Section A6.12 Human Case Report

Annex Point IIA6.12(5) 6.12.1 Medical surveillance data on manufacturing plant personnel (5)

Official use only

		1 REFERENCE
1.1	**Reference**	Ochs, U. & R. Heyne (2004): Occupational Medical Experiences with Dichlofluanid. Bayer Industry Services. 21-JAN-2004, unpublished.
1.2	**Data protection**	Yes
1.2.1	Data owner	Bayer Chemicals AG
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") Plant: LDF plant Uerdingen Production period: [redacted] Annual production volume at LDF 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	75
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: urine status and sediment, further examinations as required Technical examinations: audiogram, ergometry, visual acuity testing
3.5	**Treatment**	–

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3.6	**Remarks**	–
		4 RESULTS
4.1	**Clinical Signs**	No clinical symptoms were noted.
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 every three years on a routine basis, not directly related to exposures, since 1990.
5.2	**Results and discussion**	The routine occupational medical surveillance did not reveal any adverse effects. During the production period [redacted], no accidents with dichlofluanid occurred in the workers and no consultations of the medical department due to work or contact with dichlofluanid were required. No contact sensitizations have been seen.
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	