DOCUMENT IIIA

SECTIONS 1-5 –

ACTIVE SUBSTANCE

DDACarbonate

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SECTION 1

APPLICANT

Section 1 Applicant and Company Information

Section 1 Annex Point IIA. 1	Official use only
1.1 Name and Address	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	

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	Didecyldimethylammonium Carbonate / Bicarbonate [redacted]	
	[redacted]	
2.2 Chemical name	[redacted]	

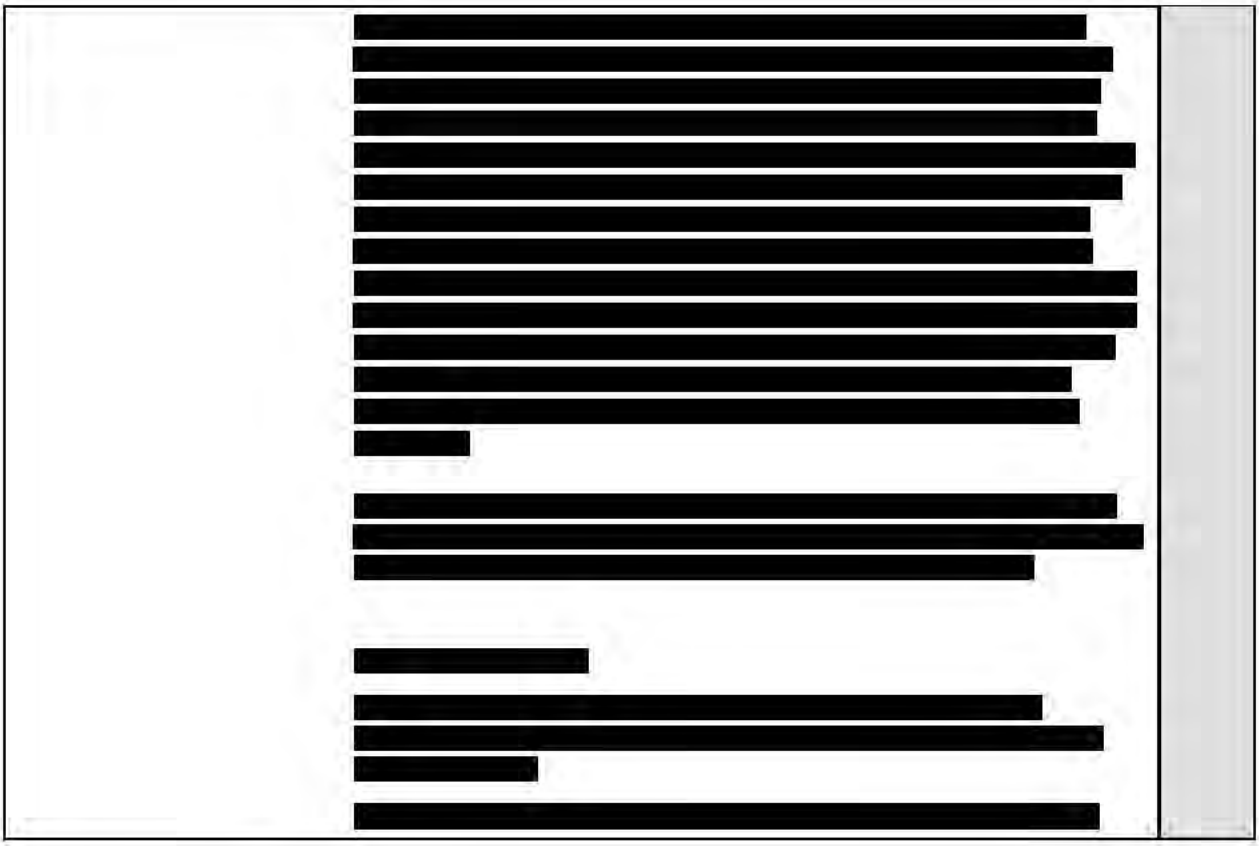
Section 2 Annex Point IIA. 2			Official use only
2.3	**Manufacturer's development code number(s)**	[redacted]	
2.4	**CAS and EC numbers**		
2.4.1	CAS number	894406-76-9	
2.4.2	EC number	None assigned yet, as DDACarbonate has been notified in the EU as a new chemical substance only in 2005.	
2.4.3	Other substance No.	None assigned	
2.5	**Molecular and structural formula, molecular mass**		
2.5.1	Molecular formula	$C_{23}H_{49}NO_3$ and $C_{45}H_{96}N_2O_3$ MF according to CAS: $C_{22}H_{48}N$. 1/3 CHO_3 . 1/3 CO_3	
2.5.2	Structural formula	[redacted]	
2.5.3	Molecular mass	387.6 (for Bicarbonate) and 713.3 (for Carbonate)	
2.6	**Method of manufacture**	[redacted]	

Section 2 Annex Point IIA. 2		Official use only
	[redacted]	
2.6.1 Stability Information	[redacted]	

Section 2 Annex Point IIA. 2	Official use only
[redacted]	
[redacted]	
2.7 Specification of purity	
2.7.1 Technical grade [redacted]	
2.7.2 Concentrated AS [redacted]	

2.8 Identity of impurities and additives

2.9	**Origin of precursor(s) of the active substance**	[redacted]
2.10	**Exposure data**	[redacted]
2.10.1	Human exposure	[redacted]
2.10.1.1	Production	[redacted]
2.10.1.2	Intended use(s)	[redacted]
2.10.1.2.1	Overview	[redacted]
2.10.1.2.2	Use process descriptions	[redacted]



2.10.1.2.3 Human (Occupational and consumer) exposure	[redacted]	
2.10.1.2.4 Exposure assessment	[redacted]	
2.10.1.2.5 Predicted occupational exposure	[redacted]	
2.10.2 Environmental exposure	[redacted]	
2.10.2.1 Production	[redacted]	

2.10.2.2 Intended uses(s)	[redacted]	
2.10.2.2.1 Overview	[redacted]	
2.10.2.2.2 Use pattern exposure estimates	[redacted]	
2.10.2.2.3 Predicted environmental concentrations	[redacted]	

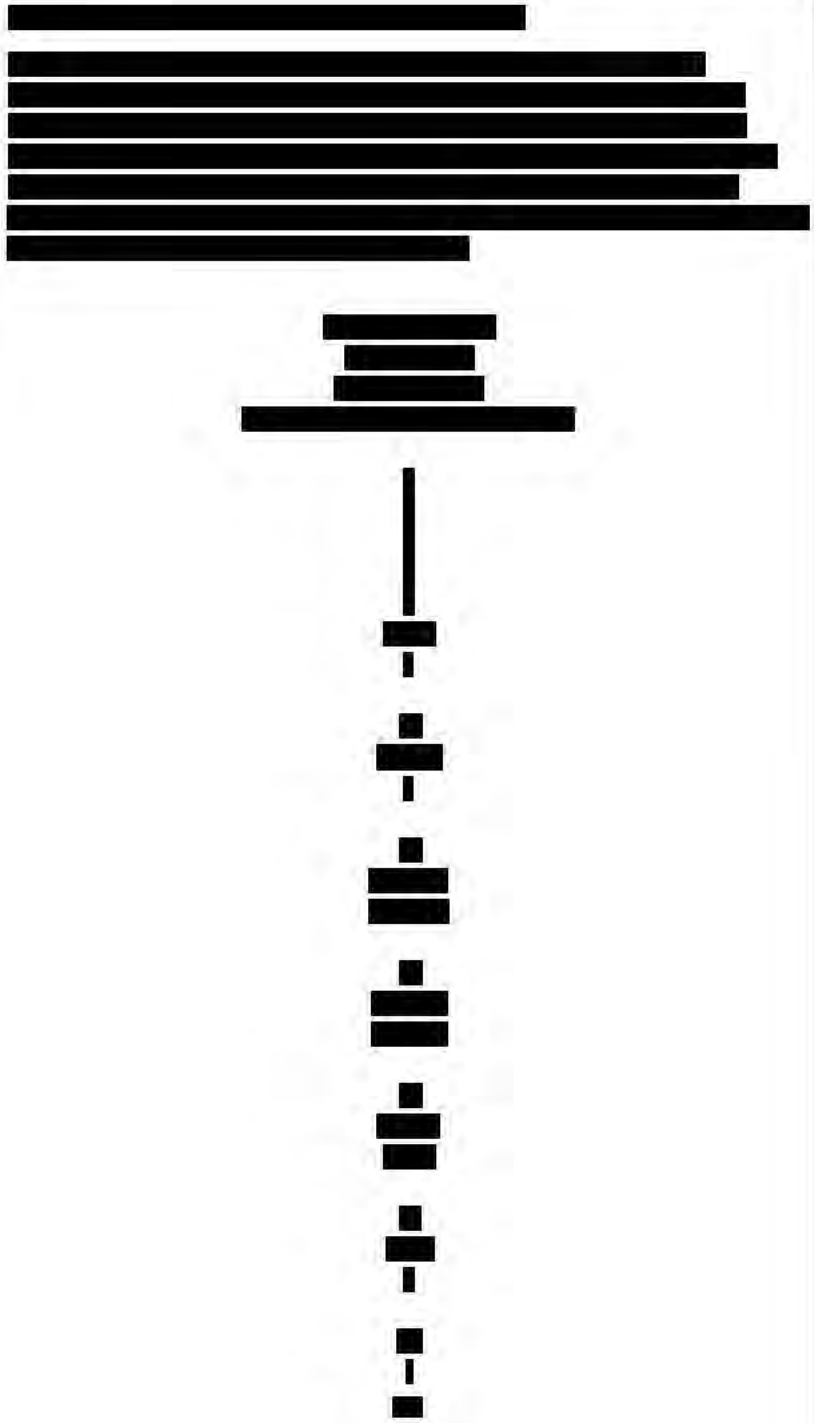
2.10.2.2.4 Determination of leaching rate	[redacted]
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 2A [redacted]

Section 2A Annex Point IIA. 2		Official use only
2.1 Common name proposed or accepted by ISO and synonyms	[redacted]	
2.2 Chemical (CAS) name	[redacted]	
2.3 Manufacturer's development code number(s)	[redacted]	
2.4 CAS and EC numbers		
2.4.1 CAS number	[redacted]	
2.4.2 EC number	[redacted]	
2.4.3 Other substance No.	[redacted]	
2.5 Molecular and structural formula, molecular mass		
2.5.1 Molecular formula	[redacted]	
2.5.2 Structural formula	[redacted]	
2.5.3 Molecular mass	[redacted]	

2.6 Method of manufacture

[redacted]



[redacted]

[redacted]

2.6.1	Stability Information	[redacted]

2.7 Specification of purity	[redacted]	
2.8 Identity of impurities and additives		
	[redacted]	
2.8.1 Common name and function	[redacted]	
2.8.2 IUPAC name	[redacted]	
2.8.3 CAS No	[redacted]	
2.8.4 EC No.: EINECS	[redacted]	
2.8.5 Other	[redacted]	
2.8.6 Molecular formula	[redacted]	
2.8.7 Structural formula	[redacted]	
2.8.8 Molecular mass	N[redacted]	
2.8.9 Concentration of the impurity or additive	[redacted]	
2.9 Origin of precursor(s) of the active substance	[redacted]	

Table 2.6.1-1 [redacted]

[redacted]				
[redacted]				
[redacted]				
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[redacted]				
[redacted]				
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[redacted]

[redacted]		
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

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[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]					
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[redacted]

[redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				

[redacted]

SECTION 3

PHYSICAL AND CHEMICAL PROPERTIES

Section 3 Physical and chemical properties

Section 3.1.1 Annex Point IIA 3.1.1		Melting point	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2004) [redacted] DETERMINATION OF GENERAL PHYSICO-CHEMICAL PROPERTIES. Safepharm Laboratories Ltd, SPL Project Number; 102/459. (unpublished). Reference No.: LR 3909	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	[redacted]	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Annex V of Directive 67/548/EEC 2004	
2.2.	**GLP (only where required)**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Method**	[redacted]	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.2	**Discussion**	[redacted]	

Section 3.1.1 Annex Point IIA 3.1.1		**Melting point**	
		[redacted]	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	[redacted]	
5.2	**Results and discussion**	[redacted]	
5.3	**Conclusion**	Mean melting range 332 to 354 ± 0.5 K Mean melting to 59 to 81°C	
5.3.1	Reliability	[redacted]	
5.3.2	Deficiencies	[redacted]	
		Evaluation by Competent Authorities	
		[redacted]	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	
Materials and Methods		[redacted]	
Results and discussion		[redacted]	
Conclusion		[redacted]	
Reliability		[redacted]	
Acceptability		[redacted]	
Remarks			
		COMMENTS FROM	
Date		[redacted]	
Materials and Methods		[redacted]	

Section 3.1.1 **Annex Point IIA 3.1.1**	**Melting point**	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

Section 3.1.2 Annex Point IIA 3.1.2		Boiling point	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2004) [redacted] DETERMINATION OF GENERAL PHYSICO-CHEMICAL PROPERTIES. Safepharm Laboratories Ltd. SPL Project Number; 102/459. (unpublished). Reference No.: LR 3909	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	[redacted]	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Annex V of Directive 67/548/EEC 2004	
2.2.	**GLP (only where required)**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Method**	[redacted]	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.2	**Discussion**	[redacted]	

Section 3.1.2 **Annex Point IIA 3.1.2**		**Boiling point**	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	[redacted]	
5.2	**Results and discussion**	[redacted]	
5.3	**Conclusion**	The test material and/or its individual components have been determined to boil over the range of 381 to 519 K at 102.14 to 103.62 kPa.	
5.3.1	Reliability	[redacted]	
5.3.2	Deficiencies	[redacted]	
		Evaluation by Competent Authorities	
		[redacted]	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	
Materials and Methods		[redacted]	
Results and discussion		[redacted]	
Conclusion		[redacted]	
Reliability		[redacted]	
Acceptability		[redacted]	
Remarks			
		COMMENTS FROM	

Section 3.1.2 **Annex Point IIA 3.1.2**	**Boiling point**	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

Section 3.1.3 Annex Point IIA 3.1.3		Relative density	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2004) [redacted] DETERMINATION OF GENERAL PHYSICO-CHEMICAL PROPERTIES. Safepharm Laboratories Ltd, SPL Project Number; 102/459. (unpublished). Reference No.: LR 3909	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	[redacted]	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Annex V of Directive 67/548/EEC 2004	
2.2.	**GLP (only where required)**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Method**	[redacted]	
		4. RESULTS	
4.1	**Results**	[redacted]	

		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	[redacted]	
5.2	**Results and discussion**	[redacted]	
5.3	**Conclusion**	Relative density has been determined to be 0.947 at 21.2 ± 0.5°C	
5.3.1	Reliability	[redacted]	
5.3.2	Deficiencies	[redacted]	
		Evaluation by Competent Authorities	
		[redacted]	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	
Materials and Methods		[redacted]	
Results and discussion		[redacted]	
Conclusion		[redacted]	
Reliability		[redacted]	
Acceptability		[redacted]	
Remarks			
		COMMENTS FROM	
Date		[redacted]	
Materials and Methods		[redacted]	
Results and discussion		[redacted]	
Conclusion		[redacted]	
Reliability		[redacted]	
Acceptability		[redacted]	

Section 3.2(1) Annex Point IIA 3.2		Vapour pressure	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] 2004, [redacted] DETERMINATION OF HAZARDOUS PHYSICO-CHEMICAL PROPERTIES. Safepharm Laboratories Limited, SPL Project Number: 102/460 (unpublished) Reference No.: LR 3899	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	[redacted]	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Annex V of Directive 67/548/EC 2004	
2.2	**GLP (only where required)**	Yes	
2.3	**Deviations**	Yes	
		3. MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Method**	[redacted]	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.2	**Discussion**	[redacted]	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	[redacted]	

Section 3.2(1) Annex Point IIA 3.2	**Vapour pressure**	
	[redacted]	
5.2 **Results and discussion**	[redacted]	
5.3 **Conclusion**	The test material is considered not to be volatile.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks		
	COMMENTS FROM	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

Section 3.2.1(1) Annex Point IIA 3.2.1	Henry's law constant	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
[redacted]		
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 3.3 Annex Point IIA. 3.3		Appearance	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, IR, NMR) and mass spectrum, molar extinction at relevant wavelengths	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2004) [redacted] DETERMINATION OF SPECTRA AND PURITY/IMPURITIES. Safepharm Laboratories Limited, SPL Project Number; 102/458. (unpublished). Reference No.: LR 3911	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	[redacted]	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes OECD Guideline No. 101 for UV/VIS determination. For the determination of other spectral data no official guidelines are available. 2004	
2.2	**GLP (only where required)**	No GLP is not considered compulsory for the determination of absorption spectra	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	

Section 3.4.1 (1) Annex Point IIA 3.4.1		Absorption spectra (UV/Vis, IR, NMR) and mass spectrum, molar extinction at relevant wavelengths	
3.1.5	Stability	[redacted]	
3.2	**Method**	[redacted]	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.2	**Discussion**	[redacted]	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	[redacted]	
5.2	**Results and discussion**	[redacted]	

Section 3.4.1 (1) **Annex Point IIA 3.4.1**	**Absorption spectra (UV/Vis, IR, NMR) and mass spectrum, molar extinction at relevant wavelengths**	
	[redacted]	
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	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks		
	COMMENTS FROM	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

Section 3.4.1(2) Annex Point IIA 3.4.1		Absorption spectra (UV/Vis, IR, NMR) and mass spectrum, molar extinction at relevant wavelengths	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2005) [redacted] DETERMINATION OF GENERAL PHYSICO-CHEMICAL PROPERTIES, Safepharm Laboratories Limited, SPL Project Number: 102/483 (unpublished). Reference No: LR 3950	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	[redacted]	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No No guideline available. An internal laboratory method was used. 2005	
2.2	**GLP (only where required)**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Method**	[redacted]	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.2	**Discussion**	[redacted]	

Section 3.4.1(2) Annex Point IIA 3.4.1		**Absorption spectra (UV/Vis, IR, NMR) and mass spectrum, molar extinction at relevant wavelengths**	
		[redacted]	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	[redacted]	
5.2	**Results and discussion**	[redacted]	
5.3	**Conclusion**	The mass spectra were consistent with the proposed chemical structure.	
5.3.1	Reliability	[redacted]	
5.3.2	Deficiencies	[redacted]	
		Evaluation by Competent Authorities	
		[redacted]	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	
Materials and Methods		[redacted]	
Results and discussion		[redacted]	
Conclusion		[redacted]	
Reliability		[redacted]	
Acceptability		[redacted]	
Remarks			

Section 3.4.1(2) **Annex Point IIA 3.4.1**	**Absorption spectra (UV/Vis, IR, NMR) and mass spectrum, molar extinction at relevant wavelengths**	
	COMMENTS FROM	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

Section 3.5 (1) Annex Point IIA 3.5		Solubility in water	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2004) [redacted] DETERMINATION OF GENERAL PHYSICO-CHEMICAL PROPERTIES, Safepharm Laboratories Limited, SPL Project Number: 102/459 (unpublished). Reference No: LR 3909	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	[redacted]	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Annex V of Directive 67/548/EC 2004	
2.2	**GLP (only where required)**	Yes	
2.3	**Deviations**	Yes	
		3. MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Method**	[redacted]	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.2	**Discussion**	[redacted]	

Section 3.5 (1) **Annex Point IIA 3.5**		**Solubility in water**	
		[redacted]	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	[redacted]	
5.2	**Results and discussion**	[redacted]	
5.3	**Conclusion**	The test material has been determined to be miscible in all proportions with water at 20.0 ± 0.5°C. An approximate quatitative value for the solubilty in water was derived to be 796 g/l at 20.0°C.	
5.3.1	Reliability	[redacted]	
5.3.2	Deficiencies	[redacted]	
		Evaluation by Competent Authorities	
		[redacted]	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	
Materials and Methods		[redacted]	
Results and discussion		[redacted]	
Conclusion		[redacted]	
Reliability		[redacted]	
Acceptability		[redacted]	

Section 3.5 (1) **Annex Point IIA 3.5**	**Solubility in water**	
Remarks		
	COMMENTS FROM	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

Section 3.6 Annex Point IIIA.3.6	Dissociation constant	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
[redacted]		
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section 3.7 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] (2004) [redacted] [redacted] DETERMINATION OF GENERAL PHYSICO-CHEMICAL PROPERTIES, Safepharm Laboratories Limited, SPL Project Number: 102/483 (unpublished). Reference No: LR 3950	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	[redacted]	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Annex V of Directive 67/548/EEC 2004	
2.2	**GLP (only where required)**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Method**	[redacted]	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.2	**Discussion**	[redacted]	
		5. APPLICANT'S SUMMARY AND CONCLUSION	

Section 3.7 Annex Point IIA 3.7		Solubility in organic solvents, including the effect of temperature on solubility
5.1	Materials and methods	[redacted]
5.2	Results and discussion	[redacted]
5.3	Conclusion	The test material was determined to be miscible in all proportions with n-octanol and methanol at 20.0 ± 0.5°C. The effect of temperature (10 and 30 ± 0.5°C) was determined to have no effect on solubility. The solubility of DDACarbonate in methanol and octanol is approximately 900 g/l.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]
		Evaluation by Competent Authorities
		[redacted]
		EVALUATION BY RAPPORTEUR MEMBER STATE
Date		[redacted]
Materials and Methods		[redacted]
Results and discussion		[redacted]
Conclusion		[redacted]
Reliability		[redacted]
Acceptability		[redacted]
Remarks		

Section 3.7 Annex Point IIA 3.7	Solubility in organic solvents, including the effect of temperature on solubility
	COMMENTS FROM
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 3.8 Annex Point IIIA.3.8	Stability in organic solvents used in biocidal products and identity of relevant breakdown products	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
[redacted]		
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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
[redacted]		
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]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	

Section 3.9 Annex Point IIA 3.9	Partition coefficient n-octanol/water including effect of pH (5 to 9) and temperature	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section 3.10(1) Annex Point IIA 3.10	Thermal stability, identity of relevant breakdown products	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
[redacted]		
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	

Section 3.10(1) **Annex Point IIA 3.10**	**Thermal stability, identity of relevant breakdown products**
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 3.10 (1) Annex Point IIA 3.10	Thermal stability, identity of relevant breakdown products	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2001) Determination of the Thermal Stability and Stability in Air of [redacted] in accordance with OECD-Guideline 113. Report No. B 012/2001; for Clariant GmbH, Industriepark Hoechst, Frankfurt, Deutschland (sponsor); from AllessaChemie GmbH – Werk Cassella-Offenbach, Analytik, Frankfurt, Deutschland testing facility (unpublished). Ref No. LR 3449	
1.2 Data protection	[redacted]	
1.2.1 Data owner	[redacted]	
1.2.2 Criteria for data protection	[redacted]	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD Guideline No. 113 Year: 2001	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	[redacted]	
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Specification	[redacted]	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	[redacted]	
3.2 Method	[redacted]	
	4. RESULTS	
4.1 Results	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	

Section 3.10 (1) **Annex Point IIA 3.10**	**Thermal stability, identity of relevant breakdown products**	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	The substance is found to be thermally stable.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

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, [redacted] DETERMINATION OF HAZARDOUS PHYSICO-CHEMICAL PROPERTIES. Safepharm Laboratories Limited, SPL Project Number: 102/460, unpublished Reference No.: LR 3899	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	[redacted]	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline Study**	Yes Annex V of Directive 67/548/EC 2004	
2.2	**GLP (only where required)**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test Material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Method**	[redacted]	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.2	**Discussion**	[redacted]	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and**	[redacted]	

Section 3.11 (1) Annex Point IIA 3.11		**Flammability including auto-flammability and identity of combustion products**	
	methods	[redacted]	
5.2	**Results and discussion**	[redacted]	
5.3	**Conclusion**	The test material was determined to be not highly flammable	
5.3.1	Reliability	[redacted]	
5.3.2	Deficiencies	[redacted]	
		Evaluation by Competent Authorities	
		[redacted]	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	
Materials and Methods		[redacted]	
Results and discussion		[redacted]	
Conclusion		[redacted]	
Reliability		[redacted]	
Acceptability		[redacted]	
Remarks			
		COMMENTS FROM	
Date		[redacted]	
Materials and Methods		[redacted]	
Results and discussion		[redacted]	
Conclusion		[redacted]	
Reliability		[redacted]	
Acceptability		[redacted]	

Section 3.11 (2) Annex Point IIA 3.11		Relative self-ignition temperature for solids	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] 2004, [redacted] DETERMINATION OF HAZARDOUS PHYSICO-CHEMICAL PROPERTIES. Safepharm Laboratories Limited, SPL Project Number: 102/460, unpublished Reference No.: LR 3899	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	[redacted]	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline Study**	Yes Annex V of Directive 67/548/EEC 2004	
2.2	**GLP (only where required)**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test Material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Method**	[redacted]	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.2	**Discussion**	[redacted]	

Section 3.11 (2) **Annex Point IIA 3.11**	**Relative self-ignition temperature for solids**	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	The test material has been determined not to have a relative self-ignition temperature below its melting point.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks		
	COMMENTS FROM	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

Section 3.11 (3) Annex Point IIA 3.11		Auto-ignition temperature for liquids and gases	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] 2004 [redacted] DETERMINATION OF HAZARDOUS PHYSICO-CHEMICAL PROPERTIES. Safepharm Laboratories Limited, SPL Project Number: 102/460, unpublished Reference No.: LR 3899	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	[redacted]	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline Study**	Yes Annex V of Directive 67/548/EEC 2004	
2.2	**GLP (only where required)**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test Material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Method**	[redacted]	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.2	**Discussion**	[redacted]	

Section 3.11 (3) **Annex Point IIA 3.11**	**Auto-ignition temperature for liquids and gases**	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	The test material has been determined to have an auto-ignition temperature of 346 ± 5°C.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks		
	COMMENTS FROM	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

Section 3.11(4) Annex Point IIA.3.1	Autoflammability	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
	[redacted]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	

Section 3.11(4) Annex Point IIA.3.1	Autoflammability
Remarks	

Section 3.12 (1) Annex Point IIA 3.12		Flash-point	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] 2004, [redacted] DETERMINATION OF HAZARDOUS PHYSICO-CHEMICAL PROPERTIES. Safepharm Laboratories Limited, SPL Project Number: 102/460, unpublished Reference No.: LR 3899	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	[redacted]	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline Study**	Yes Annex V of Directive 67/548/EEC 2004	
2.2	**GLP (only where required)**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test Material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Method**	[redacted]	
		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**	[redacted]	
5.2 **Results and discussion**	[redacted]	
5.3 **Conclusion**	The test material has been determined not to have a flash point below its boiling temperature.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks		
	COMMENTS FROM	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

Section 3.13 (1) Annex Point IIA 3.13		Surface tension	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2004) [redacted] DETERMINATION OF GENERAL PHYSICO-CHEMICAL PROPERTIES. Safepharm Laboratories Ltd, SPL Project Number; 102/459. (unpublished). Reference No.: LR 3909	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	[redacted]	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Annex V of Directive 67/548/EEC 2004	
2.2.	**GLP (only where required)**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Method**	[redacted]	
		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**	[redacted]	
5.2	**Results and discussion**	[redacted]	
5.3	**Conclusion**	The surface tension of a 1.06 g/L aqueous solution has been determined to be 31.1 mN/m at 21.4 ± 0.5°C.	
5.3.1	Reliability	[redacted]	
5.3.2	Deficiencies	[redacted]	
		Evaluation by Competent Authorities	
		[redacted]	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	
Materials and Methods		[redacted]	
Results and discussion		[redacted]	
Conclusion		[redacted]	
Reliability		[redacted]	
Acceptability		[redacted]	
Remarks			
		COMMENTS FROM	
Date		[redacted]	
Materials and Methods		[redacted]	
Results and discussion		[redacted]	
Conclusion		[redacted]	
Reliability		[redacted]	

Section 3.13 (1) **Annex Point IIA 3.13**	**Surface tension**	
Acceptability	[redacted]	

Section 3.14 (1) Annex Point IIA 3.14		Viscosity	
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (2004) [redacted] DETERMINATION OF GENERAL PHYSICO-CHEMICAL PROPERTIES, Safepharm Laboratories Limited, SPL Project Number: 102/483 (unpublished). Reference No: LR 3950	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	[redacted]	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes OECD Guideline No. 114 2004	
2.2	**GLP (only where required)**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Method**	[redacted]	
		4. RESULTS	
4.1	**Results**	[redacted]	
4.2	**Discussion**	[redacted]	

Section 3.14 (1) **Annex Point IIA 3.14**		**Viscosity**	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	[redacted]	
5.2	**Results and discussion**	[redacted]	
5.3	**Conclusion**	At 20 and 40°C, the viscosity is > 9.69 x 10^6 and > 1.28 x 10^7 mPa.s, respectively.	
5.3.1	Reliability	[redacted]	
5.3.2	Deficiencies	[redacted]	
		Evaluation by Competent Authorities	
		[redacted]	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	
Materials and Methods		[redacted]	
Results and discussion		[redacted]	
Conclusion		[redacted]	
Reliability		[redacted]	
Acceptability		[redacted]	
Remarks			
		COMMENTS FROM	
Date		[redacted]	
Materials and Methods		[redacted]	
Results and discussion		[redacted]	

Section 3.14 (1) **Annex Point IIA 3.14**	**Viscosity**	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted] -	

Section 3.15 (1) Annex Point IIA 3.15	Explosive properties	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
[redacted]		
Detailed justification:	[redacted]	

Section 3.15 (1) **Annex Point IIA 3.15**	**Explosive properties**	
	Evaluation by Competent Authorities	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section 3.16 (1) Annex Point IIA 3.16	Oxidising properties	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
[redacted]		
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	

Section 3.16 (1) **Annex Point IIA 3.16**	**Oxidising properties**	
Conclusion	[redacted]	
Remarks		

Section 3.17 Annex Point IIA. 3.17	Reactivity towards container material	Official use only
1. Wo, Catherine (2005). Bardac 22C50 - Storage stability and corrosion characteristics. Prodct Safety Laboratories (Lonza Report No. 4375)	[redacted]	
2. Herdman, D.J. (2005). Evaluation of the corrosion characteristics of Carboquat 250T using a laboratory immersion corrosion test (Osmose Research Division)	[redacted]	
3. Other results from practical experience	[redacted]	

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
[redacted]	
COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
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	[redacted]	
5.2 Organism(s) to be controlled and products, organisms or objects to be protected	[redacted]	
5.2.1 Organism(s) to be controlled	[redacted]	
5.2.2 Products, objects	[redacted]	

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	[redacted]	
Section 5 Annex Point IIA. 5	**5.3.1(1) Effects on target organisms** **Laboratory study: EN 1275 – Determination of fungistasis by MIC-test (minimal inhibitory concentration)**	

		Official use only
	REFERENCE	
Reference	[redacted] (2006). [redacted]: Test according to EN 1275 (05/97) Chemical disinfectants and antiseptics. Fungicidal effect. Test method and requirements (Phase 1) Determination of fungistasis by MIC-test (minimal inhibitory concentration). Report No. 32/05/8741/01. MPA Eberswalde. Lonza Report No. 4056	
Data protection	[redacted]	
1.1.1 Data owner	[redacted]	
1.1.2 Criteria for data protection	[redacted]	
Guideline study	Yes EN 1275 (05/97): Chemical disinfectants and antiseptics. Fungicidal effect. Test method and requirements (Phase 1) Determination of fungistasis by MIC-test (minimal inhibitory concentration).	
Deviations	No	
	2. METHOD	
Test Substance (Biocidal Product)	[redacted]	
2.1.1 Lot/Batch number	[redacted]	
2.1.2 Trade name/ proposed trade name	[redacted]	
2.1.3 Composition of Product tested	[redacted]	
2.1.4 Physical state and nature	[redacted]	
2.1.5 Monitoring of active substance concentration	[redacted]	
2.1.6 Method of analysis	[redacted]	
Reference substance	[redacted]	
2.1.7 Method of analysis for reference substance	[redacted]	

Section 5 Annex Point IIA. 5		Official use only
Testing procedure		
2.1.8 Test population / inoculum / test organism	[redacted]	
2.1.9 Test system	[redacted]	
2.1.10 Application of TS	[redacted]	
2.1.11 Test conditions	[redacted]	
2.1.12 Duration of the test / Exposure time	[redacted]	
2.1.13 Number of replicates performed	[redacted]	
2.1.14 Controls	[redacted]	
Examination		
2.1.15 Effect investigated	[redacted]	
2.1.16 Method for recording / scoring of the effect	[redacted]	
2.1.17 Intervals of examination	[redacted]	
2.1.18 Satistics	[redacted]	
2.1.19 Post monitoring of the test organism	[redacted]	
	3. RESULTS	

Section 5 Annex Point IIA. 5		Official use only
Efficacy		
3.1.1 Dose/Efficacy curve	[redacted]	
3.1.2 Begin and duration of effects	[redacted]	
3.1.3 Observed effects in the post monitoring phase	[redacted]	
Effects against organisms or objects to be protected	[redacted]	
Other effects	[redacted]	
Efficacy of the reference substance	[redacted]	
Tabular and/or graphical presentation of the summarised results	[redacted]	
Efficacy limiting factors		
3.1.4 Occurrences of resistances	[redacted]	
3.1.5 Other limiting factors	[redacted]	
	4. RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
Reasons for laboratory testing	[redacted]	
Intended actual scale of biocide application	[redacted]	
Relevance compared to field conditions		
4.1.1 Application method	[redacted]	
4.1.2 Test organism	[redacted]	
4.1.3 Observed effect	[redacted]	
Relevance for read-across	[redacted]	
	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
Materials and methods	[redacted]	

Section 5 Annex Point IIA. 5		Official use only
	[redacted]	
Reliability	[redacted]	
Assessment of efficacy, data analysis and interpretation	[redacted]	
Conclusion	Minimum Inhibitory concentrations (MIC) for aqueous dilutions of DDACarbonate against four wood fungi were detemined according to EN 1275 (05/97). The data show that Carboquat 250T is effective against four fungi which can grow on wood : *A.niger, C. globosum, M. verrucaria* and *T viride* at active substance concentrations between 1000 and 500 mg/l.	
Proposed efficacy specification	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Comments	[redacted]
Summary and conclusion	[redacted]

	COMMENTS FROM ... *(specify)*
Date	[redacted]
Comments	[redacted]
Summary and conclusion	[redacted]

Table A5.3.1(1)-1: [redacted]

[redacted]	
[redacted]	
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Table A5.3.1(1)-2: [redacted]

[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	

[redacted]

Section 5 Annex Point IIA. 5	5.3.1(2) Effects on target organisms **Laboratory study: EN 1275 – Determination of fungistasis by MIC-test (minimal inhibitory concentration)**	
	1 REFERENCE	Official use only
1.1 Reference	[redacted] (2006). [redacted]: Test according to EN 1275 (05/97) Chemical disinfectants and antiseptics. Fungicidal effect. Test method and requirements (Phase 1) Determination of fungistasis by MIC-test (minimal inhibitory concentration). Report No. 32/05/8741/07. MPA Eberswalde. Lonza Report No. 4052	
1.2 Data protection	[redacted]	
1.2.1 Data owner	[redacted]	
1.2.2 Criteria for data protection	[redacted]	
1.3 Guideline study	Yes EN 1275 (05/97): Chemical disinfectants and antiseptics. Fungicidal effect. Test method and requirements (Phase 1) Determination of fungistasis by MIC-test (minimal inhibitory concentration).	
1.4 Deviations	No	
	2 METHOD	
2.1 Test Substance (Biocidal Product)	[redacted]	
2.1.1 Lot/Batch number	[redacted]	
2.1.2 Trade name/ proposed trade name	[redacted]	
2.1.3 Composition of Product tested	[redacted]	
2.1.4 Physical state and nature	[redacted]	
2.1.5 Monitoring of active substance concentration	[redacted]	
2.1.6 Method of analysis	[redacted]	
2.2 Reference substance	[redacted]	
2.2.1 Method of analysis for reference substance	[redacted]	
2.3 Testing procedure		

Section 5 Annex Point IIA. 5	5.3.1(2) Effects on target organisms Laboratory study: EN 1275 – Determination of fungistasis by MIC-test (minimal inhibitory concentration)	
2.3.1 Test population / inoculum / test organism	[redacted]	
2.3.2 Test system	[redacted]	
2.3.3 Application of TS	[redacted]	
2.3.4 Test conditions	[redacted]	
2.3.5 Duration of the test / Exposure time	[redacted]	
2.3.6 Number of replicates performed	[redacted]	
2.3.7 Controls	[redacted]	
2.4 Examination		
2.4.1 Effect investigated	[redacted]	
2.4.2 Method for recording / scoring of the effect	[redacted]	
2.4.3 Intervals of examination	[redacted]	
2.4.4 Statistics	[redacted]	
2.4.5 Post monitoring of the test organism	[redacted]	
	3 RESULTS	

Section 5 Annex Point IIA. 5	5.3.1(2) Effects on target organisms Laboratory study: EN 1275 – Determination of fungistasis by MIC-test (minimal inhibitory concentration)	
3.1 Efficacy		
3.1.1 Dose/Efficacy curve	[redacted]	
3.1.2 Begin and duration of effects	[redacted]	
3.1.3 Observed effects in the post monitoring phase	[redacted]	
3.2 Effects against organisms or objects to be protected	[redacted]	
3.3 Other effects	[redacted]	
3.4 Efficacy of the reference substance	[redacted]	
3.5 Tabular and/or graphical presentation of the summarised results	[redacted]	
3.6 Efficacy limiting factors		
3.6.1 Occurrences of resistances	[redacted]	
3.6.2 Other limiting factors	[redacted]	
	4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1 Reasons for laboratory testing	[redacted]	
4.2 Intended actual scale of biocide application	[redacted]	
4.3 Relevance compared to field conditions		
4.3.1 Application method	[redacted]	
4.3.2 Test organism	[redacted]	
4.3.3 Observed effect	[redacted]	
4.4 Relevance for read-across	[redacted]	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Reliability	[redacted]	

Section 5 **Annex Point IIA. 5**	**5.3.1(2) Effects on target organisms** **Laboratory study: EN 1275 – Determination of fungistasis by MIC-test (minimal inhibitory concentration)**	
5.3 Assessment of efficacy, data analysis and interpretation	[redacted]	
5.4 Conclusion	Minimum Inhibitory concentrations (MIC) for aqueous dilutions of DDACarbonate against three wood fungi were detemined according to EN 1275 (05/97). The data show that DDACarbonate is effective against three fungi which can grow on wood : *Coniophora puteana, Poria placenta, Gloeophyllum trabeum* at 500 mg Carboquat 250T/l (which is equivalent to Ian active substance concentration of 250 mg/l.	
5.5 Proposed efficacy specification	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
Date **Comments** **Summary and conclusion**	**EVALUATION BY RAPPORTEUR MEMBER STATE** [redacted]	
Date **Comments** **Summary and conclusion**	**COMMENTS FROM ...** *(specify)* [redacted]	

Table A.5.3.1(2)-1: [redacted]

[redacted]	
[redacted]	
[redacted]	
[redacted]	

Table A.5.3.1(2)-2: [redacted]

[redacted]	
[redacted]	
[redacted]	
[redacted]	

[redacted]

Section 5 Annex Point IIA. 5	5.3.1(3) Effects on target organisms **Laboratory study: EN 113 and EN 84 – Determination of the protective effectiveness against wood destroying basidiomycetes**	

Official use only

1 REFERENCE

1.1 Reference

[redacted] (2006). [redacted] Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (11/96) after leaching procedure according to EN 84 (05/97). Report No. 32/05/8741/05. MPA Eberswalde.
Lonza Report No. 4053.

1.2 Data protection

[redacted]

1.2.1 Data owner

[redacted]

1.2.2 Criteria for data protection

[redacted]

1.3 Guideline study

Yes

EN 113 (11/96) after leaching procedure according to EN 84 (05/97)

1.4 Deviations

No

2 METHOD

2.1 Test Substance (Biocidal Product)

[redacted]

2.1.1 Lot/Batch number

[redacted]

2.1.2 Trade name/ proposed trade name

[redacted]

2.1.3 Composition of Product tested

[redacted]

2.1.4 Physical state and nature

[redacted]

2.1.5 Monitoring of active substance concentration

[redacted]

2.1.6 Method of analysis

[redacted]

2.2 Reference substance

[redacted]

2.2.1 Method of analysis for reference substance

[redacted]

2.3 Testing procedure

Section 5 Annex Point IIA. 5	5.3.1(3) Effects on target organisms Laboratory study: EN 113 and EN 84 – Determination of the protective effectiveness against wood destroying basidiomycetes	
2.3.1 Test population / inoculum / test organism	[redacted]	
2.3.2 Wood species (mean raw density)	[redacted]	
2.3.3 Test system	[redacted]	
2.3.4 Application of TS	[redacted]	
2.3.5 Test conditions	[redacted]	
2.3.6 Duration of the test / Exposure time	[redacted]	
2.3.7 Number of replicates performed	[redacted]	
2.3.8 Controls	[redacted]	
2.4 Examination		
2.4.1 Effect investigated	[redacted]	
2.4.2 Method for recording / scoring of the effect	[redacted]	
2.4.3 Intervals of examination	[redacted]	
2.4.4 Statistics	[redacted]	
2.4.5 Post monitoring of the test organism	[redacted]	
	3 RESULTS	
3.1 Efficacy		

Section 5 Annex Point IIA. 5	5.3.1(3) Effects on target organisms Laboratory study: EN 113 and EN 84 – Determination of the protective effectiveness against wood destroying basidiomycetes	
3.1.1 Dose/Efficacy curve	[redacted]	
3.1.2 Begin and duration of effects	[redacted]	
3.1.3 Observed effects in the post monitoring phase	[redacted]	
3.2 Effects against organisms or objects to be protected	[redacted]	
3.3 Other effects	[redacted]	
3.4 Efficacy of the reference substance	[redacted]	
3.5 Tabular and/or graphical presentation of the summarised results	[redacted]	
3.6 Efficacy limiting factors		
3.6.1 Occurrences of resistances	[redacted]	
3.6.2 Other limiting factors	[redacted]	
	4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1 Reasons for laboratory testing	[redacted]	
4.2 Intended actual scale of biocide application	[redacted]	
4.3 Relevance compared to field conditions		
4.3.1 Application method	[redacted]	
4.3.2 Test organism	[redacted]	
4.3.3 Observed effect	[redacted]	
4.4 Relevance for read-across	[redacted]	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Reliability	[redacted]	
5.3 Assessment of efficacy, data analysis and interpretation	[redacted]	

Section 5 Annex Point IIA. 5	5.3.1(3) Effects on target organisms **Laboratory study: EN 113 and EN 84 – Determination of the protective effectiveness against wood destroying basidiomycetes**	
	[redacted]	
5.4 Conclusion	The efficacy of [redacted] in wood of Pinus sylvestris inoculated with three wood destroying fungi was investigated according to EN 113 after ageing according to EN 84. The wood preservative was applied by vacuum pressure. The required preservative retention range for [redacted] was determined to be <1.9 to 7.3 kg/m^3. [redacted] was shown to be efficient for the intended use. However, it should be noted that for the purpose of Annex I Listing of the active substance an aqueous dilution of [redacted] was used as an example formulation without any other active substances or auxiliary solvents and additives, which in practice are part of real wood preservatives. Therefore, it has to be expected that the preservative retention values obtained in this test are on the upper end and will be significantly lower with real wood preservatives.	
5.5 Proposed efficacy specification	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Comments	[redacted]
Summary and conclusion	[redacted]

	COMMENTS FROM ... *(specify)*
Date	[redacted]
Comments	[redacted]
Summary and conclusion	[redacted]

Table A5.3.1(3)-1: [redacted]

[redacted]			
[redacted]			
[redacted]			
[redacted]			

[redacted]

Section 5 Annex Point IIA. 5	5.3.1(4) Effects on target organisms **Laboratory study: Determination of the toxic values against recently hatched larvae of *Hylotrupes bajulus (L.)* according to EN 47 (06/2005) – without accelerated ageing procedures**	
	1 REFERENCE	Official use only
1.1 Reference	[redacted] (2005). [redacted] Determination of the toxic values against recently hatched larvae of *Hylotrupes bajulus (L.)* according to EN 47 (06/2005) – without accelerated ageing procedures. Report No. 32/05/8741/02. MPA Eberswalde. Lonza Report No. 4055.	
1.2 Data protection	[redacted]	
1.2.1 Data owner	[redacted]	
1.2.2 Criteria for data protection	[redacted]	
1.3 Guideline study	Yes EN 47 (06/2005) – without accelerated ageing procedures	
1.4 Deviations	No	
	2 METHOD	
2.1 Test Substance (Biocidal Product)	[redacted]	
2.1.1 Lot/Batch number	[redacted]	
2.1.2 Trade name/ proposed trade name	[redacted]	
2.1.3 Composition of Product tested	[redacted]	
2.1.4 Physical state and nature	[redacted]	
2.1.5 Monitoring of active substance concentration	[redacted]	
2.1.6 Method of analysis	[redacted]	
2.2 Reference substance	[redacted]	
2.2.1 Method of analysis for reference substance	[redacted]	
2.3 Testing procedure		

Section 5 Annex Point IIA. 5	5.3.1(4) Effects on target organisms **Laboratory study: Determination of the toxic values against recently hatched larvae of *Hylotrupes bajulus (L.)* according to EN 47 (06/2005) – without accelerated ageing procedures**	
2.3.1 Test population / inoculum / test organism	[redacted]	
2.3.2 Wood species (mean raw density)	[redacted]	
2.3.3 Test system	[redacted]	
2.3.4 Application of TS	[redacted]	
2.3.5 Test conditions	[redacted]	
2.3.6 Duration of the test / Exposure time	[redacted]	
2.3.7 Number of replicates performed	[redacted]	
2.3.8 Controls	[redacted]	
2.4 Examination		
2.4.1 Effect investigated	[redacted]	
2.4.2 Method for recording / scoring of the effect	[redacted]	
2.4.3 Intervals of examination	[redacted]	
2.4.4 Statistics	[redacted]	
2.4.5 Post monitoring of the test organism	[redacted]	
	3 RESULTS	
3.1 Efficacy		

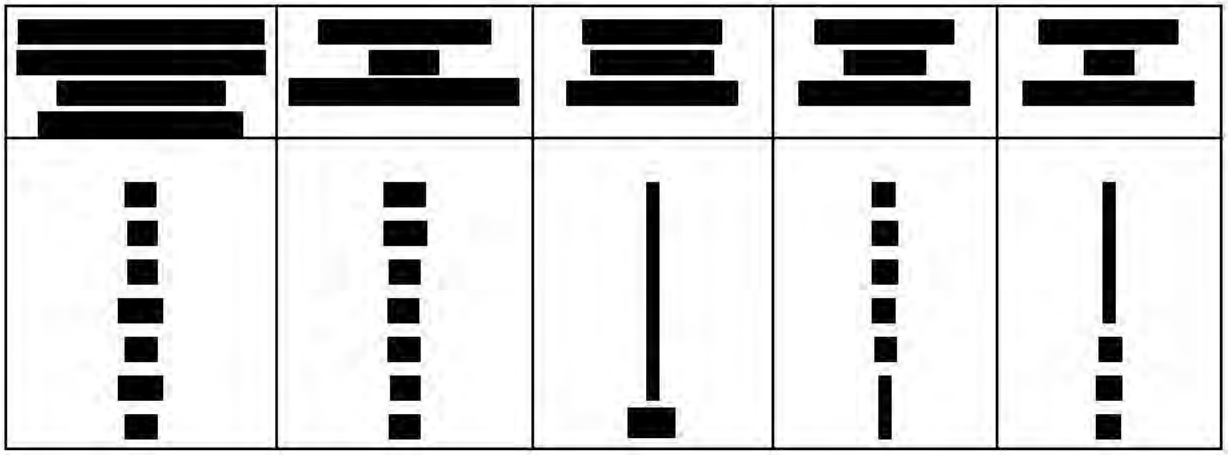
Section 5 Annex Point IIA. 5	5.3.1(4) Effects on target organisms **Laboratory study: Determination of the toxic values against recently hatched larvae of *Hylotrupes bajulus (L.)* according to EN 47 (06/2005) – without accelerated ageing procedures**	
3.1.1 Dose/Efficacy curve	[redacted]	
3.1.2 Begin and duration of effects	[redacted]	
3.1.3 Observed effects in the post monitoring phase	[redacted]	
3.2 Effects against organisms or objects to be protected	[redacted]	
3.3 Other effects	[redacted]	
3.4 Efficacy of the reference substance	[redacted]	
3.5 Tabular and/or graphical presentation of the summarised results	[redacted]	
3.6 Efficacy limiting factors		
3.6.1 Occurrences of resistances	[redacted]	
3.6.2 Other limiting factors	[redacted]	
	4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1 Reasons for laboratory testing	[redacted]	
4.2 Intended actual scale of biocide application	[redacted]	
4.3 Relevance compared to field conditions		
4.3.1 Application method	[redacted]	
4.3.2 Test organism	[redacted]	
4.3.3 Observed effect	[redacted]	
4.4 Relevance for read-across	[redacted]	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Reliability	[redacted]	
5.3 Assessment of efficacy, data analysis and	[redacted]	

Section 5 **Annex Point IIA. 5**	**5.3.1(4) Effects on target organisms** **Laboratory study: Determination of the toxic values against recently hatched larvae of *Hylotrupes bajulus (L.)* according to EN 47 (06/2005) – without accelerated ageing procedures**	
interpretation	[redacted]	
5.4 Conclusion	The efficacy of [redacted] in wood of *Pinus sylvestris* exposed to larvae of *Hylotrupes bajulus* was investigated according to EN 47 without ageing procedures. The wood preservative was applied by vacuum pressure. The required preservative retention range in terms of [redacted] was determined to be 6.6 to 10.4 kg/m^3. DDACarbonate was shown to be efficient for the intended use. However, it should be noted that for the purpose of Annex I Listing of the active substance an aqueous dilution of [redacted] was used as an example formulation without any other active substances or auxiliary solvents and additives, which in practice are part of real wood preservatives. Therefore, it has to be expected that the preservative retention values obtained in this test are on the upper end and will be significantly lower with real wood preservatives.	
5.5 Proposed efficacy specification	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Comments	[redacted]
Summary and conclusion	[redacted]

	COMMENTS FROM ... *(specify)*
Date	[redacted]
Comments	[redacted]
Summary and conclusion	[redacted]

Table A5.3.1 (4)-1: [redacted]



Section 5 Annex Point IIA. 5	5.3.1(5) Effects on target organisms **Laboratory study: Determination of the toxic values against recently hatched larvae of *Hylotrupes bajulus (L.)* according to EN 47 (06/2005) – after leaching procedure according to EN 84 (05/97)**	
	1 REFERENCE	Official use only
1.1 Reference	[redacted] (2005). [redacted] Determination of the toxic values against recently hatched larvae of *Hylotrupes bajulus (L.)* according to EN 47 (06/2005) – after leaching procedure according to EN 84 (05/97). Report No. 32/05/8741/03. MPA Eberswalde. Lonza Report No. 4054.	
1.2 Data protection	[redacted]	
1.2.1 Data owner	[redacted]	
1.2.2 Criteria for data protection	[redacted]	
1.3 Guideline study	Yes EN 47 (06/2005) – after leaching procedure according to EN 84 (05/97)	
1.4 Deviations	No	
	2 METHOD	
2.1 Test Substance (Biocidal Product)	[redacted]	
2.1.1 Lot/Batch number	[redacted]	
2.1.2 Trade name/ proposed trade name	[redacted]	
2.1.3 Composition of Product tested	[redacted]	
2.1.4 Physical state and nature	[redacted]	
2.1.5 Monitoring of active substance concentration	[redacted]	
2.1.6 Method of analysis	[redacted]	
2.2 Reference substance	[redacted]	
2.2.1 Method of analysis for reference substance	[redacted]	
2.3 Testing procedure		

Section 5 Annex Point IIA. 5	5.3.1(5) Effects on target organisms **Laboratory study: Determination of the toxic values against recently hatched larvae of *Hylotrupes bajulus (L.)* according to EN 47 (06/2005) – after leaching procedure according to EN 84 (05/97)**	
2.3.1 Test population / inoculum / test organism	[redacted]	
2.3.2 Wood species (mean raw density)	[redacted]	
2.3.3 Test system	[redacted]	
2.3.4 Application of TS	[redacted]	
2.3.5 Test conditions	[redacted]	
2.3.6 Duration of the test / Exposure time	[redacted]	
2.3.7 Number of replicates performed	[redacted]	
2.3.8 Controls	[redacted]	
2.4 Examination		
2.4.1 Effect investigated	[redacted]	
2.4.2 Method for recording / scoring of the effect	[redacted]	
2.4.3 Intervals of examination	[redacted]	
2.4.4 Statistics	[redacted]	
2.4.5 Post monitoring of the test organism	[redacted]	
	3 RESULTS	
3.1 Efficacy		

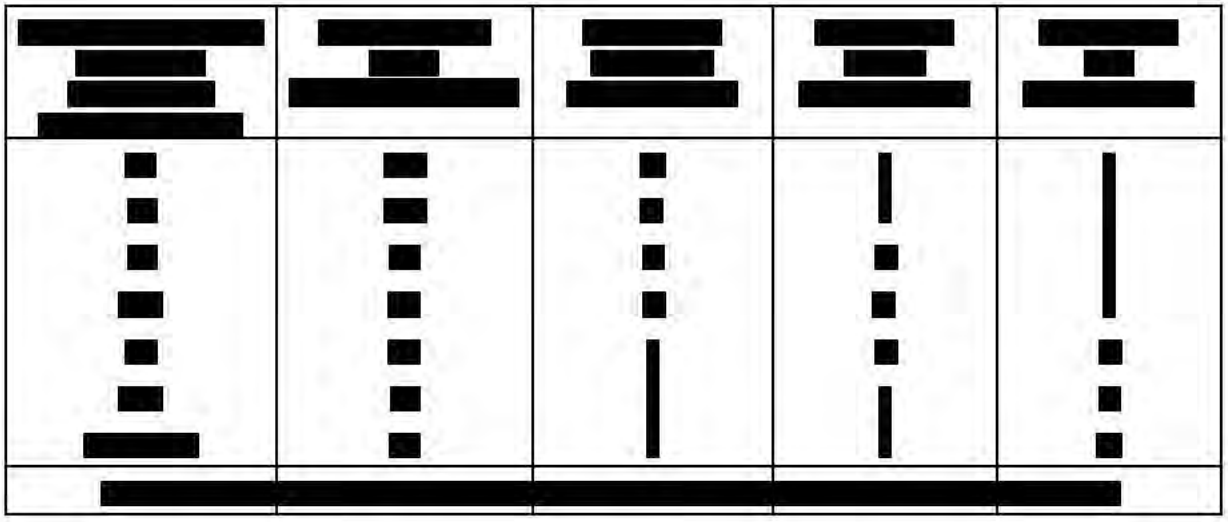
Section 5 Annex Point IIA. 5	5.3.1(5) Effects on target organisms **Laboratory study: Determination of the toxic values against recently hatched larvae of *Hylotrupes bajulus (L.)* according to EN 47 (06/2005) – after leaching procedure according to EN 84 (05/97)**	
3.1.1 Dose/Efficacy curve	[redacted]	
3.1.2 Begin and duration of effects	[redacted]	
3.1.3 Observed effects in the post monitoring phase	[redacted]	
3.2 Effects against organisms or objects to be protected	[redacted]	
3.3 Other effects	[redacted]	
3.4 Efficacy of the reference substance	[redacted]	
3.5 Tabular and/or graphical presentation of the summarised results	[redacted]	
3.6 Efficacy limiting factors		
3.6.1 Occurrences of resistances	[redacted]	
3.6.2 Other limiting factors	[redacted]	
	4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1 Reasons for laboratory testing	[redacted]	
4.2 Intended actual scale of biocide application	[redacted]	
4.3 Relevance compared to field conditions		
4.3.1 Application method	[redacted]	
4.3.2 Test organism	[redacted]	
4.3.3 Observed effect	[redacted]	
4.4 Relevance for read-across	[redacted]	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Reliability	[redacted]	
5.3 Assessment of efficacy, data analysis and	[redacted]	

Section 5 **Annex Point IIA. 5**	**5.3.1(5) Effects on target organisms** **Laboratory study: Determination of the toxic values against recently hatched larvae of *Hylotrupes bajulus (L.)* according to EN 47 (06/2005) – after leaching procedure according to EN 84 (05/97)**	
interpretation	[redacted]	
5.4 Conclusion	The efficacy of [redacted] in wood of *Pinus sylvestris* exposed to larvae of *Hylotrupes bajulus* was investigated according to EN 47 after ageing according to EN 84. The wood preservative was applied by vacuum pressure. The required preservative retention range in terms of the [redacted] was 10.2 to 15.6 kg/m^3. [redacted] was shown to be efficient for the intended use. However, it should be noted that for the purpose of Annex I Listing of the active substance an aqueous dilution of [redacted] was used as an example formulation without any other active substances or auxiliary solvents and additives, which in practice are part of real wood preservatives. Therefore, it has to be expected that the preservative retention values obtained in this test are on the upper end and will be significantly lower with real wood preservatives.	
5.5 Proposed efficacy specification	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Comments	[redacted]
Summary and conclusion	[redacted]

	COMMENTS FROM ... *(specify)*
Date	[redacted]
Comments	[redacted]
Summary and conclusion	[redacted]

Table A5.3.1(5)-1: [redacted]



5.3.2 Likely concentrations at which the active substance will be used	[redacted]	
5.4 Mode of action (including time delay)	[redacted]	
5.4.1 Mode of action	[redacted]	
5.4.2 Time delay	[redacted]	
5.5 Field of use envisaged	[redacted]	
5.6 User: industrial, professional, general public	[redacted]	
5.7 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies	[redacted]	
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]

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	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Table IIA-5.2: [redacted]

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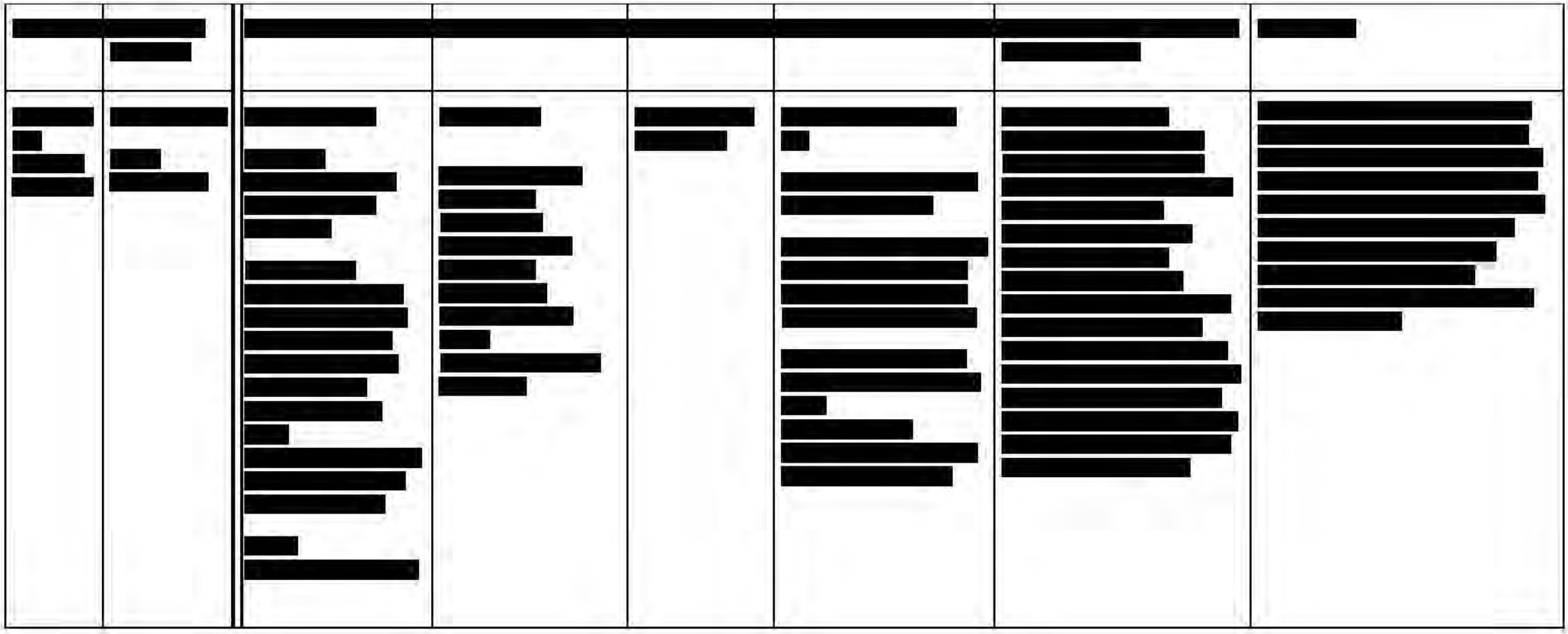
[redacted]			
[redacted]			
[redacted]			

Section 5.3: [redacted]



Section 5.3: [redacted]