Section A6.1.4e Acute Eye Irritation -Rabbit

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			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted]; Acute Eye Irritation / Corrosion Study in the Rabbit of CGA 55186 Tech. (cypermethrin); [redacted] Dates of work: 16 February 1984 – 2 March 1984	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Chimac-Agriphar s.a.	
1.2.2			
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 authorisation	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Protocol in compliance with method B.5. of Directive 92/69/EEC (corresponding OECD guideline 404, adopted 12 May 1981)	
2.2	**GLP**	No GLP was not compulsory at the time the study was performed	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	CGA 55186 tech (cypermethrin cis:trans/40:60)	
3.1.1	Lot/Batch number	307046	
3.1.2	Specification	Deviating from specification given in section 2 as follows	
3.1.2.1	Description	Liquid, viscous	
3.1.2.2	Purity	92.6% w/w	
3.1.2.3	Stability	Stable	X
3.2	**Test Animals**		
3.2.1	Species	Rabbit	
3.2.2	Strain	New Zealand white	
3.2.3	Source	[redacted]	
3.2.4	Sex	Female	
3.2.5	Age/weight at study initiation	12-14 weeks, 2050-2180 g	
3.2.6	Number of animals per group	3	
3.2.7	Control animals	No (left eye of each animal left untreated as a control)	

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3.3	**Administration/ Exposure**	
3.3.1	Preparation of test substance	Test substance was used as delivered
3.3.2	Amount of active substance instilled	0.1 ml
3.3.3	Exposure period	Test item administered only once
3.3.4	Postexposure period	11 days
3.4	**Examinations**	
3.4.1	Ophthalmoscopic examination	No
3.4.1.1	Scoring system	Cornea opacity, iris, conjunctiva and chemosis scored according to the grading system described in method B.5. of Directive 92/69/EEC)
3.4.1.2	Examination time points	60min, 24h, 48h, 72h, and again during the following observation period with slit-lamp
3.4.2	Other investigations	None
3.5	**Further remarks**	-
		4 RESULTS AND DISCUSSION
4.1	**Clinical signs**	Slight to severe irritation and swelling
4.2	**Average score**	According to EU methodology:
4.2.1	Cornea	24+48+72 h =0/0/0
4.2.2	Iris	24+48+72 h = 0/0/0
4.2.3	Conjunctiva	
4.2.3.1	Redness	24+48+72 h = 2/1.3/1.6
4.2.3.2	Chemosis	24+48+72 h = 1/0.33/0.66
4.3	**Reversibility**	Yes
		All effects reversed by the end of the 11 day observation period
4.4	**Other**	All animals showed normal body weight development
4.5	**Overall result**	Irritant but not corrosive
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	Acute eye irritation/corrosion in the rabbit of 0.1 ml cypermethrin
5.2	**Results and discussion**	Cypermethrin is irritant but not corrosive to rabbit eye
5.3	**Conclusion**	Cypermethrin is slightly irritant but does not require classification
5.3.1	Reliability	1
5.3.2	Deficiencies	No. Study was evaluated and accepted under Directive 91/414/EC

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	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	March, 2007.
Materials and Methods	The applicant's version is acceptable with the following amendments: 3.1.2.3 Stability: data not shown.
Results and discussion	Revision of results: See table A6_1_4_E-1. Results of eye irritation study.
Conclusion	The applicant's version is adopted: Cypermethrin is slightly irritant but does not require classification.
Reliability	1
Acceptability	acceptable
Remarks	-
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

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Appendix

Table A6_1_4_E-1. Results of eye irritation study

	Cornea	Iris	Conjunctiva	
			redness	chemosis
score	0 to 4	0 to 2	0 to 3	0 to4
Average score (EU methodology) 24h+48h+72h for each animal	**0/0/0**	**0/0/0**	**2/1.33/1.67**	**1/0.33/0.67**
Individual data:				
60 min	0/0/0	0/0/0	3/3/3	2/3/3
24 h	0/0/0	0/0/0	3/2/3	1/2/2
48 h	0/0/0	0/0/0	2/1/1	1/0/0
72 h	0/0/0	0/0/0	1/1/1	1/0/0
7 days	0/0/0	0/0/0	1/1/0	0/0/0
11 days	0/0/0	0/0/0	0/0/0	0/0/0
Area effected				
Maximum average score (including area affected, max 110)				
Reversibility*	c	c	c	c
average time for reversion				
Give method of calculation maximum average score. * *c :* *completely reversible* *n c :* *not completely reversible* *n :* *not reversible*				