

Section A6.12**Human Case Report****Annex Point IIA6.12(2)**

6.12.1 Medical surveillance data on manufacturing plant personnel (2)

		1 REFERENCE	
1.1 Reference		Faul, J. (1989): Euparen and Euparen M – In-Company Occupational Medical Experience. Bayer AG, 04-SEP-1989, unpublished.	
1.2 Data protection		Yes	
1.2.1 Data owner		Bayer CropScience AG	
1.2.2 Companies with letter of access		Bayer Chemicals AG	
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”) Annual production volume at Dormagen plant: ~900 metric tons.	
3.2 Persons exposed			
3.2.1 Sex		–	
3.2.2 Age/weight		–	
3.2.3 Known Diseases		–	
3.2.4 Number of persons		~45	
3.2.5 Other information		–	
3.3 Exposure		–	
3.3.1 Reason of exposure		Occupational	
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		Height, weight, respiratory flexibility of the chest, functional test of the spine, blood sedimentation rate, blood count, urinary status, SGPT, selective fluorine discharge in the urine, lung function test, chest X-ray, γ -GT	
3.5 Treatment		–	
3.6 Remarks		–	

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		4 RESULTS
4.1 Clinical Signs		No adverse somatic effects were determined.
4.2 Results of examinations		–
4.3 Effectivity of medical treatment		–
4.4 Outcome		–
4.5 Other		–
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1 Materials and methods		Workers of the FU II/III plant complex (Bayer Dormagen) have been subjected for about 20 years to an annual occupational medical examination in accordance with Guideline G 34 of the German Industrial Occupations Association (Berufsgenossenschaft).
5.2 Results and discussion		Except for two cases of allergic skin disease, no adverse somatic effects or disturbances in condition attributable to contact with the active ingredient could be determined over the 20-year observation period.
5.3 Conclusion		No adverse somatic effects were reported.

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	
Results and discussion	
Conclusion	
Remarks	The UK CA agrees with the applicants assesment.
	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	