Section A6.1.2 Acute Toxicity

Annex Point IIA6.1 6.1.2 Acute dermal toxicity in rabbits (Limit test)

Official use only

		1 REFERENCE
1.1	**Reference**	[redacted], 1986, Acute dermal toxicity of ®Preventol A4-S in albino rabbits [redacted], 1986-04-23 (unpublished)
1.2	**Data protection**	Yes
1.2.1	Data owner	Bayer Chemicals AG
1.2.2	Companies with letter of access	—
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes US-EPA-FIFRA Section 158.135, 81-2, US-EPA-TSCA Section 798.1100, Both US-EPA-Guidelines are equivalent to the OECD-Guideline 402.
2.2	**GLP**	Yes
2.3	**Deviations**	No
		3 MATERIALS AND METHODS
3.1	**Test material**	As given in section 2 of dossier.
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2 of dossier.
3.1.2.1	Description	White powder
3.1.2.2	Purity	[redacted]
3.1.2.3	Stability	At least 12 months at room temperature.
3.2	**Test Animals**	
3.2.1	Species	Rabbit
3.2.2	Strain	New Zealand White (Oryctolagus cuniculus)
3.2.3	Source	[redacted]
3.2.4	Sex	Males and females (1:1)
3.2.5	Age/weight at study initiation	Age: adult Weight: 2.65-3.04 kg
3.2.6	Number of animals per group	5 per sex per group
3.2.7	Control animals	No

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3.3	**Administration/ Exposure**	Dermal	
3.3.1	Post-exposure period	14 days	
3.3.2	Area covered	240 cm^2	
3.3.3	Occlusion	Occlusive	
3.3.4	Vehicle	—	
3.3.5	Concentration in vehicle	2000 mg/kg	
3.3.6	Total volume applied	—	
3.3.7	Duration of exposure	24 h	
3.3.8	Removal of test substance	Wiped clean using paper towel dampened with tap water.	
3.3.9	Controls	—	
3.4	**Examinations**	Clinical observations, body weight and necropsy.	
3.5	**Method of determination of LD_{50}**	Not determined.	
		4 RESULTS AND DISCUSSION	
4.1	**Clinical signs**	Erythema at the dosing site which reversed by day 6 after dosing.	
4.2	**Pathology**	No substance-related effects.	
4.3	**Other**	None	
4.4	**LD_{50}**	LD_{50} > 2000 mg/kg for males + females. No lethal effect at maximal dose.	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The study was done according to US-EPA-FIFRA Section 158.135, 81-2, and US-EPA-TSCA Section 798.1100. The acute dermal toxicity of Dichlofluanid was tested in adult New Zealand rabbits at the dermal limit dose of 2000 mg/kg. The purpose of the study was to enable the product to be classified (labelling), and to assess the potential acute health hazard when handling the substance.	
5.2	**Results and discussion**	The dermal treatment with the test substance did not produce any systemic effects on male and female rabbits which would have to be associated with the active ingredient. The only sign of toxicity observed was erythema at the dosing site. No mortality occurred. The no-observed-effect level was < 2000 mg/kg for both sexes.	X
5.3	**Conclusion**	LD_{50} > 2000 mg/kg for males + females.	
5.3.1	Reliability	1	

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5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	28/07/04
Materials and Methods	As described above [IUCLID 5.1.3 1/2]
Results and discussion	The local irritation in this study resolved by day-6 of the observation period.
Conclusion	LD_{50} > 2000 mg/kg for males + females.
Reliability	1
Acceptability	Acceptable
Remarks	The UK CA agrees with the applicants summary and conclusions. However, additional information regarding local irritation has been incorporated.
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

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Table A6_1-1.2 Table for acute dermal toxicity in rabbits

Dose [mg/kg bw]	Toxicological results*	Duration of signs	Time of death	Mortality (%)
males				
2000	0/5/5	1d-6d	—	—
LD_{50} value > 2000 mg/kg bw				
females				
2000	0/5/5	1d-6d	—	—
LD_{50} value > 2000 mg/kg bw				

*first number = number of dead animals

second number = number of animals with signs

third number = number of animals used