SECTION 6

TOXICOLOGICAL AND METABOLIC STUDIES

CONTENTS OF DOCUMENT III-A SECTION 6 TOXICOLOGICAL AND METABOLIC STUDIES

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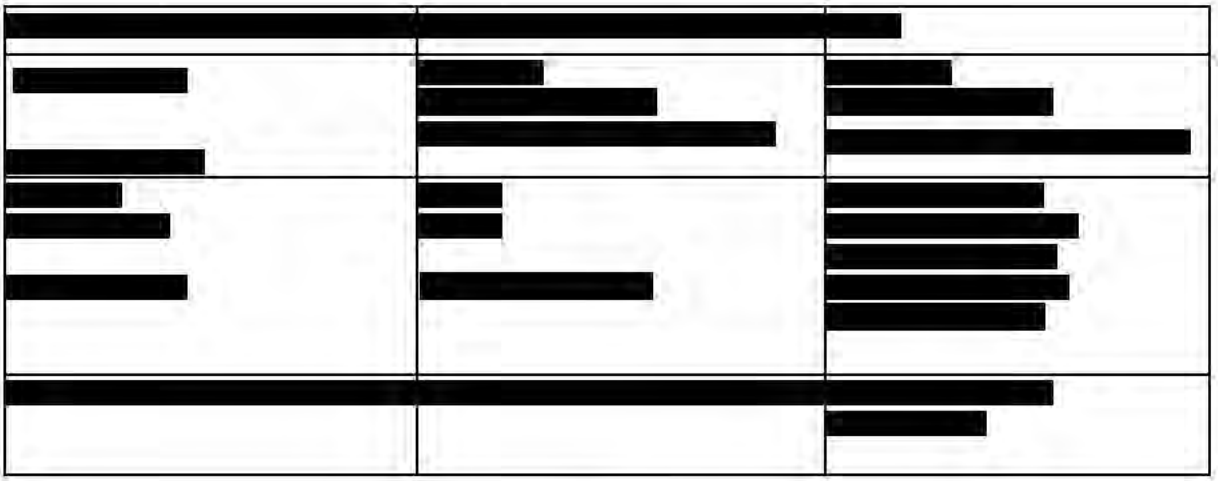

[redacted]

6.0.2 Names and synonyms of test material used for the individual studies

[redacted]

[redacted]					
[redacted]					
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Section 6.1 Acute toxicity

Annex Point IIA 6.1 – headline only

Section 6.1.1 Acute oral toxicity test in the rat

Section 6.1.1 (1) Annex Point IIA 6.1.1	Acute oral toxicity test in the rat	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1994) Acute Oral Toxicity in Rats – Median Lethal Dosage Determination Using a 5% Active Ingredient Formulation of [redacted] Hill Top Biolabs, Inc. Report No. 93-8185-21 (A) (unpublished). Reference No.: LR 3718	
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. 401; FIFRA (40 CFR) *1994*	
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 Test animals	[redacted]	
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	

Section 6.1.1 (1) Annex Point IIA 6.1.1	**Acute oral toxicity test in the rat**	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control animals	[redacted]	
3.3 Administration/ exposure	[redacted]	
3.3.1 Dose route	[redacted]	
3.3.2 Post exposure period	[redacted]	
3.3.3 Dose levels	[redacted]	
3.3.4 Vehicle	[redacted]	
3.3.5 Concentration in vehicle	[redacted]	
3.3.6 Controls	[redacted]	
3.4 Observation, Sacrifice and pathology	[redacted]	
3.4.1 Clinical signs	[redacted]	
3.4.2 Mortality	[redacted]	
3.4.3 Bodyweight	[redacted]	
3.4.4 Necropsy	[redacted]	
	4. RESULTS	
4.1 Limit test	[redacted]	
4.2 LD_{50} including confidence limits	[redacted]	
4.3 Observations, Sacrifice and pathology	[redacted]	
4.3.1 Clinical signs	[redacted]	
4.3.2 Mortality	[redacted]	
4.3.3 Bodyweight	[redacted]	
4.3.4 Gross findings at necropsy	[redacted]	

Section 6.1.1 (1) **Annex Point IIA 6.1.1**	**Acute oral toxicity test in the rat**	
	[redacted]	
4.3.5 Statistics	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	DDACarbonate is classified as "harmful if swallowed" on the basis of this study and is assigned the symbol "Xn" and the risk phrase "R22".	
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 *(specify)*	
Date	[redacted]	
Materials and methods	[redacted]	

Section 6.1.1 (1) Annex Point IIA 6.1.1	Acute oral toxicity test in the rat
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Table 6.1.1(1)-1 **Group incidence of mortality**
Dose range finding screen:

Section 6.1.2 Acute dermal toxicity test in rats

Section 6.1.2 (1) Annex Point IIA 6.1.2	Acute dermal toxicity test in rats	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2004) [redacted] [redacted] ACUTE DERMAL TOXICITY (LIMIT TEST) IN THE RAT. Safepharm Laboratories Limited. SPL Project No. 102/461(unpublished). Reference No.: LR 3900	
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; OECD Guideline No. 402 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 Test animals	[redacted]	
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control animals	[redacted]	
3.3 Administration/ exposure	[redacted]	
3.3.1 Dose route	[redacted]	
3.3.2 Duration of	[redacted]	

Section 6.1.2 (1) Annex Point IIA 6.1.2	Acute dermal toxicity test in rats	
exposure		
3.3.3 Post exposure period	[redacted]	
3.3.4 Dose levels	[redacted]	
3.3.5 Vehicle	[redacted]	
3.3.6 Concentration in vehicle	[redacted]	
3.3.7 Controls	[redacted]	
3.4 Observation, Sacrifice and pathology	[redacted]	
3.4.1 Clinical signs	[redacted]	
3.4.2 Mortality	[redacted]	
3.4.3 Bodyweight	[redacted]	
3.4.4 Necropsy	[redacted]	
	4. RESULTS	
4.1 Limit test	[redacted]	
4.2 LD_{50} including confidence limits	[redacted]	
4.3 Observations, Sacrifice and pathology	[redacted]	
4.3.1 Clinical signs	[redacted]	
4.3.2 Mortality	[redacted]	
4.3.3 Dermal irritation	[redacted]	
4.3.4 Bodyweight	[redacted]	
4.3.5 Gross findings at necropsy	[redacted]	
4.3.6 Statistics	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	

Section 6.1.2 (1) **Annex Point IIA 6.1.2**	**Acute dermal toxicity test in rats**
5.3 Conclusion	The animals showed no signs of toxicity but were killed in extremis due to the severity of the dermal reactions. The acute dermal median lethal dose may be considered to be greater than 2000 mg/Kg although there is insufficient data available to confirm this finding.
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 *(specify)*
Date	[redacted]
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 6.1.3 Acute inhalation toxicity test

Section 6.1.3 **Annex Point IIA 6.1.3**	**Acute inhalation toxicity test**	
	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]	
	Comments from other Member State *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	

Section 6.1.4 Skin and eye irritation

Section 6.1.4 (1) Annex Point IIA 6.1.4	Skin irritation study in rabbits	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1994) Primary Skin Irritation Study in Rabbits using a 50% Active Ingredient Formulation of [redacted] Hill Top Biolabs, Inc. Report No. 93-8185-21 (C) (unpublished). Reference No.: LR 3717	
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 EPA 81-5 1994	
2.2 GLP (only where required)	Yes	
2.3 Deviations	Only one animal was employed for testing and that animal was maintained only through the 24 hour reading of the study, at which time it was sacrificed due to the severity of the response.	
	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 Test animals	[redacted]	
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control animals	[redacted]	
3.3 Administration/ exposure	[redacted]	
3.3.1 Dose route	[redacted]	
3.3.2 Post exposure period	[redacted]	

Section 6.1.4 (1) Annex Point IIA 6.1.4	**Skin irritation study in rabbits**	
3.3.3 Concentration	[redacted]	
3.3.4 Duration of treatment	[redacted]	
3.3.5 Vehicle	[redacted]	
3.3.6 Concentration in vehicle	[redacted]	
3.3.7 Total volume applied	[redacted]	
3.4 Observations, Sacrifice and pathology	[redacted]	
3.4.1 Scoring system	[redacted]	
3.4.2 Examination time points	[redacted]	
3.4.3 Skin responses	[redacted]	
3.5 Further remarks	[redacted]	
	4. RESULTS	
4.1 Observations, Sacrifice and pathology	[redacted]	
4.1.1 Scores	[redacted]	
4.1.2 Skin responses	[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 is classified as "corrosive" on the basis of this study and is assigned the symbol "C" and the risk phrase "R34".	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	

Section 6.1.4 (1) Annex Point IIA 6.1.4	**Skin irritation study in rabbits**
	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 *(specify)*
Date	[redacted]
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

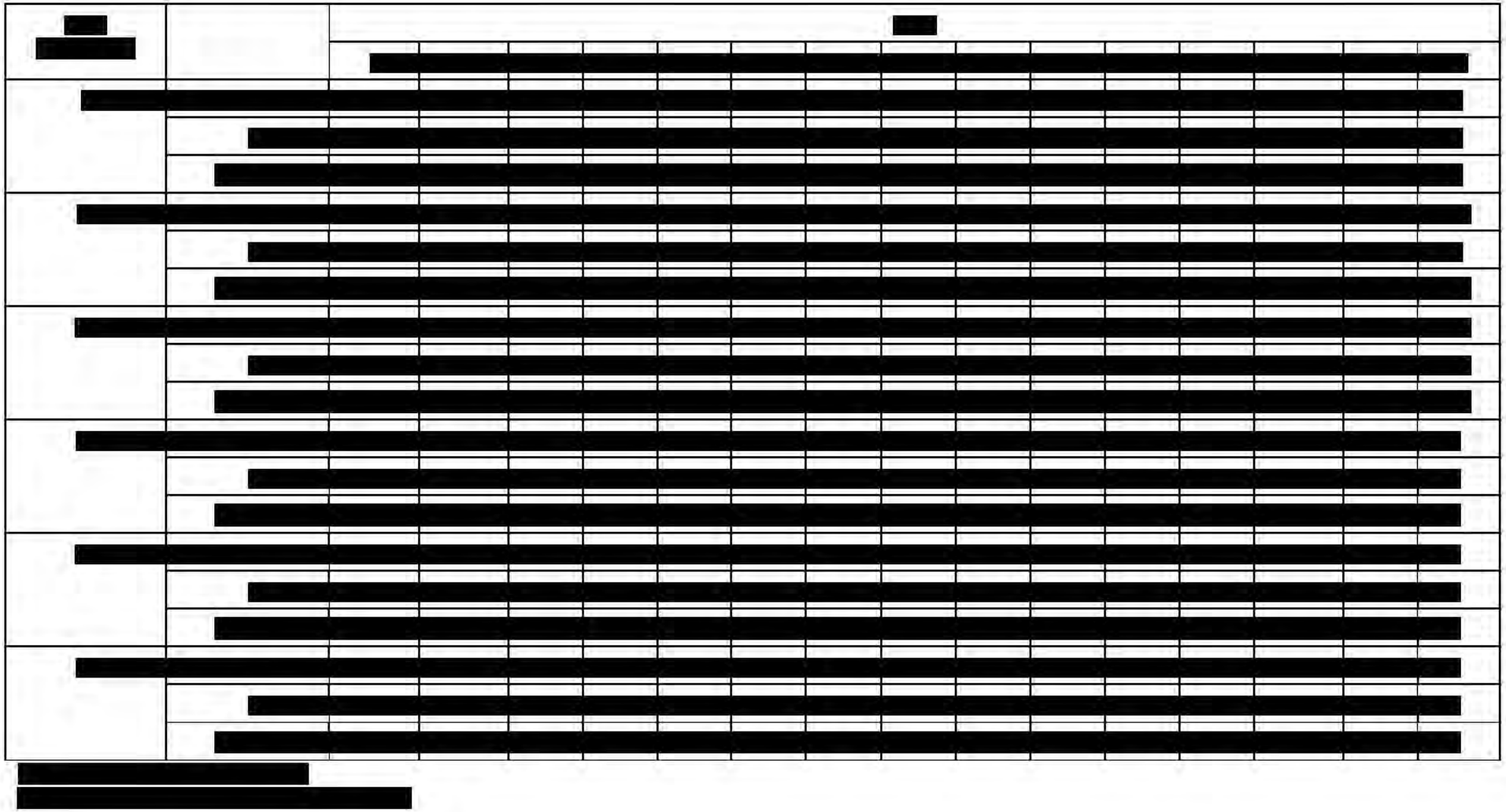
Section 6.1.4 (2) Annex Point IIA 6.1.4	Skin irritation study in rats	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2006) 21-Day Repeated Dose Dermal Irritation Study With [redacted] in Female Rats. Product Safety Laboratories. Report No. 19072 (unpublished). Reference No.: LR 4019	
1.2 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 The study was not conducted to a specific guidelines as none available 2006	
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 Test animals	[redacted]	
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.3 Administration/ exposure	[redacted]	
3.3.1 Dose route	[redacted]	
3.3.2 Post exposure period	[redacted]	
3.3.3 Concentration	[redacted]	
3.3.4 Duration of treatment	[redacted]	
3.3.5 Vehicle	[redacted]	
3.3.6 Concentration in vehicle	[redacted]	
3.3.7 Total volume	[redacted]	

Section 6.1.4 (2) Annex Point IIA 6.1.4	Skin irritation study in rats	
applied		
3.3.8 Control animals	[redacted]	
3.4 Observations, Sacrifice and pathology	[redacted]	
3.4.1 Clinical signs	[redacted]	
3.4.2 Mortality	[redacted]	
3.4.3 Skin responses	[redacted]	
3.4.4 Scoring system	[redacted]	
3.4.5 Examination time points	[redacted]	
3.4.6 Bodyweight	[redacted]	
3.4.7 Necropsy	[redacted]	
3.4.7 Histopathology	[redacted]	
3.5 Further remarks	[redacted]	
	4. RESULTS	
4.1 Observations, Sacrifice and pathology	[redacted]	
4.1.1 Clinical signs	[redacted]	
4.1.2 Mortality	[redacted]	
4.1.3 Scores	[redacted]	
4.1.4 Bodyweight	[redacted]	
4.1.5 Necropsy	[redacted]	
4.1.6 Histopathology	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	

Section 6.1.4 (2) **Annex Point IIA 6.1.4**	**Skin irritation study in rats**	
	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	NOAEC 10 µg/cm^2/day	
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 *(specify)*	
Date	[redacted]	
Materials and methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	

Section 6.1.4 (2) Annex Point IIA 6.1.4	Skin irritation study in rats
Reliability	[redacted]
Acceptability	[redacted]

Table 6.1.4(2)-1 Summary of Mean Skin Irritation Scores[1]



[redacted]

Section 6.1.4 (3) Annex Point IIA 6.1.4	Eye irritation study in rabbits	
	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 6.1.5 Skin sensitisation

Section 6.1.5 (1) Annex Point IIA 6.1.5	Skin sensitisation (guinea pig Buehler test)	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1994) Photallergy Study with [redacted] in Guinea Pigs. Hill Top Biolabs, Inc. Report No. 93-8123-21 (A) (unpublished). Reference No.: LR 3716	
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 EPA 81-6 1994	
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 Test animals	[redacted]	
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals in treated group	[redacted]	
3.2.7 Control animals (number)	[redacted]	
3.2.8 Positive control animals (number)	[redacted]	
3.3 Administration/	[redacted]	

Section 6.1.5 (1) Annex Point IIA 6.1.5	Skin sensitisation (guinea pig Buehler test)	
exposure		
3.3.1 Dose route	[redacted]	
3.3.2 Irritation phase	[redacted]	
3.3.2.1 Days of irritation applications	[redacted]	
3.3.2.2 Concentration of irritation applications	[redacted]	
3.3.2.3 Vehicle	[redacted]	
3.3.2.4 Volume applied	[redacted]	
3.3.3 Induction	[redacted]	
3.3.3.1 Days of induction applications	[redacted]	
3.3.3.2 Concentration of induction applications	[redacted]	
3.3.3.3 Vehicle	[redacted]	
3.3.3.4 Volume applied	[redacted]	
3.3.4 Challenge phase	[redacted]	
3.3.4.1 Days of induction and challenge applications	[redacted]	
3.3.4.2 Concentration of challenge applications	[redacted]	
3.3.4.3 Vehicle	[redacted]	
3.3.4.4 Volume applied	[redacted]	

Section 6.1.5 (1) **Annex Point IIA 6.1.5**	**Skin sensitisation (guinea pig Buehler test)**	
3.3.5 Positive control	[redacted]	
3.3.5.1 Concentration of positive control in vehicle	[redacted]	
3.3.2.5 Irradiation	[redacted]	
	4. RESULTS	
4.1 Observations, Sacrifice and pathology	[redacted]	
4.1.1 Skin responses at irritation	[redacted]	
4.1.2 Skin responses at induction	[redacted]	
4.1.3 Skin responses at challenge	[redacted]	
4.1.4 Number of positive controls with evidence of skin sensitisation	[redacted]	
4.1.5 Bodyweight	[redacted]	
4.1.6 Irradiation	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	Repeated cutaneous application of DDACarbonate in combination with UV irradiation resulted in mild skin irritation but did not produce evidence of skin sensitisation.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	

Section 6.1.5 (1) Annex Point IIA 6.1.5	**Skin sensitisation (guinea pig Buehler test)**
	[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 *(specify)*
Date	[redacted]
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Table 6.1.5(1)-1 Number of animals assigned to groups

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

Table 6.1.5(1)-2 Sample preparation and application

[redacted]			
[redacted]			
[redacted]			

Table 6.1.5(1)-3 [redacted]

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

Table 6.1.5(1)-4 Incidence and severity of skin reaction scores following challenge with test material and TSCA

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

Table 6.1.5(1)-5 UVA and UVB Levels at Various Phases of Testing

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

Section 6.2 Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study

Section 6.2 Annex Point IIA 6.2	Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study 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 6.2(1) Annex Point IIA 6.2	Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2001). The In Vitro Percutaneous Absorption of [redacted] Through Human Skin. Report No. 19128. Inveresk Research. (unpublished) Ref No. LON 3329	
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 for the testing of chemicals. Skin absorption: in vitro method. 1999. (Draft); OECD guidance document for the conduct of skin absorption studies. 1999. (Draft); COLIPA. Cosmetic ingredients: guidelines for percutaneous absorption/penetration. 1995. 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]	
3.1.2.1 Non-radiolabelled	[redacted]	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	[redacted]	
3.1.6 Method of analysis	[redacted]	
3.2 Test procedure	[redacted]	
3.2.1 Test system	[redacted]	
3.2.2 Method of application	[redacted]	
3.2.3 Application media	[redacted]	
3.2.4 Concentration	[redacted]	
3.2.5 Receptor fluid	[redacted]	
3.2.6 Remarks	[redacted]	

Section 6.2(1) **Annex Point IIA 6.2**	**Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study**	
	[redacted]	
	4. RESULTS	
4.1 Application rate	[redacted]$^{-2}$	
4.1.1 Target dose level	[redacted]	
4.2 Mean % recovery after 24 hours	[redacted]	
4.3 Cumulative flux	[redacted]	
4.4 Remarks	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	Less than 0.1% of the ^{14}C-DDAC penetrated human skin. Total absorption was 2.92%.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section 6.2(1) **Annex Point IIA 6.2**	**Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study**
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	Comments from other member state *(specify)*
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Table 6.2(1)-1. Mean % recovery after 24 hours

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

Section 6.2(2) Annex Point IIA 6.2	Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1989). Absorption, Distribution, Metabolism and Excretion Studies of [redacted] in the Rat. Study No. P01421. Biological Test Center, (Unpublished) Ref Nos.: LON 1779	
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 U.S. EPA Guideline 85-1 1989	
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 Test Procedure	[redacted]	
3.2.1 Method of analysis	[redacted]	
3.3 Test Animals	[redacted]	
3.3.1 Species	[redacted]	
3.3.2 Strain	[redacted]	
3.3.3 Source	[redacted]	
3.3.4 Sex	[redacted]	
3.3.5 Age/weight at study initiation	[redacted]	
3.3.6 Number of animals per group	[redacted]	
3.3.7 Control animals	[redacted]	
3.4 Administration/ exposure	[redacted]	
3.4.1 Dose route	[redacted]	

Section 6.2(2) Annex Point IIA 6.2	Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study	
	[redacted]	
3.4.2 Post exposure period	[redacted]	
3.4.3 Concentration	[redacted]	
3.4.4 Vehicle	[redacted]	
3.4.5 Concentration in vehicle	[redacted]	
3.4.6 Controls	[redacted]	
	4. RESULTS	
4.1 Results	[redacted]	
4.1.1 % Recovery	[redacted]	
4.1.2 Metabolites	[redacted]	
4.2 Remarks	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.1 Results and discussion	[redacted]	

Section 6.2(2) Annex Point IIA 6.2	**Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study**	
	[redacted]	
5.3 Conclusion	The majority of orally administered Didecyldimethylammonium Chloride is excreted via the faeces and appears to be metabolised in the gut of rats, apparently by microflora. Metabolism in females was greater than in males and lower doses were more extensively metabolised than higher doses in females. No tissue accumulation of the test substance was observed. Repeated dosing did not alter the uptake, distribution or metabolism of Didecyldimethylammonium Chloride.	
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 *(specify)*	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

Section 6.3 Short term repeated dose toxicity

Section 6.3.1 Annex Point IIA.6.3.1	Short term repeated dose toxicity (oral)	
	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 6.3.2 Annex Point IIA.6.3.2	Short term repeated dose toxicity (dermal)	
	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]	
[redacted]		

Section 6.3.3 Annex Point IIA.6.3.3	Short term repeated dose toxicity (inhalation)	
	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 6.4 Sub-chronic toxicity

Section 6.4.1 Annex Point IIA 6.4.1	Sub-chronic oral toxicity test	
	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 6.4.1(1) Annex Point IIA 6.4.1	Sub-chronic oral toxicity test	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1988). Ninety-day dietary subchronic oral toxicity study with [redacted] in rats. Union Carbide, Report No. 51-506 (unpublished) Ref No.: LON 1257	
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 U.S. EPA FIFRA Guideline 82-1; OECD Guideline 408. 1987	
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 Test animals	[redacted]	
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control Animals	[redacted]	
3.3 Administration/ exposure	[redacted]	
3.3.1 Dose route	[redacted]	
3.3.2 Duration of test/ exposure	[redacted]	
3.3.3 Frequency of exposure	[redacted]	
3.3.4 Post exposure	[redacted]	

Section 6.4.1(1) Annex Point IIA 6.4.1	Sub-chronic oral toxicity test	
period		
3.3.5 Concentration	[redacted]	
3.3.6 Vehicle	[redacted]	
3.3.7 Concentration in vehicle	[redacted]	
3.3.8 Actual dose received	[redacted]	
3.3.9 Controls	[redacted]	
3.4 Examinations	[redacted]	
3.4.1 Observations	[redacted]	
3.4.2 Clinical signs	[redacted]	
3.4.3 Mortality	[redacted]	
3.4.4 Bodyweight	[redacted]	
3.4.5 Food consumption	[redacted]	
3.4.6 Water consumption	[redacted]	
3.4.7 Ophthalmoscopic examination	[redacted]	
3.4.8 Haematology	[redacted]	
3.4.9 Clinical Chemistry	[redacted]	
3.4.10 Urinalysis	[redacted]	
3.5 Sacrifice and pathology	[redacted]	
3.5.1 Organ weights	[redacted]	
3.5.2 Gross and histopathology	[redacted]	
3.5.3 Other examinations	[redacted]	
3.5.4 Statistical analysis	[redacted]	
	4. RESULTS	
4.1 Examinations	[redacted]	
4.1.1 Observations	[redacted]	
4.1.2 Clinical signs	[redacted]	
4.1.3 Mortality	[redacted]	
4.1.4 Bodyweight	[redacted]	

Section 6.4.1(1) Annex Point IIA 6.4.1	Sub-chronic oral toxicity test	
	[redacted]	
4.1.5 Food consumption	[redacted]	
4.1.6 Water consumption	[redacted]	
4.1.7 Ophthalmoscopic examination	[redacted]	
4.1.8 Haematology	[redacted]	
4.1.9 Clinical Chemistry	[redacted]	
4.1.10 Urinalysis	[redacted]	
4.2 Sacrifice and pathology	[redacted]	
4.2.1 Organ weights	[redacted]	
4.2.2 Gross and histopathology	[redacted]	
4.2.3 Other examinations	[redacted]	
4.2.4 Statistical analysis	[redacted]	
4.3 LO(A)EL	[redacted]	
4.4 NO(A)EL	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	NOAEL = 1000 ppm (61 mg/kg/d for males, 74 mg/kg/d for females)	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	

Section 6.4.1(1) Annex Point IIA 6.4.1	**Sub-chronic oral toxicity test**
	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 *(specify)*
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 6.4.1(2) Annex Point IIA 6.4.1	Subchronic oral toxicity study.	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1990). Subchronic oral toxicity study of [redacted] in dogs. Study No. 2545-100. Hazelton Laboratories America, Inc., (unpublished) Ref No. LON 1256	
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	Not applicable 1990	
2.2 GLP (only where required)	Yes (If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)	
2.3 Deviations	Not applicable	
	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 Test animals	[redacted]	
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control Animals	[redacted]	
3.3 Administration/ exposure	[redacted]	
3.3.1 Dose route	[redacted]	
3.3.2 Duration of test/ exposure	[redacted]	
3.3.3 Frequency of exposure	[redacted]	

Section 6.4.1(2) Annex Point IIA 6.4.1	Subchronic oral toxicity study.	
	[redacted]	
3.3.4 Post exposure period	[redacted]	
3.3.5 Concentration	[redacted]	
3.3.6 Vehicle	[redacted]	
3.3.7 Concentration in vehicle	[redacted]	
3.3.8 Actual dose received	[redacted]	
3.3.9 Controls	[redacted]	
3.4 Examinations	[redacted]	
3.4.1 Observations	[redacted]	
3.4.2 Clinical signs	[redacted]	
3.4.3 Mortality	[redacted]	
3.4.4 Bodyweight	[redacted]	
3.4.5 Food consumption	[redacted]	
3.4.6 Water consumption	[redacted]	
3.4.7 Ophthalmoscopic examination	[redacted]	
3.4.8 Haematology	[redacted]	
3.4.9 Clinical chemistry	[redacted]	
3.4.10 Urinalysis	[redacted]	
3.5 Sacrifice and pathology	[redacted]	
3.5.1 Organ weights	[redacted]	
3.5.2 Gross and histopathology	[redacted]	
3.5.3 Other examinations	[redacted]	
3.5.4 Statistical analysis	[redacted]	
	4. RESULTS	
4.1 Examinations	[redacted]	
4.1.1 Observations	[redacted]	
4.1.2 Clinical signs	[redacted]	
4.1.3 Mortality	[redacted]	
4.1.4 Bodyweight	[redacted]	

Section 6.4.1(2) Annex Point IIA 6.4.1	**Subchronic oral toxicity study.**	
	[redacted]	
4.1.5 Food consumption	[redacted]	
4.1.6 Water consumption	[redacted]	
4.1.7 Ophthalmoscopic examination	[redacted]	
4.1.8 Haematology	[redacted]	
4.1.9 Clinical chemistry	[redacted]	
4.1.10 Urinalysis	[redacted]	
4.2 Sacrifice and pathology	[redacted]	
4.2.1 Organ weights	[redacted]	
4.2.2 Gross and histopathology	[redacted]	
4.2.3 Other examinations	[redacted]	
4.2.4 Statistical analysis	[redacted]	
4.3 LO(A)EL	[redacted]	
4.4 NO(A)EL	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	NOAEL = 30 mg/kg/d	
5.3.1 Reliability	[redacted]	

Section 6.4.1(2) **Annex Point IIA 6.4.1**	**Subchronic oral toxicity study.**	
	[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 (specify)	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

Section 6.4.1(3) Annex Point IIA 6.4.1	Subchronic oral toxicity test	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1988) Subchronic dietary dose range finding study with [redacted] in mice. Report No. 51-507. Union Carbide, (unpublished). Ref No: LON 1775	
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 FIFRA 82-1 1988	
2.2 GLP (only where required)	Yes	
2.3 Deviations	A limited number of endpoints were examined because this study was designed primarily for selecting doses for a chronic Oncogenicity study	
	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 Test animals	[redacted]	
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control Animals	[redacted]	
3.3 Administration/ exposure	[redacted]	
3.3.1 Dose route	[redacted]	
3.3.2 Duration of test/ exposure	[redacted]	
3.3.3 Frequency of exposure	[redacted]	

Section 6.4.1(3) Annex Point IIA 6.4.1	Subchronic oral toxicity test	
3.3.4 Post exposure period	[redacted]	
3.3.5 Concentration	[redacted]	
3.3.6 Vehicle	[redacted]	
3.3.7 Concentration in vehicle	[redacted]	
3.3.8 Actual dose received	[redacted]	
3.3.9 Controls	[redacted]	
3.4 Examinations	[redacted]	
3.4.1 Observations	[redacted]	
3.4.2 Clinical signs	[redacted]	
3.4.3 Mortality	[redacted]	
3.4.4 Bodyweight	[redacted]	
3.4.5 Food consumption	[redacted]	
3.4.6 Water consumption	[redacted]	
3.4.7 Ophthalmoscopic examination	[redacted]	
3.4.8 Haematology	[redacted]	
3.4.9 Clinical Chemistry	[redacted]	
3.4.10 Urinalysis	[redacted]	
3.5 Sacrifice and pathology	[redacted]	
3.5.1 Organ weights	[redacted]	
3.5.2 Gross and histopathology	[redacted]	
3.5.3 Other examinations	[redacted]	
3.5.4 Statistical analysis	[redacted]	
	4. RESULTS	
4.1 Examinations	[redacted]	
4.1.1 Observations		
4.1.2 Clinical signs	[redacted]	
4.1.3 Mortality	[redacted]	

Section 6.4.1(3) Annex Point IIA 6.4.1	Subchronic oral toxicity test	
	[redacted]	
4.1.4 Bodyweight	[redacted]	
4.1.5 Food consumption	[redacted]	
4.1.6 Water consumption	[redacted]	
4.1.7 Ophthalmoscopic examination	[redacted]	
4.1.8 Haematology	[redacted]	
4.1.9 Clinical Chemistry	[redacted]	
4.1.10 Urinalysis	[redacted]	
4.2 Sacrifice and pathology	[redacted]	
4.2.1 Organ weights	[redacted]	
4.2.2 Gross and histopathology	[redacted]	
4.2.3 Other examinations	[redacted]	
4.2.4 Statistical analysis	[redacted]	
4.3 LO(A)EL	[redacted]	
4.4 NO(A)EL	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	NOAEL = 600 ppm LOAEL = 1000 ppm	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	

Section 6.4.1(3) Annex Point IIA 6.4.1	**Subchronic oral toxicity test**
	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 *(specify)*
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 6.4.1(4) Annex Point IIA 6.4.1	Subchronic oral toxicity study.	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1975). 90-day feeding study in dogs with a quaternary amonium sanitizer [redacted] Study No. 2224 a. Food and Drug Research Laboratories, Inc., (unpublished) Ref No. LON 1256 A	
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	Not applicable	
2.2 GLP (only where required)	No (GLP was not compulsory at the time the study was performed)	
2.3 Deviations	Not applicable	
	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 Test animals	[redacted]	
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control Animals	[redacted]	
3.3 Administration/ exposure	[redacted]	
3.3.1 Dose route	[redacted]	
3.3.2 Duration of test/ exposure	[redacted]	
3.3.3 Frequency of	[redacted]	

Section 6.4.1(4) Annex Point IIA 6.4.1	Subchronic oral toxicity study.	
exposure		
3.3.4 Post exposure period	[redacted]	
3.3.5 Concentration	[redacted]	
3.3.6 Vehicle	[redacted]	
3.3.7 Concentration in vehicle	[redacted]	
3.3.8 Actual dose received	[redacted]	
3.3.9 Controls	[redacted]	
3.4 Examinations	[redacted]	
3.4.1 Observations	[redacted]	
3.4.2 Clinical signs	[redacted]	
3.4.3 Mortality	[redacted]	
3.4.4 Bodyweight	[redacted]	
3.4.5 Food consumption	[redacted]	
3.4.6 Water consumption	[redacted]	
3.4.7 Ophthalmoscopic examination	[redacted]	
3.4.8 Haematology	[redacted]	
3.4.9 Clinical chemistry	[redacted]	
3.4.10 Urinalysis	[redacted]	
3.5 Sacrifice and pathology	[redacted]	
3.5.1 Organ weights	[redacted]	
3.5.2 Gross and histopathology	[redacted]	
3.5.3 Other examinations	[redacted]	
3.5.4 Statistical analysis	[redacted]	
	4. RESULTS	
4.1 Examinations	[redacted]	
4.1.1 Observations	[redacted]	
4.1.2 Clinical signs	[redacted]	
4.1.3 Mortality	[redacted]	
4.1.4 Bodyweight	[redacted]	
4.1.5 Food consumption	[redacted]	
4.1.6 Water consumption	[redacted]	
4.1.7 Ophthalmoscopic examination	[redacted]	
4.1.8 Haematology	[redacted]	
4.1.9 Clinical chemistry	[redacted]	
4.1.10 Urinalysis	[redacted]	

Section 6.4.1(4) Annex Point IIA 6.4.1	**Subchronic oral toxicity study.**	
4.2 Sacrifice and pathology	[redacted]	
4.2.1 Organ weights	[redacted]	
4.2.2 Gross and histopathology	[redacted]	
4.2.3 Other examinations	[redacted]	
4.2.4 Statistical analysis	[redacted]	
4.3 LO(A)EL	[redacted]	
4.4 NO(A)EL	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	NOEL = 25 mg/kg/day (active substance) NOEL = 50 mg/kg/d as Bardac 22	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	

Section 6.4.1(4) **Annex Point IIA 6.4.1**	**Subchronic oral toxicity study.**
	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 (specify)
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 6.4.2 Annex Point IIA 6.4.1	Sub-chronic dermal toxicity test	
	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 6.4.2(1) Annex Point IIA 6.4.2	Subchronic dermal toxicity test	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1988) Ninety-day subchronic dermal toxicity study with [redacted] in rats. Union Carbide, Project No: 51-554. (unpublished) Ref No.: LON 1255	
1.2 Data protection	[redacted]	
1.2.1 Data owner	[redacted]	
1.2.2 Criteria for data protection	[redacted] May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes US EPA OPP 82-3 1988	
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 Test animals	[redacted]	
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control Animals	[redacted]	
3.3 Administration/ exposure	[redacted]	

Section 6.4.2(1) Annex Point IIA 6.4.2	Subchronic dermal toxicity test	
3.3.1 Dose route	[redacted]	
3.3.2 Duration of test/ exposure	[redacted]	
3.3.3 Frequency of exposure	[redacted]	
3.3.4 Post exposure period	[redacted]	
3.3.5 Concentration	[redacted]	
3.3.6 Vehicle	[redacted]	
3.3.7 Concentration in vehicle	[redacted]	
3.3.8 Actual dose received	[redacted]	
3.3.9 Controls	[redacted]	
3.4 Examinations	[redacted]	
3.4.1 Observations	[redacted]	
3.4.2 Clinical signs	[redacted]	
3.4.3 Mortality	[redacted]	
3.4.4 Bodyweight	[redacted]	
3.4.5 Food consumption	[redacted]	
3.4.6 Water consumption	[redacted]	
3.4.7 Ophthalmoscopic examination	[redacted]	
3.4.8 Haematology	[redacted]	
3.4.9 Clinical Chemistry	[redacted]	
3.4.10 Urinalysis	[redacted]	
3.5 Sacrifice and pathology	[redacted]	
3.5.1 Organ weights	[redacted]	
3.5.2 Gross and histopathology	[redacted]	
3.5.3 Other examinations	[redacted]	
3.5.4 Statistical analysis	[redacted]	
	4. RESULTS	
4.1 Examinations	[redacted]	
4.1.1 Observations	[redacted]	

Section 6.4.2(1) **Annex Point IIA 6.4.2**	**Subchronic dermal toxicity test**	
4.1.2 Clinical signs	[redacted]	
4.1.3 Mortality	[redacted]	
4.1.4 Bodyweight	[redacted]	
4.1.5 Food consumption	[redacted]	
4.1.6 Water consumption	[redacted]	
4.1.7 Ophthalmoscopic examination	[redacted]	
4.1.8 Haematology	[redacted]	
4.1.9 Clinical Chemistry	[redacted]	
4.1.10 Urinalysis	[redacted]	
4.2 Sacrifice and pathology	[redacted]	
4.2.1 Organ weights	[redacted]	
4.2.2 Gross and histopathology	[redacted]	
4.2.3 Other examinations	[redacted]	
4.2.4 Statistical analysis	[redacted]	
4.3 LOAEL	[redacted]	
4.4 NOAEL	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	NOAEL = 12 mg/kg body weight	
5.3.1	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	

Section 6.4.2(1) Annex Point IIA 6.4.2	**Subchronic dermal toxicity test**
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	Comments from other member state *(specify)*
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 6.4.3 Annex Point III-A.6.4.3	Subchronic toxicity test (inhalation)	
	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 6.5 Chronic toxicity

Annex Point IIA 6.5- headline only

Section 6.5 Annex Point IIA 6.5	Chronic toxicity in dogs	
	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 6.5(1) Annex Point IIA 6.5	Chronic toxicity in dogs	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1991). Chronic oral toxicity study of [redacted] in dogs. Hazelton Washington, Inc., HWA. Study No. 2545-102. (unpublished) Ref No.: LON 1778	
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 U.S. EPA FIFRA Subdivision F, Section 158.83-1; OECD Guideline 452 1989	
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 Test animals	[redacted]	
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control Animals	[redacted]	
3.3 Administration/ exposure	[redacted]	
3.3.1 Dose route	[redacted]	
3.3.2 Duration of test/ exposure	[redacted]	
3.3.3 Frequency of exposure	[redacted]	
3.3.4 Post exposure period	[redacted]	

Section 6.5(1) Annex Point IIA 6.5	Chronic toxicity in dogs	
3.3.5 Concentration	[redacted]	
3.3.6 Vehicle	[redacted]	
3.3.7 Concentration in vehicle	[redacted]	
3.3.8 Actual dose received	[redacted]	
3.3.9 Controls	[redacted]	
3.4 Examinations	[redacted]	
3.4.1 Observations	[redacted]	
3.4.2 Clinical signs	[redacted]	
3.4.3 Mortality	[redacted]	
3.4.4 Bodyweight	[redacted]	
3.4.5 Food consumption	[redacted]	
3.4.6 Water consumption	[redacted]	
3.4.7 Ophthalmoscopic examination	[redacted]	
3.4.8 Haematology	[redacted]	
3.4.9 Clinical Chemistry	[redacted]	
3.4.10 Urinalysis	[redacted]	
3.5 Sacrifice and pathology	[redacted]	
3.5.1 Organ weights	[redacted]	
3.5.2 Gross and histopathology	[redacted]	
3.5.3 Other examinations	[redacted]	
3.5.4 Statistical analysis	[redacted]	
	4. RESULTS	
4.1 Examinations	[redacted]	
4.1.1 Observations	[redacted]	
4.1.2 Clinical signs	[redacted]	
4.1.3 Mortality	[redacted]	
4.1.4 Bodyweight	[redacted]	

Section 6.5(1) Annex Point IIA 6.5	Chronic toxicity in dogs	
	[redacted]	
4.1.5 Food consumption	[redacted]	
4.1.6 Water consumption	[redacted]	
4.1.7 Ophthalmoscopic examination	[redacted]	
4.1.8 Haematology	[redacted]	
4.1.9 Clinical Chemistry	[redacted]	
4.1.10 Urinalysis	[redacted]	
4.2 Sacrifice and pathology	[redacted]	
4.2.1 Organ weights	[redacted]	
4.2.2 Gross and histopathology	[redacted]	
4.2.3 Other examinations		
4.2.4 Statistical analysis	[redacted]	
4.3 LOAEL	[redacted]	
4.4 NOAEL	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	NOAEL = 10 mg/kg/d	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	

Section 6.5(1) Annex Point IIA 6.5	Chronic toxicity in dogs
	[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 *(specify)*
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 6.5(2) Annex IIA Point 6.5	Chronic toxicity in rats.	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1991) Chronic dietary toxicity/oncogenicity study with [redacted] in rats. Report No. 53-566. Union Carbide. (unpublished) Ref No. LON 1755	
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 EPA Guideline 83-5; OECD Guideline 453 1988	
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 Test animals		
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control Animals	[redacted]	
3.3 Administration/	[redacted]	

Section 6.5(2) Annex IIA Point 6.5	Chronic toxicity in rats.	
exposure		
3.3.1 Dose route	[redacted]	
3.3.2 Duration of test/exposure	[redacted]	
3.3.3 Frequency of exposure	[redacted]	
3.3.4 Post exposure period	[redacted]	
3.3.5 Concentration	[redacted]	
3.3.6 Vehicle	[redacted]	
3.3.7 Actual dose received	[redacted]	
3.3.8 Controls	[redacted]	
3.4 Examinations	[redacted]	
3.4.1 Observations	[redacted]	
3.4.2 Clinical signs	[redacted]	
3.4.3 Mortality	[redacted]	
3.4.4 Bodyweight	[redacted]	
3.4.5 Food consumption	[redacted]	
3.4.6 Water consumption	[redacted]	
3.4.7 Ophthalmoscopic examination	[redacted]	
3.4.8 Haematology	[redacted]	
3.4.9 Clinical Chemistry	[redacted]	
3.4.10 Urinalysis	[redacted]	
3.5 Sacrifice and pathology	[redacted]	
3.5.1 Organ weights	[redacted]	
3.5.2 Gross and histopathology	[redacted]	
3.5.3 Other examinations	[redacted]	
3.5.4 Statistical analysis	[redacted]	
	4. RESULTS	
4.1 Examinations	[redacted]	
4.1.1 Observations	[redacted]	
4.1.2 Clinical signs	[redacted]	

Section 6.5(2) **Annex IIA Point 6.5**	**Chronic toxicity in rats.**
4.1.3 Mortality	[redacted]
4.1.4 Bodyweight	[redacted]
4.1.5 Food consumption	[redacted]
4.1.6 Water consumption	[redacted]
4.1.7 Ophthalmoscopic examination	[redacted]
4.1.8 Haematology	[redacted]
4.1.9 Clinical Chemistry	[redacted]
4.1.10 Urinalysis	[redacted]
4.2 Sacrifice and pathology	[redacted]
4.2.1 Organ weights	[redacted]
4.2.2 Gross and histopathology	[redacted]
4.2.3 Other examinations	[redacted]
4.2.4 Statistical analysis	[redacted]
4.3 LOAEL	[redacted]
4.4 NOAEL	[redacted]
	5. APPLICANT'S SUMMARY AND CONCLUSION
5.1 Materials and methods	[redacted]
5.2 Results and discussion	[redacted]
5.3 Conclusion	NOAEL = 750 ppm (equivalent to 32 and 41 mg/kg/d for males and females, respectively)
5.3.1 Reliability	[redacted]
5.3.2 Deficiencies	[redacted]
	Evaluation by Competent Authorities

Section 6.5(2) **Annex IIA Point 6.5**	**Chronic toxicity in rats.**
	[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 *(specify)*
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 6.6 Genotoxicity studies
Annex Point IIA 6.6- headline only

Section 6.6.1(1) Annex Point IIA 6.6.1	*In vitro* gene mutation study in bacteria	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2004) [redacted] [redacted] REVERSE MUTATION ASSAY "AMES TEST" USING *SALMONELLA TYPHIMURIUM*. Safepharm Laboratories Limited. Report/Project No. 102/464 (unpublished). Reference No.: LR 3889	
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. 471; Directive 2000/32/EC Method B13/14 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 Test species	[redacted]	
3.2.1 Cell type	[redacted]	
3.2.2 Strain	[redacted]	
3.3 Metabolic activation	[redacted]	
Metabolic activation system	[redacted]	
Positive control in presence of metabolic activation	[redacted]	
3.3.2 Positive control in absence of metabolic activation	[redacted]	
3.4 Test methods	[redacted]	

Section 6.6.1(1) **Annex Point IIA 6.6.1**	***In vitro* gene mutation study in bacteria**	
3.4.1 Negative control	[redacted]	
3.4.2 Vehicle control	[redacted]	
3.4.3 Concentrations used for cytotoxicity testing	[redacted]	
3.4.4 Concentrations used for genotoxicity testing	[redacted]	
3.4.5 Statistical methods	[redacted]	
3.4.6 Duplicate/ independent assay	[redacted]	
	4. RESULTS	
4.1 Cytotoxicity	[redacted]	
4.1.1 With metabolic activation	[redacted]	
4.1.2 Without metabolic activation	[redacted]	
4.2 Genotoxicity	[redacted]	
4.2.1 With metabolic activation	[redacted]	
4.2.2 Without metabolic activation	[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 was considered to be non-mutagenic under the conditions of this test.	
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]	

Section 6.6.1(1) **Annex Point IIA 6.6.1**	***In vitro* gene mutation study in bacteria**
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	Comments from other member state *(specify)*
Date	[redacted]
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 6.6.2(1) Annex IIA 6.6.2	***In vitro* cytogenetics study in mammalian cells (human lymphocytes)**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2004) [redacted] CHROMOSOME ABERRATION TEST IN HUMAN LYMPHOCYTES *IN VITRO*. Safepharm Laboratories Limited. Report No. 102/463 (unpublished). Reference No.: LR 3927	
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. 473; Directive 2000/32/EC Method B10 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 Test species	[redacted]	
3.2.1 Cell type	[redacted]	
3.2.2 Strain		
3.3 Metabolic activation	[redacted]	
3.3.1 Metabolic activation	[redacted]	
3.3.2 Positive control in presence of metabolic activation	[redacted]	
3.3.3 Positive control in absence of metabolic activation	[redacted]	
3.4 Test methods	[redacted]	
3.4.1 Vehicle control	[redacted]	
3.4.2 Concentrations for	[redacted]	

Section 6.6.2(1) Annex IIA 6.6.2	*In vitro* cytogenetics study in mammalian cells (human lymphocytes)	
cytotoxicity testing		
3.4.3 Concentrations for genotoxicity testing	[redacted]	
3.4.4 Duplicate/ independent assay	[redacted]	
3.4.5 Statistical methods	[redacted]	
	4. RESULTS	
4.1 Cytotoxicity	[redacted]	
4.1.1 With metabolic activation	[redacted]	
4.1.2 Without metabolic activation	[redacted]	
4.2 Genotoxicity	[redacted]	
4.2.1 With metabolic activation	[redacted]	
4.2.2 Without metabolic activation	[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 was considered to be non-clastogenic to human lymphocytes *in vitro*.	
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]	

Section 6.6.2(1) Annex IIA 6.6.2	*In vitro* cytogenetics study in mammalian cells (human lymphocytes)
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	Comments from other member state *(specify)*
Date	[redacted]
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 6.6.3 (1) Annex Point IIA 6.6.3	***In vitro* mammalian cell forward mutation assay** **(mouse lymphoma TK+/- gene mutation)**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2005) [redacted] L5178Y TK+/- MOUSE LYMPHOMA ASSAY. Safepharm Laboratories Limited. Report No. 102/484 (unpublished). Reference No.: LR 3898	
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. 476; Directive 2000/32/EC Method B17 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 Test species/strain	[redacted]	
3.2.1 Cell type	[redacted]	
3.2.2 Strain	[redacted]	
3.3 Metabolic activation	[redacted]	
3.3.1 Inducing agent	[redacted]	
3.3.2 Positive control in presence of metabolic activation	[redacted]	
3.3.3 Positive control in absence of metabolic activation	[redacted]	
3.4 Test methods	[redacted]	
3.4.1 Vehicle control	[redacted]	
3.4.2 Cytotoxicity test concentrations	[redacted]	
3.4.3 Genotoxicity test	[redacted]	

Section 6.6.3 (1) **Annex Point IIA 6.6.3**	***In vitro* mammalian cell forward mutation assay** **(mouse lymphoma TK+/- gene mutation)**	
concentrations	[redacted]	
3.4.4 Duplicate/ independent assay	[redacted]	
3.5 Statistical methods	[redacted]	
	4. RESULTS	
4.1 Cytotoxicity	[redacted]	
4.2 Genotoxicity	[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 is considered to be non-mutagenic under the conditions of the test.	
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]	

Section 6.6.3 (1) Annex Point IIA 6.6.3	*In vitro* mammalian cell forward mutation assay (mouse lymphoma TK+/- gene mutation)
Acceptability	[redacted]
Remarks	
	Comments from other member state *(specify)*
Date	[redacted]
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 6.6.4 Annex IIA 6.6.4	*In vivo* cytogenetics assay in mammalian cells (rat bone marrow micronucleus test)	
	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]	

Section 6.6.5 Annex IIA 6.6.5	*In vivo* cytogenetics assay in mammalian cells (tissue other than one marrow)	
	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]	

Section 6.6.6 Annex IIA 6.6.6	Germ cell effects	
	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]	

Section 6.6.7 Annex IIA 6.6.7	Further genetic toxicity tests on metabolites of concern	
	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		

Section 6.6.7 Annex IIA 6.6.7	Further genetic toxicity tests on metabolites of concern
	Comments from other Member State *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]

Section 6.7 Carcinogenicity study in mice and rats

Section 6.7 **Annex Point IIA 6.7**	**Carcinogenicity study in mice**	
	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]	

Section 6.7(1) Annex Point IIA 6.7	Carcinogenicity study in mice	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] in mice. Union Carbide, Report No: 53-528, (unpublished) Ref No.: LON 1776	
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 USEPA OPP 83-2 1988	
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 Test animals	[redacted]	
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Satellite group(s)	[redacted]	
3.2.8 Control Animals	[redacted]	
3.3 Administration/ exposure	[redacted]	
3.3.1 Dose route	[redacted]	
Duration of test/exposure	[redacted]	
3.3.3 Frequency of exposure	[redacted]	
3.3.4 Post exposure period	[redacted]	

Section 6.7(1) Annex Point IIA 6.7	Carcinogenicity study in mice	
3.3.5 Concentration	[redacted]	
3.3.6 Vehicle	[redacted]	
3.3.8 Actual dose received	[redacted]	
3.3.9 Controls	[redacted]	
3.4 Examinations	[redacted]	
3.4.1 Observations	[redacted]	
3.4.2 Clinical signs	[redacted]	
3.4.3 Mortality	[redacted]	
3.4.4 Bodyweight	[redacted]	
3.4.5 Food consumption	[redacted]	
3.4.6 Water consumption	[redacted]	
3.4.7 Ophthalmoscopic examination	[redacted]	
3.4.8 Haematology	[redacted]	
3.4.9 Clinical Chemistry	[redacted]	
3.4.10 Urinalysis	[redacted]	
3.5 Sacrifice and pathology	[redacted]	
3.5.1 Organ weights	[redacted]	
3.5.2 Gross and histopathology	[redacted]	
3.5.3 Statistical analysis	[redacted]	
	4. RESULTS	
4.1 Examinations	[redacted]	
4.1.1 Observations	[redacted]	
4.1.2 Clinical signs	[redacted]	
4.1.3 Mortality	[redacted]	
4.1.4 Bodyweight	[redacted]	
4.1.5 Food consumption	[redacted]	

Section 6.7(1) Annex Point IIA 6.7	Carcinogenicity study in mice	
4.1.6 Water consumption	[redacted]	
4.1.7 Ophthalmoscopic examination	[redacted]	
4.1.8 Haematology	[redacted]	
4.1.9 Clinical Chemistry	[redacted]	
4.1.10 Urinalysis	[redacted]	
4.2 Sacrifice and pathology	[redacted]	
4.2.1 Organ weights	[redacted]	
4.2.2 Gross and histopathology	[redacted]	
4.2.3 Statistical analysis	[redacted]	
4.3 LOAEL	[redacted]	
4.4 NOAEL	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	NOEL = 500 ppm (equivalent to 76.3 and 93.1 mg/kg/d for males and females, respectively) The test substance is not considered to be carcinogenic in this strain of mice under the conditions of this study.	
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]	

Section 6.7(1) Annex Point IIA 6.7	Carcinogenicity study in mice
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	Comments from other member state *(specify)*
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 6.7(2) Annex Point IIA 6.7	Carcinogenicity study in rats	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1991) Chronic dietary toxicity/oncogenicity study with [redacted] in rats. Union Carbide, Report No. 53-566. (Unpublished) Ref No. LON 1755	
1.2 Data protection	[redacted]	
1.2.1 Data owner	[redacted]	
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	Yes USEPA Guideline 83-5; OECD Guideline 453 1988	
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 Test Animals		
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.8 Control animals	[redacted]	
3.3 Administration/ exposure	[redacted]	
3.3.1 Route of exposure	[redacted]	
3.3.2 Duration of treatment	[redacted]	
3.3.3 Frequency of exposure	[redacted]	
3.3.4 Post exposure period	[redacted]	

Section 6.7(2) Annex Point IIA 6.7	Carcinogenicity study in rats	
3.3.5 Concentration	[redacted]	
3.3.6 Vehicle	[redacted]	
3.3.7 Total volume applied	[redacted]	
3.3.8 Controls	[redacted]	
3.4 Examinations	[redacted]	
3.4.1 Observations	[redacted]	
3.4.2 Clinical signs	[redacted]	
3.4.3 Mortality	[redacted]	
3.4.4 Bodyweight	[redacted]	
3.4.5 Food consumption	[redacted]	
3.4.6 Water consumption	[redacted]	
3.4.7 Ophthalmoscopic examination	[redacted]	
3.4.8 Haematology	[redacted]	
3.4.9 Clinical Chemistry	[redacted]	
3.4.10 Urinalysis	[redacted]	
3..5 Sacrifice and pathology	[redacted]	
3.5.1 Organ weights	[redacted]	
3.5.2 Gross and histopathology	[redacted]	
3.5.3 Other examinations	[redacted]	
3.5.4 Statistics	[redacted]	
	4. RESULTS	
4.1 Examinations	[redacted]	
4.1.1 Observations	[redacted]	
4.1.2 Clinical signs	[redacted]	
4.1.3 Mortality	[redacted]	
4.1.4 Body weight gain	[redacted]	

Section 6.7(2) Annex Point IIA 6.7	Carcinogenicity study in rats	
4.1.5 Food consumption	[redacted]	
4.1.6 Water consumption	[redacted]	
4.1.7 Opthalmoscopic examination	[redacted]	
4.1.8 Haematology	[redacted]	
4.1.9 Clinical chemistry	[redacted]	
4.1.10 Urinalysis	[redacted]	
4.2 Sacrifice and pathology	[redacted]	
4.2.1 Organ weights	[redacted]	
4.2.2 Gross and histopathology	[redacted]	
4.2.3 Other examinations	[redacted]	
4.2.4	[redacted]	
4.3 LO(A)EL	[redacted]	
4.4 NO(A)EL	[redacted]	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	NOEL = 750 ppm (equivalent to 32 and 41 mg/kg/d for males and females respectively) The test substance is not carcinogenic in this strain of rats under the conditions of this study.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	

Section 6.7(2) Annex Point IIA 6.7	Carcinogenicity study in rats
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	Comments from other member state *(specify)*
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 6.8 Reproductive Toxicity

Annex Point IIA 6.8 – headline only

Section 6.8.1 **Annex Point IIA 6.8.1**	**Teratogenicity test in rats**	
	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]	

Section 6.8.1(1) Annex Point IIA 6.8.1	Teratogenicity test in rats	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1991) Developmental toxicity evaluation of [redacted] administered by gavage to CD® (Sprague-Dawley) rats. Union Carbide, Project No: 53-534. (unpublished) Ref No.: LON 1781	
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 U.S. EPA Guideline 83-3; OECD Guideline 414 1991	
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 Test Animals	[redacted]	
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control animals	[redacted]	
3.3 Administration/ exposure	[redacted]	
3.3.1 Route of exposure	[redacted]	
3.3.2 Duration of treatment	[redacted]	
3.3.3 Frequency of exposure	[redacted]	
3.3.4 Vehicle	[redacted]	

Section 6.8.1(1) Annex Point IIA 6.8.1	Teratogenicity test in rats	
3.3.5 Dose levels	[redacted]	
3.3.6 Concentration in vehicle	[redacted]	
3.3.7 Actual dose administered	[redacted]	
3.3.8 Post exposure period	[redacted]	
3.4 Adult examinations	[redacted]	
3.4.1 Clinical signs	[redacted]	
3.4.2 Mortality	[redacted]	
3.4.3 Bodyweight	[redacted]	
3.4.4 Food consumption	[redacted]	
3.4.5 Water consumption	[redacted]	
3.5 Sacrifice and examinations	[redacted]	
3.5.1 Maternal findings	[redacted]	
3.5.2 Gross necropsy findings	[redacted]	
3.5.3 Organ weights	[redacted]	
3.5.4 Other	[redacted]	
3.5.5 Foetal findings	[redacted]	
3.5.6 Bodyweight	[redacted]	
3.5.7 Gross necropsy findings	[redacted]	
3.5.8 Skeletal examinations	[redacted]	
3.5.9 Visceral examinations	[redacted]	
4.6 Statistics	[redacted]	
4.7 Further remarks	[redacted]	
	4. RESULTS	
4.1 Maternal observations	[redacted]	
4.1.1 Clinical signs	[redacted]	
4.1.2 Mortality	[redacted]	
4.1.3 Body weight gain	[redacted]	
4.1.4 Food consumption	[redacted]	
4.1.5 Gross findings at necropsy	[redacted]	
4.1.6 Other	[redacted]	
4.2 Foetal observations	[redacted]	
4.2.1 Bodyweight	[redacted]	
4.2.2 Gross findings at necropsy	[redacted]	

Section 6.8.1(1) Annex Point IIA 6.8.1	**Teratogenicity test in rats**	
4.2.3 Skeletal findings	[redacted]	
4.2.4 Visceral findings	[redacted]	
4.3 Remarks	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	No developmental toxicity including teratogenicity was observed at any dosage employed. The "no observable effect level" (NOEL) for maternal toxicity was 1 mg/kg/day; the NOEL for developmental toxicity was at least 20 mg/kg/day	
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 *(specify)*	
Date	[redacted]	
Materials and Methods	[redacted]	

Section 6.8.1(1) Annex Point IIA 6.8.1	Teratogenicity test in rats
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 6.8.1(2) Annex Point IIA 6.8.1	Teratogenicity test in rabbits	
	1. REFERENCE	Official use only
1.1 Reference	[redacted]. (1989) Developmental toxicity study of [redacted] administered by gavage to New Zealand white rabbits. Union Carbide, Project No: 51-590 (unpublished) Ref No.: LON 1770	
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 U.S. EPA OPP 83-3 1989	
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 Test Animals	[redacted]	
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control animals	[redacted]	
3.3 Administration/ exposure	[redacted]	
3.3.1 Route of exposure	[redacted]	
3.3.2 Duration of treatment	[redacted]	
3.3.3 Frequency of exposure	[redacted]	
3.3.4 Vehicle	[redacted]	
3.3.5 Dose levels	[redacted]	

Section 6.8.1(2) Annex Point IIA 6.8.1	Teratogenicity test in rabbits	
3.3.6 Concentration in vehicle	[redacted]	
3.3.7 Actual dose administered	[redacted]	
3.3.8 Post exposure period	[redacted]	
3.4 Adult examinations	[redacted]	
3.4.1 Clinical signs	[redacted]	
3.4.2 Mortality	[redacted]	
3.4.3 Bodyweight	[redacted]	
3.4.4 Food consumption	[redacted]	
3.4.5 Water consumption	[redacted]	
3.5 Sacrifice and examinations	[redacted]	
3.5.1 Maternal findings	[redacted]	
3.5.2 Gross necropsy findings	[redacted]	
3.5.3 Organ weights	[redacted]	
3.5.4 Other		
3.5.5 Foetal findings		
3.5.6 Bodyweight	[redacted]	
3.5.7 Gross necropsy findings	[redacted]	
3.5.8 Skeletal examinations	[redacted]	
3.5.9 Visceral examinations	[redacted]	
3.5.10 Statistics	[redacted]	
3.5.10 Further remarks	[redacted]	
	4. RESULTS	
4.1 Maternal observations	[redacted]	
4.1.1 Clinical signs	[redacted]	
4.1.2 Mortality	[redacted]	
4.1.3 Body weight gain	[redacted]	
4.1.4 Food consumption	[redacted]	
4.1.5 Gross findings at necropsy	[redacted]	
4.1.6 Other	[redacted]	
4.2 Foetal observations	[redacted]	
4.2.1 Bodyweight	[redacted]	
4.2.2 Gross findings at	[redacted]	

Section 6.8.1(2) Annex Point IIA 6.8.1	**Teratogenicity test in rabbits**	
necropsy		
4.2.3 Skeletal findings	[redacted]	
4.2.4 Visceral findings	[redacted]	
4.3 Remarks	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	Not teratogenic; increased incidence of dead foetuses and reduced fatal weight at the maternal lethal dose of 10 mg/kg b.w. The "no observable effect level" (NOEL) for maternal toxicity was 1 mg/kg/day; the NOEL for developmental toxicity was at least 10 mg/kg/day.	
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 *(specify)*	
Date	[redacted]	
Materials and Methods	[redacted]	

Section 6.8.1(2) Annex Point IIA 6.8.1	Teratogenicity test in rabbits
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 6.8.2 Annex Point IIA 6.8.2	Two generations reproduction study	
	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]	

Section 6.8.2(1) Annex Point IIA 6.8.2	Two generations reproduction study	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1991) Two-generation reproduction study in Sprague-Dawley (CD®) rats with [redacted] administered in the diet, Union Carbide, Report No. 52-648 (unpublished) Ref No.: LON 1777	
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 U.S. EPA OPP 83-4 1991	
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 Test Animals	[redacted]	
3.2.1 Species	[redacted]	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	[redacted]	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control animals	[redacted]	
3.3 Administration/ exposure	[redacted]	
3.3.1 Route of exposure	[redacted]	
3.3.2 Duration of treatment	[redacted]	

Section 6.8.2(1) Annex Point IIA 6.8.2	Two generations reproduction study	
3.3.3 Frequency of exposure	[redacted]	
3.3.4 Vehicle	[redacted]	
3.3.5 Dose levels	[redacted]	
3.3.6 Concentration in vehicle	[redacted]	
3.3.7 Actual dose administered	[redacted]	
3.3.8 Post exposure period	[redacted]	
3.4 Examinations	[redacted]	
3.4.1 Clinical signs	[redacted]	
3.4.2 Mortality	[redacted]	
3.4.3 Bodyweight	[redacted]	
3.4.4 Food consumption	[redacted]	
3.4.5 Water consumption	[redacted]	
3.5 Sacrifice and pathology	[redacted]	
3.5.1 Organ weights	[redacted]	
3.5.2 Gross and histopathology	[redacted]	
3.5.3 Other examinations	[redacted]	
3.6 Statistics	[redacted]	
3.7 Further remarks	[redacted]	

Section 6.8.2(1) Annex Point IIA 6.8.2	Two generations reproduction study	
	[redacted]	
	4. RESULTS	
4.1 Observations (Parental data)	[redacted]	
4.1.1 Clinical signs	[redacted]	
4.1.2 Mortality	[redacted]	
4.1.3 Body weight	[redacted]	
4.1.4 Gestation period	[redacted]	
4.1.5 Food consumption	[redacted]	
4.1.6 Other	[redacted]	
4.2 Observations (Foetal data)	[redacted]	
4.2.1 Clinical signs	[redacted]	
4.2.2 Mortality	[redacted]	
4.2.3 Body weight	[redacted]	
4.2.4 Other	[redacted]	
4.3 Sacrifice and	[redacted]	

Section 6.8.2(1) **Annex Point IIA 6.8.2**	**Two generations reproduction study**	
pathology		
4.3.1 Gross and histopathology	[redacted]	
4.4 Other	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	Didecyldimethylammonium Chloride was not toxic to reproduction in this study. NOAEL (parental) = 750 ppm NOAEL (F1 offspring) = 750 ppm NOAEL (F2 offspring) = 750 ppm	
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 *(specify)*	

Section 6.8.2(1) Annex Point IIA 6.8.2	Two generations reproduction study
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 6.9 Neurotoxicity study

Section 6.9 Annex Point IIA 6.9	Neurotoxicity study	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
	[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)***	

Section 6.9 Annex Point IIA 6.9	Neurotoxicity study
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]

Section 6.10 Mechanistic study

Section 6.10(1) Annex Point IIA 6.10	Mechanistic study 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]	

Section 6.11 Other routes of administration

Section 6.11(1) Annex Point IIA 6.11	Other routes of administration	
	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]	

Section 6.12 Medical data in anonymous form

Section 6.12 Annex Point IIA. 6.12	Medical data in anonymous form	Official use only
6.12.0 Introductory remark	[redacted]	
6.12.1 Medical surveillance data on manufacturing plant personnel if available	[redacted]	
6.12.2 Direct observation, e.g. clinical cases, poisoning incidents if available	[redacted]	
6.12.3 Health records, both from industry and any other available sources	[redacted]	
6.12.4 Epidemiological studies on the general population, if available	[redacted]	
6.12.5 Diagnosis of poisoning including specific signs of poisoning and clinical tests, if available	[redacted]	
6.12.6 Sensitisation/ allergenicity	[redacted]	

Section 6.12 Annex Point IIA. 6.12	Medical data in anonymous form	Official use only
observations, if available	[redacted]	
6.12.7 Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known	[redacted]	
6.12.8 Prognosis following poisoning	[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 6.13 Toxic effects on livestock and pets

Section 6.13 Annex Point IIA 6.13	Toxic effects on livestock and pets	
	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]	

Section 6.14 Other tests related to the exposure of humans

Section 6.14 Annex Point IIA 6.14	Other tests related to the exposure of humans	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
	[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 6.15 Food and feedingstuffs

Section 6.15.1 Annex Point III-A.6.15.1	Residues in food/feedstuffs	
	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 6.15.2 Annex Point III-A.6.15.2	Behaviour of residues in food/feedstuffs	
	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 6.15.3 Annex Point III-A.6.15.3	Exposure estimation	
	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 6.15.4 Annex Point III-A.6.15.4	Proposed acceptable residues	
	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 6.15.5 Annex Point III-A.6.15.5	Other relevant information (ADI, MRL, etc.)	
	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 6.15.6 Annex Point III-A.6.15.6	Summary of 6.15	
	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 6.16 Other tests related to the exposure of humans

Section 6.16 **Annex Point IIA 6.16**	**Any other tests related to the exposure of the active substance to humans, in its proposed biocidal products that are considered necessary may be required**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
[redacted]		
	[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 6.17 Toxic effects of metabolites from treated plants

Section 6.17 Annex Point IIA 6.17	Toxic effects of metabolites from treated plants JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
	[redacted]	
	Evaluation by Competent Authorities	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
	Comments from other Member State *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	

Section 6.18 Summary of mammalian toxicology and conclusions

Section 6.18 Annex Point IIA. 6.18	Summary of mammalian toxicology and conclusions (in Doc. II-A)	Official use only
Pharmacokinetics	[redacted]	
Acute Toxicity	[redacted]	
Irritation and Sensitization	[redacted]	
Repeated dose toxicity, neurotoxicity and carcinogenicity	[redacted]	

	[redacted]	
Mutagenicity	[redacted]	
Reproduction and Development	[redacted]	
Conclusion	[redacted]	