

Draft Assessment Report (DAR)

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**Initial risk assessment provided by the rapporteur Member State
The Netherlands for the existing active substance**

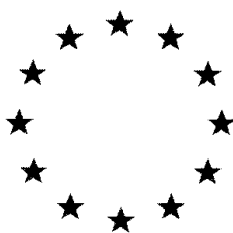
ETRIDIAZOLE

**of the third stage (part B) of the review programme
referred to in Article 8(2) of Council Directive 91/414/EEC**

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ETRIDIAZOLE

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Annex B

Rapporteur Member State: The Netherlands

April 2007

Draft Assessment Report and Proposed Decision of the Netherlands prepared in the context of the possible inclusion of etridiazole in Annex I of Council Directive 91/414/EEC

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WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

B.1 Identity

B.1.1 Identity of active substance (Annex IIA 1 and 3.1)

All points of Annex IIA, Section I are addressed in Volume 1, Level 1.

B.1.2 Identity of the plant protection product (Annex IIIA 1)

All points of Annex IIIA, Section 1 are addressed in Volume 1, Level 1.

B.1.3 References relied on

No specific references for this section.

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

B.2 Physical and chemical properties

B.2.1 Physical and chemical properties of the active substance (Annex IIA 2)

See Table B.2.1.

B.2.2 Physical, chemical and technical properties of the plant protection product (Annex IIIA 2)

See Table B.2.2.

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

Table B.2.1-1 Summary of the physical and chemical properties of the active substance (studies were conducted under GLP and completed to an acceptable standard and results were considered to be valid unless specified otherwise).

section (Annex point)	study	purity	method	results	comment	reference
B.2.1.1 (IIA 2.1)	Melting point	99.7%	OECD 102, freezing temperature.	22.0°C		Riggs, 2001
B.2.1.2 (IIA 2.1)	Boiling point	99.3%	OECD 103, dynamic method.EEC method A 2	113°C at reduced pressure (0.53 kPa Measure up to 360°C)		Riggs, 2001
B.2.1.3 (IIA 2.1)	Thermal stability				Up to a temperature of 113°C (boiling point at reduced pressure) no decomposition was observed.	
B.2.1.4 (IIA 2.2)	Relative density	99.7%	OECD 109, oscillating density meter.	1.497 at 25°C.		Riggs, 2001
B.2.1.5 (IIA 2.3)	Vapour pressure	Tech. a.s.	OECD 104, gas saturation method.	0.01073 mm Hg at 25°C (equivalent to 1.43 Pa, calculated by RMS)	The vapour pressure of the purified material should have been determined. However, a specific method was used and based on the composition of the technical material (purity ≥96%) no significant influence of the impurities on the vapour pressure is expected. Study acceptable.	Thomson, 1993
B.2.1.6 (IIA 2.3)	Volatility, Henry's law constant		Calculation.	3.02 Pa.m ³ .mol ⁻¹ at 25°C	A vapour pressure of 1.43 Pa and a water solubility of 117.1 mg/L were used to calculate	

section (Annex point)	study	purity	method	results	comment	reference
B.2.1.7 (IIA 2.4)	Appearance: physical state	99.7% Tech. a.s. 98.9%	EPA 63-3, visual assessment.	Pure material at 20°C: semisolid (mixture of a clear, colourless solid and a clear colourless liquid). Pure material at 25°C: liquid with low viscosity and volatility. Technical material at 20°C: semisolid (mixture of a clear, colourless solid and a yellow liquid). Technical material at 25°C: liquid with low viscosity and volatility.	the Henry's law constant.	Riggs, 2001
B.2.1.8 (IIA 2.4)	Appearance: colour	99.7% Tech. a.s. 98.9%	EPA 63-2, ASTM D1535	Pure material at 20°C and 25°C: clear and colourless. Technical material at 20°C: clear colourless solid and yellow liquid with Munsell notation 5Y 9.0/8.0 Technical material at 25°C: yellow liquid with Munsell notation 4Y 8.5/8.0		Riggs, 2001
B.2.1.9 (IIA 2.4)	Appearance: odour	99.7% 98.9%	EPA 63-4, olfactory assessment.	Pure material at 20°C and 25°C: sweet sulphurous odour. Technical material at 20°C and 25°C: strong sour pungent odour.		Riggs, 2001
B.2.1.10 (IIA 2.5)	Spectra	99.7%	Standard UV/Vis, IR, NMR and MS methodology.	UV/Vis-spectrum: acetonitrile solution, 0.2891x10 ⁻³ mol/L. Molar absorption coefficient at 220 nm: 5444 L/(molxcm). The maximum molar absorption coefficient of etridiazole (99.6%) over the range 290 to 800 nm was calculated to be 2.13 L/(molxcm) at 290 nm (see section B.2.1.16).		Blaszczynski, 2003

section (Annex point)	study	purity	method	results	comment	reference
B.2.1.11 (IIA 2.6)	Solubility in water	Tech. a.s.	EPA D-63-8	determined. The results supported the structure of Etridiazole. 117.1 mg/L in water at 25°C; 85.8 mg/L in buffer pH 4 at 25°C; 88.9 mg/L in buffer pH 7 at 25°C; 89.7 mg/L in buffer pH 10 at 25°C.	Method does comply with EEC A.6. The test was performed with the technical material instead of the purified material; however, based on the composition of the technical material (purity ≥96%) no significant influence of the impurities on the water solubility is expected. Study acceptable.	Mitchell, 1993
B.2.1.12 (IIA 2.7)	Solubility in organic solvents	Tech. a.s. 99.5%	Direct addition, visual assessment.	At 20°C Etridiazole is miscible in all proportions with n-Heptane, toluene, xylenes, dichloromethane, 1,2-dichloroethane, methanol, acetone, ethyl acetate and n-octanol	<0.1 mg/l very slightly soluble 0.1-10 slightly soluble 10-1000 moderately soluble >1000 readily soluble	Riggs, 2004
B.2.1.13 (IIA 2.8)	Partition co-efficient	98.2%	EPA D PB 83-153890, flask-shaking method.	Log P _{ow} (aqueous pH7 buffer/n-octanol) at 26°C to 27.5°C: 3.37	Not GLP, performed in 1987 (predated to GLP). Method does comply with EEC A.8.	Batorewicz, 1987

section (Annex point)	study	purity	method	results	comment	reference																																																						
B.2.1.15 (IIA 2.9)	Hydrolysis rate	Etridia zole (Terra zole) 3-C ¹⁴ , purity 98%	Guideline not specified.	<p>The hydrolysis half-life at about 50 mg/L at 25°C in distilled water, 0.01M phosphate buffered solutions of pH 5.2, 7.1 and 8.9 in the dark was 98, 92, 98, and 88 days, respectively.</p> <p>The acid, 3-carboxy-5-ethoxy-1,2,4-thiadiazole was the only product of hydrolysis (65-72% AR). In an additional study the following half-life days were obtained at;</p> <p>25°C:</p> <table><tr><th>Buffer (pH)</th><th>Concentration (mg/L)</th><th>Half-life (days)</th></tr><tr><td>3.0</td><td>6.23</td><td>96</td></tr><tr><td>6.0</td><td>6.23</td><td>98</td></tr><tr><td>9.3</td><td>6.23</td><td>97</td></tr></table> <p>35°C:</p> <table><tr><th>Buffer (pH)</th><th>Concentration (mg/L)</th><th>Half-life (days)</th></tr><tr><td>3.0</td><td>6.23</td><td>32</td></tr><tr><td>6.0</td><td>6.23</td><td>31</td></tr><tr><td>9.3</td><td>6.23</td><td>24</td></tr><tr><td>3.0</td><td>43.6</td><td>33</td></tr><tr><td>6.0</td><td>40.0</td><td>32</td></tr><tr><td>9.3</td><td>55.6</td><td>30</td></tr></table> <p>45°C:</p> <table><tr><th>Buffer (pH)</th><th>Concentration (mg/L)</th><th>Half-life (days)</th></tr><tr><td>3.0</td><td>6.23</td><td>11</td></tr><tr><td>6.0</td><td>6.23</td><td>12</td></tr><tr><td>9.2</td><td>6.23</td><td>5.9</td></tr><tr><td>3.2</td><td>40.0</td><td>9.3</td></tr><tr><td>6.0</td><td>58.0</td><td>13.2</td></tr><tr><td>9.2</td><td>59.4</td><td>8.4</td></tr></table>	Buffer (pH)	Concentration (mg/L)	Half-life (days)	3.0	6.23	96	6.0	6.23	98	9.3	6.23	97	Buffer (pH)	Concentration (mg/L)	Half-life (days)	3.0	6.23	32	6.0	6.23	31	9.3	6.23	24	3.0	43.6	33	6.0	40.0	32	9.3	55.6	30	Buffer (pH)	Concentration (mg/L)	Half-life (days)	3.0	6.23	11	6.0	6.23	12	9.2	6.23	5.9	3.2	40.0	9.3	6.0	58.0	13.2	9.2	59.4	8.4	Not GLP, performed in 1975 (predated to GLP). Half-life's were calculated by RMS. Study methods agreed with OECD 111. Study acceptable.	Thomas, 1975
Buffer (pH)	Concentration (mg/L)	Half-life (days)																																																										
3.0	6.23	96																																																										
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9.2	6.23	5.9																																																										
3.2	40.0	9.3																																																										
6.0	58.0	13.2																																																										
9.2	59.4	8.4																																																										

section (Annex point)	study	purity	method	results	comment	reference
				Data indicate that the rate of hydrolysis increases with temperature and at pH of 9. Oxalic acid was identified at pH 9, 45°C and 50 mg/L level as a product of hydrolysis in addition to 3-carboxy-5-ethoxy-1,2,4-thiadiazole.		
B.2.1.16 (IIA 2.9)	Photochemical degradation	99.6%	Standard UV/Vis methodology.	The maximum molar absorption coefficient of etridiazole (99.6%) over the range 290 to 800 nm was calculated to be 2.13 L/(molxcm) at 290 nm.	Since no molar absorption coefficient value was greater than 10, an aqueous photolysis study is not needed.	Dzialo, 2001
B.2.1.17 (IIA 2.9)	Quantum yield		Statement	Since etridiazole does not appreciably absorb light in wavelengths relevant to natural sunlight, the first-order aqueous photodegradation rate constant was not determined. Consequently, the quantum yield of etridiazole was also not determined.	The statement is acceptable.	Schocken, 2001
B.2.1.18 (IIA 2.9)	Dissociation constant (pKa)	98.2%	EPA D 63-10, spectrophotometric method.	Pka = 2.77 at 25°C		Thomson, 1993
B.2.1.19 (IIA 2.10)	Stability in air, photochemical oxidative degradation		Atkinson Calculation	Half-life in air based on hydroxyl radical concentration of 1.56×10^6 OH/cm ³ (12-h day time): 1.556 days (18.674 hours).		Schocken, 2001
B.2.1.20 (IIA 2.11)	Flammability and auto-flammability (technical active substance)	Tech. a.s. 99.8%	EEC A.15	A.15, auto-ignition temperature: 342°C A.10, flammability: not applicable for liquids.		Tremain, 2001
B.2.1.21 (IIA 2.12)	Flash point (technical active substance)	Tech. a.s. 99.8%	EEC A.9, closed-cup.	111°C		Tremain, 2001
B.2.1.22 (IIA 2.13)	Explosive properties (technical active)	Tech. a.s. 99.8%	EEC A.14, fall hammer and Koenen test.	Not explosive.		Tremain, 2001

section (Annex point)	study	purity	method	results	comment	reference
	substance)					
B.2.1.23 (IIA 2.15)	Oxidising properties (technical active substance)	Tech. a.s.	Not specified.	No oxidizing or reducing properties.	Method does comply with EPA D 63-14. Oxidizing and reducing characteristics were determined through contact with water, ammonium phosphate, potassium permanganate and zinc.	Thomson, 1993
B.2.1.23 (IIA 2.15)	Oxidising properties		Structural formula assessment.	Based on the chemical structure the result of the oxidising properties has been predicted negative.	The assessment is acceptable.	Tremain, 2005
B.2.1.24 (IIA 2.14)	Surface tension	Tech. a.s. 99.8%	EEC A.5	71.9 mN/m (59.6 mg/L) at 22°C		Evans, 2001

Table B.2.1-2 Summary of the physical and chemical properties of the metabolite 5-ethoxy-1,2,4-thiadiazole-carboxylic acid (studies were conducted under GLP and completed to an acceptable standard and results were considered to be valid unless specified otherwise).

section (Annex point)	study	purity	method	results	comment	reference
B.2.1.5 (IIA 2.3)	Vapour pressure		Calculation using modelling software EPIWIN v3.12	Estimated as 0.01 Pa at 25°C (modified grain method)	Not GLP. For acids the estimation is less reliable. The value should be used with great care.	Anonymus, 2006
B.2.1.10 (IIA 2.5)	Spectra	99.75 %	Standard UV/Vis methodology.	Molar absorption coefficient for the absorbance maxima: at 244 nm 3699 L/(molxcm); at 218 nm: 5748 L/(molxcm). Test solution: 79.2x10 ⁻⁶ Mol/L etridiazole in water. ¹ H-NMR and ¹³ C-NMR spectra were also provided and were acceptable.	Not GLP.	Hull, 2001
B.2.1.11 (IIA 2.6)	Solubility in water		Calculation using modelling software EPIWIN v3.12	2.6 g/L at 25°C (based on estimated log Pow of 1.58) or 38.5 g/L (base on fragments estimation)	Not GLP. It is difficult to assess the values. For acids the estimation is not always reliable. Based on the determined value for the logPow and the logPow used in the first estimation, the value of 2.6 is probably a large underestimation of the solubility	Strunk, 1999 Anonymus, 2006
B.2.1.13 (IIA 2.8)	Partition co-efficient	100%	OECD 117, HPLC method.	Log P _{ow} = 0.7 (pH of eluent: 1.36)		Vanstone, 1999
B.2.1.18 (IIA 2.9)	Dissociation constant (pKa)		OECD 112, titration method	Pka = 2.44 at 23°C		Yu, 1998
B.2.1.19 (IIA 2.10)	Stability in air, photochemical oxidative degradation		Atkinson Calculation	Half-life in air based on hydroxyl radical concentration of 1.56x10 ⁶ OH/cm ³ (12-h day time): 1.447 days (17.36 hours).		Anonymus, 2006

Table B.2.1.3 Summary of the physical and chemical properties of the metabolite 5-ethoxy-3-dichloromethyl-1,2,4-thiadiazole (studies were conducted under GLP and completed to an acceptable standard and results were considered to be valid unless specified otherwise).

section (Annex point)	Study	purity	method	Results	comment	reference
B.2.1.5 (IIA 2.3)	Vapour pressure		Calculation using modelling software EPIWIN v3.12	Estimated as 0.15 Pa at 25°C (modified grain method)	Not GLP. Comparing the results from the estimation for the parent and this compound, the value for the VP is expected to be between 1.5 and 0.15 Pa.	Anonymous, 2006
B.2.1.10 (IIA 2.5)	Spectra	99.75 %	Standard UV/Vis methodology.	Molar absorption coefficient for the absorbance maxima: at 228.1 nm 6069 L/(molxcm); at 204 nm 5659 L/(molxcm). Test solution: 0.256x10 ⁻³ Mol/L in methanol.	Not GLP.	Hull, 2001
B.2.1.11 (IIA 2.6)	Solubility in water		Calculation using modelling software EPIWIN v3.12	192 mg/L at 25°C (based on log Pow)	Not GLP. This result should be considered the maximum value, as the estimated solubility for etridiazole using the same method gives an overestimation for the water solubility with a factor of 3.	Anonymous, 2006

B.2.1.13 (IIA 2.8)	Partition co-efficient	98%	Not specified.	The Log Pow was determined to be 2.6-2.8 in n-octanol:water mixtures (1:1) at 2.6-7.1 mg/L starting concentration in n-octanol at 25°C.	Not GLP, performed in 1976 (predated to GLP). The report lacked detail on test procedures, test conditions, analytical method and deviated from the current OECD guideline. Therefore, the reported value is considered not reliable based on this report alone. However as the estimated value is in good agreement this value is accepted.	Esposito, 1976
B.2.1.13 (IIA 2.8)	Partition co-efficient		Calculation using modelling software EPIWIN v3.12	The estimated Log Pow was 2.68	The estimated Log Pow is in good agreement with the value as determined. The determined value is therefore accepted.	Anonymus, 2006
B.2.1.19 (IIA 2.10)	Stability in air, photochemical oxidative degradation		Atkinson Calculation	Half-life in air based on hydroxyl radical concentration of 1.56×10^6 OH/cm ³ (12-h day time): 1.495 days (17,942 hours).		Anonymus, 2006

B.2.2 Physical, chemical and technical properties of the plant protection product

Table B.2.2 Summary of the physical and chemical properties of the plant protection product

Product name: AATERRA[®] ME with 700 g/L Etridiazole (studies were conducted under GLP and completed to an acceptable standard and results were considered to be valid unless specified otherwise).

section (Annex point)	study	method	results	comment	reference
B.2.2.1 (IIIA 2.1)	Appearance: physical state	Visual assessment.	Clear, yellow/light brown mobile liquid.	The physical state was reported in the accelerated storage stability report.	Maude, 1998
B.2.2.2 (IIIA 2.1)	Appearance: colour	Visual assessment.	Clear, yellow/light brown.	The colour was reported in the accelerated storage stability report.	Maude, 1998
B.2.2.3 (IIIA 2.1)	Appearance: odour	Olfactory assessment.	Odour characteristic for Etridiazole 700 g/L ME.	The odour was reported in the accelerated storage stability report.	Maude, 1998
B.2.2.4 (IIIA 2.2)	Explosive properties	EEC A.14, fall hammer and Koenen test.	Not explosive.		Tremain, 1998
B.2.2.5 (IIIA 2.2)	Oxidising properties	Statement	The formulation contains a high amount of active substance (700 g/L). None of the auxiliary materials are known as oxidizers. Since the active substance is non-oxidizing, there is no reason to assume the formulation AATERRA ME will contain any oxidizing properties.	Acceptable. The formulation is not oxidising	
B.2.2.6 (IIIA 2.3)	Flammability	EEC method A 10, A 11 or A 12	Not required since test substance is a liquid.		
B.2.2.7 (IIIA 2.3)	Auto-flammability	EEC A.15EEC method A 15 or A 16 or UN- Bowes-	382°C.		Tremain, 1998

section (Annex point)	study	method	results	comment	reference
		Cameron- Cage-Test			
B.2.2.8 (IIIA 2.3)	Flash point	CIPAC MT 12, Closed-Cup.	>100°C. liquids containing flammable solvents	Method equivalent to EEC A.9. The sample contains water and therefore the flame extinguished on testing up to and above the boiling point of water.	Parsons, 1997
B.2.2.9 (IIIA 2.4)	Acidity/alkalinity	CIPAC MT 31 CIPAC Method MT 31 and MT 75	% acidity as Sulphuric Acid: 0.45		White, 2001
B.2.2.10 (IIIA 2.4)	pH	CIPAC MT 75 CIPAC MT 75	pH of 1% dilution: 3.6 to 4.0 Where relevant, pH of 1% aqueous dilution, emulsion or dispersion	Result taken from storage stability studies (14 days at 54°C, 2 months at 40°C and 2 years at ambient).	Maude, 1998 Roberts, 1997 Maude, 1999
B.2.2.11 (IIIA 2.5)	Surface tension	EEC A.5 EEC method A 5	38.9 mN/m (1.16 g/L; 19.5°C) liquids % suspension = 40.5 mN/m		Hogg, 1998
B.2.2.12 (IIIA 2.5)	Viscosity	Not specified. OEC D Test Guideline 114	113.4 cP at 20°C (2 minutes at 6 rpm) 103.3 cP at 20°C (2 minutes at 60 rpm) liquids for ULV Non-Newtonian liquids	Results are reported with full details of the test methodology (cone/plate technique). Method acceptable.	McKelvie, 1997
B.2.2.13 (IIIA 2.6)	Relative density	EEC A.3, oscillating density meter.	1.27 g/cm ³ at 20°C liquids		McKelvie, 1997
B.2.2.14 (IIIA 2.6)	Bulk (tap) density		Not required since test substance is a liquid.		
B.2.2.14 (IIIA 2.7)	Storage stability	CIPAC MT 46	14 days at 54°C and 2 months at 40°C in 1 litre HDPE polyamide coextruded bottles; the content of Etridiazole, appearance (including packaging), pH and the emulsion stability did not change significantly after storage for 14 days at 54°C or 2 months at 40°C.		Maude, 1998
B.2.2.14	Storage stability	CIPAC MT 39	7 days at 0°C; on warming to room		Roberts, 1997

section (Annex point)	study	method	results	comment	reference
(IIIA 2.7)			temperature needle crystals became apparent. The crystals were easily reconstituted back into solution with gentle agitation. pH and the emulsion stability did not change significantly after storage for 7 days at 0°C.		
B.2.2.15 (IIIA 2.7)	Shelf life	CIPAC MT 75 CIPAC MT 36	Storage in HDPE coextruded bottles (commercial; sealed) at ambient for 2 years; the content of Etridiazole, appearance (including packaging), pH and the emulsion stability did not change significantly after storage for 2 years at ambient. If <2 years, shelf life in months at appropriate temps. required	Study agreed with GIFAP Monograph No. 17.	Maude, 1999
B.2.2.16 (IIIA 2.8)	Wettability		Not required for a ME formulation		
B.2.2.17 (IIIA 2.8)	Persistent foaming	CIPAC MT 47	0.01%, 1.00% and 5% v/v in standard water D at room temperature. Max. 16.5 mL foam at t=0 (5% v/v product in water). Max. 15.0 mL foam after 30 minutes (5% v/v product in water).		McKelvie, 1997
B.2.2.18 (IIIA 2.8)	Suspensibility		Not required for a ME formulation water dispersible solid products (e.g. WP, WDG or SC)		
B.2.2.19 (IIIA 2.8)	Suspension stability Spontaneity		Not required for a ME formulation		
B.2.2.20 (IIIA 2.8)	Dilution stability		Not required for a ME formulation		
B.2.2.21 (IIIA 2.8)	Dry sieve test	CIPAC Method MT 59.1	Not required for a ME formulationsolids diluted for use		
B.2.2.22 (IIIA 2.8)	Wet sieve test		Not required for a ME formulationsolids diluted for use		
B.2.2.23 (IIIA 2.8)	Particle size distribution	OECD Method 110	Not required for a ME formulationsolids diluted for use		

section (Annex point)	study	method	results	comment	reference
B.2.2.24 (IIIA 2.8)	Content of dust/fines	CIPAC MT 58.3 or MT 170	Not required for a ME formulationsolids diluted for use	GLP	
B.2.2.25 (IIIA 2.8)	Attrition and friability	CIPAC Method MT 171 or OECD Method 110	Not required for a ME formulationsolids diluted for use		
B.2.2.26 (IIIA 2.8)	Emulsifiability, re- emulsifiability and emulsion stability	CIPAC MT 36.1 (visual examination)C IPAC Methods MT 36 or MT 173	The emulsions showed satisfactory emulsion characteristics (no separation and no foam after 24 hours) in Standard Water D at 30°C at a concentration of 5%.	Result taken from storage stability studies (14 days at 54°C, 2 months at 40°C and 2 years at ambient).	Maude, 1998 Roberts, 1997 Maude, 1999
B.2.2.27 (IIIA 2.8)	Stability of dilute emulsion		Not required for a ME formulationsolids diluted for use		
B.2.2.28 (IIIA 2.8)	Flowability	CIPAC Method MT 172	Not required for a ME formulationsolids diluted for use		
B.2.2.29 (IIIA 2.8)	Pourability (rinsibility)	MT 148	1 litre HDPE/PA-COEX round bottle Poured residue: 0.70% Rinsed residue: 0.09%		Panton, 1997
B.2.2.30 (IIIA 2.8)	Dustability	CIPAC Method MT 34	Not required for a ME formulationsolids diluted for use		
B.2.2.31 (IIIA 2.8)	Adherence and distribution to seeds	CIPAC Method MT 175	Not required, not used for seed treatment. distribution and adhesion of seed treatments		
2.9.1	Physical compatibility with other products		Not applicable/not required for a water based ME formulation.		
2.9.2	Chemical compatibility with other products		Not applicable/not required for a water based ME formulation.		

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B.2.3 Summary of physical and chemical properties

B.2.3.1 Active substance

Physical and chemical properties of the active substance

Etridiazole pure is a clear and colourless liquid at 25°C with a freezing temperature of 22°C, a boiling temperature of 113°C (at reduced pressure; 0.53 kPa) and a vapour pressure of 1.43 Pa at 25°C. Up to a temperature of 318°C no decomposition was observed. Etridiazole Technical is a yellow liquid with low viscosity. The (technical) substance has a flash point of 111°C, an auto-ignition temperature of 342°C and has neither explosive properties nor oxidizing properties. Its water solubility at 25°C is 117.1 mg/L (85.8, 88.9 and 89.7 mg/L at pH 4, 7 and 10, respectively). The log Pow is 3.37 and the pKa is 2.77 at 25°C. The hydrolysis half-life of Etridiazole at 25°C in buffered solutions of pH 5.2, 7.1, 8.9 and distilled water is 88 to 98 days. Etridiazole does not appreciably absorb light in wavelengths relevant to natural sunlight (maximum ϵ over the range 290 to 800 nm: 2.13 L/(mol \times cm) at 290 nm). Consequently, photochemical degradation was not determined.

B.2.3.2 Plant protection product

AATERRA ME (700 g/L Etridiazole) is a clear, yellow/light brown mobile liquid. The product has a flash point >100°C, an auto-ignition temperature of 382°C and has neither explosive nor oxidizing properties. The pH of a 1% dilution is 3.6 to 4.0. An accelerated storage test of 14 days at 54°C and 2 months at 40°C, a shelf-life study of 2 years at ambient and a low temperature stability test of 7 days at 0°C have determined the physico-chemical stability of the product.

B.2.4 References relied on**References for the active substance**

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
2.1.1/01	Riggs, A.S.	2001	The melting point (freezing point), boiling point and relative density of purified etridiazole Report Crompton Co. Ontario, Canada No.Grl-Fr-11781 TER – 35 GLP, Unpublished	Y	CHEM
2.1.2/01	Riggs, A.S.	2001	The melting point (freezing point), boiling point and relative density of purified etridiazole Report Crompton Co. Ontario, Canada No.Grl-FR-11781 TER - 35 GLP, Unpublished	Y	CHEM
2.2/01	Riggs, A.S.	2001	The melting point (freezing point), boiling point and relative density of purified etridiazole Report Crompton Co. Ontario, Canada No.GRL-FR-11781 TER – 35 GLP, Unpublished	Y	CHEM
2.3.1/01	Thomson, P.A.	1993	Determination of the vapour pressure for terrazole technical using gas saturation. Report Uniroyal Chemical Ltd. Research Laboratory, Ontario, Canada No.GRL-FR-10312 TER – 36 GLP, Unpublished	Y	CHEM
2.4.1/01	Riggs, A.S.	2001	The colour, physical state and odour of technical and purified etridiazole Report Crompton Co. Research Laboratories, Canada No.GRL-FR-11783 TER – 37 GLP, Unpublished	Y	CHEM
2.4.2/01	Riggs, A.S.	2001	The colour, physical state and odour of technical and purified etridiazole Report Crompton Co. Research Laboratories, Canada No.GRL-FR-11783, 2001-070 TER – 37 GLP, Unpublished	Y	CHEM
2.5.1/01	Błaszczynski, E.	2003	UV/VIS, IR, NMR, and MS spectra of etridiazole Report Crompton Co. Uniroyal Chemical Division, Middlebury, U.S.A. No.2003-015 TER – 161 GLP, Unpublished	Y	CHEM
2.5.2/01	Hull, L.B.	2001	Determination of the Ultraviolet/Visible absorption spectrum of etridiazole impurities 5-ethoxy-1,2,4-thiadiazole-3-carboxylic acid and 5-ethoxy-3-dichloromethyl-1,2,4-thiadiazole Report Uniroyal Chemical Co. Inc., Middlebury U.S.A. No.2001-091 TER – 42 Non- GLP, Unpublished	Y	CHEM

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
2.5.2/02	Strunk, R.J.	1999	1H and 13C NMR spectra of 5-ethoxy-1,2,4-thiadiazole-3- carboxylic acid Report Uniroyal Chemical Co. Inc., Middlebury U.S.A. No.99050 TER – 43 GLP, Unpublished	Y	CHEM
2.6/01	Mitchell, D.S.	1993	Solubility of terrazole in water and aqueous buffer solutions Report Uniroyal Chemical Ltd.,Canada No.GRL-FR-10411 TER – 44 GLP, Unpublished	Y	CHEM
2.7/01	Riggs, A.S.	2004	Solubility of etridiazole in organic solvents Report Crompton Co., Research Laboratories, Ontario, Canada No GRL-12143 TER – 221 GLP, Unpublished	Y	CHEM
2.8/01	Batorewicz, W.	1987	Determination of the partition coefficient (Kow) for Terrazole Report Uniroyal Chemical Co. Inc., Naugatuck U.S.A. No.87105 TER – 47 GLP, Unpublished	Y	CHEM
2.8/02	Esposito, A.J.	1986	Chemodynamic parameter of dichlorometabolite (3- dichloromethyl-5- ethoxy- 1.2.4-thiadiazole) of terrazole partition coefficient n-octanol vs water Report Central Analytical Department Olin Corporation, U.S.A. No.CASR-23-76 TER – 48 Non-GLP, Unpublished	Y	CHEM
2.8/03	Vanstone, C.A.	1999	Determination of the partition coefficient (n-octanol/water) of 5- ethoxy-1,2,4-thiadiazole-carboxylic acid. (T-02) Report Uniroyal Chemical Research Laboratory Ontario, Canada No.GRL-FR-11525 TER – 49 GLP, Unpublished	Y	CHEM
2.3; 2.6; 2.8; 2.10; 2.8/04	Anonymus	2006	Estimation of physical chemical properties of 5-ethoxy-1,2,4-thiadiazole-carboxylic acid with EPWIN v 3.12 Non GLP, Unpublished	N	CHEM
2.3; 2.6; 2.8; 2.10; 2.8/05	Anonymus	2006	Estimation of physical chemical properties of 5-ethoxy-3-dichloromethyl-1,2,4-thiadiazole with EPWIN v 3.12 Non GLP, Unpublished	N	CHEM
2.9.1/01	Thomas, R.J.	1975	Analytical investigations concerned with the rate of hydrolysis of terrazole 3-C14 Report Central Analytical Department Olin Corporation Connecticut, U.S.A. No.CASR-7-75 TER – 50 Non-GLP, Unpublished	Y	CHEM

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
2.9.2/01	Dzialo, D.G.	2001	Molar absorptivities of etridiazole relevant to sunlight Report Uniroyal Chemical Co. Inc., Middlebury U.S.A. No.2001-130 TER - 51 GLP, Unpublished	Y	CHEM
2.9.3/01	Schocken, M.J.	2001	Etridiazole quantum yield and theoretical lifetime in upper surface water Report Uniroyal Chemical Co. Inc., Middlebury U.S.A. No.2001-163 TER - 52 Non-GLP, Unpublished	Y	CHEM
2.9.4/01	Thomson, P.A.	1993	Determination of the dissociation constant of etridiazole, the active component in Terrazole technical Report Uniroyal Chemical Ltd., Canada No.GRL-FR-10313 TER - 53 GLP, Unpublished	Y	CHEM
2.9.4/02	Yu, W.S.	1998	Determination of the dissociation constant of 5-ethoxy- 1,2,4- thiadiazole- 3-carboxylic acid Report Uniroyal Chemical Co., Canada No.GRL-FR-11250 TER - 54 GLP, Unpublished	Y	CHEM
2.10/01	Schocken, M.J.	2001	Gas-phase oxidation rate and half-life of etridiazole in the troposphere Report Uniroyal Chemical Co. Inc., Middlebury U.S.A. No.2001-153 TER - 55 Non-GLP, Unpublished	Y	CHEM
2.11.2 /01	Tremain, S.P.	2001	Etridiazole technical SI 7843: determination of hazardous physico-chemical properties Report Safepharm Laboratories Ltd., United Kingdom No.666/056 TER - 56 GLP, Unpublished	Y	CHEM
2.12/01	Tremain, S.P.	2001	Etridiazole technical SI 7843: determination of hazardous physico-chemical properties Report Safepharm Laboratories Ltd., United Kingdom No.666/056 TER - 56 GLP, Unpublished	Y	CHEM
2.13/01	Tremain, S.P.	2001	Etridiazole technical SI 7843: determination of hazardous physico-chemical properties Report Safepharm Laboratories Ltd., United Kingdom No.666/056 TER - 56 GLP, Unpublished	Y	CHEM

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
2.14/01	Evans, A.J., Mullee, D.M.	2001	Etridiazole technical SI 7843: determination of surface tension Report Safepharm Laboratories Ltd., United Kingdom No.666/057 TER - 57 GLP, Unpublished	Y	CHEM
2.15/01	Thomson, P.A.	1993	The oxidizing and reducing characteristics of terrazole technical. Report Uniroyal Chemical Co. Ltd., Canada No.GRL-FR-10319 TER - 58 GLP, Unpublished	Y	CHEM

References for the plant protection product

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
2.2.1/01	Tremain, S.P., Bartlett, A.J.	1998	Etridiazole 700 g/l ME: determination of hazardous physico-chemical properties Report Safepharm Laboratories Ltd., United Kingdom 666/011 TER – 72 GLP, Unpublished	Y	CHEM
2.3/01	Parsons, A.H.	1997	To determine the flash point of a sample of etridiazole 700g/l ME Report G.C. Laboratories Ltd., Great Britain J 11470 0119 TER – 73 GLP, Unpublished	Y	CHEM
2.3/02	Tremain, S.P., Bartlett, A.J.	1998	Etridiazole 700 g/l ME: determination of hazardous physico-chemical properties Report Safepharm Laboratories Ltd., United Kingdom 666/011 TER – 72 GLP, Unpublished	Y	CHEM
2.4.1/01	White, G.A.	2001	Determination of the free acidity or alkalinity of Aaterra (etridiazole) 700g/l ME, UBI 6576.00 Report G.C. Laboratories Ltd., Great Britain J13686 CAP F200 TER – 75 GLP, Unpublished	Y	CHEM
2.5.2/01	Mckelvie, M.J.	1997	Determination of the viscosity, density and persistent foam on a sample of etridiazole 700g/l ME Report Uniroyal Chemical Ltd., Brooklands Farm, England FSR 060 TER – 74 GLP, Unpublished	Y	CHEM

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
2.5.3/01	Hogg, A.S., Bartlett, A.J.	1998	Etridiazole 700 g/l ME: determination of surface tension Report SafePharm Laboratories Ltd., United Kingdom 666/010 TER – 76 GLP, Unpublished	Y	CHEM
2.6.1/01	Mckelvie, M.J.	1997	Determination of the viscosity, density and persistent foam on a sample of etridiazole 700g/l ME Report Uniroyal Chemical Ltd., Brooklands Farm, England FSR 060 TER – 74 GLP, Unpublished	Y	CHEM
2.7.1/01	Maude, S.J.	1998	Determination of the accelerated storage stability of etridiazole 700 g/l ME in 1 litre high density polyethylene polyamide coextruded bottles with evaluation of physical state, and analysis of active ingredient content, emulsion stability and pH determination Report Uniroyal Chemical Ltd., Brooklands Farm, England FSR 057 TER – 77 GLP, Unpublished	Y	CHEM
2.7.2/01	Mckelvie, M., Roberts, S.	1997	Determination of the low temperature storage stability of etridiazole 700 g/l ME with evaluation of physical state, emulsion stability and pH determination Report Uniroyal Chemical Ltd., Brooklands Farm, England FSR 061 TER – 78 GLP, Unpublished	Y	CHEM
2.7.3/01	Maude, S.J.	1999	Determination of the storage stability (24 months) of etridiazole 700 g/l ME in 1 litre high density polyethylene polyamide coextruded bottles with evaluation on physical state and analysis of active ingredient content, emulsion stability and pH determination Report Uniroyal Chemical Ltd., Brooklands Farm, England FSR 059 TER – 80 GLP, Unpublished	Y	CHEM
2.8.2/01	Mckelvie, M.J.	1997	Determination of the viscosity, density and persistent foam on a sample of etridiazole 700g/l ME Report Uniroyal Chemical Ltd., Brooklands Farm, England FSR 060 TER – 74 GLP, Unpublished	Y	CHEM

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
2.8.8.2 /01	Mckelvie, M., Panton, W.	1997	Determination of the pourability of etridiazole 700 g/l ME in 1 litre high density polyethylene polyamide co-extruded bottles Report Uniroyal Chemical Ltd., Brooklands Farm, England FSR 062 TER – 81 GLP, Unpublished	Y	CHEM

B.3 Data on application and further information

B.3.1 Data on application relevant to the active substance (Annex IIA 3.1 to 3.6)

B.3.1.1 Function (Annex IIA 3.1)

Etridiazole is a fungicide.

B.3.1.2 Effects on harmful organisms (Annex IIA 3.2.1)

Etridiazole is a contact fungicide with protective and curative action. Its protective action is restricted to the plant root zones in the soil or growth substrate. Etridiazole is a strong growth inhibitor of *Phytophthora* and *Pythium spp.*

B.3.1.3 Translocation in plants (Annex IIA 3.2.2)

Etridiazole is translocated from the root zone to fruits (as indicated by the plant metabolism study in cucumber). Because of the relatively rapid metabolism of etridiazole, no or low levels of etridiazole residues are expected in plants.

B.3.1.4 Fields of use (Annex IIA 3.3)

Glasshouse substrate grown fruiting vegetables (tomatoes, peppers, cucumbers) and non-soil bound glasshouse ornamentals.

B.3.1.5 Pests controlled and crops protected (Annex IIA 3.4.1, 3.4.2)

Etridiazole controls the following pests on:

- fruiting vegetables: *Pythium*, *Phytophthora capsica* (peppers) and *Phytophthora nicotianae* (tomatoes) (cucumber);
- pot plants and ornamentals: *Phytophthora* and *Pythium*;

Etridiazole is used on substrate grown vegetables (tomatoes, peppers, cucumbers) and non-soil bound glasshouse ornamentals.

B.3.1.6 Mode of action (Annex IIA 3.5.1)

Etridiazole is a fungicide with limited properties, which rapidly impairs growth and causes eventual death of both mycelium and spores. At normal rates it is highly selective to certain fungal species and can have a beneficial effect on natural plant mycorrhizal fungi.

The primary mode of action is the interaction of the fungicide with flavin containing enzymes, especially cytochrome c reductase. This blocks the electron transfer chain between cytochromes b and c within the mitochondria. Synthesis of triglycerides and sterolesters is inhibited while the sythesis of free fatty acids and phospholipids by lipid peroxidation is stimulated. Mitochondrial respiration is significantly reduced and the biochemical changes causes permanent damage to the mitochondrial cell wall.

B.3.1.7 Information relative to the formation of active metabolites or degradation products (Annex IIA 3.5.2, 3.5.3)

There are no known active metabolites or degradation products to which the active substance must be converted to exert its intended effect.

B.3.1.8 Information on the possible occurrence of the development of resistance or cross-resistance (Annex IIA 3.6)

Up till now, there is no evidence that etridiazole has induced resistance. Furthermore, etridiazole has not shown in-cross resistance with other active substances. In order to reduce the risk of resistance development to etridiazole, the use of etridiazole will be restricted.

B.3.2 Data on application relevant to the plant protection product (Annex IIIA 3)

Product name: AATERRA ME.

B.3.2.1 Field of use (Annex IIIA 3.1)

Intended for agricultural use in glasshouse substrate grown fruiting vegetables (tomatoes, peppers, cucumbers) and non-soil bound glasshouse ornamentals.

B.3.2.2 Nature of the effects on harmful organisms (Annex IIIA 3.2)

The effect of AATERRA ME is by contact fungicide with protective and curative action and is a strong growth inhibitor of *Phytophthora* and *Pythium* diseases around the root systems of plants.

B.3.2.3 Pests controlled and crops protected (Annex IIIA 3.3)

AATERRA ME is effective against soil and root fungi on substrate tomatoes, peppers, cucumbers and non-soil bound glasshouse ornamentals.

Rate of application (Annex IIIA 3.4)

AATERRA ME is intended to be used as a fungicide on:

- (substrate grown) tomato and peppers and will be applied as 0.4 L undiluted product per ha per application (is equivalent to 0.28 kg as/ha (max 2 applications). Per hectare 30,000 plants are treated. 75-100 mL water per plant is used. The diluted product contains 0.13 – 0.18 ml AATERRA ME per liter water which is equivalent to 0.091 – 0.126 ml a.s. per liter water.
- (substrate grown) cucumbers and will be applied as 0.4 L undiluted product per ha per application (is equivalent to 0.28 kg as/ha) (max 2 applications). Per hectare 14,000 plants are treated. 75-100 mL water per plant is used. The

diluted product contains 0.286 – 0.381 ml AATERRA ME per liter water which is equivalent to 0.20 – 0.28 ml a.s. per liter water.

- non-soil bound ornamental crops and will be applied as 10 L undiluted product per ha (is equivalent to 7 kg a.s./ha and 0.7 g a.s./m² (max 1 application)). The product is diluted 10-fold. The application rate of the 10-fold diluted product is 100 L diluted product per ha. The diluted product contains 100 ml AATERRA ME per liter water which is equivalent to 70 ml a.s. per liter water.

Concentration of active substance in material used (Annex IIIA 3.5)

AATERRA ME is an ME formulation containing 700 g/L of pure etridiazole.

Description of the method of application, type of equipment used and type and volume of diluent per unit of area or volume (Annex IIIA 3.6)

AATERRA ME is intended to be used on:

- (substrate grown) tomato, peppers and cucumbers and will be applied through irrigation system;
- non-soil bound ornamental crops and will be applied through irrigation system;

Number and timing of applications and duration of protection afforded (Annex IIIA 3.7)

Glasshouse grown fruiting vegetables:

AATERRA ME will be applied through irrigation system maximum twice. First application is at the moment the first fruits are harvested. If needed, the application must be repeated after minimal 2 weeks. The duration of protection afforded by each application is 3-4 weeks.

For non-soil-bound ornamental plants:

AATERRA ME will be applied through irrigation system maximum twice. The application is required before or directly after planting. If needed, the application must be repeated after 2 weeks. The duration of protection afforded by each application is 3-4 weeks.

B.3.2.4 Minimum waiting periods or other precautions between last application and sowing or planting of succeeding crops. Limitations on choice of succeeding crops (Annex IIIA 3.8)

It is not necessary to define waiting periods, since etridiazole has no phytotoxic effects on succeeding crops. There are no limitations on choice of succeeding crops.

B.3.2.5 Proposed instructions for use as printed, or to be printed, on labels (based on document E)

Labels have been submitted.

B.3.3 Summary of data on application

See Table 3.3.1.

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Table 3.3.1 Summary of intended uses (Annex IIA 3.4; Annex IIIA 3.3 - 3.7, 3.9)

Summary of intended uses

Crop and/or situation (a)	Member State or Country	Product name	F G I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
					Type (d-f)	Conc of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Non-soil bound glasshouse ornamental crops	EU	AATERRA	G	Soil and root fungi (Pythium & Phytophthora)	ME	700 g/l	Application through drip-irrigation	n.a.	1-2	2 weeks	-	1000 min	0.7 g/m ² substrate (7 kg/ha)	n.a.	
Substrate grown tomatoes	EU	AATERRA	G	Soil and root fungi (Pythium & Phytophthora)	ME	700 g/l	Application through drip-irrigation	ca. 81	1-2	2 weeks	-	1000 min	0.28-0.56 kg/ha	3	
Substrate grown peppers	EU	AATERRA	G	Soil and root fungi (Pythium & Phytophthora)	ME	700 g/l	Application through drip-irrigation	ca. 81	1-2	2 weeks	-	1000 min	0.28-0.56 kg/ha	7	
Substrate grown cucumbers	EU	AATERRA	G	Soil and root fungi (Pythium & Phytophthora)	ME	700 g/l	Application through drip-irrigation	ca. 81	1-2	2 weeks	-	1000 min	0.28 kg/ha	14	

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
- (i) g/kg or g/l
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

B.3.4 Further information on the active substance (Annex IIA 3.7 to 3.9)**B.3.4.1 Recommended methods and precautions concerning handling, storage, transport or fire (Annex IIA 3.7)**

For details see Material Safety Data Sheet of etridiazole.

This information is presented in the form of the safety data sheet according to Council Directive 91/155/EEC.

B.3.4.1.1 Handling

The usual precautions for handling chemicals should be observed. Wear recommended personal protection equipment. Warn personnel about the dangers of the product. Keep container tightly closed.

B.3.4.1.2 Storage

Store in a dry and cool place.

B.3.4.1.3 Transport

The following information was submitted by the notifier:

Land transport:

ADR/RID: Class 9

Warning sign, Hazard No. 90, Substance No. 3077

UN No.: 3077

Packing group: III

Proper shipping name: Environmentally hazardous substance, solid, n.o.s.

Sea transport:

IMO/IMDG: Class 9

UN No: 3077

Packing group: III

EMS: None

Marine pollutant: not available

Proper shipping name: None

Air transport:

ICAO/IATA: Class 9

Un No.: 3077

Packing group: III

Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Etridiazole)

Fire

Extinguish media: Alcohol-type foam or universal-type foams (large fires). CO₂, dry chemical (small fires). Unsuitable extinguish media: water jets.

Protective equipment:

Wear self contained breathing apparatus. Wear suitable body covering protective clothing.

B.3.4.2 Procedures for destruction or decontamination of the active substance, contaminated packaging and contaminated material**B.3.4.2.1 Controlled incineration**

Etridiazole does not have a halogen content greater than 60%, hence pyrolytic behaviour under controlled conditions is not required. The recommended means of safe disposal is by controlled incineration at an approved chemical waste facility (combustion temperature > 850°C, presence of more than 6% oxygen, residence time at least 2 seconds).

B.3.4.2.2 Others

The following methods of safe disposal than controlled incineration are recommended.

Disposal of an empty package: empty container completely and triple rinse with water. Add rinses to the spraying liquid to be used. The rinsed container can be disposed of as normal industrial non-chemical waste.

Disposal of contaminated materials: contaminated materials should be cleaned with water containing a household detergent using Personal protection Equipment as recommended in the MSDS. Materials that cannot be cleaned and collected cleaning liquid must be disposed of as chemical waste.

Disposal of product: by incineration in a special incinerator for chemicals.

B.3.4.3 Emergency measures in the case of an accident

There is no readily available method for decontamination of water. Precaution must be taken to avoid contamination. Do not allow spills to escape into sewage system or water courses.

In the event of spillage into watercourses inform the relevant authorities and others who may be affected.

Containment of spillages in water:

Decontamination may be achieved through microbial degradation and/or physical dilution of the concentration in the contaminated area, since etridiazole is demonstrated to be susceptible to microbial degradation.

First aid:

After inhalation:	Move person to the fresh air. Seek medical advice immediately.
After eye contact:	Rinse eye thoroughly with water during several minutes. Seek medical advice if discomfort persists.
After skin contact:	Remove contaminated clothing. Rinse affected skin with copious amounts of water, using a mild cleaning agent. Obtain medical attention if contact has been widespread and prolonged, or if irritation persists.
After ingestion:	Do not induce vomiting. Rinse mouth with water. Give two glasses of milk or water at once. Obtain medical attention in all cases.

B.3.4.4 Summary of further information and assessment

No further information.

B.3.5 Further information of the plant protection product (Annex IIIA 4)

Product name: AATERRA ME

B.3.5.1.1 Packaging, compatibility on the preparation with proposed packaging materials (Annex IIIA 4.1)

It is proposed that AATERRA ME is packed in 1 L round co-extruded polyethylene/polyamide bottles.

Bottle 1L:

Closure : Polyethylene white pigmented screw cap with induction screw cap
Filling quantity : nominal content 1 L (maximum 1160 mL)
Material : co-ex polyethylene/polyamide
Dimensions : height 0.234 m, diameter 0.0885 mm,
empty weight 0.073 kg (without closure), opening Φ 42 mm.

External packaging:

1 Litre is packed in 12 X 1L corrugated cardboard UN-approved outer box.

B.3.5.1.2 Packaging suitability

Since the container is UN approved, no further testing is required.

B.3.5.1.3 Packaging resistance

After 2 years of storage at ambient temperature, the packaging showed no sign of deformation and the closure was intact.

B.3.5.2 Procedures for cleaning application equipment (Annex IIIA 4.2)

Wear appropriate protective equipment. If the product is applied through the fertigation system, there is in general no need for cleaning between or after the treatments. Ensure the fertigation systems are completely drained before storage. Store PPE in a properly designated store, away from sources of contamination. Keep clean and dirty PPE separated to avoid cross contamination.

B.3.5.3 Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment (Annex IIIA 4.3)**Pre-harvest interval (in days)**

When the formulation is applied according to the good agricultural practices and to the label recommendations a PHI of 3, 7 and 14 days is proposed for tomatoes, peppers and cucumbers respectively.

A pre-harvest interval is not applicable for non-soil bound glasshouse ornamentals.

Re-entry period (in days) for livestock, to areas to be grazed.

Not relevant since it concerns glass-house applications.

Re-entry period (in hours or days) for man to crops, buildings or spaces treated

No bystanders should be allowed in greenhouses during the application of AATERRA ME. A risk assessment for re-entry activities was not performed due to lack of data. Additional data need to be provided by the notifier (see appendix 3 of document B.6).

Withholding period (in days) for animal foodstuffs

No withholding period is defined (use on tomatoes, peppers, cucumbers and ornamentals which are normally not fed to livestock).

Waiting period (in days) between application and handling treated products

A risk assessment for re-entry activities was not performed due to lack of data. Additional data need to be provided by the notifier (see appendix 3 of document B.6).

Waiting period (in days) between last application and sowing or planting of succeeding crops

Not relevant for the intended uses.

Conditions under which the product should not be used

No restrictions should be imposed on the use of the product in relation to specific agricultural, plant health or environmental conditions.

B.3.5.4 Recommended methods and precautions concerning: handling, storage, transport or fire (Annex IIIA 4.4)**Handling**

The usual precautions for handling chemicals should be observed. Read the label before handling the container. Wear suitable protective clothing including eye/face protection and gloves. Do not eat, drink or smoke when handling the containers. Ensure adequate ventilation and keep away from sources of ignition. Check containers are not leaking before handling. Ensure that the correct amount of product is used to treat the required area minimising the amount of surplus remaining at the end of treatment. Further details in MSDS of AATERRA ME.

Storage

The usual precautions for storage of chemicals should be observed. Keep product only in the original container in a cool well-ventilated place. Keep locked up, out of reach of children and away from food, drink and animal feedingstuffs. Further details in MSDS of AATERRA ME.

Transport

Land transport:

ADR/RID: Class 9

Warning sign, Hazard No. 90, Substance No. 3082

UN No.: 3082

Packing group: III

Proper shipping name: Environmentally hazardous substance, liquid, n.o.s.

Sea transport:

IMO/IMDG: Class 9 (Miscellaneous)

UN No: 3082

Packing group: III

EMS: None

Marine pollutant: not available

Proper shipping name: None

Air transport:

ICAO/IATA: Class 9

Un No.: 3082

Packing group: III

Proper shipping name: None

For further details reference is made to the MSDS of AATERRA ME.

Fire

Standard measure include: Do not breathe fumes. Toxic and irritant fumes may be formed including oxides of carbon and nitrogen. Wear chemical protection suit and positive-pressure breathing apparatus. Extinguish with water or dry chemical. Use as little water as possible. Prevent run-off water from entering drains if possible. For further details reference is made to the MSDS of AATERRA ME.

Waste

It is recommended to purchase and store quantities of product required in the short term. Do not open more containers than is necessary for immediate requirements.

B.3.5.5 Emergency measures in the case of an accident (Annex IIIA 4.5)Containment of spillages:

Small spills must be collected using an adsorbent (e.g. sand, earth, vermiculite). Collect absorbed material in a suitable container for disposal. Large spills must be diked with adsorbent. Pump excess material into a suitable container (e.g. metal drum, metal tank).

For further details reference is made to the MSDS of AATERRA ME.

Decontamination of areas, vehicles and buildings:

Wear appropriate protective equipment. If the product is applied through the fertigation system, there is in general no need for cleaning between or after the treatments.

For further details reference is made to the MSDS of AATERRA ME.

Fist aid:

After inhalation: Remove to fresh air. Obtain medical attention immediately.

After skin contact: Remove contaminated clothing. Rinse affected skin with copious amounts of water, using a mild cleaning agent. Obtain medical attention if contact has been widespread and prolonged, or if irritation persists.

After eye contact: Flush eyes immediately with water and continue washing for several minutes. Obtain medical attention if discomfort.

After ingestion: Do not induce vomiting. Rinse mouth with water. Give two glasses of milk or water at once. Obtain medical attention in all cases.

B.3.5.6 Procedures for destruction or decontamination of the plant protection product and its packaging (Annex IIIA 4.6)

B.3.5.6.1 Possibility of neutralisation

A neutralisation procedure cannot be proposed.

B.3.5.6.2 Controlled incineration

The recommended means of safe disposal is by controlled incineration at an approved chemical waste facility. In order to continue perfect combustion, it is desirable that the combustion temperature is between 800°C and 950°C in a 210 litre steel drum. Complete combustion will give CO₂, H₂O and N₂/N-oxides and possible some HCl. For further details reference is made to the MSDS of AATERRA ME.

B.3.5.6.3 Others

No other method than controlled incineration for disposal of the plant protection product, contaminated packaging and contaminated materials is available.

B.3.5.7 Summary of further information and assessment

No further information.

B.3.6 References relied on

Annex point / reference no.	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data protection claimed Y/N	Owner
II A.3	Braas	2005	report AM 950/65/2005 Crompton Europe B.V. Report No: not allocated Not GLP, not published	Y	CHEM

B.4 Proposals for classification and labelling

B.4.1 Proposals for the classification and labelling of the active substance (Annex IIA 10)

Physical and chemical properties

No classification and labelling is needed based on the physical and chemical properties of the active substance Etridiazole.

Human health effects

Justified proposals for classification and labelling of the active substance, relating to human health effects, according to Directive 2001/59/EC are listed below.

Hazard symbol	:	Xn (optional Xi)
Indication of danger	:	Harmful (optional Irritant)
Risk phrases	:	R22; Harmful if swallowed. R43; May cause sensitisation by skin contact. R40; Limited evidence of a carcinogenic effect..
Safety phrases	:	S36; Wear suitable protective clothing. S37; Wear suitable gloves.

Justification for the proposal

- R22 Based on the results of the acute oral toxicity study.
 R43 Based on the results of the skin sensitisation study.
 R40 Based on the results of the carcinogenicity studies and mechanistic studies.
 S36 Obligatory for substances labelled with R40 and/or R43.
 S37 Obligatory for substances labelled with R40 and/or R43.

Currently, etridiazole is classified in Annex I to Directive 67/548/EEC with (relating to human health effects): R40 (carcinogen category 3), R23 and R21/R22.

Ecotoxicological effects

In acute toxicity tests with technical etridiazole in fish, *Daphnia magna* and algae, the lowest LC/EC50 values were 2.4, 3.1 and 0.30 mg/L, respectively. Etridiazole has a log Pow value of >3.0, and the experimentally determined BCF is >100. It is proposed therefore, that on the basis of its acute toxicity etridiazole should be categorised as "Dangerous for the environment" (N), "Very toxic to aquatic organisms" (R50) and "May cause long-term adverse effects in the aquatic environment" (R53).

It is recommended that the active substance also carries the following 'S' safety phrases:

- S57 Use appropriate containment to avoid environmental contamination

- S60 This material and its container must be disposed of as hazardous waste
 S61 Avoid release to the environment. Refer to special instructions/Safety data sheet

Justification for the proposal:

- N, R50, R53 Based on the acute toxicity and the BCF
 S57 Recommended for preparations labelled with R50
 S60, S61 Recommended for preparations labelled with R50/R53

B.4.2 Proposals for the classification and labelling the formulation (Annex IIIA 12.3)

Physical and chemical properties

No classification and labelling is needed based on the physical and chemical properties of AATERRA ME.

Human health effects

Justified proposals for classification and labelling of the preparation AATERRA ME, relating to human health effects, according to Directive 2001/59/EC are listed below.

Hazard symbol	:	Xn (optional Xi)
Indication of danger	:	Harmful (optional Irritant)
Risk phrases	:	R36; Irritating to eyes. R38; Irritating to skin. R43; May cause sensitisation by skin contact. R40; Limited evidence of a carcinogenic effect.
Safety phrases	:	S36; Wear suitable protective clothing. S37; Wear suitable gloves.

Justification for the proposal

- R36 Based on the results of the eye irritation study.
 R38 Based on the results of the skin irritation study.
 R43 Based on the results of the skin sensitisation study.
 R40 Since the product contains 700 g/L etridiazole, and etridiazole is labelled with R40.
 S36 Obligatory for formulations labelled with R40 and/or R43.
 S37 Obligatory for formulations labelled with R40 and/or R43.

Ecotoxicological effects

Tests with Aaterra ME were not submitted. Since the formulated product contains >25% of the active substance, the hazard classification and labelling of the plant protection product is identical to that of

the active substance, in agreement with the recommendations in Dangerous Preparation Directive 99/45/EC and the 28th adaptation of the Dangerous Substance Directive 67/548/EC.

B.4.3 References relied on

The proposed classification and labelling for the active substance is based on the evaluation as presented in section B.2, B.6 and B.9.

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

B.5 Methods of analysis**B.5.1 Analytical methods for technical active substance (Annex IIA 4.1.1) and plant protection product (Annex IIIA 5.1.1)****B.5.1.1 Technical active substance (IIA 4.1.1)****STUDY 1****Characteristics**

Reference	: Yu, W.S., 2001 (IIA 4.1.1/01)	GLP statement	: Yes
Type of study	: Analytical methods for technical active substance and plant protection product	Guideline	: Not indicated
Year of execution	: 2001	Acceptability	: Acceptable
Test substance	: Etridiazole (Technical, Lot no. 1 RC 109 867, purity not reported, Analytical, Lot no. not reported, purity not reported)	Method reference	: GRL-GM-1174 AC-1227B

Description of the method

Etridiazole Technical (0.2 g) was dissolved in 25.0 mL internal standard solution (pentachlorobenzene, 5 g/L in acetone). Etridiazole was analyzed by GC-FID (10% SP-2100 on 100/120 Supelcoport, 6' x ¼" OD x 2 mm ID).

Results

See Table 5.1-1. Specificity was confirmed by GC-MS.

Conclusion

The method is acceptable for the determination of etridiazole in technical material.

Guidelines & Limitations

None.

B.5.1.2 Plant protection product (IIIA 5.1.1)**STUDY 1****Characteristics**

Reference	: Parsons, A.H., 1996 (IIIA 5.1.1/01)	GLP statement	: Yes
Type of study	: Analytical methods for technical active substance and plant protection product	Guideline	: Not stated
Year of execution	: 1996	Acceptability	: Acceptable
Test substance	: Etridiazole (Product, Lot no. EVO 50028-176, purity not stated, Analytical, Lot no. AS 17302, purity 99.1%)	Method reference	: M 461/A

Description of the method

Etridiazole formulation (no further specified) (0.15-0.20 g) was dissolved in 10.0 mL internal standard solution (di-n-amyl phthalate, 20 g/L in acetonitrile), further diluted with 65 mL acetonitrile and made up to 100 mL with water. Etridiazole was analyzed by HPLC-UV (Phenomex Prodigy 5 ODS2, 250 mm

x 4.6 mm i.d., 5 µm) using 75/25 (v/v) acetonitrile/water as mobile phase (1mL/min) with UV detection at 260 nm.

Results

See Table 5.1-1. Specificity was confirmed (by comparing UV and IR spectra of the isolated etridiazole peak and an etridiazole reference standard).

Conclusion

The method is acceptable for the determination of etridiazole in the plant protection product Etridiazole EVO-50028-176 which is identical to Aaterra ME.

Guidelines & Limitations

none.

Table B.5.1-1 Summary of method validation (etridiazole in technical active material and formulations).

	Linearity (linear between mg/mL or mg/L) (correlation coefficient)	Precision – Repeatability (%RSD)	Accuracy (% Recovery, by standard addition)	Interference/ Specificity	LOQ % (w/w)	Reference
Company Method Reference Etridiazole in technical material	3.12 – 12.82 mg/mL n=6 (0.999996)	n=5 (RSD 0.15%)	n=4 (recovery 100.1%)	No interference	0.03% (w/w)	Yu, 2001, 5.1.1/01
Company Method Reference Etridiazole in plant protection product	500 – 1500 mg/L n=5 (r=0.9999)	n=5, duplo injections, 55.45% (RSD 0.77%)	n=5, duplo injections (recovery 100.1%, RSD 1.12%)	No interference	Not determined	Parsons, 1996, 5.1.2/01

B.5.2 Analytical methods (residue) for plants, plant products, foodstuffs of plant and animal origin, feedingstuffs (Annex IIA 4.2.1 and Annex IIIA 5.2)

The following residue definitions were determined (section B.7):

Residue definition for plant products

The residue definition for post-registration monitoring is proposed as etridiazole, 3-hydroxymethyl etridiazole (3-hydroxymethyl-5-ethoxy-1,2,4-thiadiazole) and 5-hydroxyethoxy etridiazole acid (3-carboxy-5-hydroxyethoxy-1,2,4-thiadiazole) for tomato, sweet peppers and cucumbers. As indicated in section B.7, the residue definition is *provisional*.

Residue definition for animal products

No definition of residues in animal products was required because tomatoes, sweet peppers and cucumbers are not fed to animals.

STUDY 1

Characteristics

Reference	: Blaszczyński, E., 2002 (IIA 4.2.1/01)	GLP statement	: Yes
Type of study	: Analytical methods for plants, animal tissues, milk and eggs	Guidelines	: SANCO/825/00 rev.6 OPPTS 860.1340 and 860.1000
Year of execution	: 2002	Acceptability	: Acceptable for pre- and post-registration
Test substance	: Etridiazole (Lot no. AC-1322-17, purity 99.6%)	Method reference	: AC-3012A

Description of the method (etridiazole)

Samples (green bell peppers, ~10 g) were homogenized. Hexane was added (25 mL) to the homogenate and the sample was mixed and sonicated. The hexane phase was removed following centrifugation and concentrated. Internal standard solution (3-dichloromethyl-5-ethoxy-1,2,4-thiadiazole, 10 µg/mL in hexane) was added and the final volume adjusted to 1 or 10 mL. Analysis (for etridiazole) was by GC (Rtx-200 trifluoropropylmethyl polysiloxane column, 60m x 0.25 mm i.d., film thickness 0.50 µm) with MS detection (ratio m/z 211/184 (quantification) and 183/211, 213/211 (verification)). Reference standards prepared in hexane were used as calibration standards.

Results

See Table B.5.2-1. Specificity was confirmed (GC-MS, 3 ions). Interferences were <10% of the LOQ.

Conclusions

Method AC-3012 can be considered suitable in pre- and post registration studies for the analysis of etridiazole in green bell peppers with an LOQ of 0.01 mg/kg.

Guidelines & Limitations

1. An (acceptable) ILV is provided under STUDY 2.
2. A correction was made for interferences in blank samples. This is considered acceptable because

interferences were <10% of the LOQ.

STUDY 2

Characteristics

Reference	: Simons, C., 2002 (IIA 4.2.1/02)	GLP statement	: Yes
Type of study	: Analytical methods for plants, animal tissues, milk and eggs	Guidelines	: SANCO/825/00 rev.6 OPPTS 860.1340 and 860.1000
Year of execution	: 2002	Acceptability	: Acceptable for pre- and post-registration
Test substance	: Etridiazole (Lot no. AC-1366-104C, purity 99.7%)	Method reference	: AC-3012A

Description of the method (etridiazole)

The study was submitted as ILV for STUDY 1. The method was exactly the same as the method described in STUDY 1.

Results

See Table B.5.2-1. Specificity was confirmed (GC-MS, 3 ions). No interferences were detected in blank controls.

Conclusions

The ILV fulfilled the criteria as outlined in SANCO/825/00. Method AC-3012A can therefore be considered suitable in pre- and post registration studies for the analysis of etridiazole in green bell peppers with an LOQ of 0.01 mg/kg.

Guidelines & Limitations

None.

STUDY 3

Characteristics

Reference	: Batorewicz, W., 2002 (IIA 4.2.1/03)	GLP statement	: Yes
Type of study	: Analytical methods for plants, animal tissues, milk and eggs	Guidelines	: SANCO/825/00 rev.6 OPPTS 860.1340 and 860.1000
Year of execution	: 2002	Acceptability	: Acceptable for pre- and post-registration
Test substance	: Etridiazole acid (Lot no. AGD-1785-057, purity 99.8%)	Method reference	: AC-3011A

Description of the method (etridiazole acid)

Samples (green bell peppers, ~10 g) were homogenized. Water was added (25 mL) to the homogenate and the sample was mixed, sonicated and filtered. The filtrate was extracted with t-butyl methyl ether. The ether was evaporated to dryness and the residue redissolved in 10% H₂SO₄ in anhydrous ethanol. After derivatisation (formation of ethyl-ester) for 30 minutes at 50°C, the solution was neutralised (phosphate buffer pH 7) and extracted with hexane. Following concentration (LOQ level only) of the hexane phase, internal standard solution (methyl-5-ethoxy-1,2,4-thiadiazole-3-carboxylate, 10 µg/mL in hexane) was added. Analysis was by GC (Rtx-200 trifluoropropylmethyl polysiloxane column, 60m x 0.25 mm i.d., film thickness 0.50 µm) with MS detection (m/z ratio 202/188 (quantification) and m/z ratio 130/202 and 174/202 (verification)). Reference standards

prepared in hexane were used as calibration standards.

Results

See Table B.5.2-1. Specificity was confirmed (GC-MS, 3 ions). Interferences were <10% of the LOQ.

Conclusions

Method AC-3011A can be considered suitable in pre- and post registration studies for the analysis of etridiazole acid in green bell peppers with an LOQ of 0.025 mg/kg.

Guidelines & Limitations

1. An (acceptable) ILV is provided under STUDY 4.
2. A correction was made for interferences in blank samples. This is considered acceptable because interferences were <10% of the LOQ.
3. The yield of the derivatisation procedure is not reported. The good recoveries of fortified samples indicate the yield is acceptable and reproducible.

STUDY 4

Characteristics

Reference	: Simons, C., 2002 (IIA 4.2.1/04)	GLP statement	: Yes
Type of study	: Analytical methods for plants, animal tissues, milk and eggs	Guidelines	: SANCO/825/00 rev.6 OPPTS 860.1340
Year of execution	: 2002	Acceptability	: Acceptable for pre- and post-registration
Test substance	: Etridiazole acid (Lot no. RJS1732-100, purity 100%)	Method reference	: AC-3011A

Description of the method (etridiazole acid)

The study was submitted as ILV for STUDY 3. The method was exactly the same as the method described in STUDY 3.

Results

See Table B.5.2-1. Specificity was confirmed (GC-MS, 3 ions). No interferences were detected in blank controls.

Conclusions

The ILV fulfilled the criteria as outlined in SANCO/825/00. Method AC-3011A can therefore be considered suitable in pre- and post registration studies for the analysis of etridiazole acid in green bell peppers with an LOQ of 0.025 mg/kg.

Guidelines & Limitations

None.

STUDY 5

Characteristics

Reference	: Guenther Kempe, 2003 (IIA 4.2.1/05)	GLP statement	: No
Type of study	: Multiresidue methods (S19) to measure azole fungicides in crop samples; Chapter from "Handbook of residue analytical methods for agrochemicals"	Guidelines	: SANCO/825/00 rev.6 OPPTS 860.1340
Year of execution	: Not relevant	Acceptability	: Not Acceptable
Test substance	: Etridiazole	Method reference	: DFG S19

Description of the method

In a handbook for analytical residue methods the results are described for several compounds, including etridiazole. It is reported that etridiazole showed a good ECD and NPD sensitivity, making it basically suitable for multi residue methods. According to the text the S19 method (extraction E1, extraction and subsequent liquid/liquid partition, for wet materials) showed a recovery of 60-90%, but <10% recovery with extraction module E2 (almost same extraction as for E1, only for dry material). GCMS is possible with 7 mass fragment to monitor.

Results

No actual data was given, only the very brief summary as mentioned above. No metabolites were tested.

Conclusions

The extraction appears to be critical as the recoveries for module E1 and E2 are very different. No LOQ is given. No metabolite is tested, therefore the method is not suitable for the provisional residue definition.

Guidelines & Limitations

None.

STUDY 6

Characteristics

Reference	: Thiem, 1994 (IIA 4.2.1/06)	GLP statement	: Yes
Type of study	: Testing of terrazole and its monoacid metabolite through FDA multiresidue protocols B, C, D and E.	Guidelines	: SANCO/825/00 rev.6 OPPTS 860.1340
Year of execution	: 1994	Acceptability	: Not Acceptable
Test substance	: Etridiazole and Etridiazole acid (3-carboxy-5-ethoxy-1,2,4-thiadiazole)	Method reference	: FDA

Description of the method

The FDA Multi-residue protocol D was found to give complete a recovery for etridiazole of 220% at 0.05 mg/kg (grain sample). Also etridiazole acid (3-carboxy-5-ethoxy-1,2,4-thiadiazole) was tested for suitability of the multi-residue method. The compound was not recovered from the clean-up step with florisil (after methylation with diazomethane) and consequently, the method was not suitable (no further testing was done). Also without florisil clean-up the metabolite was not found using protocol D.

Results

No recovery data for the etridiazole acid is possible as there is no recovery. For etridiazole the

recovery is concentration dependend. At 0.05 mg/kg the recoer was 220% (n=2) and at 0.25 mg/kg 80% (n=2).

Conclusions

The extraction protocol is unknown. No comparison can therefore be made with the S19 method (or the Dutch MRM1 method). However the results indicate that a multiresidue method for all the metabolites is not possible.

Guidelines & Limitations

None.

Table B.5.2-1 Summary of method description and validation (treated plants, plant products, foodstuffs, feedingsstuffs, environmental samples).

Substrate	Analyte	Dissolution/ extraction	Partitioning/ clean-up	Quantifi- cation	Limit of quantifi- cation (mg/kg)	Recovery fortifica- tion level (mg/kg)	Recover- ies range (mean)	Repea- tability RSD (%) (n)	Linearity demon- strated	Ref.
Pepper	Etridiazole	Hexane extraction	None	GC-MS	0.01	0.01	89-112 (99)	7.9 (10)	Yes	Blaszczynski, 2002 5.2/01
						0.10	88-102 (96)	4.2 (10)		
Pepper (ILV)	Etridiazole	Hexane extraction	None	GC-MS	0.01	0.01	101-115 (107)	5.3 (5)	Yes	Simons, 2002a 5.2/02
						0.10	96-110 (102)	6.2 (5)		
Pepper	Etridiazole acid	Water extraction	t-butyl methyl ether extraction followed by derivatisation to the ethyl-ester and hexane extraction.	GC-MS	0.025	0.025	64-104 (80)	17 (10)	Yes	Batorewicz, 2002 5.2/03
						0.25	80-90 (84)	3.8 (10)		
Pepper (ILV)	Etridiazole acid	Water extraction	t-butyl methyl ether extraction followed by derivatisation to the ethyl-ester and hexane extraction.	GC-MS	0.025	0.025	67-78 (70)	6.0 (5)	Yes	Simons, 2002b 5.2/04
						0.25	80-87 (85)	3.7 (5)		

B.5.3 Analytical methods (residue) soil, water, air (Annex IIA 4.2.2 to 4.2.4; Annex IIIA 5.2)

The residue definition in the environmental compartments soil, water and air was determined in section B.8. Here the following was stated:

Detailed guidance to define the environmental residue is not available. Provisionally therefore, the active substance and major metabolites are listed in the definition. The major components of the environmental residue are therefore as follows:

Soil: Etridiazole, dichloro-etridiazole, etridiazole acid

Water: Etridiazole, etridiazole acid

Air: Etridiazole, dichloro-etridiazole (*provisional*), etridiazole acid (*provisional*)

STUDY 1

Characteristics

Reference	: Carter, D.S., 2000 (IIA 4.2.2/01)	GLP statement	: No
Type of study	: Analytical methods for soil, air and water	Guidelines	: Not specified
Year of execution	: 1996-1998	Acceptability	: Acceptable
Test substance	: Etridiazole (Lot no. AC-1322-17, purity 99.6%); dichloro-etridiazole (Lot no. 2333-92-BTF, purity 99.8%); etridiazole acid (Lot no. RJS1610-152, purity 100%)	Method reference	: AC 6003

Description of the method (etridiazole, dichloro-etridiazole, etridiazole acid)

Soil (5 g wet mass) was subjected to multiple diethyl ether extractions. The combined extracts were concentrated to the aqueous phase and the pH was made basic by addition of concentrated NH_4OH prior to extraction with hexane (etridiazole and dichloro-etridiazole extraction). The remaining aqueous phase was acidified (H_2SO_4) and extracted with methyl t-butyl ether (etridiazole acid extraction). The ether was evaporated to dryness and the residue redissolved in 10% H_2SO_4 in anhydrous ethanol. After derivatisation (formation of ethyl-ester) for 15-20 minutes at 50°C , the solution was neutralised (phosphate buffer pH 7) and extracted with diethylether/hexane. All hexane extracts were combined and concentrated to a final volume of 1 mL prior to GC-TSD analysis (DB-17 narrow bore capillary column, 30m x 0.25 mm i.d., film thickness 0.25 μm). Reference standards prepared in hexane were used as calibration standards.

Validation was performed for six soil depths from two sites (i.e. a total of 12 soil types). Soils are representative for agricultural soils and included clay, loamy sand and sandy loam textures and organic matter ranged from 0.3-2.2%. For each soil type, two samples were fortified at 0.01, 0.05 and 0.1 mg/kg. Hence, per fortification level 24 determinations were made. The analysis were performed over a period of ~1 year (October 1996 until September 1997).

Results

See Table B.5.3-1. Chromatograms of a confirmatory GC-MS method were provided. No interferences were observed (based upon visual examination of chromatograms of untreated controls).

Conclusion

Method AC 6003 is considered suitable for the determination of etridiazole, dichloro-etridiazole and etridiazole acid in soil with an LOQ of 0.01 mg/kg.

Guidelines & Limitations

1. The yield of the derivatisation procedure is not reported. The good recoveries of fortified samples indicate the yield is acceptable and reproducible.

STUDY 2

Characteristics

Reference	: Rooseboom-Reimers, A., 2000 (IIA 4.2.2/02)	GLP statement	: Yes
Type of study	: Analytical methods for soil, air and water	Guidelines	: SANCO/825/00
Year of execution	: 2000	Acceptability	: Not acceptable
Test substance	: Etridiazole (Lot no. AC-1366-104C, purity 99.7%); dichloro-etridiazole (Lot no. 2333-92-BTF, purity 99.8%); etridiazole acid (Lot no. RJS1610-152, purity 100%)	Method reference	: Not specified

Description of the method (etridiazole, dichloro-etridiazole, etridiazole acid)

Soil (20 g wet mass) was subjected to extraction with pH 11 water:hexane (2:1 v/v) after the addition of atrazine and fluroxypyr internal standards. The hexane phase was removed and the remaining soil:water phase was extracted with hexane. The hexane phases were combined, concentrated, reconstituted in ethyl acetate and analysed for etridiazole and dichloro-etridiazole. The water phase was cleaned with dichloromethane, acidified to pH <2 (H₂SO₄) and subjected to C18-SPE. Etridiazole acid was eluted using 0.05% acetic acid in ethyl acetate. The eluate was derivatised using diazomethane. The derivative was analysed after concentration and addition of hexachlorobenzene internal standard. Analysis was by GC (HP-5 MS, 30m x 0.25 mm i.d., film thickness 0.25 µm) with mass detection (monitoring of 3 ions, quantification mass 211, 160 and 184 for etridiazole, etridiazole acid derivative and dichloro-etridiazole, respectively). Reference standards prepared in blank extracts were used as calibration standards.

Validation was performed for one soil (either (not specified in report) a sand or loamy sand soil with 2.5-3.7% OC). Five samples were fortified at 0.02 and 4 mg/kg.

Results

See Table B.5.3.-01. Interferences were <30% of the LOQ (based upon visual examination of chromatograms of untreated controls). The recoveries for etridiazole and dichloro-etridiazole at 0.02 mg/kg exceeded 110% (111 and 115%, respectively). Because the RSDs were acceptable (≤15%), the use of this method in submitted pre-registration studies is accepted, but not for post-registration monitoring purposes.

Conclusion

The method is considered suitable for the determination of etridiazole, dichloro-etridiazole and etridiazole acid in soil with an LOQ of 0.02 mg/kg as part of pre-registration studies. Because of the use of diazomethane, the method for etridiazole acid is no longer acceptable for further pre-registration work and post-registration monitoring.

Guidelines & Limitations

Diazomethane is not allowed as derivatising agent.

STUDY 3

Characteristics

Reference	: Hull, L.B. and Bartorewicz, W., 1999 (IIA 4.2.3/01)	GLP statement	: Yes
Type of study	: Analytical methods for soil, air and water	Guidelines	: OPPTS 850.7100 96/46EC
Year of execution	: 1998-1999	Acceptability	: Acceptable for pre- and post-registration
Test substance	: Etridiazole (Lot no. AC-1322-17, purity 99.6%); dichloro-etridiazole (Lot no. 2333-92-BTF, purity 99.8%); etridiazole acid (Lot no. RJS1610-152, purity 100%)	Method reference	: AC-7001

Description of the method (etridiazole, dichloro-etridiazole, etridiazole acid)

Surface water (1L, TOC 3.3 mg/L, pH 7.3, TSS 4 mg/L) was passed through a DVB C-18 Speedisk. Etridiazole and dichloro-etridiazole were eluted from the disk with hexane. The water was subsequently passed through a SAX Speedisk for the extraction of etridiazole acid. Etridiazole acid was eluted with 10 mL of 1% H₂SO₄ in ethanol. The eluate was heated to 50°C for 30-45 minutes (derivatisation to the ethyl-ester), the solution was neutralised (phosphate buffer pH 7) and extracted with hexane. Both hexane extracts were concentrated to an end volume of 1 mL prior to GC-NPD analysis (DB-17 narrow bore capillary column, 30m x 0.25 mm i.d., film thickness 0.25 µm). Reference standards prepared in hexane were used as calibration standards.

Results

See Table B.5.3-1. Chromatograms of a confirmatory GC-MS/MS method were provided (monitoring of 3 ions for each analyte). Interferences were <30% of the LOQ (based upon examination of chromatograms of untreated controls).

Conclusion

Method AC-7001 is considered suitable for the determination of etridiazole, dichloro-etridiazole and etridiazole acid in surface (and drinking) water with an LOQ of 0.1 µg/L.

Guidelines & Limitations

1. No validation in drinking water was performed. However, as the drinking water criterion (0.1 µg/L) was met for surface water (which is considered the more difficult matrix), the method is also considered applicable for drinking water.

2. A correction was made for interferences in control samples. This is considered acceptable because interferences were <30% of the LOQ.
3. The yield of the derivatisation procedure is not reported. The good recoveries of fortified samples indicate the yield is acceptable and reproducible.

STUDY 4

Characteristics

Reference	: Rooseboom-Reimers, A., 2000 (IIA 4.2.2/02)	GLP statement	: Yes
Type of study	: Analytical methods for soil, air and water	Guidelines	: SANCO/825/00
Year of execution	: 2000	Acceptability	: Not acceptable as post-registration monitoring method
Test substance	: Etridiazole (Lot no. AC-1366-104C, purity 99.7%); dichloro-etridiazole (Lot no. 2333-92-BTF, purity 99.8%); etridiazole acid (Lot no. RJS1610-152, purity 100%)	Method reference	: Not specified

Description of the method (etridiazole, dichloro-etridiazole, etridiazole acid)

Groundwater (100 mL) was acidified to pH <2 (H₂SO₄) and subjected to C18-SPE. Etridiazole, dichloro-etridiazole and etridiazole acid were eluted using 0.05% acetic acid in ethyl acetate. The eluate was derivatised using diazomethane. The analytes were analysed after concentration and addition of hexachlorobenzene internal standard. Analysis was by GC (HP-5 MS, 30m x 0.25 mm i.d., film thickness 0.25 µm) with mass detection (monitoring of 3 ions, quantification mass 211, 160 and 184 for etridiazole, etridiazole acid derivative and dichloro-etridiazole, respectively). Reference standards prepared in blank extracts were used as calibration standards.

Validation was performed for one type of groundwater (no properties reported). Five samples were fortified at 0.1 and 10 µg/L.

Results

See Table B.5.3-1. Interferences were <30% of the LOQ (based upon visual examination of chromatograms of untreated controls).

Conclusion

The method is considered suitable for the determination of etridiazole, dichloro-etridiazole and etridiazole acid in groundwater with an LOQ of 0.1 µg/L as part of pre-registration studies. Because of the use of diazomethane, the method is no longer acceptable for further pre-registration work and post-registration monitoring.

Guidelines & Limitations

Diazomethane is not allowed as derivatising agent.

STUDY 5

Characteristics

Reference	: Class, T., 2001 (IIA 4.2.4/01)	GLP statement	: Yes
Type of study	: Analytical methods for soil, air and water	Guidelines	: SANCO/825/00 rev. 6
Year of execution	: 2001	Acceptability	: Acceptable
Test substance	: Etridiazole (Lot no. AC-1366-104C, purity 99.7%)	Method	: Not indicated
		reference	

Description of the method (etridiazole)

The front sections of XAD-2 adsorption tubes (100 mg adsorbent in the front and 50 mg in the back section) were fortified with etridiazole (0.5 and 5.0 µg). Air was passed through each tube at a rate of 1.7 L/min for 6 hours (total 0.6 m³, equivalent to 0.9 and 9 µg/m³ of etridiazole, respectively). For both concentrations, air conditions were ~25°C, 26% rH and ~35°C, 91% rH. Front and back sections were extracted separately in ethyl acetate. Extracts were analyzed by GC-MS (CP Sil 8 CB column, 30 m x 0.32 mm i.d., 0.25 µm film thickness) (m/z 211 for quantitation and m/z 213 and 183 for confirmation). Reference standards prepared in ethyl acetate were used as calibration standards.

Results

See Table B.5.3-1. No interferences in the blanks and no breakthrough (<1% in back section of the trap) were observed.

Conclusion

The method is considered suitable for the analysis of etridiazole in air with an LOQ of 0.9 µg/m³ (sampling at a rate of 1.7 L/min during 6 hours; conditions ~25°C, 26% rH and ~35°C, 91% rH).

Guidelines & Limitations

Considering an AOEL of 0.03 mg/kg bw/d, the target LOQ is ≤0.9 µg/m³, hence the achieved LOQ of 0.9 µg/m³ is sufficient.

Table B.5.3-1 Summary of method description and validation (soil, water and air).

Substrate	Analyte	Dissolution/ extraction	Partitioning/ clean-up	Quantifi- cation	Limit of quantifi- cation (mg/kg)	Recovery fortifica- tion level (mg/kg)	Recover- ies range (mean)	% Repea- tability RSD (%) (n)	Linearity demon- strated	Ref.
Soil	Etridiazole	Diethyl ether extraction	Hexane (alkaline) partitioning	GC-TSD	0.01	0.01	80-115 (93)	10 (24)	No ^(A)	Carter, 2000, 5.3/01
						0.05	72-112 (90)	11 (24)		
						0.10	77-109 (91)	9.0 (24)		
Soil	Dichloro- etridiazole	Diethyl ether extraction	Hexane (alkaline) partitioning	GC-TSD	0.01	0.01	80-120 (96)	11 (24)	No ^(A)	Carter, 2000, 5.3/01
						0.05	74-113 (93)	11 (24)		
						0.10	79-115 (93)	9.4 (24)		
Soil	Etridiazole acid	Diethyl ether extraction	t-butyl methyl ether extraction (acid) followed by derivatisation to the ethyl-ester and hexane extraction.	GC-TSD	0.01	0.01	74-116 (96)	11 (24)	No ^(A)	Carter, 2000, 5.3/01
						0.05	73-116 (90)	14 (24)		
						0.10	76-101 (90)	8 (24)		
Soil	Etridiazole	water pH 11:hexane	hexane layer	GC-MS	0.02 ^(C)	0.02	98-118 (111)	7.1 (5)	Yes	Rooseb oom- Reimers , 2003, 5.3/02
						4	105-116 (111)	4.8 (4) ^(A)		

Soil	Dichloro- etridiazole	water pH 11:hexane	hexane layer	GC-MS	0.02 ^(C)	0.02	90-132 (115)	15 (5)	Yes	Rooseb oom- Reimers , 2003, 5.3/02
						4	94-114 (107)	8.5 (4) ^(B)		
Soil	Etridiazole acid	water pH 11:hexane	acidified water layer subjected to C18-SPE followed by derivatisation (diazomethane) to the methyl-ester.	GC-MS	0.02 ^(C)	0.02	70-100 (80)	15 (5)	Yes	Rooseb oom- Reimers , 2003, 5.3/02
						4	75-81 (78)	2.8 (5)		
Water (TOC 3.3 mg/L, pH 7.3, TSS 4 mg/L)	Etridiazole	C-18 Speedisk	Elute with hexane	GC-NPD	0.1 µg/L	0.1 µg/L	75-99 (92)	9.9 (8)	Yes	Hull and Bartore wicz, 1999, 5.3/03
						0.5 µg/L	81-103 (96)	7.5 (8)		
Water (TOC 3.3 mg/L, pH 7.3, TSS 4 mg/L)	Dichloro- etridiazole	C-18 Speedisk	Elute with hexane	GC-NPD	0.1 µg/L	0.1 µg/L	83-113 (99)	12 (8)	Yes	Hull and Bartore wicz, 1999, 5.3/03
						0.5 µg/L	75-93 (89)	6.4 (8)		
Water (TOC 3.3 mg/L, pH 7.3, TSS 4 mg/L)	Etridiazole acid	SAX Speedisk	Elute with 1% H ₂ SO ₄ in ethanol followed by derivatisation to the ethyl-ester and hexane extraction.	GC-NPD	0.1 µg/L	0.1 µg/L	74-112 (91)	17 (8)	Yes	Hull and Bartore wicz, 1999, 5.3/03
						0.5 µg/L	67-79 (73)	5.4 (8)		
Ground- water	Etridiazole	acidification followed by C-18 SPE	derivatisation (diazomethane)	GC-MS	0.1 µg/L ^(C)	0.1 µg/L	68-110 (89)	17 (5)	Yes	Rooseb oom- Reimers , 2003, 5.3/04
						10 µg/L	85-99 (93)	6.3 (5)		
Ground- water	Dichloro- etridiazole	acidification followed by	derivatisation (diazomethane)	GC-MS	0.1 µg/L ^(C)	0.1 µg/L	89-132 (106)	16 (5)	Yes	Rooseb oom-

		C-18 SPE				10 µg/L	88-107 (99)	7.7 (5)		Reimers , 2003, 5.3/04
Ground- water	Etridiazole acid	acidification followed by C-18 SPE	derivatisation (diazomethane)	GC-MS	0.1 µg/L ^(C)	0.1 µg/L	62-88 (79)	13 (5)	Yes	Rooseb oom- Reimers , 2003, 5.3/04
Air 25°C, 26% rH, 1.7 L/min for 6 hours	Etridiazole	Flow of air through XAD-2 tubes. Extraction with ethyl acetate	-	GC-MS	0.9 µg/m ³	0.9 µg/m ³	89-107 (97)	7 (5)	Yes	Class, (2001) 5.3/05
Air 35°C, 91% rH, 1.7 L/min for 6 hours	Etridiazole	As above	-	GC-MS	0.9 µg/m ³	0.9 µg/m ³	98-105 (102)	3 (5)		
						9 µg/m ³	81-102 (90)	12 (5)		
						9 µg/m ³	83-89 (87)	3 (4) ^(B)		

(A) A quadratic calibration curve was used ($r^2 \geq 0.99$)

(B) One outlier was removed based on the Dixon test.

(C) Not accepted for post-registration monitoring purposes.

WARNING: This document forms part of an EC evaluation data package and should not be relied on for isolation. Registration must not be granted on the basis of this document.

B.5.4 Analytical methods (residue) for body fluids and tissues (Annex IIA 4.2.5; Annex IIIA 5.2)

Etridiazole is not classified as toxic (T). An analytical method for *body fluids* and *tissues* is therefore not required.

B.5.5 Evaluation and assessment

Analytical methods for technical active substance and plant protection product

A GC-FID method was submitted for the determination of etridiazole in technical material. A HPLC-UV method was submitted for the determination of etridiazole in the plant protection product EVO-50028-176 (identical to Aaterra ME). The identity of etridiazole in technical material was confirmed by GC-MS (technical material) or comparison of UV/IR spectra (product). The validation results fulfilled all criteria.

Analytical methods (residue) for plants, plant products, foodstuffs of plant and animal origin, feedingstuffs

A GC-MS method (AC-3012A) was submitted for the determination of etridiazole in green peppers (study 1, LOQ 0.01 mg/kg). The study contained fully acceptable validation results. An ILV for green peppers was submitted (study 2) and deemed acceptable.

As indicated by the notifier, several multi-residue methods may be suitable for the determination of etridiazole in plant products (e.g. DFG multi-residue method S19-E1). The results from two studies indicate that the S19 method is probably suitable for the determination of etridiazole, but not for the metabolites.

A GC-MS method (AC-3011A) was submitted for the determination of etridiazole acid in green peppers (study 3, LOQ 0.025 mg/kg). The study contained fully acceptable validation results. An ILV for green peppers was submitted (study 4) and deemed acceptable. The method may not be required because etridiazole acid is not included in the *provisional* residue definition for monitoring.

Additional methodology for the metabolites included in the residue definition for plant products should be submitted unless non-inclusion of the metabolites in the residue definition is accepted by the RMS (provisional data gap).

Analytical methods for soil, water and air

Analytical methods were submitted for the determination of etridiazole, dichloro-etridiazole and etridiazole acid in soil and water (surface water) and of etridiazole in air.

One GC-TSD method (AC-6003) was submitted for the determination of etridiazole, dichloro-etridiazole and etridiazole acid in soil (study 1). The method was fully validated and confirmed by GC-MS. Method AC-6003 is considered suitable for the determination of etridiazole, dichloro-etridiazole and etridiazole acid in soil with an LOQ of 0.01 mg/kg. One GC-MS method was submitted for the

determination of etridiazole, dichloro-etridiazole and etridiazole acid in soil (study 2). The study was not accepted for post-registration monitoring purposes because of the use of diazomethane as derivatising agent.

One GC-NPD method (AC-7001) was submitted for the determination of etridiazole, dichloro-etridiazole and etridiazole acid in surface water (study 2). The method was fully validated and confirmed by GC-MS. Method AC-7001 is considered suitable for the determination of etridiazole, dichloro-etridiazole and etridiazole acid in surface water (LOQ 0.1 µg/L). The method is also suitable for drinking and groundwater (because surface water is considered the more difficult matrix). The LOQ of 0.1 µg/L for surface water is below the level of the lowest appropriate toxicity value for aquatic organisms (in this case the NOEC for rainbow trout (0.12 mg/L) (See B.9.2.2)). The established LOQ is also <NOEC/10 (i.e. including the risk assessment safety factor of 10). In addition, one GC-MS method was submitted for the determination of etridiazole, dichloro-etridiazole and etridiazole acid in groundwater (study 4). The study was not accepted for post-registration monitoring purposes because of the use of diazomethane as derivatising agent.

One GC-MS method was submitted for the determination of etridiazole in air (study 3). The method was fully validated and confirmed by GC-MS. The method is considered suitable for the analysis of etridiazole in air with an LOQ of 0.9 µg/m³ (~25°C, ~26% rH and ~35°C, ≥80% rH; 1.7 L/min during 6 hours). The method is considered suitable for post-registration monitoring because the LOQ (0.9 µg/m³) is below the limit of 9 µg/m³ calculated as: limit = AOEL*0.1*60/20 (AOEL = 0.03 mg/kg bw/day) as set in Volume 3 B.6.

Additional methodology for the metabolites included in the residue definition for air should be submitted unless non-inclusion of the metabolites in the residue definition is accepted (provisional data gap).

Analytical methods for body fluids and tissues

Etridiazole is not classified as toxic (T). An analytical method for body fluids and tissues is therefore not required.

B.5.6 References relied on

Annex point / reference number	Author(s)	Year	Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA 4.1.1/01	Yu, W.S.	2001	Determination of etridiazole in terrazole technical by gas chromatography Report Crompton Co. Research Laboratories, Canada No.GRL-GM-1174 TER – 59 GLP, Unpublished	Y	CHEM
IIA 4.1.1/02	Parsons, A.H.	1996	Validation of method for determination of etridiazole in technical materials and formulations Report G.C. Laboratories Ltd., Great Britain No.J 10415/ B TER - 60 GLP, Unpublished	Y	CHEM
IIA 4.2.1/01	Blaszczynski, E.	2002	Analytical method for the determination of etridiazole (terrazole®), 5-ethoxy-3-trichloromethyl-1,2,4-thiadiazole, in peppers - method validation Report Uniroyal Chemical Co. Inc., Middlebury, U.S.A. No.2001-158 TER - 25 GLP, Unpublished	Y	CHEM
IIA 4.2.1/02	Simons, C.	2002	Independent laboratory validation for the determination of etridiazole (terrazole®), 3-trichloromethyl-5-ethoxy-1,2,4-thiadiazole, in peppers (Uniroyal Chemical Analytical Method No. AC-3012a) Report Exygen Research, U.S.A., No.004-057 TER - 88 GLP, Unpublished	Y	CHEM
IIA 4.2.1/03	Batorewicz, W.	2002	Analytical method for the determination of etridiazole (terrazole® acid metabolite, 5-ethoxy-1,2,4-thiadiazole-3-carboxylic acid, in peppers - method validation Report Uniroyal Chemical Co. Inc., Middlebury, U.S.A. No.2001-159 TER - 24 GLP, Unpublished	Y	CHEM
IIA 4.2.1/04	Pfleegor, C.	2002	Independent laboratory validation for the determination of etridiazole (terrazole®) acid metabolite (5-ethoxy-1,2,4-thiadiazole-3-carboxylic acid) in peppers (uniroyal chemical analytical method no. Ac-3011a) Report Exygen Research, U.S.A. No.004-058 TER - 68 GLP, Unpublished	Y	CHEM
IIA 4.2.1/05	Kempe, G.	2003	Chapter "Multi-residue methods (S19) to measure azole fungicides in crop samples", from "handbook of residue analytical methods for agrochemicals" page 1099-1127 2003 John Wiley & Sons Ltd. Non GLP, Published	N	CHEM

Annex point / reference number	Author(s)	Year	Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA 4.2.1/06	Thiem, D.A.	1994	Testing of terrazole and its monoacid metabolite through FDA multiresidue protocols B, C, D and E. Colorado Analytical Reaserch & development corporation, U.S.A. Studyno: RP-94010 27 may 1994 GLP, unpublished	Y	CHEM
IIA 4.2.2/01	Carter, D.S.	2000	Analytical method for etridiazole and its metabolites, 3-dichloromethyl-5-ethoxy-1,2,4-thiazole and 5-ethoxy-1,2,4-thiadiazole-3-carboxylic acid in soil Report Uniroyal Chemical Co. Inc., Middlebury, U.S.A. No.98242 AC 6003 TER - 63 GLP, Unpublished	Y	CHEM
IIA 4.2.2/02 and 4.2.3/02	Rooseboom-Reimers, A.	2003	Validation of the determination of etridiazole and its main degradation products in water and soil Report TNO Nutrition and Food Research Institute, The Netherlands No.010.50676 TER - 162 GLP, Unpublished	Y	CHEM
IIA 4.2.3/01	Hull, L.B., Batorewicz, W.	1999	Analytical method for determining etridiazole and its metabolites in water Report Uniroyal Chemical Co.Inc, Middlebury U.S.A. No.98249 TER - 64 GLP, Unpublished	Y	CHEM
IIA 4.2.4/01	Class, T.	2001	Development and validation of an analytical method for the determination of etridiazole in air Report Ptn Europe GmbH, Germany No.B 464 G TER - 65 GLP, Unpublished	Y	CHEM