

Section A7.1.1.1 Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA7.6.2.1

artificial seawater

		Official use only
1 REFERENCE		
1.1 Reference	K. Erstling, 2001, Abiotic degradation, Bayer AG, Zentrale Analytik, Leverkusen, Germany, Report No. G 01/0142/01 LEV (unpublished), 2001-10-19	
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, EG guideline 92/69, method C.7 (OECD guideline No. 111)	
2.2 GLP	Yes	
2.3 Deviations	No	
3 MATERIALS AND METHODS		
3.1 Test material	Dichlofluanid (Preventol A 4-S)	
3.1.1 Lot/Batch number	██████████	
3.1.2 Specification	As given in section 2 of dossier	
3.1.3 Purity	Content of test substance: ██████	
3.1.4 Further relevant properties	-	X
3.1.5 Composition of Product	-	X
3.1.6 Specific chemical analysis	The concentrations of the test compound in the test solutions were analysed by HPLC under the conditions showed in table A7_1_1_1_1-1.	X
3.2 Reference substance	No	X
3.2.1 Initial concentration of reference substance	-	
3.3 Testing procedure		X
3.3.1 Test medium	The test medium was artificial seawater which was prepared according to ASTM destination: D 1141-90. The composition of the artificial seawater is shown in table A7_1_1_1_1-2.	
3.3.2 Test system	As given in EG guideline 92/69, method C.7 (OECD guideline No. 111)	
3.3.3 Test conditions	The test was conducted at different temperatures:	

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		10, 20 and 25 °C;	
		The pH value of the artificial seawater was adjusted to 8.2	
3.3.4	Method of preparation of test solution	As given in EG guideline 92/69, method C.7	
3.3.5	Initial TS concentration	Not mentioned	X
3.3.6	Duration of test	Duration of the tests is different depending on the test temperatures: 10 °C: approx. 5.5 hours, 20 °C: approx. 3.5 hours, 25 °C: approx. 1.5 hours	
3.3.7	Analytical parameter	Determination of the test compound concentrations in the test solutions.	X
3.3.8	Sampling	Sampling was performed at different time intervals during the experiments.	X
3.3.9	Intermediates/ degradation products	Not identified	X
3.3.10	Controls	No controls performed	X
3.3.11	Statistics	The calculation of the half times and the reaction constants were based on linear regression (ln c versus t and ln k versus T ⁻¹ , respectively) following the first order concentration-time law.	
		4 RESULTS	
4.1	Degradation of test substance		X
4.1.1	Graph	Provided in the report	X
4.1.2	Degradation	Results of the degradation test see table A7_1_1_1_1-3	
4.1.3	Other observations	No	
4.1.4	Degradation of TS in abiotic control	No abiotic control performed	X
4.1.5	Degradation of reference substance	-	
4.1.6	Intermediates/ degradation products	n.a.	X
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	Materials and methods	The abiotic degradation test of dichlofluanid in artificial seawater was performed according to the EG guideline 92/69, method C.7 (OECD guideline No. 111). The study shows no significant deviations from the test guideline.	

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5.2	Results and discussion	<p>Results of the degradation test are given in A7_1_1_1_1-3.</p> <p>The half times are determined to be 3.269, 1.205 and 0.767 hours at 10, 20 and 25 °C respectively.</p> <p>The degradation reactions are given by pseudo-first order reactions.</p> <p>The correlation coefficient for $\ln k$ versus T^{-1} was calculated; the value of -0.99994 proves the correctness of the results.</p>
5.3	Conclusion	<p>Validity criteria can be considered as fulfilled.</p> <p>The test substance is degradable according to EG guideline 92/69, method C.7 (OECD guideline No. 111) at pH 8.2 in artificial seawater.</p>
5.3.1	Reliability	2
5.3.2	Deficiencies	Yes, no initial test substance concentration mentioned

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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	11/11/04
Materials and Methods	<p>Applicant's version is acceptable with the following comments:</p> <p>3.1.4 No information is given on the solubility of Preventol A4-S in seawater</p> <p>3.1.5 and 3.1.6 These sections have been created and are not part of the Technical Notes on Guidance.</p> <p>3.2 No reference substance used.</p> <p>3.3 This section should be 'Test Solution' according to the Technical Notes for Guidance. 'Test Solution' information appears to be given under 3.3.4, whilst the 'Testing Procedures' section should be numbered 3.4. The sub-section headings given within the 'Testing Procedures' section do not match those in the Technical Notes on Guidance, but cover most of the information required. No replicates appear to have been used in this study.</p> <p>3.3.5 The initial test substance concentration is not mentioned, although appears to be around 400 mg/l.</p> <p>3.3.7 (and 3.1.6) The analytical details do not mention the use of standards, method of calibration or quantification. The retention time for dichlofluanid is not given, and there is no indication of whether any breakdown products could interfere with the measurements.</p> <p>3.3.8 Sampling intervals are given in the report, but not in the summary.</p>
Results and discussion	<p>Applicant's version is acceptable with the following comments:</p> <p>4.1 The section heading should be 'Concentration and Hydrolysis Values' and not 'Degradation of the Test Substance' according to the Technical Notes on Guidance. The sub-section headings within this section do not match either sub-section or section headings as defined for '4. Results' within the Technical Notes on Guidance.</p> <p>4.1.1 Graphs and tabulated results are given in the report, but not in the summary. They are reported as being for Preventol A4-S but it is not clear whether they are for the preparation or dichlofluanid <i>per se</i>.</p> <p>4.1.6 (and 3.3.9) Transformation products were not identified</p>
Conclusion	Applicant's version is acceptable
Reliability	2
Acceptability	<p>Acceptable</p> <p>The reporting of this study is not in line with format given in the Technical Notes on Guidance. However most of the relevant data are included.</p>
Remarks	All endpoints and data presented in the summary and tables have been checked against the original summary and are correct.

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breakdown products**

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	COMMENTS FROM ...
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>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</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>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Table A7_1_1_1-1 Conditions for the analysis of the test solutions

Criteria	Details
Procedure	HPLC
Column type	Length: 250 mm, inner diameter: 4.0 mm
Stationary phase	LiChrospher 100 RP 18, particle diameter: 5 µm
Mobile phase	250 ml demineralised water adjusted to pH 2.5 with phosphoric acid (w = 0.85) + 750 ml acetonitrile
Flow rate	1.0 ml/min., isocratic conditions
Column temperature	40 °C
Detection	UV, 196 nm
Injection volume	100 µl

Table A7_1_1_1-2 Composition of the test medium (*artificial seawater*)

Compound	Concentration (g/l)
NaCl	24.50
MgCl ₂	5.2
NaSO ₄	4.09
CaCl ₂	1.160
KCl	0.6948
NaHCO ₃	0.2015
KBr	0.1011
H ₃ BO ₃	0.0273
SrCl ₂	0.025
NaF	0.0032

A pH value of 8.2 was adjusted by adding sodium hydroxide solution

Table A7_1_1_1-3: Results of degradation

Temperature [°C]	Half-time, t (1/2) [h]	Rate constant, k [sec ⁻¹]	Correlation coefficient, r ²
10	3.269	5.88994 x 10 ⁻⁰⁵	0.99947
20	1.205	1.59734 x 10 ⁻⁰⁴	0.99935
25	0.767	2.51110 x 10 ⁻⁰⁴	0.99913