2.7 Specification of purity	[redacted] Didecylmethylpoly (oxyethyl) ammonium Propionate is not produced or sold as a solid material but always exists in process solvents (diol/water). For purity specifications of the technical and other substances used for fate and toxicity testing please refer to Table 2.1-1. During the Completeness Check of the information for identity,	X

Section 2 Annex Point IIA. 2		Official use only
	specification and purity of Didecylmethylpoly (oxyethyl) ammonium Propionate as submitted with the full dossier in March 2004, the Rapporteur requested further clarification and information on identity and specification. Among others, also an option was provided for selection of a category of quaternary ammonium compounds within the substance should be assessed. The identified category and additional data on identity, purity and specification are included as ANNEX 2.7-1.	
2.8 Identity of impurities and additives	This information is considered commercially sensitive. Please, refer, to the *Confidential Annex*.	
2.9 Origin of precursor(s) of the active substance	Synthesis	
Evaluation by Competent Authorities		

Section 2 Annex Point IIA. 2	Official use only
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable, with the following exceptions: [redacted]
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.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	Discuss if deviating from view of rapporteur member state

Section 2 **Annex Point IIA. 2**		Official use only
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*	

2.10 Exposure data		
2.10.1 Human exposure		
2.10.1.1 Production	The production of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate 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)	-	
2.10.1.2.1 Overview	The potential worker exposure from handling of cut lumber that has been treated with wood preservative containing N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate 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 N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate (consumers are not involved in paint application processes). Hence consumer exposure will be comparable to "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. **Use pattern 1: Dipping/ immersion process:** 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 for 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 of the preservative to drain. Drips are collected and recycled. **Use pattern 2: Storage of wood treated by dipping process:** The treated wood is then removed for storage. The dipping facilities are enclosed, and are equipped with vapour trapping and air emission control. **Use pattern 3: 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 will vary 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. Use pattern 4: Storage of wood treated by vacuum pressure process: The treated wood is then unloaded and stored. For both application processes, the preservative is delivered to the processing plant by tanker in the form of a concentrate. The concentrate contains 8.4% of the active substance N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate. It is diluted down to a suitable working strength with water. The degree of dilution will vary depending on the wood species, type of wood product and anticipated use. The requirements for N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate in both processes vary up to [redacted]. **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.	
2.10.1.2.3 Human (Occupational and consumer) exposure	The following are descriptions of main types of workers involved with occupational use of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate 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 will wear gloves, coveralls, and foot protection and will be 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 will be exposed to the wood preservative in the process plant. These are considered in the following table 2.10.1.2.3-1: The potential exposure route is inhaled and dermal 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.	
2.10.1.2.4 Exposure assessment	The model subdivides the wood treatment process into 8 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 personal protection equipment (PPE) is employed. In reality PPE will be worn, hence the estimates obtained will be overestimates. The processes involved have been subdivided into 8 different patterns of use to reflect the range of exposures that are possible. The relevant routes of exposure are anticipated to be dermal and inhalation. As a worst case scenario, all calculations are based on the knowledge that the wood treatment solution employed contains 0.672% a.s.. The neat concentrate of the substance (containing 8.4% 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: 436 Melting point: -50°C Boiling point 180°C Vapour pressure at 25°C 1.8E-06Pa Octanol-water partition coefficient: 3.1 (QSAR, TGD Part III pg 548, reverse calculation from BCF value) Water solubility: 1E+06mg/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 N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate 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 to 4 (see Document IIIA Section 2.10.1.2.2 for use pattern descriptions) Local total daily intake for humans: Use pattern 1: $1.81E^{-6}$ mg/kg/d Use pattern 2: $9.76E^{-7}$ mg/kg/d Use pattern 3: $1.65E^{-5}$ mg/kg/d Use pattern 4: $9.76E^{-7}$ mg/kg/d	
2.10.2 Environmental		

exposure		
2.10.2.1 Production	As workers will 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)		
2.10.2.2.1 Overview	An evaluation of the potential environmental effects of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate 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). The exposure estimates for each compartment in use patterns 1-4 and for the sewage treatment plant in use pattern 5 are addressed using the EUSES v.1.0 programme, with the following general values: Molecular weight: 436 Melting point: -50°C Boiling point: 180°C Vapour pressure: $1.8E^{-6}$ Pa at 25°C Partition coefficient (log Pow): 3.1 (QSAR TGD pt III, pg 548, reverse calculation from BCF value) Water solubility: $1E^{6}$ mg/L High Production Volume Chemical Volume of chemical imported to EU: 130 tonnes/year Industry category: 15/0 Others Use category: 55/0 Others Organic carbon-water partition coefficient: 1,599,564 Readily biodegradable (assumption) Bioconcentration factor for fish: 81 **Use pattern 1: Dipping/ immersion process:** Application rate: 0.67 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: 1.34 kg Number of emission days per year: 150 (worst-case site-specific information) Total tonnage of a.s. processed per site per year: 201 kg (worst case) Total tonnage of a.s. used in region: 13,000 kg (widespread use, 10% of tonnage used in default region) Fraction of main local source: 0.0155 (worst case scenario: tonnage per site/regional tonnage) Fraction of chemical used for application: 1 (worst case)	

Fraction of chemical in formulation: 0.0067 (concentration of a.s. in dipping solution)

Main category processing: Non-dispersive use

Default STP used

Fraction released to air: $1E^{-3}$ (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 (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 $5.55E^{-5}$ 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: 0.427 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: 4.57 kg

Fraction of main local source: 0.0155 (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: 0.0067

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: 0.5 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: 25 kg

Number of emission days per year: 150 (worst-case site-specific information)

Total tonnage of a.s. processed per site per year: 3,750 kg (worst case)

Total tonnage of a.s. used in region: 13,000 kg (widespread use, 10% of tonnage used in default region)

Thus, fraction of main local source: 0.288 (worst case scenario: tonnage

per site/regional tonnage)

Fraction of chemical used for application: 1 (worst case)

Fraction of chemical in formulation: 0.001 (concentration of a.s. in vacuum pressure solution)

Main category processing: Non-dispersive use

Default STP used

Fraction released to air: $1E^{-3}$ (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

Use pattern 4: Storage of wood treated by vacuum pressure process

Leaching rate: 2.6% over 14 days (equivalent to $4.14E^{-5}$ 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: 0.239 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: 2.56 kg

Fraction of main local source: 0.288 (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: 0.001

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 Use 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 use classes, as outlined in ESD, are Classes 1, 2, 3 and 4A. N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate is not used in applications falling under Classes 4B and 5. No scenarios have been proposed for use classes 1 and 2, and the emissions are considered to be negligible. Thus, the predicted environmental concentrations available for classes 3 and 4A only will be 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 will be 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 $5.55E^{-5}$ kg a.s./m^2 over 14 days – see Section 2.10.2.2.4)

Leachable area of wood barrier: 3000 m^2 (ESD)

Amount of a.s. leached per barrier: 0.167 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: 1.78 kg

Total tonnage of a.s. used in region: 13 tonnes (widespread use, 10% of tonnage used in default region)

Fraction of main local source: $1.11E^{-4}$ (worst case scenario: tonnage per noise barrier/regional tonnage)

Fraction of chemical used for application: 1 (worst case)

Fraction of chemical in formulation: 0.0067 (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 $5.55E^{-5}$ 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: $1.11E^{-4}$ 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 $5.55E^{-5}$ 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: 6.94E^{-3}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 5.55E^{-5} 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: 3.94E^{-4} 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 5.55E^{-5} 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: 5.55E^{-5} 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: 8.31E^{-6} mg/L Local PEC in sediment during emission episode: 0.289 mg/kg PEC for micro-organisms in the STP: 7.84E^{-5} mg/L Terrestrial environment: Local PEC in pore water of agricultural soil: 1.18E^{-6} mg/L. Local PEC in agric. soil (total) averaged over 30 days: 0.0333 mg/kg Atmosphere: Concentration in air during emission episode: 3.73E^{-7} mg/m^3 Annual average local PEC in air (total): 1.53E^{-7} mg/m^3 **Use Pattern 2: Storage of dipped/ immersed wood:** Aquatic environment: Local PEC in surface water during emission episode: 6E^{-6} mg/L Local PEC in sediment during emission episode: 0.209 mg/kg PEC for micro-organisms in the STP: 0 mg/L Terrestrial environment: Local PEC in pore water of agricultural soil: 2.95E^{-8} mg/L Local PEC in agric. soil (total) averaged over 30 days: 8.33E^{-4} mg/kg Atmosphere:	

Concentration in air during emission episode: 0 mg/m^3
Annual average local PEC in air (total): 1.74E^{-14} mg/m^3

Use Pattern 3: Vacuum pressure application:
Aquatic environment:
Local PEC in surface water during emission episode: 4.88E^{-5} mg/L
Local PEC in sediment during emission episode: 1.7 mg/kg
PEC for micro-organisms in the STP: 0.00146 mg/L

Terrestrial environment:
Local PEC in pore water of agricultural soil: 2.14E^{-5} mg/L.
Local PEC in agric. soil (total) averaged over 30 days: 0.604 mg/kg

Atmosphere:
Concentration in air during emission episode: 6.94E^{-6} mg/m^3
Annual average local PEC in air (total): 2.85E^{-6} mg/ m^3

Use Pattern 4: Storage of vacuum-pressure-treated wood:
Aquatic environment:
Local PEC in surface water during emission episode: 6E^{-6} mg/L
Local PEC in sediment during emission episode: 0.209 mg/kg
PEC for micro-organisms in the STP: 0 mg/L

Terrestrial environment:
Local PEC in pore water of agricultural soil: 2.95E^{-8} mg/L.
Local PEC in agric. soil (total) averaged over 30 days: 8.33E^{-4} mg/kg

Atmosphere:
Concentration in air during emission episode: 0 mg/ m^3
Annual average local PEC in air (total): 1.74E^{-14} mg/ m^3

Use Pattern 5: Treated wood in service: Noise barrier
PEC for micro-organisms in the STP: 3.67E^{-3} mg/L (EUSES derived)

Amount of a.s. leached per barrier: 0.167kg
(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

$Clocal_{soil,leach,time1}$ = 2.95E^{-6} kg/kg_{wwt}
Localised PEC in soil during emission episode: 2.95 mg/kg (ESD derived)

Use Pattern 6: Treated wood in service: Fence
Amount of a.s. leached per fence: 1.11E^{-4} 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)

$Clocal_{soil,leach,time1} = 6.53E^{-6}$ kg/kg_{wwt}
Localised PEC in soil during emission episode: 6.53 mg/kg

Use Pattern 7: Treated wood in service: House
Amount of a.s. leached per house: $6.94E^{-3}$ kg
(wet) Soil volume: 0.5 m^3
Bulk density of wet soil: 1700 kg_{wwt}/m^3
Fraction released to soil: 1 (ESD)

$Clocal_{soil,leach,time1} = 8.16E^{-6}$ kg/kg_{wwt}
Localised PEC in soil during emission episode: 8.16 mg/kg

Use Pattern 8: Treated wood in service: Transmission pole
Amount of a.s. leached per transmission pole: $3.94E^{-4}$ kg
(wet) Soil volume: 0.2 m^3
Bulk density of wet soil: 1700 kg_{wwt}/m^3
Fraction released to soil: 1 (ESD)

$Clocal_{soil,leach,time1} = 1.16E^{-6}$ kg/kg_{wwt}
Localised PEC in soil during emission episode: 1.16 mg/kg

Use Pattern 9: Treated wood in service: Fence post
Amount of a.s. leached per fence post: $5.55E^{-5}$ kg
(wet) Soil volume: 0.05 m^3
Bulk density of wet soil: 1700 kg_{wwt}/m^3
Fraction released to soil: 1 (ESD)

$Clocal_{soil,leach,time1} = 6.53E^{-7}$ kg/kg_{wwt}
Localised PEC in soil during emission episode: 0.653 mg/kg

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

Use Pattern 1:
Concentration in fish from surface water for predators: $5.24E^{-4}$ mg/kg
Local concentration in earthworms from agricultural soil: $1.92E^{-4}$ mg/kg

Use Pattern 2:
Concentration in fish from surface water for predators: $4.86E^{-4}$ mg/kg
Local concentration in earthworms from agricultural soil: $1.63E^{-4}$ mg/kg

Use Pattern 3:
Concentration in fish from surface water for predators: $1.2E^{-3}$ mg/kg

	Local concentration in earthworms from agricultural soil: $7E^{-4}$ mg/kg **Use Pattern 4:** Concentration in fish from surface water for predators: $4.86E^{-4}$ mg/kg Local concentration in earthworms from agricultural soil: $1.63E^{-4}$ 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. Read-across from didecyldimethylammonium chloride is considered appropriate because the physical/chemical and ecotoxicological properties of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate and didecyldimethylammonium chloride are essentially identical. If we assume 1 m^3 ≡ 1000 l Thus, 1 m^3 ≡ 1000 x 1000 ml 1 m^3 = $1E^6$ ml Volume of one wooden block = 6.9 ml. Number of wooden blocks/ m^3 = $1E^6$/6.9 = 144927 blocks Dimensions of wooden blocks = 19 mm x 19 mm x 19 mm (0.019 m x 0.019m x 0.019m) 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 (worst case) Application rate = 0.67 kg a.s./m^3 Leaching rate = 2.6% Thus leaching rate = 0.67 x 0.026 = 0.0174 kg/m^3 As 1 m^3 of wooden blocks is equivalent to 313.9m^2 Thus, leaching rate ≡ $5.55E^{-5}$ kg/m^2 over 14 days ii) Use pattern 3: Vacuum process (worst case) Application rate = 0.5 kg a.s./m^3 Leaching rate = 2.6% Thus leaching rate = 0.5 x 0.026 = 0.013 kg/m^3 As 1 m^3 of wooden blocks is equivalent to 313.9m^2 Thus, leaching rate ≡ $4.14E^{-5}$ kg/m^2 over 14 days	
Evaluation by Competent Authorities		

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	Acceptable
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 stae*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

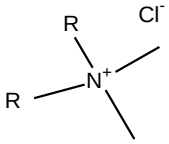
ANNEX 2.1-1
Read across of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate with data of Didecyldimethylammonium Chloride

The data on physico-chemical properties are provided for each individual compound.

Physical chemical properties	**BARDAP 26**	**DDAC**
Physical state (at ntp)	Yellow liquid	Light-coloured solid
Melting temperature	<-50°C.The substance does not have melting point. The substance does not have a freezing point down to –50°C.	Melted at 188 – 205°C followed by decomposition at ca 280°C.
Boiling temperature	180 – 195°C	Decomposition at ca 280°C without boiling
Relative density	0.942 at 20°C	0.902 at 20°C
Vapour pressure	1.8E-6 Pa at 20°C	5.9E-06 Pa at 20°C
Henry's Law constant	H = 3.03E-11 $Pa.m^3/mol$	H = 4.27E-9 $Pa.m^3/mol$
Partition coefficient	Not determined as the substance is ionic and surface active.	Not determined as substance is ionic and surface active
Water solubility	Completely miscible with water	500 g/l at 20°C and pH ca 2.2-9.2
Dissociation constant	Not applicable, as the substance is irreversibly ionised.	Not applicable, as the substance is irreversibly ionised.
Surface tension	Not conducted, expected to be surface active based on structure	27.0 mN/m at 20°C (1g/l)
Solubility in ethanol	> 250 g/l at 20°C	> 250 g/l at 20°C
Solubility in octanol	>250 g/l at 20°C	> 250 g/l at 20°C
Flammability	Not highly flammable	Not highly flammable
Self ignition temperature	> 400°C	ca. 195°C
Explosive properties	Does not possess explosive properties	Does not possess explosive properties
Oxidising properties	Does not possess oxidising properties.	Does not possess oxidising properties.
Reactivity towards container materials	Non-reactive to metals and plastics	Non-reactive to metals and plastics

Section 2A Identity of Didecyldimethylammonium Chloride (CAS RN 7173-51-5) used for read across in Sections 6 and 7

Section 2A **Annex Point IIA. 2**			Official use only
2.1	**Common name proposed or accepted by ISO and synonyms**	Didecyldimethylammonium Chloride DDAC There are two dialkyldimethyl ammonium chlorides included in a category of quaternary ammonium biocides. The category is comprised of the following substances: Notified Substance / CAS RN Didecyldimethylammonium Chloride / 7173-51-5 Di-C_{8-10}-dimethylammonium Chloride / 68424-95-3 Only **Didecyldimethylammonium Chloride (CAS RN 7173-51-5)** is included in this submission for Product Type 8 (Wood Preservatives). [redacted] 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.	
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) [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)	

Section 2A **Annex Point IIA. 2**			Official use only
2.5.2	Structural formula	 $R = C_{10}H_{21}$ (for Product Type 8)	
2.5.3	Molecular mass	362.1 g/mol (for Product Type 8)	
2.6	**Method of manufacture**	This information is considered commercially sensitive. Please, refer, to the *Confidential Annex.*	
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. DDAC is also photolytically stable in the absence of a photosensitiser (see Section 7.1.1.1.2). DDAC is readily biodegradable and, therefore, the primary source of degradation at very low concentrations of DDAC is microbial. 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). 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. 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) 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**	This information is considered commercially sensitive. Please, refer, to the *Confidential Annex*.	
2.9	**Origin of precursor(s) of the active substance**	Synthesis	

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]
Materials and methods	
Conclusion	
Reliability	
Acceptability	
Remarks	[redacted]
COMMENTS FROM ...	
Date	*Give date of comments submitted*
Results and discussion	*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*
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*
Remarks	

Table 2.6.1-1: Stability Analysis Data – DDAC [redacted]

[redacted]

ND = Not determined

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

- Not Applicable

SECTION 3

PHYSICAL AND CHEMICAL PROPERTIES

Section 3.1.1 (1) **Annex Point IIA 3.1.1**		**Melting point**	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2002). Determination of the Freezing Temperature of Bardap 26 AS/ [redacted] No. B 010/2002 (unpublished). LONZA Report No. 3528	
1.2	**Data Protection**	Yes	
1.2.1	Data owner	LONZA AG and Clariant GmbH	
1.2.2	Criteria for data protection	Data on existing a. s. submitted for the first time for entry into Annex I/IA.	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Directive 92/69/EEC, Method A.1. and OECD Guideline No. 102 Year: 2002	
2.2 **(only where required)**	**GLP**	Yes	
2.3	**Deviations**	No [redacted]	
		3. MATERIALS AND METHODS	
3.1	**Test material**	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	
3.1.1	Lot/batch number	[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: Bardap 26 AS/ [redacted] was tested	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	Stable at room temperature	
3.2	**Method**	Directive 92/69/EEC, Method A1 and OECD Guideline No. 102.	
		4. RESULTS	

Section 3.1.1 (1) **Annex Point IIA 3.1.1**	**Melting point**	
4.1 Results	[redacted]	
4.2 Discussion	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The study was done according to the Directive 92.69.EEC, Method A1 and OECD Guideline No. 102.	
5.2 Results and discussion	The substance has no freezing point down to a temperature of –50°C.	
5.3 Conclusion	The test substance does not possess melting point as it does not melt.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	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	
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*	

Section 3.1.1 (1) Annex Point IIA 3.1.1	Melting point	
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	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2002). Determination of the Boiling Temperature of Bardap 26 AS/ [redacted] Report No. B 011/2002 (unpublished). LONZA Report No. 3527	
1.2	**Data protection**	Yes	
1.2.1	Data owner	LONZA AG and Clariant GmbH	
1.2.2	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I/IA	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Directive 92/69/EEC, Method A2 and OECD Guideline No. 103. Year: 2002	
2.2	**GLP (only where required)**	Yes	
2.3	**Deviations**	No [redacted]	
		3. MATERIALS AND METHODS	
3.1	**Test Material**	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	
3.1.1	Lot/Batch number	[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: Bardap 26 AS/ [redacted] tested	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	Stable at room temperature	
3.2	**Method**	Directive 92/69/EEC, Method A2 and OECD Guideline No. 103.	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.2	**Discussion**	[redacted]	
		5. APPLICANT'S SUMMARY AND CONCLUSION	

Section 3.1.2(1) **Annex Point IIA 3.1.2**	**Boiling point**	
5.1 Materials and methods	The study was done according to the Directive 92/69/EEC, Method A2 and OECD Guideline No. 103.	
5.2 Results and discussion		
5.3 Conclusion	The test substance has a boiling point range of 180 - 195ºC.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	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 [redacted]	
Remarks		
	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*	

Section 3.1.2(1) Annex Point IIA 3.1.2	Boiling point	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

Section 3.1.3(1) Annex Point IIA 3.1.3		Relative density	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2002). Determination of the Relative Density of Bardap 26 AS/ [redacted] [redacted] Report No. B 012/2002 (unpublished). LONZA Report No. 3526	
1.2	**Data protection**	Yes	
1.2.1	Data owner	LONZA AG and Clariant GmbH	
1.2.2	Criteria for data protection	Data on existing a. s. submitted for the first time for entry into Annex I/IA.	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Directive 92/69/EEC, Method A3 and OECD Guideline No. 109. Year: 2002	
2.2	**GLP (only where required)**	Yes	
2.3	**Deviations**	No [redacted]	
		3. MATERIALS AND METHODS	
3.1	**Test material**	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	
3.1.1	Lot/Batch number	[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: Bardap 26 AS/ [redacted] tested	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	Stable at room temperature	
3.2	**Method**	Directive 92/69/EEC, Method A3 and OECD Guideline No. 109.	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.2	**Discussion**		
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and**	The study was done according to the Directive 92/69/EEC, Method A3	

Section 3.1.3(1) Annex Point IIA 3.1.3	**Relative density**	
methods	and OECD Guideline No. 109.	
5.2 Results and discussion	The test substance has a relative density of 0.942 at 20°C.	
5.3 Conclusion	The test substance has a relative density of 0.942 at 20°C.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	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	
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**	[redacted] (2002). [redacted] (Bardap 26 AS) Vapour Pressure. [redacted] Report No. 20020180.01 (unpublished). LONZA Report No. 3522	
1.2	**Data protection**	Yes	
1.2.1	Data owner	LONZA AG and Clariant GmbH	
1.2.2	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I/IA	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Directive 92/69/EEC, Method A4 and OECD Guideline No. 104. Year: 2002	
2.2	**GLP (only where required)**	Yes	
2.3	**Deviations**	No [redacted]	
		3. MATERIALS AND METHODS	
3.1	**Test material**	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	
3.1.1	Lot/Batch number	[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: Bardap 26 AS/ [redacted] tested	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	Stable at room temperature	
3.2	**Method**	Directive 92/69/EEC, Method A4 and OECD Guideline No. 104.	
		4. RESULTS	
4.1	**Results**	[redacted]	
		5. APPLICANT'S SUMMARY AND CONCLUSION	

Section 3.2(1) **Annex Point IIA 3.2**	**Vapour pressure**	
5.1 Materials and methods	The study was done according to the Directive 92/69/EEC, Method A4 and OECD Guideline No. 104.	
5.2 Results and discussion	The test substance possesses a vapour pressure of 1.8E-06 Pa at 20ºC.	
5.3 Conclusion	The test substance has a low vapour pressure.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	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	
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 3.2.1	Henry's law constant	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
Evaluation by Competent Authorities		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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** **at 20°C and 101.3 kPa**	Official use only
3.3.1 Physical State	[redacted]	
3.3.2 Colour	[redacted]	
3.3.3 Odour	[redacted]	

Section 3.4.1 (1) Annex Point IIA 3.4.1	Absorption spectra (UV/Vis and IR) and mass spectrum, molar extinction at relevant wavelengths	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2001) Bardap 26 – Spectral Data for Biocidal Products Directive. [redacted] (unpublished). LONZA Report No. 3524	
1.2 Data protection	Yes	
1.2.1 Data owner	LONZA AG	
1.2.2 Criteria for data protection	Data on existing a.s. submitted for the first time for its entry into Annex I/IA.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	No In-house testing method 2001 Remark: No guideline was used (as not being available) to perform the study since the cited SOPs are not guidelines as well.	
2.2 GLP (only where required)	No	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	
3.1.1 Lot/Batch number	[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: Bardap 26 tested	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	Stable at room temperature	
3.2 Method	In-house test method	
	4. RESULTS	
4.1 Results	[redacted]	

Section 3.4.1 (1) **Annex Point IIA 3.4.1**	**Absorption spectra (UV/Vis and IR) and mass spectrum, molar extinction at relevant wavelengths**	
4.2 Discussion	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The test was carried out according to the in-house testing method.	
5.2 Results and discussion	The recorded spectra of the test substance correspond with the proposed structure.	
5.3 Conclusion	The recorded spectra do not show any absorption bands which are in disagreement with the proposed structure.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	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	
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*	

Section 3.4.1 (1) Annex Point IIA 3.4.1	Absorption spectra (UV/Vis and IR) and mass spectrum, molar extinction at relevant wavelengths	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

Section 3.4.1 (2) **Annex Point IIA 3.4.1**		**Absorption spectra (NMR)**	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2001) Investigation of [redacted] with ^{1}C-NMR spectroscopy. [redacted] (unpublished). LONZA Report No. 3529	
1.2	**Data protection**	Yes	
1.2.1	Data owner	LONZA AG and Clariant GmbH	
1.2.2	Criteria for data protection	Data on existing a.s. submitted for the first time for its entry into Annex I/IA.	
		3. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No In-house testing method 2001 Remark: No guideline was used (as not being available) to perform the study since the cited SOPs are not guidelines as well.	
2.2	**GLP (only where required)**	No	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	
3.1.1	Lot/Batch number	[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] was tested	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	Stable at room temperature	
3.1	**Method**	In-house testing method	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.2	**Discussion**	[redacted]	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The test was carried out according to the in-house testing method.	
5.2	**Results and**	The recorded spectra of the test substance correspond with the proposed	

Section 3.4.1 (2) **Annex Point IIA 3.4.1**	**Absorption spectra (NMR)**	
discussion	structure.	
5.3 Conclusion	The recorded spectra do not show any absorption bands which are in disagreement with the proposed structure.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	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	
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 3.5(1) **Annex Point IIA 3.5**		**Solubility in water**	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2002). Determination of the Water Solubility of Bardap 26 AS/ [redacted] Report No. B 013/2002 (unpublished). LONZA Report No. 3525	
1.2	**Data protection**	Yes	
1.2.1	Data owner	LONZA AG and Clariant GmbH	
1.2.2	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I/IA	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Directive 92/69/EEC, Method A6 and OECD Guideline No. 105 Year: 2002	
2.2	**GLP** **(only where required)**	Yes	
2.3	**Deviations**	Yes [redacted]	
		3. MATERIALS AND METHODS	
3.1	**Test material**	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	
3.1.1	Lot/Batch number	[redacted]	

Section 3.5(1) Annex Point IIA 3.5		Solubility in water	
3.1.2	Specification	As given in section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein: Bardap 26 AS/ [redacted] tested	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	Stable at room temperature	
3.2	**Method**	The water solubility was determined according to Directive 92/69/EEC, Method A6 and OECD Guideline No. 105.	
		4. RESULTS	
4.1	**Water solubility**	[redacted]	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The water solubility was determined in accordance with the Directive 92/69/EEC, Method A6 and OECD Guideline No. 105.	
5.2	**Results and discussion**	The substance was found to be completely miscible with water at all proportions at room temperature.	
5.3	**Conclusion**	The test substance is completely soluble in water in the pH range 5 - 9.	
5.3.1	Reliability	[redacted]	
5.3.2	Deficiencies	No	
		Evaluation by Competent Authorities	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	
Materials and Methods		[redacted]	
Results and discussion		[redacted]	
Conclusion		[redacted]	

Section 3.5(1) Annex Point IIA 3.5	Solubility in water	
Reliability	[redacted]	
Acceptability	Acceptable [redacted]	
Remarks		
	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 3.6 Annex Point IIIA.3.6	Dissociation constant	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
Evaluation by Competent Authorities		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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) Annex Point IIA 3.7	Solubility in organic solvents, including the effect of temperature on solubility	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2003). Didecylmethylpoly(oxyethyl)ammonium Propionate (Bardap 26 AS) Solubility in Ethanediol and Octanol. [redacted] (unpublished). [redacted] Report No.: LZA248/033929 LONZA Report No. 3750	
1.2 Data protection	Yes	
1.2.1Data owner	LONZA AG	
1.2. Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes Directive 92/69/EEC, Method A6 2004	
2.2 GLP (only where required)	Yes	
2.3 Deviations	Yes [redacted]	

Section 3.7(1) **Annex Point IIA 3.7**	**Solubility in organic solvents, including the effect of temperature on solubility**	
	3. MATERIALS AND METHODS	
3.1 Test material	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	
3.1.1 Lot/Batch number	[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: Bardap 26 AS tested	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	Stable at room temperature. [redacted]	
3.2 Method	Directive 92/69/EEC, Method A6	
	4. RESULTS	
4.1 Results	[redacted]	
4.2 Discussion	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The study was carried out in accordance with Directive 98/8/EC and Directive 92/69/EEC, Method A6. A known weight of test substance was shaken with increasing volumes of solvent in a stepwise manner and dissolution was assessed visually.	
5.2 Results and discussion	The test substance dissolved fully at a concentration of 250 g/l.	
5.3 Conclusion	The solubility of Bardap 26 AS is greater than 250 g/l in both ethanol and octanol. No further testing was required.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	

Section 3.7(1) Annex Point IIA 3.7	Solubility in organic solvents, including the effect of temperature on solubility
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	acceptable [redacted]
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*

Section 3.8 Annex Point IIIA.3.8	Stability in the organic solvents used in biocidal products and the identity of relevant breakdown products	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
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*

Section 3.8 Annex Point IIIA.3.8	Stability in the organic solvents used in biocidal products and the identity of relevant breakdown products
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 3.9 Annex Point IIA 3.9	Partition coefficient n-octanol-water including effect of pH (5 to 9) and temperature	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [X]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	

Section 3.9 Annex Point IIA 3.9	Partition coefficient n-octanol-water including effect of pH (5 to 9) and temperature
	[redacted]
Undertaking of intended data submission [ ]	
Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted].
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 3.10 Annex Point IIA.3.10	Thermal stability, identity of relevant breakdown products	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
Evaluation by Competent Authorities		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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 3.11 (1) Annex Point IIA 3.11	Flammability including auto-flammability and identity of combustion products	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2004). Didecylmethylpoly(oxyethyl)ammonium Propionate (Bardap 26 AS). Auto-ignition temperature (Liquid and Gases). [redacted] (unpublished). [redacted] Report No.: LZA266/042169 LONZA Report No. 3828	
1.2 Data protection	Yes	
1.2.1 Data owner	LONZA AG	
1.2.2 Criteria for data protection	Data on existing a. s. submitted for the first time for entry into Annex I/IA.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes Directive 92/69/EEC, Method A15 Year: 2004	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No [redacted]	
	3. MATERIALS AND METHODS	
3.1 Test Material	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	
3.1.1 Lot/Batch number	[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: Bardap 26 AS tested	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	Stable at room temperature	
3.2 Method	Directive 92/69/EEC, Method A15	
	4. RESULTS	
4.1 Results	[redacted]	
4.2 Discussion	[redacted]	

Section 3.11 (1) **Annex Point IIA 3.11**	**Flammability including auto-flammability and identity of combustion products**	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The study was done according to the Directive 92/69/EEC, Method A15	
5.2 Results and discussion	The auto-ignition temperature of the test substance was found to be 264°C.	
5.3 Conclusion	The test substance has an auto-ignition temperature of 264°C.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
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	
Date	*Give date of the comments submitted*	

Section 3.11 (1) Annex Point IIA 3.11	Flammability including auto-flammability and identity of combustion products	
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 stae*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

Section 3.12 (1) Annex Point IIA 3.12		Flash point	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2003). Didecylmethylpoly(oxyethyl)ammonium Propionate (Bardap 26 AS) Flash Point. [redacted] (unpublished). [redacted] Report No.: LZA249/033839 LONZA Report No. 3749.	
1.2	**Data protection**	Yes	
1.2.1	Data owner	LONZA AG	
1.2.2	Criteria for data protection	Data on existing a. s. submitted for the first time for entry into Annex I/IA.	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Directive 92/69/EEC, Method A9 Year: 2003	
2.2	**GLP (only where required)**	Yes	
2.3	**Deviations**	No [redacted]	
		3. MATERIALS AND METHODS	
3.1	**Test Material**	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	
3.1.1	Lot/Batch number	[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: Bardap 26 AS tested	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	Stable at room temperature. [redacted]	
3.2	**Method**	Directive 92/69/EEC, Method A9	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.2	**Discussion**	[redacted]	
		5. APPLICANT'S SUMMARY AND CONCLUSION	

Section 3.12 (1) **Annex Point IIA 3.12**	**Flash point**	
5.1 Materials and methods	The study was done according to the Directive 92/69/EEC, Method A9	
5.2 Results and discussion	The corrected values for flash point after two tests were found to be 134°C and 134°C.	
5.3 Conclusion	The test substance has a flash point of 134°C.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	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	
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 3.13 (1) Annex Point IIA 3.13		Surface tension	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2006). Bardap 26 AS. Physicochemical Properties. [redacted] (unpublished). Report No.: LZA0269/062503 Lonza Report No.: 4018	
1.2	**Data protection**	Yes	
1.2.1	Data owner	LONZA AG	
1.2.2	Criteria for data protection	Data on existing a. s. submitted for the first time for entry into Annex I/IA.	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Directive 92/69/EEC, Method A5 OECD Guideline No. 115 Year: 2004	
2.2	**GLP (only where required)**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test Material**	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	
3.1.1	Lot/Batch number	[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. Bardap 26 AS was tested	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	Stable at room temperature. [redacted]	
3.2	**Method**	Directive 92/69/EEC, Method A5 and OECD guideline No. 115.	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.2	**Discussion**	[redacted]	
		5. APPLICANT'S SUMMARY AND CONCLUSION	

Section 3.13 (1) **Annex Point IIA 3.13**	**Surface tension**	
5.1 Materials and methods	The study was done according to the OECD Guideline No 115 and Directive 92/69/EEC, Method A5.	
5.2 Results and discussion	The surface tension of a 1 g/l aqueous solution of the test substance was found to be 30.5 mN/m at 20°C (Harkins-Jordan corrected value).	
5.3 Conclusion	The test substance is considered to be surface active.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	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 [redacted]	

Section 3.13 (1) Annex Point IIA 3.13	Surface tension	
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*	

Section 3.14 (1) **Annex Point IIA 3.14**		**Viscosity**	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2003). Didecylmethylpoly(oxyethyl)ammonium Propionate (Bardap 26 AS) Viscosity. [redacted] (unpublished). [redacted] Report No.: LZA250/033939 Lonza Report No. 3772.	
1.2	**Data protection**	Yes	
1.2.1	Data owner	LONZA AG	
1.2.2	Criteria for data protection	Data on existing a. s. submitted for the first time for entry into Annex I/IA.	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes OECD Test Guideline 114, CIPAC Method MT22 Year: 2003	
2.2 **(only where required)**	**GLP**	Yes	
2.3	**Deviations**	No [redacted]	
		3. MATERIALS AND METHODS	
3.1	**Test Material**	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	
3.1.1	Lot/Batch number	[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: Bardap 26 AS was tested	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	Stable at room temperature. [redacted]	
3.2	**Method**	OECD Test Guideline 114, CIPAC Method MT22	
		4. RESULTS	
4.1	**Results**	[redacted]	

Section 3.14 (1) **Annex Point IIA 3.14**	**Viscosity**	
4.2 Discussion	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The study was carried out in accordance with OECD Test Guideline 114 and CIPAC Method MT22.	
5.2 Results and discussion	The variable nature of the test substance suggested that it was non-Newtonian in behaviour and therefore not ideally suited to the method used.	
5.3 Conclusion	The kinematic viscosity of the test substance was 1800 mm^2/s at 20°C. The dynamic viscosity was 1.7 Pa s at 20°C.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
Evaluation by Competent Authorities		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	Not acceptable [redacted]	

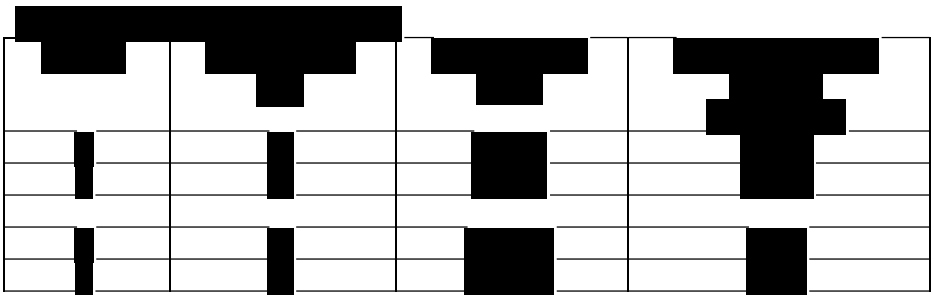
Section 3.14 (1) **Annex Point IIA 3.14**	**Viscosity**	
Remarks	[redacted]	
	COMMENTS FROM	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating 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*	

[redacted]

Section 3.14 (2) **Annex Point IIA 3.14**		**Viscosity**	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2006). Bardap 26 AS. Physicochemical Properties. [redacted] (unpublished). [redacted]. Report No.: LZA0269/062503 Lonza Report No. 4018	
1.2	**Data protection**	Yes	
1.2.1	Data owner	LONZA AG	
1.2.2	Criteria for data protection	Data on existing a. s. submitted for the first time for entry into Annex I/IA.	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes OECD Test Guideline 114 Year: 2003	
2.2 **(only where required)**	**GLP**	Yes	
2.3	**Deviations**	No [redacted]	
		3. MATERIALS AND METHODS	
3.1	**Test Material**	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	
3.1.1	Lot/Batch number	[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: Bardap 26 AS was tested	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	Stable at room temperature. [redacted]	
3.2	**Method**	OECD Test Guideline 114	
		4. RESULTS	
4.1	**Results**	[redacted]	

Section 3.14 (2) **Annex Point IIA 3.14**	**Viscosity**	
4.2 Discussion	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The study was carried out in accordance with OECD Test Guideline 114 using a rotational viscometer.	
5.2 Results and discussion	The mean measured dynamic viscosity of the test substance was approx. 3000 mPa.s at 20°C and approx. 400 mPa.s at 40°C.	
5.3 Conclusion	Bardap 26 AS demonstrated non-Newtonian flow behaviour.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	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 [redacted]	

Section 3.14 (2) **Annex Point IIA 3.14**	**Viscosity**	
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*	



Section 3.15 Annex Point IIA.3.15	Explosive properties	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
Evaluation by Competent Authorities		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	

Section 3.15 Annex Point IIA.3.15	Explosive properties
Conclusion	[redacted]
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 3.16 **Annex Point IIA.3.16**	**Oxidising properties**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
Evaluation by Competent Authorities		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Section 3.16 Annex Point IIA.3.16	Oxidising properties
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 3.17 Annex Point IIA. 3.17	Reactivity towards container material	Official use only
	Chemical reactivity towards container material (Annex IIA, 3.17) Test method: Chemical compatibility according to test guideline AV 90.1, TRV 002, A and B Date of investigation: a) [redacted] b) [redacted] Reference: Internal data of manufacturer Test substance: a) Bardap 26 [redacted] Test material: a) [redacted] Results: [redacted] As demonstrated above, PVC, polyolefin, Teflon, Kynar, Kalrez and vinyl ester are satisfactory to temperatures recommended by manufacturer. Natural rubber, neoprene and Buna-N should be avoided. It is recommended that specific applications be pre-tested.	
	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
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 4

ANALYTICAL METHODS FOR DETECTION AND DETERMINATION

Section 4 Analytical methods for detection and determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives

Section 4.1(1) **Annex Point IIA.4.2b**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – HPLC-ELSD**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
Evaluation by Competent Authorities		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section 4.1(1) **Annex Point IIA.4.2b**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – HPLC-ELSD**
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
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	

[redacted]

Section 4.1(2) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – HPLC-ELSD**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2007) Determination of quaternary ammonium compounds and related quaternary impurities by HPLC-ELSD. Study No.CSPE-44/BS-07-70. [redacted] (Unpublished). Lonza Report No. 4134	
1.2 Data protection	Yes	
1.2.1 Data owner	Lonza AG	
1.2.2 Criteria for data protection	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	No No guidelines available	
2.2 GLP (only where required)	No, the developing laboratory operates under ISO 9001.	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material (standards)	1. Didecyldimethylammonium bromide (the bromide salt was used instead of the chloride salt as this was not commercially available in pure form) 2. C12-Alkyldimethylbenzylammonium chloride 3. C14-Alkyldimethylbenzylammonium chloride 4. C16-Alkyldimethylbenzylammonium chloride	
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Purity	[redacted]	
3.1.3 Stability	Stable at room temperature.	
3.1 Test material (production batches)	1. Didecyldimethylammonium chloride (DDAC; Bardac 22) 2. C12-C14-Alkyldimethylbenzylammonium chloride (C12-14-ADBAC; Barquat LB and MS) 3. C12-C16-Alkyldimethylbenzylammonium chloride (C12-16-ADBAC; Barquat DM and MB) 4. C12-C18-Alkyldimethylbenzylammonium chloride (C12-18-ADBAC; Barquat CB) 5. C12-C14-Alkyldimethylethylbenzylammonium chloride (Ethyl-ADBAC)	
3.1.1 Lot/Batch number	[redacted]	

Section 4.1(2) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – HPLC-ELSD**	
	[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: Barquat LB, Barquat DM, Barquat MB, Barquat MS, Bardac 22 and Ethyl-ADBAC were tested	
3.1.3 Description	Liquids; with the exception of Bardac MS, which is a solid	
3.1.4 Purity	[redacted]	
3.1.5 Stability	Stable at room temperature.	
3.2 Test procedure	[redacted]	
3.3 Test system		
3.3.1 Chromatography system	[redacted]	
3.3.2 Column	[redacted]	
3.3.3 Detector	[redacted]	
3.3.4 Mobile phase and gradient	[redacted]	

Section 4.1(2) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – HPLC-ELSD**	
3.3.5 Conditions	[redacted]	
	4. RESULTS	
4.1 Results		
4.1.1 Precision (repeatability and replicate injections)	[redacted]	
4.1.2 Accuracy	[redacted]	

Section 4.1(2) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – HPLC-ELSD**	
	[redacted]	
4.1.3 Non-analyte interference	[redacted]	
4.1.4 Sensitivity	[redacted]	
4.1.5 Specificity	[redacted]	
4.2 Remarks	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	High pressure liquid chromatography evaporative light scattering (HPLC-ELSD) was validated for quaternary ammonium compounds (QUATS) and their related quaternary impurities. Using this method, representative samples of technical production batches were analysed. Solutions of the standard substances were prepared in water : acetonitrile 60:40 covering the nominal range from approx. 1600 – 6400 ng. Example	

Section 4.1(2) Annex Point IIA 4.1	Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – HPLC-ELSD	
	chromatograms of representative technical batches were prepared.	
5.2 Results and discussion	The method was validated in terms of precision (repeatability and replicate injections), accuracy, non-analyte interference, sensitivity and specificity. Intra-laboratory repeatability was demonstrated. All quality parameters were within acceptable limits.	
5.3 Conclusion	An analytical method for the determination of the active substances Didecyldimethylammonium chloride, Alkyldimethylbenzylammonium chlorides and Alkyldimethylethylbenzylammonium chloride and its quaternary impurities using HPLC-ELSD was successfully validated. All quality parameters were within acceptable limits. The method was accurate, specific and sensitive enough to detect impurities ≥ 0.1 %. The method is suitable to determine the active substance and its related quaternary impurities in technical production material.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods		
Results and discussion		
Conclusion	[redacted]	
Reliability		
Acceptability		
Remarks		
	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*	

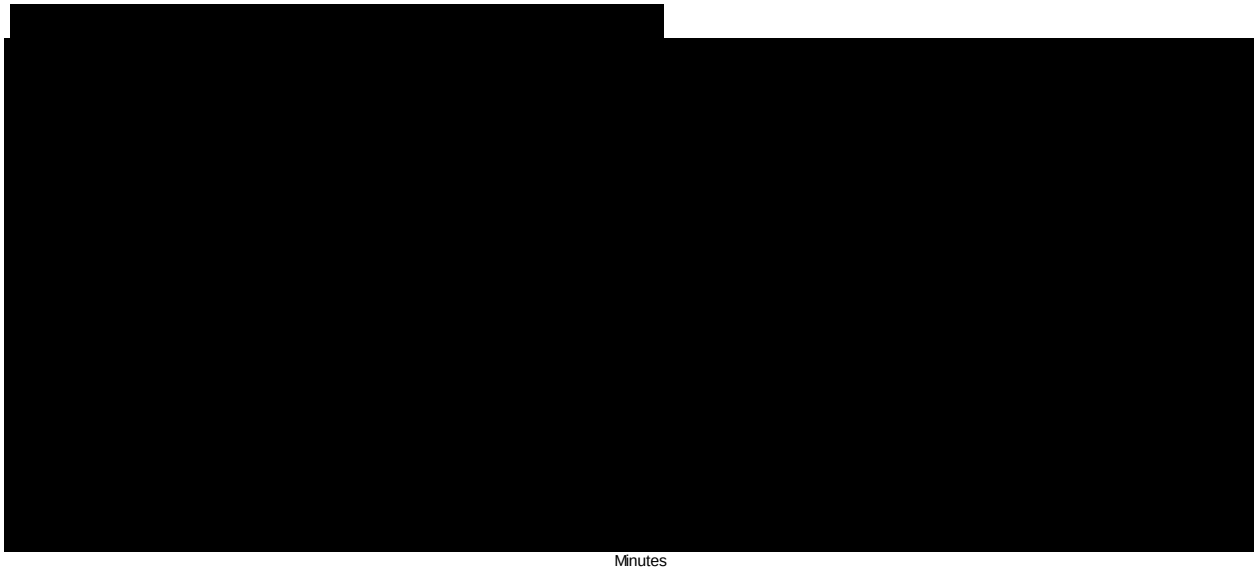
Section 4.1(2) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – HPLC-ELSD**
Conclusion	*Discuss if deviating from 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*

[redacted]

[redacted]

[redacted]

[redacted]



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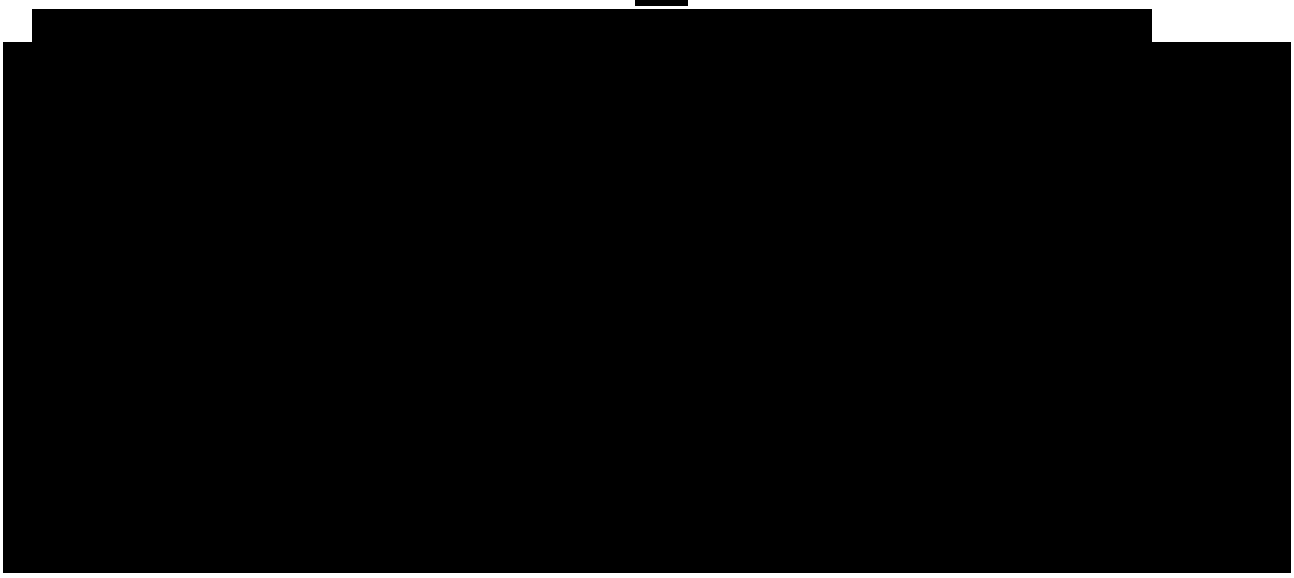

Section 4.1(3) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers)**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1994) Bardac® 2280 – Characterization of the Test Substance. Report No. 94-013. [redacted] Ltd. (Unpublished) Ref No. D136 (LON 3843)	
1.2 Data protection	Yes	
1.2.1 Data owner	The Dialkyl Project	
1.2.2 Criteria for data protection	Data submitted to the MS before 14 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	No – GLP chemical characterization for toxicity testing	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	Bardac 2280	
3.1.1 Lot/Batch number	[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. Bardac 2280 was tested. Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution. As given in section II of Annex IIA of Directive 98/8/EC, especially 2.7 and 2.8 of Annex IIA.	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	The a.s., DDAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2 Chromatograph details		
3.2.1 Chromatograph	[redacted]	

Section 4.1(3) Annex Point IIA 4.1	Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers)	
3.2.2 Column	[redacted]	
3.2.3 Integrator	[redacted]	
3.3 Chromatography conditions		
3.3.1 Flow rate	[redacted]	
3.3.2 Temperature	[redacted]	
3.3.3 Injection volume	[redacted]	
3.4 Remarks	[redacted]	
	4. RESULTS	
4.1 Chromatography results	[redacted]	
4.2 Remarks	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	Gas chromatograph with flame ionization detector was used to determine the distribution of alkyl chain lengths and the other components of Didecyldimethylammonium Chloride. The test substance was diluted in isopropanol to approximately 5% active and injected (0.2 µl) into the GC. Following peak assignment relative to standard chromatograms, the alkyl chain length distribution was calculated assuming relative response coefficients of unity.	
5.2 Results and discussion	The test substance was a clear brownish-yellow liquid with a slight off-white amorphous solid precipitate containing 80.7% active. The quat type was confirmed to be Dialkyldimethylammonium Chloride. The alkyl chain length distribution was found to be within Bardac 2280 specifications (>90% didecyl; <10% octyl decyl; <2.0% dioctyl). Chromatography results are summarized in table 4.1(1)-2, below.	
5.3 Conclusion	The active substance comprised one main component (didecyl = 99.2%) and two minor components (<1.0%).	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	EVALUATION BY COMPETENT AUTHORITIES	

Section 4.1(3) Annex Point IIA 4.1	Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers)
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
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.* *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 4.1(3)-1. [redacted]

[redacted]

Table 4.1(3)-2. [redacted]

[redacted]

Section 4.1(4) **Annex Point IIA 4.1**		**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) - ION CHROMATOGRAPHY**	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2004) N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate – Screening by Ion Chromatography. Report No.: LZA/243. [redacted] (Unpublished) Lonza Report No. 3834	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Lonza AG	
1.2.2	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I/IA	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No No guidelines available	
2.2	**GLP (only where required)**	No, not required	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Didecylmethylpoly(oxyethyl)ammonium Propionate	
3.1.1	Lot/Batch number	[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: Bardap 26 AS was tested	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	Stable at room temperature.	
3.2	**Test procedure**	[redacted]	
3.3	**Test system**		
3.3.1	Chromatography system	[redacted]	
3.3.2	Column	[redacted]	
3.3.3	Data capture system	[redacted]	
3.3.4	Mobile phases	[redacted]	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.1.1	Sensitivity	[redacted]	

Section 4.1(4) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) - ION CHROMATOGRAPHY**	
4.1.2 Variability	[redacted]	
4.1.3 Selectivity	[redacted]	
4.2 Remarks	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	A 5000 mg/l aqueous solution of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate was analysed using a Dionex ion chromatography system with Turbochrom software.	
5.2 Results and discussion	The analysis showed two main components, two minor components and four impurities. The system was sensitive enough to detected impurities down to 0.1%. Retention times did not vary significantly. The selectivity was enough to separate C_3 and C_{10} components in a methyl trialkylammonium chloride mixture.	
5.3 Conclusion	Analysis of the three samples by ion chromatography showed that N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate comprised two main components (>10%), two minor components (1-10%) and four impurities (0.1 – 1.0%).	
5.3.1 Reliability	[redacted]	X
5.3.2 Deficiencies	No	X
Evaluation by Competent Authorities		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	

Section 4.1(4) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) - ION CHROMATOGRAPHY**
Acceptability	Not acceptable [redacted]
Remarks	
	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 4.1(4)-1. [redacted]

[redacted]

Section 4.2a(1) Annex Point IIA 4.2	Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (a) Soil	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2003) Didecylmethylpoly(oxyethyl)ammonium Propionate Validation of Methodology for the Determination of Residues in Soil. Report No. LZA244/033605. [redacted] (Unpublished) Lonza Report No. 3709	
1.2 Data protection	Yes	
1.2.1 Data owner	LONZA AG	
1.2.2 Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes 91/414/EEC as amended by 96/46/EC, SANCO/3029/99 rev.4 2000	
2.2 GLP (only where required)	Yes	
2.3 Deviations	[redacted]	
	3. MATERIALS AND METHODS	
3.1 Test material	Didecylmethylpoly(oxyethyl)ammonium Propionate	
3.1.1 Lot/Batch number	[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: Bardap 26 was tested	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	Stable at room temperature. [redacted]	
3.2 Test procedure	[redacted]	
3.2.1 Soil types	[redacted]	
3.2.2 Calibration standards	[redacted]	

Section 4.2a(1) **Annex Point IIA 4.2**		**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (a) Soil**	
3.2.3	Validation range	[redacted]	
		4. RESULTS	
4.1	**Accuracy data**	[redacted]	
4.2	**Limit of quantitation (LOQ)**	[redacted]	
4.3	**Limit of detection (LOD)**	[redacted]	
4.4	**Remarks**	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate can be accurately determined in soil at a limit of quantitation of 0.01mg/kg. The limit of detection of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate in soil is 0.002 mg/kg.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The study was carried out in accordance with 91/414/EEC as amended by 96/46/EC, SANCO/3029/99 rev.4 guidelines to validate analytical methods in clay loam and sandy loam soil samples. Quantitation was by liquid chromatography with mass spectrometric detection (LC-MS).	X
5.2	**Results and discussion**	The mean recovery of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate in clay loam was 85% (cv 4.2%) and 90% in sandy loam (cv 8.1%). The limit of quantitation was 0.01mg/kg and the limit of detection was 0.002mg/kg. Statement from Laboratory (HLS) regarding recoveries in soil: The study was carried in accordance with SANCO/3029/99 rev. 4 of 11 July 2000 (i.e. not SANCO/825); therefore, no matrix effect investigation was formally required. However, as the calibration solutions were prepared in the appropriate final solvent and no unusually high or low recoveries were observed at the either the low or high fortification levels, this suggests that no matrix effects were present.	X
5.3	**Conclusion**	0.01mg/kg of the test substance can be accurately quantitated in soil.	X
5.3.1	Reliability	[redacted]	X
5.3.2	Deficiencies	No	
		Evaluation by Competent Authorities	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	

Section 4.2a(1) Annex Point IIA 4.2	Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (a) Soil
Materials and Methods	[redacted]

Section 4.2a(1) Annex Point IIA 4.2	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (a) Soil**
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable, [redacted]
Remarks	
	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*

[redacted]

Section 4.2b Annex Point IIA.4.2b	Analytical methods for environmental media (air)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
Evaluation by Competent Authorities		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification		
Conclusion	[redacted]	
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 4.2c(1) Annex Point IIA 4.2	Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (c) Water	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2003) Didecylmethylpoly(oxyethyl)ammonium Propionate Validation of Methodology for the Determination of Residues in Drinking, Ground and Surface Water. Report No. LZA245/033612. [redacted] [redacted] (Unpublished) Lonza Report No.: 3714	
1.2 Data protection	Yes	
1.2.1 Data owner	LONZA AG	
1.2.2 Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes Directive 91/414/EEC as amended by 96/46/EC, SANCO/3029/99 rev.4 2000	
2.2 GLP (only where required)	Yes	
2.3 Deviations	All data (linearity, recovery rates, LOD, LOQ) should refer to monomer (n=1) component only instead of Bardap 26 AS as reported in the study.	
	3. MATERIALS AND METHODS	
3.1 Test material	Didecyldimethylpoly(oxyethyl)ammonium Propionate	
3.1.1 Lot/Batch number	[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: Bardap 26 was tested	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	Stable at room temperature. [redacted]	
3.2 Test procedure	[redacted]	

Section 4.2c(1) Annex Point IIA 4.2	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (c) Water**	
3.2.1 Water types	[redacted]	
3.2.2 Calibration standards	[redacted]	
3.2.3 Validation range	[redacted]	
	4. RESULTS	
4.1 Accuracy data	[redacted]	
4.2 Limit of quantitation (LOQ)	[redacted]	
4.3 Limit of detection (LOD)	[redacted]	
4.4 Remarks	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The study was carried out in accordance with 91/414/EEC as amended by 96/46/EC, SANCO/3029/99 rev.4 guidelines to validate analytical methods in drinking, ground and surface water samples. Quantitation was by liquid chromatography with mass spectrometric detection (LC-MS).	X
5.2 Results and discussion	The mean recovery of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate in drinking water was 93% (cv 10.8%), surface water was 89% (cv 14.2%) and ground water was 85% (cv 9.5%). The limit of quantitation was 0.1µg/l and the limit of detection was 0.01µg/l. Statement from Laboratory (HLS) regarding recoveries in water: The study was carried in accordance with SANCO/3029/99 rev. 4 of 11 July 2000 (i.e. not SANCO/825); therefore, no matrix effect investigation was formally required. However, as the calibration solutions were prepared in the appropriate final reconstitution solvent and no unusually high or low recoveries were observed at the either the low or high fortification levels, this suggests that no matrix effects were present.	X
5.3 Conclusion	0.1 µg/l of the test substance can be accurately quantitated in water.	X
5.3.1 Reliability	[redacted]	X
5.3.2 Deficiencies	No	

Section 4.2c(1) **Annex Point IIA 4.2**	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following:** **(c) Water**
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]

Section 4.2c(1) Annex Point IIA 4.2	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (c) Water**
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable, [redacted]
Remarks	
	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 4.2c(1)-1. [redacted]

[redacted]

Section 4.2d Annex Point IIA.4.2d	Analytical methods for environmental media (human body fluids and tissues)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date [redacted]

Evaluation of applicant's justification

Conclusion [redacted]

Remarks

COMMENTS FROM OTHER MEMBER STATE *(specify)*

Date *Give date of comments submitted*

Section 4.2d Annex Point IIA.4.2d	Analytical methods for environmental media (human body fluids and tissues)
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 4.3 Annex Point IIIA.4.3	Analysis in foodstuffs	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	

Section 4.3 **Annex Point IIIA.4.3**	**Analysis in foodstuffs**	
	[redacted]	
Undertaking of intended data submission [ ]		
Evaluation by Competent Authorities		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification		
Conclusion	[redacted].	
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 5

EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES

Section 5 Effectiveness against target organisms and intended uses

Section 5 Annex Point IIA. 5			Official use only
5.1	**Function**	N,N-didecyl-N-methyl-poly(oxyethyl)ammonium Propionate (DMPAP) acts as a fungistatic and an insecticide	
5.2	**Organism(s) to be controlled and products, organisms or objects to be protected**		
5.2.1	Organism(s) to be controlled	Wood destroying basidiomycetes (most representative species listed below) • *Coniophora puteana // Coniophora spec.* • *Coriolus versicolor* • *Gloeophyllum trabeum* • *Poria vaillantii // Poria spec.* • *Fomes spec.* • *Trametes spec.* Wood staining moulds (most representative species listed below) • *Aureobasidium pullulans* • *Sclerophoma pityopila* • *Ophistostoma piliferum* • *Aspergillus niger* • *Aspergillus terreus* • *Chaetomium globosum* • *Paecilomyces variotii* • *Penicillium funicolosum* • *Trichoderma viridae* Wood boring insects (most representative species listed below) • *Hylotrupes bajulus* • *Anobium punctatum* • *Lyctus brunneus* • Termites	
5.2.2	Products, objects	DMPAP is used for preventive protection of wood and constructional timbers in hazard classes 1 to 4A according to ISO draft standard (Table IIA-5.2).	

Section 5 **Annex Point IIA. 5**		Official use only
5.3 Effects on target organisms and likely concentration at which the active substance will be used		
5.3.1 Effects on target organisms	[redacted]	X

Section 5 Annex Point IIA. 5		Official use only
	[redacted]	
5.3.2 Likely concentrations at which the active substance will be used	[redacted]	
5.4 Mode of action (including time delay)		
5.4.1 Mode of action	[redacted]	

Section 5 **Annex Point IIA. 5**		Official use only
	[redacted]	
5.4.2 Time delay	[redacted]	
5.5 Field of use envisaged	[redacted]	X
5.6 User: industrial, professional, general public	[redacted]	~~X~~
5.7 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies		
5.7.1 Development of resistance	[redacted]	
5.7.2 Management strategies	[redacted]	
5.8 Likely tonnage to be placed on the market per year	[redacted]	

Table IIA-5.2: [redacted]

[redacted]

[redacted]

[redacted]

Table IIA-5.3(2): [redacted]

[redacted]

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 [redacted]
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*