Section A6.12 Human Case Report

Annex Point IIA6.12(2) 6.12.1 Medical surveillance data on manufacturing plant personnel (2)

Official use only

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 Bayer AG, 04-SEP-1989, unpublished.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: [redacted].
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**	–

Section A6.12 Human Case Report

Annex Point IIA6.12(2) 6.12.1 Medical surveillance data on manufacturing plant personnel (2)

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 applicant's assessment.
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*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*
Remarks	