

Section A6.12**Human Case Report****Annex Point IIA6.12**

6.12.6 Sensitisation/allergenicity observations

		1 REFERENCE	
1.1 Reference		██████████ (1987): Euparen: Epicutaneous testing for skin allergenic potential to volunteers. ██████████, 9-JUN-1987, unpublished.	
1.2 Data protection		Yes	
1.2.1 Data owner		██████████	
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 (NOT APPLICABLE)	
		3 MATERIALS AND METHODS	
3.1 Substance		Dichlofluanid ("Euparen")	
3.2 Persons exposed			
3.2.1 Sex		10 males, 1 female	
3.2.2 Age/weight		Not specified.	
3.2.3 Known Diseases		–	
3.2.4 Number of persons		11	
3.2.5 Other information		–	
3.3 Exposure		–	
3.3.1 Reason of exposure		Not specified.	
3.3.2 Frequency of exposure		–	
3.3.3 Overall time period of exposure		–	
3.3.4 Duration of single exposure		–	
3.3.5 Exposure concentration/dose		–	
3.3.6 Other information		–	
3.4 Examinations		Occlusive epicutaneous test.	
3.5 Treatment		–	
3.6 Remarks		–	

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		4 RESULTS
4.1 Clinical Signs	–	
4.2 Results of examinations		Except for one person, no positive reactions were determined among the 11 tested volunteers known to have previously handled Euparen. In the one positive case, no definite reaction could be determined following 24-hour skin contact under occlusive conditions; positive assessments (slight erythema) were made after 48 and 72 hours.
4.3 Effectivity of medical treatment	–	
4.4 Outcome	–	
4.5 Other	–	
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1 Materials and methods		A study using volunteers with proven contact with Euparen was conducted. Various █████ consulting offices nominated relevant candidates, who were then subjected to epicutaneous testing by local dermatologists. A solution of 2 g Euparen/100 ml water was applied occlusively, and in some cases openly, to the dorsal skin of the volunteers at dilutions of 1:10, 1:100, and occasionally 1:1000.
5.2 Results and discussion		Except for one person, no positive reactions were determined among the 11 tested volunteers known to have previously handled Euparen. The results were considered positive in one case. No definite reaction could be noted after 24 h of exposure. The positive assessments were made at 48 and 72 hours. A clear reaction would be expected after 24 hours if the substance had a definite skin allergenic potential. The slight signs of erythema observed after 48 and 72 hours cannot be attributed to the substance with any certainty, as the volunteer also proved to be allergic to clinical dressing tape. The test concentration of 1:10 which resulted in weak positive reactions in this volunteer produced no reactions among the other 10 subjects. No reaction was noted in any of the volunteers at a dilution of 1:100.
5.3 Conclusion		The results indicate that Euparen does not have a skin allergenic potential to humans.

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	9/02/05
Materials and Methods	The UK CA agrees with the applicant's version
Results and discussion	The UK CA agrees with the applicant's version
Conclusion	The UK CA agrees with the applicant's version
Remarks	
COMMENTS FROM ... (specify)	
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	