Section A6.12 Human Case Report

Annex Point IIA6.12(4) 6.12.1 Medical surveillance data on manufacturing plant personnel (4)

Official use only

		1 REFERENCE
1.1	**Reference**	Kehrig, B. & W. Steffens (2003): Occupational Medical Experiences with Dichlofluanid in the FL-Plant, Dormagen. Bayer AG, 19-DEC-2003, unpublished.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") Production period: since [redacted] Annual production volume at FL 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	15
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**	Full physical examination with orientating neurological status (reflexes, sensibility, coordination) and skin status Laboratory examinations: blood sedimentation rate, blood count, AST, ALT, γ-GT, creatinine, cholesterol, glucose, urine status Technical examinations: audiogrann, ergometry, visual acuity testing, spirography, chest X- ray, sonography (if necessary)

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3.5	**Treatment**	–
3.6	**Remarks**	–
		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**	Occupational medical surveillance of workers exposed to dichlofluanid was performed annually on a routine basis, not directly related to exposures, since 1986.
5.2	**Results and discussion**	The routine occupational medical surveillance did not reveal any adverse effects. During the formulation periods since 1986, no accidents with dichlofluanid occurred in the workers and no consultations of the medical department due to work or contact with dichlofluanid were required.
5.3	**Conclusion**	No adverse effects could be determined.

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	