Section A7.1.1.2.1

Annex Point IIA7.6.1.1

Biodegradability (ready) of

DIMETHYLAMINOSULFANILID (DMSA) (1)

			Official use only
	1	**REFERENCE**	
1.1	**Reference**	G. Mueller, 1999, Investigation of the ecological properties of DMSA, Bayer AG, Institute of environmental analysis, Leverkusen, Germany, Report No. 770 A/98 (= study number) (unpublished), 1999-04-29	
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**	
2.1	**Guideline study**	Yes, Council directive 92/69 EEC, method C.4-D (OECD guideline No. 301 F)	
2.2	**GLP**	Yes	
2.3	**Deviations**	Yes, the following deviation is mentioned in the report: adaption to the test substance over a period of four weeks with 100 mg/l test substance as sole C-source.	
	3	**MATERIALS AND METHODS**	
3.1	**Test material**	Dimethylaminosulfanilid (DMSA)	
3.1.1	Lot/Batch number	███████████	
3.1.2	Specification		X
3.1.3	Purity	████	
3.1.4	Further relevant properties	-	X
3.1.5	Composition of Product	-	
3.1.6	TS inhibitory to microorganisms	EC50 = 1140 mg/l (result of the respiration inhibition test with activated sludge; study number 689 A/97 B, 1998-01-30, amended 2002-09-03)	
3.1.7	Specific chemical analysis	There was no specific chemical analysis conducted in addition to the BOD measurement during the study.	X
3.2	**Reference substance**	Yes, Aniline (Purity 99.5%)	
3.2.1	Initial concentration of reference substance	100 mg/l	
3.3	**Testing procedure**		

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3.3.1	Inoculum / test species	Test organism was a mixed population of aquatic microorganisms (activated sludge) from the aeration tank of a waste water plant treating predominantly domestic sewage (Wupper area water authority). Without pre-treatment.	X
3.3.2	Test system	The test was performed in test flasks. The oxygen consumption was determined using a respirometer.	X
3.3.3	Test conditions	Flask 20, 21, 22: activated sludge + dimethylaminosulfanilid Flask 12, 15, 16: blank control Flask 17, 18, 19: activated sludge + Aniline Flask 23, 24: toxicity control; Concentration of activated sludge in the test flasks: 30 mg ss/l; Test temperature was 20 ± 1 °C	X
3.3.4	Method of preparation of test solution	Direct weighing of the test substance	
3.3.5	Initial TS concentration	100 mg/l (Theoretical oxygen demand: 1598 mg O_2/g)	
3.3.6	Duration of test	28 days	
3.3.7	Analytical parameter	Biological oxygen demand (BOD)	
3.3.8	Sampling	Measurements of the BOD in the test flasks were performed after 2, 6, 8, 10, 14, 16, 20, 22, 24 and 28 days	X
3.3.9	Intermediates/ degradation products	Not identified	
3.3.10	Nitrate/nitrite measurement	No	X
3.3.11	Controls	Blank control and toxicity control	
3.3.12	Statistics	n.a.	

4 RESULTS

4.1 Degradation of test substance

4.1.1	Graph	Provided in the report	X
4.1.2	Degradation	63% biodegradability after 28 days	
4.1.3	Other observations	No	X
4.1.4	Degradation of TS in abiotic control	No abiotic degradation performed	
4.1.5	Degradation of reference substance	A degradation of 81% was achieved for Aniline within 14 days, 95% after 28 days (degradation curve is given in the report on page 16).	
4.1.6	Intermediates/ degradation products	n.a.	

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		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	Materials and methods	The biodegradability test of dimethylaminosulfanilid (DMSA) was performed according to the Council directive 92/69 EEC, method C.4-D (Manometric Respirometry) (OECD guideline No. 301 F). The test substance is suspended in a mineral medium, inoculated with a mixed population of aquatic microorganisms and incubated for 28 days under aerobic conditions in the dark. During this period the biodegradation of the test substance is determined by registrating the oxygen consumption.	
		The following deviation is mentioned in the report: Adaption to the test substance over a period of four weeks with 100 mg/l test substance as sole C-source.	
5.2	Results and discussion	The biodegradability of the test substance dimethylaminosulfanilid (DMSA) was determined to be 63% after 28 days.	
		A degradation of 81% was achieved for the reference substance Aniline within 14 days, 95% after 28 days.	
		Theoretical oxygen demand: test substance: 1598 mg O_2/g, reference substance: 2409 mg O_2/g.	
		The used concentrations of the test substance did not show toxic effects to bacteria (toxicity control).	
5.3	Conclusion	The validity criteria can be considered as fulfilled.	X
		The test substance is biodegradable, so it may be widely eliminated from the surface water.	
5.3.1	Reliability	2	
5.3.2	Deficiencies	Yes,	
		no data about the composition of the mineral medium and pH	

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Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	25/11/04
Materials and Methods	Applicant's version is acceptable with the following comments:
	3.1.2 Specification details have not been provided.
	3.1.4 No further relevant properties were given, although the water solubility of DMSA should have been quoted.
	3.1.7 Specific analysis of the test substance or any transformation products was not carried out.
	3.3.1 No pre-treatment of the inoculum is stated. However, it is adapted to the test substance as sole C-source for 4 weeks (according to the deviation in 2.3), and this could increase the likelihood of the test substance meeting the criteria for ready biodegradation.
	3.3.2 and 3.3.3 Details on the test system and conditions are incompletely reported. There is no mention of the medium used or pH.
	3.3.8 The lack of daily measurements of BOD has made it difficult to evaluate the 10-day window criteria.
	3.3.10 No nitrate/nitrite measurement made although DMSA is N-containing and nitrification could affect the interpretation of the BOD measurements.
Results and discussion	Applicant's version is acceptable with the following comments:
	4.1.1 The data given in the report (graph) support the result of 63 % degradation in 28 days. The graph also indicates that the 10 % degradation level is reached around day 3, and the 60 % degradation level is achieved around day 14.
	4.1.3 A plateau was observed in the data from day 14 - 28 (at about 60 % degradation level) which could indicate a more persistent metabolite.
Conclusion	Applicant's version is acceptable with the following comment:
	5.3 As the 10 day window criteria was not met (10 – 60 % estimated over 11 days) and the sludge had been pre-adapted the test substance cannot be classified as readily biodegradable.
	However the UK CA considers that the study remains acceptable as pre-conditioning of aquatic environment to DMSA is highly likely where the use of existing products containing dichlofluanid (parent compound) are allowed (i.e. UK PT 8 and 14). The UK CA therefore regards this study to be representative of a simulation test and the endpoint valid for use in risk assessment.
	The plateau observed at about 60 % degradation level (from day 14 - 28) could indicate the presence of a more persistent metabolite, which may or may not be present as bound or non-bound residues.

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Reliability	2
Acceptability	Acceptable
Remarks	All endpoints and data presented in the summary and tables have been checked against the original summary and are correct.

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *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*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	