

FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: TERBUT 500 SC

Product name(s): La Zina 500 SC; Tekno 500 SC

Chemical active substance(s):

Terbuthylazine, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: PUH Chemirol Sp. z o.o.

Submission date: November 2019

MS Finalisation date: November 2020; 06.2022

Version history

When	What
November 2019	Submission dossier
November 2020	Finalisation
June 2022	Final Version after Commenting period

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8 Fate and behaviour in the environment (KCP 9)

zRMS comments:

All comments and conclusions of the zRMS are presented in grey. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information is struck through and shaded for transparency. **New information after commenting are presented in yellow.**

Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL,CZ	Maize (ZEAMX)	F	Dicotyledonous weeds	Spray, medium sprayer	Spring BBCH 12-16	a)1 b)1	n/a	a) 1.0 l/ha b) 1.0 l/ha	a) 0.5 kg a.s./ha b) 0.5 kg a.s./ha	200-400	n/a	
1	PL,CZ	Maize (ZEAMX)	F	Dicotyledonous weeds	Spray, medium sprayer	Spring BBCH 00-05	a)1 b)1	n/a	a) 1.0 l/ha b) 1.0 l/ha	a) 0.5 kg a.s./ha b) 0.5 kg a.s./ha	200-400	n/a	
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3													
4													
Minor uses according to Article 51 (zonal uses)													
5													
6													
Minor uses according to Article 51 (interzonal uses)													
7													
8													

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
 (c) g/kg or g/l

(d) Select relevant
 (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
 (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
 2 Use official codes/nomenclatures of EU Member States
 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and 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
 8 The maximum number of application possible under practical conditions of use must be provided.
 9 Minimum interval (in days) between applications of the same product
 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
 13 PHI - minimum pre-harvest interval
 14 Remarks may include: Extent of use/economic importance/restrictions

Table 8.1-2: Assessed (critical) uses during approval of Terbutylazine concerning the Section Environmental Fate (Terbutylazine SAN-CO/11337/2011 rev 2 - 17 June 2011)

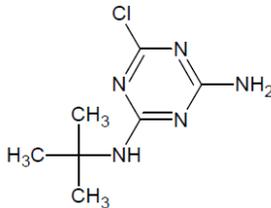
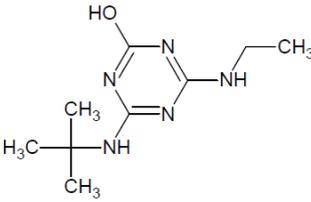
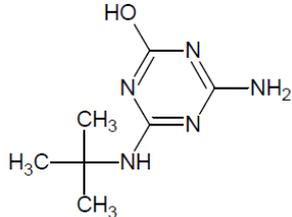
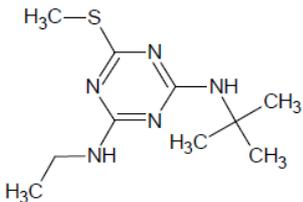
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I**	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
	N.EU	Maize	F	Dicot and monocot weeds	Tractor - mounted sprayer	preemergence - 8 leaf	1	N/A	4L/ha	750 g as/ha	200-500	Not applicable	
	France (N) Germany (N) The Neth- erlands (N)	Maize	F	Annual and perennial broad leaved weeds	Tractor - mounted sprayer	Preemergence Early post emergence (12-16)	1	N/A	1.5 – 1.69 L/ha	740 – 844 g a.s/ha	200 - 500	Not applicable	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

8.2 Metabolites considered in the assessment

Table 8.2-1: Metabolites of terbutylazine potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
MT1 desethyl- terbutylazine (GS 26379)	201.7		Soil (lab): max 25.1% AR Maximum occurrence observed in sediment/ water studies: 7.3 %	PEC _{gw} : leaching potential to groundwater PEC _{soil} PEC _{sw/sed} : if not covered by EU assessment
MT13 Hydroxy- terbutylazine Or 2-hydroxy ter- butylazine GS 23158	211.3		Soil (Lab): max 34.5 % AR Maximum occurrence observed in sediment/ water studies: 20.0 %	PEC _{soil} PEC _{gw} : leaching potential to groundwater
MT14 desethyl- hydroxyterbutylazine or desethyl-2-hydroxy terbutylazine GS 28620	183.2		Soil (Lab): mx 1.7% AR Maximum occurrence observed in sediment/ water studies: N/A (soil metabolite only)	PEC _{soil} PEC _{gw} : leaching potential to groundwater PEC _{sw}
MT26	241.4		Maximum occurrence observed in sediment/ water studies: 7.4 %	PEC _{sw}

8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

Studies on aerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- **Terbuthylazine** - EFSA Journal 2011; 9(1):1969

8.3.1.1 Terbuthylazine and its metabolites

Table 8.3-1: Summary of aerobic degradation rates for Terbuthylazine - laboratory studies

Terbuthylazine	Aerobic conditions							
	Soil name and classification	% OM	pH (KCl or CaCl ₂)	temp. °C / soil moisture for study (% w/w)	Soil moisture at pF 2 (% w/w)	DT _{50, actual} (d)	DT _{50, ref} 20 °C pF2 (d)	Min chi ² error (%)
Gartenacker Sandy Loam	3.79	7.25	20 °C / 26.73 %	48.92	78.7	51.6	1.7	SFO
Pappelacker Loamy Sand	1.9	7.6	20 °C / 15.8 %	29.3	93.1	60.4	2.9	SFO
Weide Sandy Loam	2.24	7.5	20 °C / 18.96 %	36.6	65.0	41.0	2.5	SFO
Speyer 2.2 Loamy Sand	3.91	6.1	20 °C / 19.2 %	12.1	167	167	2.1	SFO
Borstel Loamy Sand	2.59	5.8	20 °C / 10.88 %	14 ^b	143	120	1.0	SFO
Lorsch Sandy Clay Loam	3.1	5.3	20 °C / 19.92 %	22 ^b	110	103	1.4	SFO
Gartenacker Silt Loam 1.57 kg/ha	3.59	7.32	20 °C / 29.17 %	48.61	77.0	53.9	4.4	SFO
Gartenacker Silt Loam 0.15 kg/ha	3.59	7.32	20 °C / 29.17 %	48.61	59.7	41.8	4.9	SFO
Collombey Sand	2.29	7.7	20 °C / 16.8 %	25.31	80.0	60.0	5.9	SFO
Les Evouettes Silt Loam	2.41	6.1	20 °C / 22.12 %	40.21	58.4	38.2	7.7	SFO
Speyer 2.2 Loamy Sand	4.4	6.0	20 °C / 16.16 %	21.21	122	101	2.2	SFO
Speyer 2.3 Sandy Loam	1.28	6.6	20 °C / 12.56 %	18.61	112	85.2	2.4	SFO
Les Evouettes Loam	6.4	6.8	20 °C / 35.85 %	47.8	69.7	57.0	4.3	SFO
Speyer 2.2 Loamy Sand	3.95	6.18	20 °C / 17.72 %	14 ^b	136	138	5.6	SFO
Sisseln Sandy Loam	2.71	7.16	20 °C / 20.96 %	19 ^b	83.7	83.7	4.1	SFO
Collombey Loamy Sand	2.02	7.45	20 °C / 16.12 %	14 ^b	73.6	73.6	4.2	SFO
Diegten Clay Loam	2.74	6.9	20 °C / 20.76 %	28 ^b	117	94.9	1.9	SFO
Geometric mean^a					91.1	72.0	-	-
Median					88.4	75.1	-	-

(a) Geometric mean for replicate soil values calculated first (excluding the two Les Evouettes soils that were considered to be substantially differ-

ent from each other due to contrasting organic matter contents e.g. 2.41 and 6.4% organic matter)
 (b) FOCUS default moisture content based on soil texture
 Note that the t-test result was >99% for every soil

Table 8.3-2: Summary of aerobic degradation rates for Desethyl-terbuthylazine (MT1)- laboratory studies

Desethyl-terbuthylazine	Aerobic conditions (where metabolite applied as starting material)							
	Soil name and classification	% OM	pH (KCl or CaCl ₂)	temp. °C / soil moisture for study (% w/w)	Soil moisture at pF 2 (% w/w)	DT _{50, actual} (d)	DT _{50, ref} 20 °C pF2 (d)	Min chi ² error (%)
Borstel – Loamy Sand	2.63	5.79	20 °C / 10.9 %	14 ^a	83.9	70.3	1.9	SFO
Gartenacker* - Loam	3.20	7.28	20 °C / 26.7 %	25 ^a	61.8	61.8	3.1	SFO
Lorsch – Sandy Clay Loam	3.16	5.25	20 °C / 19.9 %	22 ^a	40.7	38.0	3.3	SFO
Speyer 2.3 – Sandy Loam	2.1	6.4	20 °C / 15.6 %	19 ^a	61.8	53.8	6.7	SFO
Speyer 2.1 – Sand	1.07	5.9	20 °C / 12.4 %	12 ^a	45.2	45.2	4.9	SFO
Speyer 2.2 – Loamy Sand	4.00	5.6	20 °C / 19.2 %	14 ^a	50.7	50.7	4.1	SFO
Westmaas – Silt Loam	2.41	7.4	20 °C / 15.6 %	26 ^a	93.8	65.6	6.0	SFO
Geometric mean					60.0	54.0	-	-
Median					61.8	53.8	-	-

a FOCUS default moisture content based on soil texture
 b t-test result was >99% for every soil

Table 8.3-3: Summary of aerobic degradation rates for Hydroxy-terbuthylazine (MT13)- laboratory studies

Hydroxy-terbuthylazine	Aerobic conditions (where metabolite applied as starting material)							
	Soil type	% OM	pH (K Cl)	temp. °C / soil moisture for study (% w/w)	Soil moisture at pF 2 (% w/w)	DT _{50, actual} (d)	DT _{50, ref} 20 °C pF2 (d)	Min chi ² error (%)
Borstel – Loamy Sand	2.6	5.8	20 °C / 10.88 %	14 ^a	207	173	4.7	SFO
Gartenacker – Loam	2.8	7.6	20 °C / 25.08 %	25 ^a	298	298	2.2	SFO
Vetroz – Silt Loam	3.1	7.7	20 °C / 23.56 %	26 ^a	281	278	2.9	SFO
Cranfield 115 – Clay Loam	2.9	7.4	20 °C / 22.1 %	28 ^a	>1000	>1000	3.3	SFO
Cranfield 164 – Silt Loam	5.2	6.5	20 °C / 29.12 %	26 ^a	>1000	>1000	3.7	SFO
Cranfield 243 – Sandy Loam	1.9	4.3	20 °C / 20.44 %	22.7 ^a	645	600	1.7	SFO
Geometric mean					473^b	453^b	-	-

a FOCUS default moisture content based on soil texture
 b the geomean was calculated assuming a default DT50 of 1000 d for Cranfield 115 and Cranfield 164 soils (the results for the Cranfield 115 and Cranfield 164 soils were excluded from the geometric mean calculated by the Applicants on the basis

of unacceptable parameter significance based on results of the t-test (Applicants geomean DT50, actual = 325 d, DT50, ref = 305d))

Hydroxy-terbuthylazine	Aerobic conditions (where metabolite formed from parent terbuthylazine during the study)						
	Soil type	% OM	pH (KCl or CaCl ₂)	Visual inspection	Form. frac. (ffm)	Min chi ² error (%)	Method of calc.
	Gartenacker Sandy Loam	3.79	7.25	Acceptable	0.080	12.1	SFO using a fixed DT ₅₀ of 325 d
	Pappelacker Loamy Sand	1.9	7.6	Acceptable	0.065	28.0	SFO using a fixed DT ₅₀ of 325 d
	Weide Sandy Loam	2.24	7.5	Acceptable	0.059	28.6	SFO using a fixed DT ₅₀ of 325 d
	Speyer 2.2 Loamy Sand	3.91	6.1	Acceptable	0.313	26.4	SFO using a fixed DT ₅₀ of 325 d
	Borstel Loamy Sand	2.59	5.8	Very good	0.219	3.0	SFO using a fixed DT ₅₀ of 325 d
	Lorsch Sandy Clay Loam	3.1	5.3	Very good	0.379	7.0	SFO using a fixed DT ₅₀ of 325 d
	Gartenacker Silt Loam 2.6 kg/ha	3.59	7.32	Acceptable	0.064	18.1	SFO using a fixed DT ₅₀ of 325 d
	Gartenacker Silt Loam 0.25 kg/ha	3.59	7.32	Acceptable	0.073	21.8	SFO using a fixed DT ₅₀ of 325 d
	Collombey Sand	2.29	7.7	Acceptable	0.301	18.2	SFO using a fixed DT ₅₀ of 325 d
	Les Evouettes Silt Loam	2.41	6.1	Good	0.381	9.6	SFO using a fixed DT ₅₀ of 325 d
	Speyer 2.2 Loamy Sand	4.4	6.0	Good	0.379	12.0	SFO using a fixed DT ₅₀ of 325 d
	Speyer 2.3 Sandy Loam	1.28	6.6	Acceptable	0.250	27.1	SFO using a fixed DT ₅₀ of 325 d
	Speyer 2.2 Loamy Sand	3.95	6.18	Reasonable	0.515	23.1	SFO using a fixed DT ₅₀ of 325 d
	Sisseln Sandy Loam	2.71	7.16	Acceptable	0.149	15.0	SFO using a fixed DT ₅₀ of 325 d
	Collombey Loamy Sand	2.02	7.45	Good	0.112	15.4	SFO using a fixed DT ₅₀ of 325 d
	Diegten Clay Loam	2.74	6.9	Very good	0.203	3.8	SFO using a fixed DT ₅₀ of 325 d
Arithmetic mean^a					0.217	-	-
Median^a					0.207	-	-

^a Average formation fraction for replicate soil values calculated first prior to derivation of overall mean or median all studies performed at 20°C

Table 8.3-4: Summary of aerobic degradation rates for Desethyl hydroxy-terbuthylazine (MT14)- laboratory studies

Desethyl hydroxy-terbuthylazine	Aerobic conditions (where metabolite applied as starting material)								
	Soil type	% OM	pH (KCl)	temp. °C / soil moisture for study (% w/w)	Soil moisture at pF 2 (% w/w)	DT _{50, actual} (d)	DT _{50, ref} 20 °C pF2 (d)	Min chi ² error (%) ^b	Method of calc.
	Borstel – Loamy Sand	2.6	5.8	20 °C / 10.88 %	14 ^a	135	113	7.7	SFO
	Gartenacker – Loam	2.8	7.6	20 °C / 25.08 %	25 ^a	50.1	50.1	5.3	SFO
	Lorsch – sandy clay loam	3.1	5.3	20 °C / 19.92 %	22 ^a	377	351	5.1	SFO
	Vetroz – Silt Loam	3.1	7.7	20 °C / 23.56 %	26 ^a	69.7	65.1	4.0	SFO
Geometric mean						115	107	-	-

a FOCUS default moisture content based on soil texture

b t-test result was >99% for every soil except Lorsch where it was >97%

Table 8.3-5: Summary of aerobic degradation rates for LM5 laboratory studies

LM5	Aerobic conditions (where metabolite was formed from parent desethyl-hydroxy terbuthylazine)									
	Soil type	% OM	pH (KCl)	temp. °C / soil moisture for study (% w/w)	Soil moisture at pF 2 (% w/w)	DT _{50, actual} (d)	DT _{50, ref} 20 °C pF2 (d)	Formation fraction	Min chi ² error (%) ^b	Method of calc.
	Gartenacker – Loam	2.8	7.6	20 °C / 25.08 %	25 ^a	119	119	0.491	4.72 (p = 0.0812)	SFO
	Vetroz – Silt Loam	3.1	7.7	20 °C / 23.56 %	26 ^a	146	136	0.440	3.00 (p = 0.1570)	SFO
Geometric mean						132	128	0.466 (arithmetic mean)	-	-

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Studies on anaerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- **Terbuthylazine** - EFSA Journal 2011; 9(1):1969

8.3.2.1 Terbuthylazine and its metabolites

Table 8.3-16: Summary of anaerobic degradation route for Terbuthylazine - laboratory studies

Mineralization after 100 days	≤ 0.1 % after 100 - 118 d, [14C-triazine ring]-label
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	(n= 2)
Non-extractable residues after 100 days	30.1 – 39.43 % after 100 - 118 d, [¹⁴ C-triazine ring]-label (n= 2)
Metabolites that may require further consideration for risk assessment – name and/or code, % of applied (range and maximum)	Max values from studies: desethyl-terbuthylazine (MT1) – 0.3 – 4.5 % at 30 - 56 d (n= 2) hydroxy-terbuthylazine (MT13) – 1.0 – 8.16 % at 91 - 100 d (n= 2) [¹⁴ C-triazine ring]-label

Table 8.3-17: Summary of anaerobic degradation rate for Terbuthylazine - laboratory studies

Terbuthylazine	Anaerobic conditions						
	Soil type	OM %	pH	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	DT ₅₀ (d) 20 °C pF2/10kPa	St. (r ²)
Gartenacker – Sandy loam - SYN	3.79	7.25	20 oC / flooded soil	108.3 / 359.9	N/A	0.981	SFO
Speyer 2.3 – Sandy Loam - SYN	2.07	6.3	20 oC / flooded soil	131 / 436	N/A	0.966	SFO
Geometric mean				119.1			

8.4 Field studies (KCP 9.1.1.2)

Studies on field degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion All relevant data are presented in :

-Terbuthylazine - EFSA Journal 2011; 9(1):1969

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

8.4.1.1 Terbutylazine and its metabolites

Table 8.4-1: Summary of aerobic degradation rates for Terbutylazine - field studies

Terbutylazine	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	% OM	pH	Depth (cm)	DT _{50,ref} 20 °C pF2 (d)	DT _{90,ref} 20 °C pF2 (d)	Min chi ² error (%)	t-test (%)	Method of calc. ^a
Loam – Bare soil	St Aubin, Switzerland	3.1	7.2	0 – 10	18.0	59.8	5.4	> 99%	SFO
Silt loam – Bare soil	Eschwege, Germany	4.0	6.2	0 – 20	17.3	57.5	16.8	> 99%	SFO
Silt loam – Bare soil	Goch, Germany	6.4	6.25	0 – 20	30.1	99.8	8.1	> 99%	SFO
Silty clay loam – Bare soil	Keeken, Germany	7.6	6.1	0 – 20	26.1	86.9	17.4	> 99%	SFO
Silt loam – Bare soil	Pleidsheim, Germany	2.1	6	0 – 20	17.4	57.7	19.0	> 99%	SFO
Loamy sand – Bare soil	Lorsch Helming, Germany	1.4	5.25	0 – 20	6.83	22.7	21.0	> 99%	SFO
Loamy sand – Bare soil	Weeze Wemb, Germany	3.8	6.2	0 – 20	12.3	40.7	17.3	> 99%	SFO
Clay loam – Bare soil	Grisolles, Southern France	1.62	7.3	0 – 30	53.1	176	12.7	> 99%	SFO
Silt loam – Bare soil	Molinella, Italy ^d	1.31	7.6	0 - 30	148	491	12.8	> 99%	SFO
Silt loam – Bare soil	St Firmin, France (North) (1.0)	1.6	8.4	0 – 10	24.7	82.2	8.9	> 99%	SFO
Silt loam – Bare soil	St Firmin, France (North) (1.5)	1.6	8.4	0 – 10	21.0	69.8	9.9	> 99%	SFO
Sand – Bare soil	Nevoy, France (North) (1.0)	1.0	8.6	0 – 10	12.1	40.2	9.1	> 99%	SFO
Sand – Bare soil	Nevoy, France (North) (1.5)	1.0	8.6	0 – 10	18.9	62.7	7.3	> 99%	SFO

Terbutylazine	Aerobic conditions									
	Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	% OM	pH	Depth (cm)	DT _{50,ref} 20 °C pF2 (d)	DT _{90,ref} 20 °C pF2 (d)	Min chi ² error (%)	t-test (%)	Method of calc. ^a
Silt loam – Bare soil	Charny, France (North) (1.0)	1.0	5.9	0 – 10	16.8	55.9	10.1	> 99%	SFO	
Silt loam – Bare soil	Charny, France (North) (1.0)	1.0	5.9	0 – 10	22.6	75.1	8.3	> 99%	SFO	
Silty sand – Bare soil	Ports sur Vienne, France (North) (1.0)	1.9	6.6	0 – 10	13.6	45.0	5.0	> 99%	SFO	
Silty sand – Bare soil	Ports sur Vienne, France (North) (1.5)	1.9	6.6	0 – 10	27.3	90.6	14.0	> 99%	SFO	
Sandy silt loam – Bare soil	Eraclea, Italy (1.0) ^b	3.4	7.6	0 – 10	77.9	259	40.0	> 82%	SFO	
Sandy silt loam – Bare soil	Eraclea, Italy (1.0) ^b	3.4	7.6	0 – 10	10.0	33.3	20.9	> 97%	SFO	
Clay – Bare soil	Emilia, Italy	3.3	7.5	0 – 10	31.3	104	7.9	> 99%	SFO	
Clay – Bare soil	Emilia Italy	3.3	7.5	0 – 10	30.6	102	6.0	> 99%	SFO	
Soft clayey sand – Bare soil	Hilgermissen, Germany ^c	1.5	5.9	0 – 10	35.8	119	12.5	> 99%	SFO	
Clayey sand – Bare soil	Leutzke, Germany	2.9	5.5	0 – 10	10.1	33.5	25.6	> 99%	SFO	
Geometric mean ^c						22.4	74.4	-	-	-
Median ^c						19.4	64.3	-	-	-

Table 8.4-2: Summary of aerobic degradation rates for Desethyl-terbuthylazine - field studies

Desethyl terbuthylazine	Aerobic conditions (where metabolite formed from parent terbuthylazine during the study)									
	Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	% OM	pH	DT _{50,ref} 20 °C pF2 (d)	DT _{90,ref} 20 °C pF2 (d)	Form. frac. (ffm)	Min chi ² error (%)	t-test (%)	Method of calc. ^d
Loam – Bare soil	St Aubin, Switzerland	3.1	7.2	16.5	54.9	0.298	17.1	>99%	SFO	
Silt loam – Bare soil	Pleidsheim, Germany	2.1	6	30.9	103	0.117	13.7	>77%	SFO	
Loamy sand – Bare soil	Lorsch Helming, Germany	1.4	5.25	1.72	5.72	0.320	21.6	>64%	SFO	
Clay loam – Bare soil	Grisolles, Southern France	1.62	7.3	46.8	155	0.829	14.9	>99%	SFO	
Silt loam – Bare soil	Molinella, Italy	1.31	7.6	223	740	0.497	7.1	>75%	SFO	
Silt loam – Bare soil	St Firmin, France (North) (1.0)	1.6	8.4	15.9	52.7	0.818	18.2	>92%	SFO	
Silt loam – Bare soil	St Firmin, France (North) (1.5)	1.6	8.4	19.5	64.8	0.438	5.4	>95%	SFO	
Silt loam – Bare soil	Charny, France (North) (1.0)	1.0	5.9	52.7	175	0.289	6.2	>97%	SFO	
Silt loam – Bare soil	Charny, France (North) (1.0)	1.0	5.9	77.8	258	0.249	11.4	>96%	SFO	
Soft clayey sand – Bare soil	Hilgermissen, Germany	1.5	5.9	26.2	87.1	0.678	9.3	>99%	SFO	
Arithmetic mean^{a,b}					-	-	0.45	-	-	-
Geometric mean^{a,c}					26.9	89.2	-	-	-	-
Median^{a,c}					28.6	95.1	-			

Table 8.4-3: Summary of aerobic degradation rates for Hydroxy-terbuthylazine - field studies.

Hydroxy-terbuthylazine	Aerobic conditions (where metabolite formed from parent terbuthylazine during the study)						
	Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	% OM	pH	Visual inspection	Form. frac. (ffim)	Min chi ² error (%)
Loam – Bare soil	St Aubin, Switzerland	3.1	7.2	Reasonable	0.079	22.7	SFO using a fixed DT ₅₀ of 305 d
Sand – Bare soil	Nevoy, France (North) (1.0)	1.0	8.6	Acceptable	0.174	22.3	SFO using a fixed DT ₅₀ of 305 d
Sand – Bare soil	Nevoy, France (North) (1.5)	1.0	8.6	Good	0.466	13.6	SFO using a fixed DT ₅₀ of 305 d
Silty sand – Bare soil	Ports sur Vienne, France (North) (1.5)	1.9	6.6	Reasonable	0.213	21.4	SFO using a fixed DT ₅₀ of 305 d
Soft clayey sand – Bare soil	Hilgermissen, Germany	1.5	5.9	Acceptable	0.169	32.3	SFO using a fixed DT ₅₀ of 305 d
Arithmetic mean^a					0.195	-	-
Median^a					0.191	-	-

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Studies on accumulation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- **Terbuthylazine** - EFSA Journal 2011; 9(1)

8.4.2.1 Terbuthylazine – soil accumulation testing

According to the EFSA Journal 2011; 9(1):1969 and Addendum to the DAR- there were No evidence of accumulation of terbuthylazine, desethyl-terbuthylazine, hydroxyterbuthylazine or desethyl-hydroxyterbuthylazine after repeated applications at 7 locations in Northern Italy.

8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- **Terbuthylazine** - EFSA Journal 2011; 9(1):1969.

8.5.1 Terbuthylazine and its metabolites

Table 8.5-1: Summary of soil adsorption/desorption for Terbuthylazine

Terbuthylazine ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.2 Loamy Sand – OXON	2.29	6.0	N/A	N/A	5.34	233	0.98
Les Evouettes Sandy Loam – OXON	1.20	5.9	N/A	N/A	2.95	246	0.90
Sisseln Sandy Loam – OXON	1.57	7.1	N/A	N/A	2.37	151	0.93
Vetroz Silt Loam - OXON	4.1	7.3	N/A	N/A	8.18	200	0.90
Pappelacker Loamy Sand – SYN	1.1	7.6	N/A	N/A	2.10	191	0.92
Lorsch Sandy Clay Loam – SYN	1.8	5.3	N/A	N/A	5.86	318	0.94
Gartenacker Loam – SYN	2.0	7.1	N/A	N/A	3.74	187	0.88
Vetroz Silt Loam - SYN	4.7	7.2	N/A	N/A	10.49	223	0.97
Borstel Loamy Sand – SYN*	1.48	6.1	N/A	N/A	4.93	333	0.91
Arithmetic mean					5.1	231	0.93
pH dependence, Yes or No			Possible weak negative correlation between sorption and soil pH ($r^2 = 0.5456$)				

NR = not recorded

Table 8.5-2: Summary of soil adsorption/desorption for metabolite desethyl-terbuthylazine

Desethyl-terbuthylazine (MT1) ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Collombey Loamy Sand - SYN	0.80	7.3	N/A	N/A	0.594	74.0	0.85
Les Evouettes Silt Loam – SYN	2.40	7.2	N/A	N/A	1.43	59.0	0.86
Vetroz Silt Loam - SYN	4.70	7.2	N/A	N/A	3.29	70.0	0.91
Speyer 2.1 Sand – OXON	0.6	5.9	N/A	N/A	0.43	67.2	0.95
Speyer 2.2 Loamy Sand – OXON	2.3	5.6	N/A	N/A	1.9	81.7	0.91
Beek Silt Loam – OXON	0.6	6.6	N/A	N/A	0.28	43.8	0.94
Marknesse Silt Loam - OXON	1.3	7.5	N/A	N/A	1.24	96.9	0.92
Lorsch Sandy Clay Loam - SYN	1.84	5.25	N/A	N/A	1.56	85.0	0.94
Borstel Loamy Sand – SYN*	1.48	6.1	N/A	N/A	1.80	122	0.77
Arithmetic mean					1.34	72.2	0.91
pH dependence (yes or no)				No			

* Data from this soil not included in arithmetic mean as the study was submitted after risk exposure modelling was completed. A re-calculated Kfoc would = 77.7 mL/ g.

Table 8.5-3: Summary of soil adsorption/desorption for metabolite hydroxy-terbuthylazine

Hydroxy-terbuthylazine (MT13) ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Cranfield 115 Clay Loam – OXON	1.7	7.9	N/A	N/A	3.51	208.6	0.82
Cranfield 164 Silt Loam – OXON	3.0	7.1	N/A	N/A	5.94	196.9	0.8
Cranfield 243 Sandy Loam - OXON	1.1	5.4	N/A	N/A	2.14	193.1	0.85
Borstel Sandy Loam - SYN	1.3	5.0	N/A	N/A	3.64	279.7	0.87
Collombey Loamy Sand - SYN	0.80	7.3	N/A	N/A	1.19	149	0.91
Les Evouettes Silt Loam - SYN	2.40	7.2	N/A	N/A	2.49	104	0.79
Vetroz Silt Loam - SYN	4.70	7.2	N/A	N/A	8.36	178	1.31
Arithmetic mean					3.90	187	0.91
pH dependence (yes or no)				No			

Table 8.5-4: Summary of soil adsorption/desorption for metabolite Desethyl -hydroxy-terbuthylazine

Desethyl-hydroxy-terbuthylazine (MT14) ‡							
Soil Type	OC %	Soil pH (CaCl ₂)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Borstel Loamy Sand	1.3	5.0	1.8	136	1.44	111	0.93
Lorsch Sandy Clay Loam	1.8	5.3	3.8	211	3.39	188	0.97
Gartenacker Loam/Silt Loam	2.0	7.1	1.2	59	1.10	55	0.98
Vetroz Silt Loam	4.7	7.2	2.8	60	2.67	57	0.98
Wisborough- Silty Clay Loam	3.44	5.02	4.40	375	3.36	98	0.8892
18 Acres - Sandy Clay Loam	1.95	5.27	4.79	242	3.34	171	0.9166
Kochi - Loam	1.17	5.65	8.26	213	2.98	254	0.8991
Bosket - Loam*	0.58	5.68	3.97	158	5.83	1010	0.9572
Ushiku - Sandy Clay Loam	1.98	5.99	6.98	1208	2.83	143	0.8674
Tsukuba - Loam	3.87	6.49	5.23	152	5.07	131	0.8881
Pappelacker - Sandy Loam	2.76	7.06	0.78	28	0.61	22	0.9220
Champaign - Silty Clay	2.52	7.34	4.62	236	2.50	99	0.8787
Median (all data, n=12)					2.91	121	0.92
pH dependence (yes or no)					No		

Table 8.5-5: Summary of soil adsorption/desorption for metabolite Terbutryn MT26

Terbutryn (MT26) ‡							
Soil Type	OC %	Soil pH (KCl)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Pappelacker - Sandy Loam	1.1	7.6	N/A	N/A	4.3	392	1.01
Speyer 2.1 - sand	0.6	7.4	N/A	N/A	3.7	605	1.06
Gartenacker Loam/Silt Loam	2.1	7.3	N/A	N/A	10.5	504	1.39
Vetroz Silt Loam	4.7	7.2	N/A	N/A	25.1	533	1.01
Illarsaz – silt loam	19.8	6.7	N/A	N/A	109.9	555	1.02
Arithmetic mean					13	518	1.04
pH dependence (yes or no)			No evidence from narrow pH range studied				

8.5.2 Column leaching (KCP 9.1.2.1)

Studies on column leaching with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

EU approved endpoints were evaluated during Annex I inclusion All relevant data are presented in :

- **Terbuthylazine** - EFSA Journal 2011; 9(1) :1969

8.5.4.2 Terbutylazine

Column leaching	Eluation (mm): 200 mm Time period (d): 2 d
	Leachate: < 0.01 - 0.04 % total residues/radioactivity in leachate 82.45 - 90.14 % active substance and 0.46 - 1.49 % extractable metabolites in soil. 45.48 – 87.37 % total residues/radioactivity retained in top 2 cm

8.5.3 Lysimeter studies (KCP 9.1.2.2)

Studies on column leaching with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :
Terbutylazine - EFSA Journal 2011; 9(1) :1969

8.5.3.1 Terbutylazine and metabolites.

Lysimeter/ field leaching studies ‡ (SYN)	Location: Schmallenberg/Grafschaft, Germany
Summary of metabolite codes:-	Study type (e.g.lysimeter, field): lysimeter (x2):
MT1 = GS26379	Soil properties (0 – 30 cm): Borstel Sandy Loam, pH =
MT13 = GS23158	5.7, OC= 1.5 % , MWHC = not stated (FC = 20 – 34 %
MT14 = GS28620	by volume)
MT19 = GS17792	Dates of application : 28/05/1990
MT20 = GS28273	Crop : maize followed by the rotational crops winter wheat and winter barley.
MT22 = G28279	Number of applications: 1 application to maize in first year only
LM1 = MT24 = G35713	Duration: 2 years,
LM2 = MT28 = CSAA036479	Application rate: 700 - 790 g/ha
LM3 = SM9 = CSCD692760	Average annual rainfall (mm): 863 mm
LM4 = CSAA404949	Average annual leachate volume (mm): 418.3 mm
LM5 = MT23 = SM12 = GS16984	% radioactivity in leachate (maximum/year): 1.45 – 1.48
LM6 = SM6 = CSCD648241	% AR
	Annual average maximum concentrations (e.g. 1st or 2nd yr, Lysimeter 38 or 44):
	< 0.02 µg/L terbutylazine,
	< 0.02 µg/L desethyl-terbutylazine,
	0.03 µg/L hydroxy-terbutylazine.
	0.03 µg/L G 28273 (MT20)
	0.05 µg/L GS 17792 (MT19)
	< 0.02 µg/L G 28279 (MT22), G 28260 (MT14)
	1.96 µg/L Unidentified radioactivity

	<p>Bi-annual average concentrations (e.g. 1st and 2nd yr, Lysimeter 38 and 44): < 0.02 µg/L terbuthylazine, < 0.02 µg/L desethyl-terbuthylazine, 0.02 µg/L hydroxy-terbuthylazine. 0.02 µg/L G 28273 (MT20) 0.03 µg/L GS 17792 (MT19) < 0.02 µg/L G 28279 (MT22), G 28260 (MT14) 1.21 µg/L Unidentified radioactivity Amount of radioactivity in the soils at the end of the study = 65.6 – 75.2 % AR; consisting of: 5.9 – 6.4 % AR as terbuthylazine, 1.2 – 1.5 % AR as desethyl-terbuthylazine, 0.2 – 0.5 % AR as hydroxy-terbuthylazine, < LOD – 0.2 % AR as G 28279 (MT22), 0.1 – 0.2 % AR as GS 28260 (MT14)</p>
<p>Lysimeter/ field leaching studies ‡ (SYN)</p>	<p>Location: Itingen, Switzerland Study type (e.g.lysimeter, field): lysimeter Soil properties (0 – 30 cm): Neustadt Sand, pH = 6.1, OC= 1.05, MWHC = 34.5 % Dates of application : May 1992 Crop : maize followed by two rotations of winter wheat Interception estimated: 25 % (based on standard crop interception values and growth stage of maize at time of application) Number of applications: 1 application to maize in first year only Duration: Application rate: 891 g/ha Average annual rainfall (mm): 1090 mm Average annual leachate volume (mm): 413.2 mm % radioactivity in leachate (maximum/year): 2.34 % AR Structural assignments for the parent and metabolites in the leachate were determined based on analysis during the original study coupled with additional information from further more recent accurate mass structural elucidation work. Parent and desethyl terbuthylazine were identified in the original study. Two further metabolites were plausibly assigned to LM3 and LM6 based on the additional mass spectral elucidation work. Assignment of other peaks was less certain based on matching relative retention times since matching HPLC conditions between this study and later definitive studies were not available. Quantitative concentrations are also uncertain due to the presence of multiple components in single peaks. Annual average concentrations (µg/l parent equivalents) Lysimeter 27:</p>

	<p>< 0.05 µg/L terbuthylazine (1st year); < 0.05 µg/L terbuthylazine (2nd year); < 0.05 µg/L terbuthylazine (mean of 1st and 2nd year) < 0.05 µg/L desethylterbuthylazine (1st year); < 0.05 µg/L desethylterbuthylazine (2nd year); < 0.05 µg/L desethylterbuthylazine (mean of 1st and 2nd year) 0.12 µg/L LM1* (1st year); 0.33 µg/L LM1* (2nd year); 0.25 µg/L LM1* (mean of 1st and 2nd year) 0.17 µg/L LM2* (1st year); 0.17 µg/L LM2* (2nd year); 0.17 µg/L LM2* (mean of 1st and 2nd year) 0.43 µg/L LM3 (1st year); 1.09 µg/L LM3 (2nd year); 0.84 µg/L LM3 (mean of 1st and 2nd year) 0.36 µg/L LM5* (1st year); 0.70 µg/L LM5* (2nd year); 0.57 µg/L LM5* (mean of 1st and 2nd year) 0.07 µg/L MT14 and LM4* (1st year); 0.11 µg/L MT14 and LM4* (2nd year); 0.09 µg/L MT14 and LM4* (mean of 1st and 2nd year) 0.05 µg/L LM6 (1st year); 0.50 µg/L LM6 (2nd year); 0.33 µg/L LM6 (mean of 1st and 2nd year) 0.25 µg/L LM7* (1st year); 0.05 µg/L LM7* (2nd year); 0.12 µg/L LM7* (mean of 1st and 2nd year) *= structures tentatively assigned to peaks Additional unidentified radioactivity (sum of smaller peaks) 0.11 µg/L (1st year); 0.29µg/l (2nd year); 0.22µg/l (mean of 1st and 2nd year) Amount of radioactivity in the soils at the end of the study = 67.7 % AR; consisting of (0 – 18 cm depth only) 0.92 % AR as parent 0.92 % AR as desethyl-terbuthylazine, 11.97 % AR as hydroxy-terbuthylazine, 1.52 % as desethyl-hydroxy-terbuthylazine, 6.29 % unidentified</p>
<p>Lysimeter/ field leaching studies ‡ (OXON)</p>	<p>Location: Itingen, Switzerland Study type (e.g.lysimeter, field): lysimeter (x2) Soil properties (0 – 30 cm): Neustadt Sand, pH = 6.1, OC= 1.05, MWHC = 34.5 % Dates of application : 18/05/93 Crop : maize, followed by two rotations of winter wheat</p>

	<p>Number of applications: 1 application to maize in first year only. Duration: 2 years Application rate: 905 g/ha/lysimeter 7; 929 g/ha/lysimeter 9 (application in first year only) Average annual rainfall (mm): 1090 mm Average annual leachate volume (mm): 485.6 mm % radioactivity in leachate (maximum/year): 1.60 - 1.70 % AR Annual average concentrations (e.g. 1st and 2nd yr, Lysimeter 7 and 9): not detected – terbuthylazine, desethyl terbuthylazine, hydroxy terbuthylazine 0.04/0.06µg/l LM1 (lysimeter 7/9, 1st year); 0.12/0.15µg/l LM1 (lysimeter 7/9, 2nd year) 0.04/0.03µg/l LM2 (lysimeter 7/9, 1st year); 0.10/0.10µg/l LM2 (lysimeter 7/9, 2nd year) 0.26/0.31µg/l LM3 (lysimeter 7/9, 1st year); 0.85/0.83µg/l LM3 (lysimeter 7/9, 2nd year) 0.38/0.40µg/l LM4 (lysimeter 7/9, 1st year); 0.14/0.18µg/l LM4 (lysimeter 7/9, 2nd year) 0.10/0.08µg/l LM5 (lysimeter 7/9, 1st year); 0.71/0.62µg/l LM5 (lysimeter 7/9, 2nd year) 0.03/0.01µg/l LM6 (lysimeter 7/9, 1st year); 0.53/0.40µg/l LM6 (lysimeter 7/9, 2nd year) 0.08/0.08µg/l LM7 (lysimeter 7/9, 1st year); 0.06/0.03µg/l LM7 (lysimeter 7/9, 2nd year) Amount of radioactivity in the soils at the end of the study = 76.20 - 80.62 %AR; consisting of (0 – 38 cm depth only – max values) 6.4 % AR as terbuthylazine 1.0 % AR as desethyl-terbuthylazine, 53.8 % AR as hydroxy-terbuthylazine, 30 - 52 % AR unextracted radioactivity</p>
<p>Lysimeter/ field leaching studies ‡ (SYN)</p>	<p>Location: Lorsch, Hessen, Germany Study type (e.g.lysimeter, field): Field leaching study Soil properties (0 – 30 cm): sandy loam, pH = 5.2 – 6.3, OC= 2.3 – 2.6, MWHC = not reported Dates of application : 1990, 1992, 1994 – 1997, 1999 - 2000 Crop : maize in application years. Interception estimated: 25 % (based on standard crop interception values and growth stage of maize at time of application) Number of applications: 8 applications, maximum of 1 per year Duration: 11 years Application rate: 735 g/ha in 1990; 750 g/ha in all other application years Average annual rainfall (mm): 587 mm (NB. data from 1993, 1995 and 1998 not reported) Average annual leachate volume (mm): Not applicable % radioactivity in leachate (maximum/year):</p>

	<p>Not applicable.</p> <p>Frequency of detections, detections above >0.1µg/l and maximum conc.:</p> <p>Terbuthylazine: 1 detection out of 418 samples; 0% (~0 samples) >0.1µg/l; maximum concentration = 0.09µg/l.</p> <p>Desethyl terbuthylazine: 0 detections out of 419 samples; Desethyl hydroxyterbuthylazine: 17 detections out of 51 samples; 24% (~12 samples) >0.1µg/l; maximum concentration = 0.41µg/l.</p> <p>2-hydroxy terbuthylazine: 10 detections out of 51 samples, 0%(0 samples) >0.1µg/l; maximum concentration = 0.08µg/l.</p> <p>Individual annual maximum concentrations (e.g. 1st, 2nd, 3rd yr):</p> <p>< 0.05 µg/L terbuthylazine < 0.05 µg/L desethyl-terbuthylazine, 0.06 µg/L 2-hydroxy-terbuthylazine 0.25 µg/L desethylhydroxy-terbuthylazine</p> <p>Individual annual average concentrations (e.g. 1st, 2nd, 3rd yr):</p> <p>< 0.05 µg/L terbuthylazine < 0.05 µg/L desethyl-terbuthylazine, < 0.05 µg/L 2-hydroxy-terbuthylazine < 0.05 - 0.12 µg/L desethylhydroxy-terbuthylazine</p> <p>Amount of radioactivity in the soils at the end of the study = not reported</p> <p>Note that 2-hydroxy terbuthylazine was only analysed for in 1999-2000 and 2000-2001. Desethylhydroxy terbuthylazine was only analysed for in 1997-1998, 1999-2000 and 2000-2001.</p>
	<p>Location: 10 sites in 5 regions (Emilia Romagna, Friuli Venezia – Giulia, Lombardia, Piemonte, Veneto) in Northern Italy</p> <p>Study type (e.g. lysimeter, field): field leaching study</p> <p>Soil properties: texture class – 5 sandy loams, 3 loams, 1 sandy clay and 1 clay loam; pH = 4.9-7.7; OC = 0.9 – 3.6%; MWHC = not reported</p> <p>Groundwater depth: 0.12 to 7.1m below ground surface</p> <p>Dates of application : 2005 to 2007</p> <p>Crop : maize</p> <p>Irrigation: sprinkler, basin, border or no irrigation</p> <p>Interception estimated: 0 % (applications made shortly after seeding maize)</p> <p>Number and rate of applications: between 2005 and 2007, 7 sites had 3 annual applications of 856 g terbuthylazine/ha. The remaining 3 sites had either 2 or 1 annual application.</p>

	<p>Duration: bi-monthly sampling for 3 years (17 sampling events)</p> <p>Average annual rainfall (mm): Reported to be below the overall average for the period 2000-2007 but supplemented by irrigation at 9 out of 10 sites.</p> <p>Frequency of detections, detection >0.1µg/l and maximum conc. (excluding basin irrigated sites, n=8):</p> <p>Terbuthylazine: 62 detections out of 395 samples; 3% (~13 samples) >0.1µg/l; maximum concentration = 3.20µg/l.</p> <p>Desethyl terbuthylazine: 125 detections out of 395 samples; 5% (~21 samples) >0.1µg/l; maximum concentration = 3.18µg/l.</p> <p>Desethyl hydroxyterbuthylazine: 57 detections out of 144 samples; 29% (~42 samples) >0.1µg/l; maximum concentration = 2.65µg/l.</p> <p>2-hydroxy terbuthylazine: 2 detections out of 144 samples, 0%(0 samples) >0.1µg/l; maximum concentration = 0.05µg/l.</p> <p>LM5: 11 detections out of 21 samples; 29% (~6 samples) > 0.1µg/l; maximum concentration = 0.68µg/l.</p> <p>LM6: 9 detections out of 21 samples; 38% (~8 samples) >0.1µg/l; maximum concentration = 1.58µg/l.</p> <p>Annual average concentrations:</p> <p>0.03 – 0.58 µg/L terbuthylazine (basin irrigation)</p> <p><0.01 – 0.07 µg/L terbuthylazine (sprinkler or border irrigation)</p> <p>0.07 – 0.73 µg/L desethyl terbuthylazine (basin irrigation)</p> <p><0.01 – 0.22 µg/L desethyl terbuthylazine (sprinkler or border irrigation)</p> <p>< 0.05 – 0.05 µg/L (single sample) 2-hydroxy terbuthylazine (analysed for 2007 only)</p> <p>0.04 – 0.37 µg/L desethyl hydroxy-terbuthylazine (analysed for the 2007 season only)</p> <p><0.05 – 0.48 µg/L GS16984 (LM5) (analysed for the 2007 season only)</p> <p><0.05 – 1.3 µg/L CSCD648241 (LM6) (analysed for the 2007 season only)</p> <p>Note that as high concentrations were also found in the upstream monitoring wells, parts of residues found in downstream monitoring wells are likely to derive from previous usage following several years of commercial application in the upstream areas.</p>
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8.5.4 Field leaching studies (KCP 9.1.2.3)

Field leaching study was performed for terbuthylazine and evaluated during EU review, according to the EFSA Journal 2011; 9(1):1969

<p>Lysimeter/ field leaching studies ‡ (SYN)</p> <p>Summary of metabolite codes:- MT1 = GS26379 MT13 = GS23158 MT14 = GS28620 MT19 = GS17792 MT20 = GS28273 MT22 = G28279 LM1 = MT24 = G35713 LM2 = MT28 = CSAA036479 LM3 = SM9 = CSCD692760 LM4 = CSAA404949 LM5 = MT23 = SM12 = GS16984 LM6 = SM6 = CSCD648241</p>	<p>Location: Schmallenberg/Grafschaft, Germany Study type (e.g.lysimeter, field): lysimeter (x2): Soil properties (0 – 30 cm): Borstel Sandy Loam, pH = 5.7, OC= 1.5 % , MWHC = not stated (FC = 20 – 34 % by volume) Dates of application : 28/05/1990 Crop : maize followed by the rotational crops winter wheat and winter barley. Number of applications: 1 application to maize in first year only Duration: 2 years, Application rate: 700 - 790 g/ha Average annual rainfall (mm): 863 mm Average annual leachate volume (mm): 418.3 mm % radioactivity in leachate (maximum/year): 1.45 – 1.48 % AR Annual average maximum concentrations (e.g. 1st or 2nd yr, Lysimeter 38 or 44): < 0.02 µg/L terbuthylazine, < 0.02 µg/L desethyl-terbuthylazine, 0.03 µg/L hydroxy-terbuthylazine. 0.03 µg/L G 28273 (MT20) 0.05 µg/L GS 17792 (MT19) < 0.02 µg/L G 28279 (MT22), G 28260 (MT14) 1.96 µg/L Unidentified radioactivity Bi-annual average concentrations (e.g. 1st and 2nd yr, Lysimeter 38 and 44): < 0.02 µg/L terbuthylazine, < 0.02 µg/L desethyl-terbuthylazine, 0.02 µg/L hydroxy-terbuthylazine. 0.02 µg/L G 28273 (MT20) 0.03 µg/L GS 17792 (MT19) < 0.02 µg/L G 28279 (MT22), G 28260 (MT14) 1.21 µg/L Unidentified radioactivity Amount of radioactivity in the soils at the end of the study = 65.6 – 75.2 % AR; consisting of: 5.9 – 6.4 % AR as terbuthylazine, 1.2 – 1.5 % AR as desethyl-terbuthylazine, 0.2 – 0.5 % AR as hydroxy-terbuthylazine, < LOD – 0.2 % AR as G 28279 (MT22), 0.1 – 0.2 % AR as GS 28260 (MT14)</p>
<p>Lysimeter/ field leaching studies ‡ (SYN)</p>	<p>Location: Itingen, Switzerland Study type (e.g.lysimeter, field): lysimeter Soil properties (0 – 30 cm): Neustadt Sand, pH = 6.1,</p>

	<p>OC= 1.05, MWHC = 34.5 % Dates of application : May 1992 Crop : maize followed by two rotations of winter wheat Interception estimated: 25 % (based on standard crop interception values and growth stage of maize at time of application) Number of applications: 1 application to maize in first year only Duration: Application rate: 891 g/ha Average annual rainfall (mm): 1090 mm Average annual leachate volume (mm): 413.2 mm % radioactivity in leachate (maximum/year): 2.34 % AR Structural assignments for the parent and metabolites in the leachate were determined based on analysis during the original study coupled with additional information from further more recent accurate mass structural elucidation work. Parent and desethyl terbuthylazine were identified in the original study. Two further metabolites were plausibly assigned to LM3 and LM6 based on the additional mass spectral elucidation work. Assignment of other peaks was less certain based on matching relative retention times since matching HPLC conditions between this study and later definitive studies were not available. Quantitative concentrations are also uncertain due to the presence of multiple components in single peaks. Annual average concentrations ($\mu\text{g/l}$ parent equivalents) Lysimeter 27: < 0.05 $\mu\text{g/L}$ terbuthylazine (1st year); < 0.05 $\mu\text{g/L}$ terbuthylazine (2nd year); < 0.05 $\mu\text{g/L}$ terbuthylazine (mean of 1st and 2nd year) < 0.05 $\mu\text{g/L}$ desethylterbuthylazine (1st year); < 0.05 $\mu\text{g/L}$ desethylterbuthylazine (2nd year); < 0.05 $\mu\text{g/L}$ desethylterbuthylazine (mean of 1st and 2nd year) 0.12 $\mu\text{g/L}$ LM1* (1st year); 0.33 $\mu\text{g/L}$ LM1* (2nd year); 0.25 $\mu\text{g/L}$ LM1* (mean of 1st and 2nd year) 0.17 $\mu\text{g/L}$ LM2* (1st year); 0.17 $\mu\text{g/L}$ LM2* (2nd year); 0.17 $\mu\text{g/L}$ LM2* (mean of 1st and 2nd year) 0.43 $\mu\text{g/L}$ LM3 (1st year); 1.09 $\mu\text{g/L}$ LM3 (2nd year); 0.84 $\mu\text{g/L}$ LM3 (mean of 1st and 2nd year) 0.36 $\mu\text{g/L}$ LM5* (1st year); 0.70 $\mu\text{g/L}$ LM5* (2nd year); 0.57 $\mu\text{g/L}$ LM5* (mean of 1st and 2nd year) 0.07 $\mu\text{g/L}$ MT14 and LM4* (1st year); 0.11 $\mu\text{g/L}$</p>
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	<p>MT14 and LM4* (2nd year); 0.09 µg/L MT14 and LM4* (mean of 1st and 2nd year) 0.05 µg/L LM6 (1st year); 0.50 µg/L LM6 (2nd year); 0.33 µg/L LM6 (mean of 1st and 2nd year) 0.25 µg/L LM7* (1st year); 0.05 µg/L LM7* (2nd year); 0.12 µg/L LM7* (mean of 1st and 2nd year) *= structures tentatively assigned to peaks Additional unidentified radioactivity (sum of smaller peaks) 0.11 µg/L (1st year); 0.29µg/l (2nd year); 0.22µg/l (mean of 1st and 2nd year) Amount of radioactivity in the soils at the end of the study = 67.7 % AR; consisting of (0 – 18 cm depth only) 0.92 % AR as parent 0.92 % AR as desethyl-terbuthylazine, 11.97 % AR as hydroxy-terbuthylazine, 1.52 % as desethyl-hydroxy-terbuthylazine, 6.29 % unidentified</p>
<p>Lysimeter/ field leaching studies ‡ (OXON)</p>	<p>Location: Itingen, Switzerland Study type (e.g.lysimeter, field): lysimeter (x2) Soil properties (0 – 30 cm): Neustadt Sand, pH = 6.1, OC= 1.05, MWHC = 34.5 % Dates of application : 18/05/93 Crop : maize, followed by two rotations of winter wheat Number of applications: 1 application to maize in first year only. Duration: 2 years Application rate: 905 g/ha/lysimeter 7; 929 g/ha/lysimeter 9 (application in first year only) Average annual rainfall (mm): 1090 mm Average annual leachate volume (mm): 485.6 mm % radioactivity in leachate (maximum/year): 1.60 - 1.70 % AR Annual average concentrations (e.g. 1st and 2nd yr, Lysimeter 7 and 9): not detected – terbuthylazine, desethyl terbuthylazine, hydroxy terbuthylazine 0.04/0.06µg/l LM1 (lysimeter 7/9, 1st year); 0.12/0.15µg/l LM1 (lysimeter 7/9, 2nd year) 0.04/0.03µg/l LM2 (lysimeter 7/9, 1st year); 0.10/0.10µg/l LM2 (lysimeter 7/9, 2nd year) 0.26/0.31µg/l LM3 (lysimeter 7/9, 1st year); 0.85/0.83µg/l LM3 (lysimeter 7/9, 2nd year) 0.38/0.40µg/l LM4 (lysimeter 7/9, 1st year);</p>

	<p>0.14/0.18µg/l LM4 (lysimeter 7/9, 2nd year) 0.10/0.08µg/l LM5 (lysimeter 7/9, 1st year); 0.71/0.62µg/l LM5 (lysimeter 7/9, 2nd year) 0.03/0.01µg/l LM6 (lysimeter 7/9, 1st year); 0.53/0.40µg/l LM6 (lysimeter 7/9, 2nd year) 0.08/0.08µg/l LM7 (lysimeter 7/9, 1st year); 0.06/0.03µg/l LM7 (lysimeter 7/9, 2nd year) Amount of radioactivity in the soils at the end of the study = 76.20 - 80.62 %AR; consisting of (0 – 38 cm depth only – max values) 6.4 % AR as terbuthylazine 1.0 % AR as desethyl-terbuthylazine, 53.8 % AR as hydroxy-terbuthylazine, 30 - 52 % AR unextracted radioactivity</p>
<p>Lysimeter/ field leaching studies ‡ (SYN)</p>	<p>Location: Lorsch, Hessen, Germany Study type (e.g.lysimeter, field): Field leaching study Soil properties (0 – 30 cm): sandy loam, pH = 5.2 – 6.3, OC= 2.3 – 2.6, MWHC = not reported Dates of application : 1990, 1992, 1994 – 1997, 1999 - 2000 Crop : maize in application years. Interception estimated: 25 % (based on standard crop interception values and growth stage of maize at time of application) Number of applications: 8 applications, maximum of 1 per year Duration: 11 years Application rate: 735 g/ha in 1990; 750 g/ha in all other application years Average annual rainfall (mm): 587 mm (NB. data from 1993, 1995 and 1998 not reported) Average annual leachate volume (mm): Not applicable % radioactivity in leachate (maximum/year): Not applicable. Frequency of detections, detections above >0.1µg/l and maximum conc.: Terbuthylazine: 1 detection out of 418 samples; 0% (~0 samples) >0.1µg/l; maximum concentration = 0.09µg/l. Desethyl terbuthylazine: 0 detections out of 419 samples; Desethyl hydroxyterbuthylazine: 17 detections out of 51 samples; 24% (~12 samples) >0.1µg/l; maximum concentration = 0.41µg/l. 2-hydroxy terbuthylazine: 10 detections out of 51 samples, 0%(0 samples) >0.1µg/l; maximum concentration = 0.08µg/l. Individual annual maximum concentrations (e.g. 1st, 2nd, 3rd yr): < 0.05 µg/L terbuthylazine < 0.05 µg/L desethyl-terbuthylazine, 0.06 µg/L 2-hydroxy-terbuthylazine 0.25 µg/L desethylhydroxy-terbuthylazine Individual annual average concentrations (e.g. 1st, 2nd,</p>

	<p>3rd yr): < 0.05 µg/L terbuthylazine < 0.05 µg/L desethyl-terbuthylazine, < 0.05 µg/L 2-hydroxy-terbuthylazine < 0.05 - 0.12 µg/L desethylhydroxy-terbuthylazine Amount of radioactivity in the soils at the end of the study = not reported Note that 2-hydroxy terbuthylazine was only analysed for in 1999-2000 and 2000-2001. Desethylhydroxy terbuthylazine was only analysed for in 1997-1998, 1999-2000 and 2000-2001.</p>
	<p>Location: 10 sites in 5 regions (Emilia Romagna, Friuli Venezia – Giulia, Lombardia, Piemonte, Veneto) in Northern Italy Study type (e.g. lysimeter, field): field leaching study Soil properties: texture class – 5 sandy loams, 3 loams, 1 sandy clay and 1 clay loam; pH = 4.9-7.7; OC = 0.9 – 3.6%; MWHC = not reported Groundwater depth: 0.12 to 7.1m below ground surface Dates of application : 2005 to 2007 Crop : maize Irrigation: sprinkler, basin, border or no irrigation Interception estimated: 0 % (applications made shortly after seeding maize) Number and rate of applications: between 2005 and 2007, 7 sites had 3 annual applications of 856 g terbuthylazine/ha. The remaining 3 sites had either 2 or 1 annual application. Duration: bi-monthly sampling for 3 years (17 sampling events) Average annual rainfall (mm): Reported to be below the overall average for the period 2000-2007 but supplemented by irrigation at 9 out of 10 sites. Frequency of detections, detection >0.1µg/l and maximum conc. (excluding basin irrigated sites, n=8): Terbuthylazine: 62 detections out of 395 samples; 3% (~13 samples) >0.1µg/l; maximum concentration = 3.20µg/l. Desethyl terbuthylazine: 125 detections out of 395 samples; 5% (~21 samples) >0.1µg/l; maximum concentration = 3.18µg/l. Desethyl hydroxyterbuthylazine: 57 detections out of 144 samples; 29% (~42 samples) >0.1µg/l; maximum concentration = 2.65µg/l.</p>

	<p>2-hydroxy terbuthylazine: 2 detections out of 144 samples, 0%(0 samples) >0.1µg/l; maximum concentration = 0.05µg/l.</p> <p>LM5: 11 detections out of 21 samples; 29% (~6 samples) > 0.1µg/l; maximum concentration = 0.68µg/l.</p> <p>LM6: 9 detections out of 21 samples; 38% (~8 samples) >0.1µg/l; maximum concentration = 1.58µg/l.</p> <p>Annual average concentrations:</p> <p>0.03 – 0.58 µg/L terbuthylazine (basin irrigation)</p> <p><0.01 – 0.07 µg/L terbuthylazine (sprinkler or border irrigation)</p> <p>0.07 – 0.73 µg/L desethyl terbuthylazine (basin irrigation)</p> <p><0.01 – 0.22 µg/L desethyl terbuthylazine (sprinkler or border irrigation)</p> <p>< 0.05 – 0.05 µg/L (single sample) 2-hydroxy terbuthylazine (analysed for 2007 only)</p> <p>0.04 – 0.37 µg/L desethyl hydroxy-terbuthylazine (analysed for the 2007 season only)</p> <p><0.05 – 0.48 µg/L GS16984 (LM5) (analysed for the 2007 season only)</p> <p><0.05 – 1.3 µg/L CSCD648241 (LM6) (analysed for the 2007 season only)</p> <p>Note that as high concentrations were also found in the upstream monitoring wells, parts of residues found in downstream monitoring wells are likely to derive from previous usage following several years of commercial application in the upstream areas.</p>
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8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

Terbuthylazine - EFSA Journal 2011; 9(1):1969.

8.6.1 Terbutylazine and its metabolites

Table 8.6-1: Summary of degradation in water/sediment of Terbutylazine

Water / sediment system	pH water phase	pH sed	t. °C	DT ₅₀ -DT ₉₀ whole sys.	St. (r ²)	DT ₅₀ -DT ₉₀ water	St. (r ²)	DT ₅₀ - DT ₉₀ sed	St. (r ²)	Method of calculation
River Rhine sandy loam - SYN	8.3	7.7	20	73 days / 242 days	0.9917	6 days / 131 days	0.9994	NC	-	SFO – whole system DFOP – water phase
Pond Ormalingen silt loam - SYN	8.1	7.5	20	33 days / 110 days	0.9994	6 days / 47 days	0.9991	NC	-	SFO – whole system DFOP – water phase
River Rhine Loamy sand – OXON	8.2	7.3	20	83.5 days / 277.5 days	0.9991	31.4 days / 104.4 days	0.850	NC	-	SFO
Pond Anwil clay loam - OXON	8.3	6.6	20	118.5 days / 393.8 days	0.967	32.1 days / 106.7 days	0.870	NC	-	SFO
Geometric mean			20	69.9 days / 232.2 days		NC – not all SFO		NC		SFO

NC = not calculated

Table 8.6-2: Summary of observed metabolites

desethyl-terbutylazine (MT1) Water/sediment system	8.8 % whole system (110 d), 2.8 % sed (110 d), 8.0 % water (365 d)	Evaluated on EU level (Y) EFSA Journal 2011; 9(1):1969
hydroxy-terbutylazine (MT13) Water/sediment system	20 % whole system (365 d), 14.5 % sed (272 d), 5.7 % water (365 d)	Evaluated on EU level (Y) EFSA Journal 2011; 9(1):1969
terbutryn (MT26) Water/sediment system	7.4 % whole system (365 d), 7.4 % sed (272 d), 0.3 % water (118 d)	Evaluated on EU level (Y) EFSA Journal 2011; 9(1):1969

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

8.7.1 Justification for new endpoints

All endpoints used for PEC soil calculations are EU approved and were evaluated on EU level and presented in:

- Terbutylazine - EFSA Journal 2011; 9(1):1969).

8.7.2 Active substance(s) and relevant metabolite(s)

Table 8.7-1: Input parameters related to application for PEC_{soil} calculations

Use No.	1
Crop	maize
Application rate (g as/ha)	terbutylazine: 500 g as./ha
Number of applications/interval	1/-
Crop interception (%)	0%
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm – no tillage

Table 8.7-2: Input parameter for active substance(s) and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Terbutylazine	229.7	-	DT50: 46.6 d Kinetics: SFO Field or Lab: representative worst case un-normalised values from field studies.	EFSA Journal 2011; 9(1):1969
Desethyl-terbutylazine (MT1)	201.7	32.9%	DT50:223d Kinetics: SFO Field or Lab: representative worst case un-normalised values from field studies	EFSA Journal 2011; 9(1):1969
Hydroxy-terbutylazine	211.3	34.5%	DT50:453 d Kinetics: SFO using a fixed DT50 Field or Lab: representative worst case un-normalised values from field studies	EFSA Journal 2011; 9(1):1969
Desethyl hydroxy-terbutylazine (MT14)	183.2	28	135	Yes / EFSA Journal 2011; 9(1):1969

8.7.2.1 Terbuthylazine and its metabolites

Table 8.7-3: PEC_{soil} for Terbuthylazine on maize

PEC _{soil} (mg/kg)		Maize			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.6667	-	-	-
Short term	24h	0.6568	0.6617	-	-
	2d	0.6471	0.6569	-	-
	4d	0.6282	0.6472	-	-
Long term	7d	0.6007	0.6331	-	-
	14d	0.5413	0.6018	-	-
	21d	0.4878	0.5726	-	-
	28d	0.4396	0.5453	-	-
	50d	0.3169	0.4703	-	-
	100d	0.1506	0.3469	-	-
Plateau concentration (5 cm) after year 10		0.0029	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.6696	-	-	-

PEC_{soil} of metabolites

Table 8.7-4: PEC_{soil} for Desethyl-terbuthylazine on maize

PEC _{soil} (mg/kg)		Maize			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.1276	-	-	-
Short term	24h	0.1276	0.1276	-	-
	2d	0.1275	0.1276	-	-
	4d	0.1275	0.1276	-	-
Long term	7d	0.1274	0.1275	-	-
	14d	0.1270	0.1275	-	-
	21d	0.1264	0.1275	-	-
	28d	0.1256	0.1274	-	-
	50d	0.1220	0.1269	-	-
	100d	0.1106	0.1252	-	-
Plateau concentration (5 cm) after year 10		0.0805	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.2081	-	-	-

Table 8.7-5: PEC_{soil} for Hydroxy-terbuthylazine on maize

PEC _{soil} (mg/kg)		Maize			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.1631	-	-	-
Short term	24h	0.1631	0.1631	-	-
	2d	0.1631	0.1631	-	-
	4d	0.1631	0.1631	-	-
Long term	7d	0.1631	0.1631	-	-
	14d	0.1628	0.1631	-	-
	21d	0.1624	0.1631	-	-
	28d	0.1619	0.1630	-	-
	50d	0.1596	0.1627	-	-
	100d	0.1519	0.1616	-	-
Plateau concentration (5 cm) after year 10		0.2554	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.4186	-	-	-

Table 8.7-6: PEC_{soil} Desethyl hydroxy-terbuthylazine (MT14) for MT14 on maize

PEC _{soil} (mg/kg) 111.7 g/ha		maize	
		Single application	
		Actual	TWA
Initial		0.149	0.149
Short term	24h	0.148	0.149
	2d	0.147	0.148
	4d	0.146	0.147
Long term	7d	0.144	0.146
	14d	0.139	0.144
	21d	0.134	0.141
	28 d	0.129	0.139
	50d	0.115	0.131
	100d	0.089	0.116
Plateau concentration		0.027	
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.176	

8.7.2.2 PEC_{soil} of TERBUT 500 SC

Table 8.7-5: PEC_{soil} for TERBUT 500 SC on maize

Active substance/ reparation	Application rate (g/ha)	PEC _{act} (mg/kg)	PEC _{twa21 d} (mg/kg)	Tillage depth (cm)	PEC _{soil,plateau} (mg/kg)	PEC _{accu} = PEC _{act} + PEC _{soil,plateau} (mg/kg)
TERBUT 500 SC	1105	1.4733	1.2654	5 cm	0.0065	1.4798

Comments zRMS:

The calculations were accepted.

The EU agreed endpoints (EFSA Journal 2011; 9(1):1969) were used for calculations. The interception values based on the FOCUS guidance (*Generic Guidance for Tier 1 FOCUS Ground Water Assessments (version: 2.2, May 2014)*) was considered.

Calculations were performed with consideration of the critical use pattern proposed in GAP.

Terbutylazine

PEC_{soil} initial = 0.6667 mg/kg

Desethyl-terbutylazine (MT1)

PEC_{soil} initial = 0.1276 mg/kg

Hydroxy-terbutylazine

PEC_{soil} initial = 0.1631 mg/kg

TERBUT 500 SC = PEC_{soil} initial = 1.4798 mg/kg

PEC values for terbutylazine and its metabolites are suitable for use in risk assessment.

The PECs for metabolite desethyl hydroxy-terbutylazine (MT14) were calculated by zRMS.

Desethyl hydroxyl- terbutylazine (MT14)

PEC_{soil} initial = 0.149 mg/kg

PEC_{soil} accumulation = 0.176 mg/kg

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

8.8.1 Justification for new endpoints

All endpoints used for PEC ground water calculations are EU approved and were evaluated on EU level and presented in:

Terbutylazine - EFSA Journal 2011; 9(1):1969

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

Table 8.8-1: Input parameters related to application for PEC_{gw} calculations

Use No.	
Crop	Maize
Application rate (g as/ha)	Terbutylazine: 500 g as/ha
Number of applications/interval (d)	1/-
Relative application date	
Crop interception (%)	0%
Frequency of application	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.3

8.8.2.1 Terbutylazine and its metabolites

Table 8.8-2: Input parameters related to active substance terbutylazine and metabolite(s) for PEC_{gw} calculations

Compound	terbutylazine	MT1	MT13	MT14	Value in accordance with EU endpoint y/n
Molecular mass (g/mol)	229.7	201.7	211.3	183.2	Yes / EFSA Journal 2011; 9(1):1969
Solubility in water (mg/L) at 20°C	8.5	327.1	7.19	18 (25°C)	Yes / EFSA Journal 2011; 9(1):1969
Saturated vapour pressure (Pa)	9.0 x 10 ⁻⁵ , set to 0 as terbutylazine DT ₅₀ was derived from field studies	0*	0*	0*	Yes / EFSA Journal 2011; 9(1):1969
DT ₅₀ in soil (d) (geometric mean)	19.4 (median of field studies)	26.9	453	107	Yes / EFSA Journal 2011; 9(1):1969
K _{foc} (mL/g) (arithmetic mean) lowest K _{foc} value of 151 L/kg	151	78	187.1	121	Yes / EFSA Journal 2011; 9(1):1969
K _{fom} (mL/g)	87.6	45.2	108.5	70.2	Calculated from K _{foc} (K _{fom} = K _{foc} /1.724)
1/n (arithmetic mean)	0.93	0.895	0.91	0.92	Yes / EFSA Journal 2011; 9(1):1969

Compound	terbuthylazine	MT1	MT13	MT14	Value in accordance with EU endpoint y/n
Plant uptake factor	0.267	0	0	0	Value for terbuthylazine is calculated on the basis of $TSCF=0.784\exp\{-[\log(Kow)-1.78]^2/2.44\}$, 0 is a FOCUS default
Formation fraction	-	From terbuthylazine: 0.45	From terbuthylazine: 0.207	From desethyl-terbuthylazine: 0.28	Yes / EFSA Journal 2011; 9(1):1969
Compound	LM3	LM5	LM6	Value in accordance with EU endpoint y/n	
Molecular mass (g/mol)	198.2	184.2	198.2	Additional Report to the DAR, Volume 3, part 4, B.8	
Solubility in water (mg/L) at 25°C	18	18	18	Additional Report to the DAR, Volume 3, part 4, B.8	
Saturated vapour pressure (Pa) at 20°C	0*	0*	0*	Additional Report to the DAR, Volume 3, part 4, B.8	
DT ₅₀ in soil (d)	453	128	453	Additional Report to the DAR, Volume 3, part 4, B.8	
K _{foc} (mL/g) (arithmetic mean)	99	106	124	Additional Report to the DAR, Volume 3, part 4, B.8	
K _{fom} (mL/g)	57.4	61.5	71.9	Additional Report to the DAR, Volume 3, part 4, B.8	
1/n (arithmetic mean)	0.9	0.9	0.9	FOCUS default	
Plant uptake factor	0	0	0	FOCUS default	
Formation fraction	From desethyl hydroxy-terbuthylazine: 0.201	From desethyl hydroxy-terbuthylazine: 0.45	From desethyl hydroxy-terbuthylazine: 0.201	Additional Report to the DAR, Volume 3, part 4, B.8	

* Delete row in case of no pH dependency

Table 8.8-3: PEC_{gw} for terbuthylazine and metabolite(s) on maize (with FOCUS PEARL 4.4.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)						
		terbuthylazine	MT1	MT13	MT14	LM3	LM5	LM6
maize	Châteaudun	0.000107	0.04776	10.222	1.2858	2.0856	1.341	1.7637
	Hamburg	0.002804	0.2393	12.60	2.0987	2.352	1.692	2.001
	Kremsmünster	0.000885	0.1343	8.702	1.369	1.763	1.168	1.510
	Okehampton	0.00317	0.2531	9.288	1.815	1.383	1.272	1.277
	Piacenza	0.001256	0.1410	10.616	1.420	2.207	1.298	1.879
	Porto	0.000115	0.0386	5.346	0.7870	0.980	0.7104	0.8481
	Sevilla	<0.0001	0.000508	2.964	0.1249	1.141	0.2423	0.7771
	Thiva	<0.0001	0.009341	14.62	1.0487	3.56	1.563	2.937

Table 8.8-4: PEC_{gw} for terbuthylazine and metabolite(s) on maize (with FOCUS PELMO 5.5.3)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)						
		terbuthylazine	MT1	MT13	MT14	LM3	LM5	LM6
maize	Châteaudun	<0.001	0.018	9.776	0.956	2.096	1.193	1.782
	Hamburg	0.002	0.179	10.963	1.778	2.071	1.518	1.809
	Kremsmünster	0.001	0.126	8.816	1.305	1.803	1.183	1.522
	Okehampton	0.003	0.192	8.606	1.609	1.350	1.196	1.236
	Piacenza	0.003	0.198	7.689	1.328	1.424	1.023	1.274
	Porto	<0.001	0.050	5.204	0.828	0.957	0.689	0.817
	Sevilla	<0.001	<0.001	3.259	0.056	1.217	0.154	0.842
	Thiva	<0.001	0.007	11.780	0.726	2.859	1.169	2.352

Monitoring Studies for Tebuthylazine in ground water According to the EFSA Journal 2011; 9(1):1969:

- a) a) Full sample details not provided. 27103 sample data from Germany for the occurrence of terbuthylazine in groundwater. 328 detections of terbuthylazine were observed with 41 > (0.15% of the total analyses) displaying residues in excess of 0.1 µg/L. The Applicant states that none of these exceedences were due to the correct GAP for approved uses being applied.
- b) Full sample details not provided. Groundwater samples from more than 1000 intakes from 15 municipalities in counties around Denmark in 1990 – 2001 were analysed for residues of plant protection products and their degradation products. The mean depth to the top of the groundwater sample was 24 - 25 m with a mean intake length of 3.5 m. In addition to the groundwater survey, the report also contained information on the analyses of water samples taken from a group of “other borings” which are not used to extract groundwater for drinking purposes. 1016 intakes were analysed for terbuthylazine (the number of analyses was 4086). There were 17 (1.7 %) intakes with detections of terbuthylazine,

however, none of them contained concentrations $\geq 0.1 \mu\text{g/L}$. With regard to the group “other borings”, 1156 and 311 borings were analysed for terbuthylazine and desethyl-terbuthylazine (MT1) respectively with 1492 and 527 individual analyses respectively. Terbuthylazine and desethyl-terbuthylazine (MT1) were found in 18 (1.6 %) and 14 (4.5 %) borings, with 3 (0.3 %) and 4 (1.3 %) of these findings being detected at concentrations $\geq 0.1 \mu\text{g/L}$.

- c) Danish government monitoring programme selected two sites (Jyndevad and Silstrup) in Denmark to assess the leaching potential of pesticides including terbuthylazine. Applications were made to maize in May 2001 at Jyndevad and in May/June 2002 at Silstrup. Soil pore waters and groundwaters were analysed monthly for terbuthylazine and desethyl-terbuthylazine, additionally at Silstrup hydroxy-terbuthylazine, hydroxy-desethyl-terbuthylazine (MT1) and atrazine-desisopropyl-2-hydroxy (MT22) were also monitored for from February 2003.

At Jyndevad, terbuthylazine was not detected in either the soil pore water or the groundwater at concentrations $> 0.01 \mu\text{g/L}$ in the two year monitoring period. Desethyl-terbuthylazine (MT1) was detected in pore water at 1 m depth in all but three of the monthly samples between October 2001 (five months after application) and May 2003 at concentrations of $0.020 - 0.056 \mu\text{g/L}$, however it was not detected in pore waters at 2 m and was only detected once in any of the downstream groundwater monitoring wells.

At Silstrup terbuthylazine residues in well water at 1.5-2.5 m depth ranged from $0.013-0.124 \mu\text{g/L}$ over the year with one sample containing $> 0.1 \mu\text{g/L}$. Residues of desethyl-ranged from $0.046-0.143 \mu\text{g/L}$ over the year with two samples containing $> 0.1 \mu\text{g/L}$. Residues from deeper screens were always $< 0.08 \mu\text{g/L}$ for both terbuthylazine and desethyl-terbuthylazine. Of the remaining metabolites hydroxy-terbuthylazine (MT13) was not detected in the well water. Hydroxy-desethyl-terbuthylazine (MT1) was only detected once in the well water at a depth of 1.5 – 2.5 m at a concentration of $0.016 \mu\text{g/L}$. Atrazine-desisopropyl-2-hydroxy (MT22) was detected three times in the well at 1.5 – 2.5 m depth at concentrations around $0.01 \mu\text{g/L}$. It was also detected once at a depth of 3.5 – 4.5 m at a concentration of $0.047 \mu\text{g/L}$.

- d) Targeted groundwater monitoring studies were conducted in Germany in areas of documented use of terbuthylazine containing products. Typical maize regions were investigated i.e. Schleswig-Holstein, Mecklenburg-West Pomerania, Muenster-Emsland (stretching from the federal state North Rhine-Westfalia to Lower Saxony), Rottal (Bavaria) and the Upper Rhine Valley (stretching from the federal state Baden-Wuerttemberg to Hesse). Groundwater was collected from monitoring screen typically situated 5 m below ground surface. Confirmed usage of terbuthylazine containing products in upstream areas ($2.5 \times 2.5\text{km}$ or 625 ha) was determined via farmer surveys and interviews over three years (2002 – 2004). Results for each site represent the sum over this period as follows:- Wanderup 277 ha, Alt-Bennebek 497ha, Breiholz-Ost 198 ha, Hagen-Suedost 61 ha, Luettow 57 ha, Torgelow 225 ha, Lelkendorf 72 ha, Warnow 60 ha, Pinnow 288ha, Tabeckendorf 114 ha, Postmuenster 92 ha, Hammersbach 102 ha, Kirchham-Pfaffenhof 336 ha, Simbach-Stoelln 137 ha, Biblis 82 ha, Lorsch 56 ha, Rheinhausen-Oberhausen 198 ha, Breisach-Weingenossenschaft 240 ha, Grezhausen 69 ha, Rehderfeld 154 ha, Flechum 114 ha, Dalumer Moor 174 ha, Bexten 139 ha, Große-Luettke 103 ha, and Veltrup 202 ha. The overall mean hectarage treated was reported to be 120 ha across all sites and only those sites that received at least 50 ha of treatment were included in the final 25 sites monitored. The groundwater table was mostly less than 5 meters below ground surface and a wide range of soil properties was covered by the selected regions. No residues of terbuthylazine and desethyl-terbuthylazine were detected in any of the ground water monitoring samples analysed. Small residues of GS 28620 (MT14) and GS 23158 (MT13) were found in water samples taken from ground water monitoring wells at two locations. The residues of GS 28620 (MT14) occurred in May-July 2003 and ranged from $0.05-0.06 \mu\text{g/l}$. The residues of GS 23158 (MT13) were detectable but not quantifiable (i.e. < 0.05 but $> 0.02 \mu\text{g/l}$). In addition, the lysimeters metabolites LM3, LM5 and LM6 were detected at 19 of the 25 locations, confirming the linkage to terbuthylazine treated areas in the catchment. Residues of the metabolite CSCD648241 (LM6) in 29 samples from 25 individual sampling points were determined to be between $< 0.05 \mu\text{g/l}$ and $0.66 \mu\text{g/l}$. Residues of the metabolite GS16984 (MT23, LM5) in 29 samples from 25 individual sampling points, were determined to be between $< 0.05 \mu\text{g/l}$ and $0.98 \mu\text{g/l}$. The metabolite CSCD692760 (LM3) was detected at 19 (10 above the LOQ and 9 below the LOQ) of the 25 locations. Quantifiable residues ranged from $0.06-0.69 \mu\text{g/l}$.

- e) In 1997, a monitoring study was carried out in four maize cultivated areas in the plain of the river Po in Italy to evaluate the degree of contamination of the groundwater table. No residues of terbuthylazine were detected above 0.1 µg/l in the 1997 study. A follow-up study was conducted in 2006 in the same areas identified in the previous monitoring study. The majority of superficial wells sampled were over 20 m deep, with deep wells often greater than 50m. In these follow-up studies 8 out of approximately 100 wells were found to contain residues of terbuthylazine or its metabolites desethyl-terbuthylazine and hydroxy-terbuthylazine above 0.1 µg/l. However the average age of the wells was over 30 years and characterised by degraded materials, rust, holes or cracks etc and as a whole, the 90th percentile terbuthylazine and metabolite residues were all <0.05 µg/l on the basis of this monitoring.
- f) A retrospective monitoring study was conducted in four regions of Portugal from 1999 to 2007. As a retrospective study, only limited details on the history of pesticide use in the upstream areas was available. However throughout the eight year duration of the study, 773 water samples were taken and analysed for terbuthylazine and desethyl-terbuthylazine from 68 different sampling sites, generating a total of 1546 data points. Sampling sites covered a relatively wide variety of sales history, cropping density, depth to groundwater and nitrate concentration (this last parameter used as general indicator for the vulnerability of an aquifer to agricultural practices). Although terbuthylazine has not been in widespread use in two of the monitored regions, it has been extensively used in vineyards in the Oeste and the Douro valley at a rate of 490 g/ha (1400 g/ha in row). Neither terbuthylazine nor desethyl-terbuthylazine residues exceeded 0.05 µg/l at the 90th percentile of the population. Overall the RMS considered that the additional data from the Portuguese monitoring programs did provide useful information. However it should be noted that the monitoring is only of partial relevance in the regions where prior use of terbuthylazine is known to be extensive, and also taking into account that the use covers applications to vineyards rather than the extensive use on maize as investigated in the German and Italian studies. Taking these caveats into account, the RMS considers that the data should be viewed as providing supporting information alongside the monitoring data from other regions, as well as taking into account the results of the standard first tier FOCUS groundwater exposure assessments.
- g) Retrospective monitoring studies were conducted in 3 regions of Spain covering use of terbuthylazine on olive crops in Andalucia (2000 to 2003), use on maize and citrus crops in South Eastern Spain (2000 to 2001) and use on maize and vineyards in Northern Spain (2000- 2001). As retrospective studies, only limited details on the history of pesticide use in the upstream areas was available. In addition in many cases, the relatively large distance between the discharge point and the upland aquifer made it difficult to relate monitored residues back to a specific product use pattern. However throughout each study sampling sites were selected using local knowledge of cropping density, regional product sales data, hydrogeological information and information pertaining to the integrity of the respective sampling sites. In three regions the 90th percentile concentration was less than 0.1 µg/l for both terbuthylazine and metabolite desethyl-terbuthylazine (the only metabolite monitored for). However it should be noted that methods of analysis were unvalidated and the LOQ was only reported to be 0.1 µg/l in the studies conducted in South Eastern Spain. In Andalucia, following extensive use of terbuthylazine on olive crops, the 90th percentile concentration of terbuthylazine was 0.14 µg/l. However the majority of detections in this region came from springs discharging groundwater into lagoons, troughs or drainage canals that were not protected from direct contamination. Overall the RMS considered that the additional data from the Spanish monitoring programs did provide limited useful information. However it should be noted that the monitoring is only of partial relevance in the regions where prior use of terbuthylazine is known to be extensive, and also taking into account that the monitoring covers areas where terbuthylazine may be applied to olive crops, citrus and vineyards in addition to use on maize in two of the three regions investigated. In addition, the sampling of groundwater from springs discharging to surface water bodies meant that the influence of direct contamination (rather than conventional leaching) could not be excluded. Taking these caveats into account, the RMS considers that the data should be viewed as providing limited supporting information only alongside the monitoring data from other regions, as well as taking into account the results of the standard first tier FOCUS groundwater exposure assessments.

Assessment of relevance of ground water metabolites is performed and presented in section b10 of dRR.

Comments RMS:

The calculations were accepted.

The calculations have been done according to FOCUS Groundwater guidelines. Models FOCUS-PEARL and FOCUS-PELMO have been used.

All parameters have been taken according to List of Endpoints EFSA Journal 2011; 9(1):1969 or DAR.

The PEC_{GW} for terbuthylazine, below the trigger value 0,1 µg/L. The calculation of the TSCF from logKow by using the Briggs equation considers not the state-of-the-art to predict the plant uptake and is not applicable for ground water risk assessment. However, due to low concentrations of active substance in groundwater <0.001 µ/L and the results of monitoring studies, in the opinion of RMS, it is not necessary recalculation of PEC_{gw} for active substance.

The results of the simulations in both mentioned FOCUS groundwater models indicate that the overall maximum PEC_{GW} of metabolites were above 0.1 µg/L in most of the scenarios considered.

Updated *peer review of the pesticide risk assessment for the active substance terbuthylazine in light of confirmatory* (10.2903/j.efsa.2019.5817 includes an assessment in regard to metabolites.

The information concerning the environmental metabolites MT1, MT13, MT14, LM1, LM2, LM3, LM4, LM5, LM6 and assessment of their potential relevance is provided in this dRR, Section 10.

PEC_{gw} for terbuthylazine on maize calculated with plant uptake factor 0.

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth (µg/L)	80 th Percentile PEC _{GW} at 1 m Soil Depth (µg/L)
		PEARL	PELMO
		terbuthylazine	
maize	Châteaudun	< 0.001	< 0.001
	Hamburg	0.002	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	0.003	< 0.001
	Piacenza	0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Member States should decide whether the above assumptions relating to monitoring studies are acceptable for their geoclimatic conditions or the refinements for risk assessment for groundwater could be provided to interested MS.

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

8.9.1 Justification for new endpoints

All endpoints used for PEC surface water calculations are EU approved and were evaluated on EU level

and presented in:

Terbuthylazine - EFSA Journal 2011; 9 (1) :1969

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

Table 8.9-1: Input parameters related to application for PEC_{sw/sed} calculations

Plant protection product	TERBUT 500 SC
Use No.	1
Crop	maize
Application rate (kg as/ha)	terbuthylazine: 500 g as/ha
Number of applications/interval (d)	1/0
Application method	boom sprayer
Models used for calculation	FOCUS SWASH v3.1, FOCUS PRZM v3.3.1, FOCUS MACRO v5.5.3, FOCUS TOXWA v3.3.1

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for PEC_{sw/sed} calculations for the application of TERBUT 500 SC

Crop	Scenario	Application window used in modelling
Maize	D3	25 April – 25 May
	D4	30 April – 30 May
	D5	30 April – 30 May
	D6	10 April – 10 May
	R1	23 April – 23 May
	R2	21 April – 21 May
	R3	21 April – 21 May
	R4	31 March – 30 April

8.9.2.1 Terbuthylazine and its metabolites

Table 8.9-3: Input parameters related to active substance terbuthylazine and metabolite(s) for PEC_{sw/sed} calculations STEP 1/2 and 3(4)

Compound	Terbuthylazine	Desethyl-terbuthylazine	Hydroxy-terbuthylazine	Desethyl hydroxyl-terbuthylazine	Terbutryn (MT26)	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	229.7	201.7	211.3	183.2	241.4	EFSA Journal 2011; 9(1):1969
Saturated vapour pressure (Pa)	0	0	0	0	0	EFSA Journal 2011; 9(1):1969
Diffusion coefficient in water	4.3 x 10 ⁻⁵	not required for Step 1+2/	not required for Step 1+2	not required for Step 1+2	4.3 x 10 ⁻⁵	default

Compound	Terbuthylazine	Desethyl- terbuthylazine	Hydroxy- terbuthylazine	Desethyl hy- droxyl- terbuthylazine	Terbutryn (MT26)	Value in accordance to EU end- point y/n/ Reference
(m ² /d)						
Diffusion coefficient in air (m ² /d)	0.43	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	0.43	default
Water solubility (mg/L)	8.5	327.1	7.19	18	8.5	EFSA Journal 2011; 9(1):1969
K _{foc} (mL/g)	151	78	187.1	121	518	EFSA Journal 2011; 9(1):1969
Plant Uptake	0.5	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	0	default
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/	not required for Step 1+2/	not required for Step 1+2/	0.05 (MACRO) 0.50 (PRZM)	default
DT _{50,soil} (d)	20 d (median of field data; SFO) [updated DT50 of 20.0 d assuming a Q10 of 2.58 should be used]	26.9 (geometric mean of field data; SFO)	453 days (geometric mean of lab data; SFO)	107d (geometric mean of lab data used as a conservative input parameter; SFO)	0.1 d	EFSA Journal 2011; 9(1):1969
DT _{50,water} (d)	1000d	1000 d	1000 d	1000 d	1000 d	EFSA Journal 2011; 9(1):1969
DT _{50,sed} (d)	69.9 d	1000 d	1000 d	1000 d	190 d	
DT _{50,whole system} (d)	69.9 d	1000 d	1000d	1000 d	190 d	
Maximum occurrence observed (% molar basis with respect to the parent)		Maximum occurrence observed in soil: 45 % Maximum occurrence observed in sediment/ water studies: 7.3 %	Maximum occurrence observed in soil: 34.5 % Maximum occurrence observed in sediment/ water studies: 20.0 %	Maximum occurrence observed in soil: 28 % Maximum occurrence observed in sediment/ water studies: N/A (soil metabolite only)	Maximum occurrence observed in soil: 0.001 % Maximum occurrence observed in sediment/ water studies: 7.4 %	EFSA Journal 2011; 9(1):1969

PEC_{sw/sed}

Table 8.9-4: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for terbuthylazine following single/multiple application(s) of TERBUT 500 SC to maize

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	143.33	drainage/run off	128.72	213.15
Step 2	---	28.19	drainage/run off	27.36	41.80
Northern Europe	March-May	28.19	drainage/run off	27.36	41.80
Step 3					
D3	ditch	2.623	drainage	0.1474	0.6979
D4	pond	0.1470	drainage	0.1426	0.4745
D4	stream	2.250	drainage	0.07577	0.1434
D5	pond	0.1529	drainage	0.1417	0.3861
D5	stream	2.255	drainage	0.02573	0.1362
D6	ditch	2.631	drainage	0.1923	0.7918
R1	pond	0.2214	run off	0.2097	0.4821
R1	stream	6.948	run off	0.2378	1.346
R2	stream	5.317	run off	0.2078	1.173
R3	stream	2.564	run off	0.05756	0.3907
R4	stream	17.37	run off	0.8174	4.626

* single applications should be marked.

** twa-time as required by ecotox

FOCUS Step 4

Table 8.9-5: Global maximum PEC_{sw} values for terbuthylazine, following single application(s) of TERBUT 500 SC to maize according to the central zone GAP according to surface water Step 4 with 5 meters buffer zone using vfs mode

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 4					
D3	ditch	0.8597	drainage	0.04829	0.2368
D4	pond	0.1446	drainage	0.1404	0.4596
D4	stream	0.9494	drainage	0.07577	0.1358
D5	pond	0.1416	drainage	0.1315	0.3636
D5	stream	0.9586	drainage	0.02573	0.09903
D6	ditch	0.8669	drainage	0.06731	0.2847
R1	pond	0.09461	run off	0.08392	0.1872

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
R1	stream	0.7632	run off	0.006863	0.07739
R2	stream	1.015	run off	0.004337	0.05641
R3	stream	1.080	run off	0.01937	0.1680
R4	stream	0.7631	run off	0.006839	0.07718

Metabolite(s) of terbuthylazine

Table 8.9-6: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Terbutyn following single application(s) to maize

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominat entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	8.03	drainage/run off	7.59	40.67
Step 2	---	1.58	drainage/run off	1.52	7.97
Northern Europe	March-May	1.58	drainage/run off	1.52	7.97
Step 3					
D3	ditch	0.000061	drainage	0.000010	0.002539
D4	pond	0.00038	drainage	0.00379	0.01339
D4	stream	0.000059	drainage	0.000011	0.001514
D5	pond	0.000898	drainage	0.000898	0.02127
D5	stream	0.000091	drainage	0.000006	0.002130
D6	ditch	0.000069	drainage	0.000017	0.004682
R1	pond	0.000730	run off	0.000727	0.01949
R1	stream	0.000532	run off	0.000019	0.004185
R2	stream	0.000397	run off	0.000016	0.004876
R3	stream	0.000312	run off	0.000018	0.001927
R4	stream	0.002578	run off	0.000123	0.01587

* single applications should be marked.

** twa-time as required by ecotox

Table 8.9-7: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Desethyl-terbuthylazine following single application(s) to maize

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominat entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	69.63	drainage/run off	69.09	54.25

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominat entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 2	---	12.72	drainage/run off	12.62	9.91
Northern Europe	March-May	12.72	drainage/run off	12.62	9.91

Table 8.9-8: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Hydroxy-terbuthylazine following single application(s) to maize

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominat entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	67.72	drainage/run off	67.07	126.30
Step 2	---	13.41	drainage/run off	13.27	24.98
Northern Europe	March-May	13.41	drainage/run off	13.27	24.98

Table 8.9-9: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Desethyl Hydroxy-terbuthylazine following single application(s) to maize

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominat entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	32.05	drainage/run off	31.82	38.78
Step 2	---	6.25	drainage/run off	6.20	7.56
Northern Europe	March-May	6.25	drainage/run off	6.20	7.56

Comments ZRMS:

The calculations PEC_{SW/SED} were accepted.

The calculations have been done according to FOCUS surface water. STEP 1 & 2 and STEP 3 and STEP 4 were used for PEC_{SW} and PEC_{SED} assessment. All parameters have been taken according to List of End-points EFSA Journal 2011; 9(1):1969.

According to Polish national requirements, D3, D4 and R1 scenarios are obligatory and were considered in PEC_{SW} calculations.

The predicted concentrations in surface water and sediment of terbuthylazine and its metabolites are appropriate to be used for the subsequent risk assessment for aquatic organisms.

8.9.2.2 PEC_{sw/sed} of TERBUT 500 SC

Calculation of drift loading into surface water

Input

Application Rate (g ai/ha): 1105 Crop: Maize

Number of Applications: 1 Waterbody: focus_ditch

Use FOCUS (step 3) or mitigation distances (m)? FOCUS values

Info: Dimensions of receiving water body and field site (m)

Width: 1 Depth: 0.30 Length: 100

Distance: Crop <-0.80 --> Top of bank <-0.50 --> Water

Info: Drift regression terms to provide overall 90th percentile drift data

Regression parameters A: 2.7593 B: -0.9778 C: 2.7593 D: -0.9778

Distance for change in regression (m) 1.0

Output: Drift deposition in water body per drift event

Drift percentile per event 90 based on a total of 1 applications.

	at edge nearest field	farthest from field	areic mean
Distance from crop: (m)	1.30	2.30	
% of application rate:	2.1349	1.2221	1.5936

Output: Drift loading onto water body

Mass loading per drift event: 1.7609 mg per m² of water surface area.

Nominal concentration in water, resulting from drift event: 5.8697 ug/L. (for comparison with modelling result)

Data sources: Save Screen Print

Spray drift data are from BBA, (2000) and AgDRIFT 1.11, (1999).
 Calculations of percentile drift are from spreadsheet of Travis, (1998).
 Regressions of drift curves and spreadsheet calculations are by Russell and Yon, (2000 and 2001). Close

The PEC values of LA ZINA in surface water have been assessed by RMS with the FOCUS SWASH “drift calculator”.

The PEC_{sw} has been calculated for single application and for the highest application rate recommended 1 kg product/ha for use in maize.

The PEC_{sw} values for LA ZINA on maize

Mitigation distances from crop (m)	Drift values (%)	Mass loading per drift event (mg/m ² of water surface area)	PEC _{sw} (µg/L)
FOCUS value	2.13	1.7752	2.6560
1	2.76	2.1471	3.2123
5	0.57	0.5820	0.8707
10	0.29	0.3087	0.4618
20	0.15	0.1604	0.2399

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Table 8.10-1 Summary of atmospheric degradation and behaviour

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	Not studied - no data requested
Photochemical oxidative degradation in air ‡	DT ₅₀ of 13.55 hours derived by the Atkinson model. OH (12 h) concentration assumed = $1.5 \times 10^6 \text{ cm}^{-3}$.
Volatilisation ‡	from plant surfaces (BBA guideline): $\leq 10.2 \%$ after 24 hours
	from soil surfaces (BBA guideline): $\leq 13.8 \%$ after 24 hours
Metabolites	None
PEC (air)	
Method of calculation	There is currently no guidance on determining the predicted environmental concentrations of pesticides in air.
PEC_(a)	
Maximum concentration	N/A

The vapour pressure at 20 °C of the active substance terbuthylazine 1 is $< 10^{-5}$ Pa. Hence the active substance terbuthylazine is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance terbuthylazine due to volatilization with subsequent deposition should be considered.

Comments ZRMS:

Accepted. The PEC in air was not required.

Appendix 1 Lists of data considered in support of the evaluation

The following lists should include all product data considered in support of the evaluation, even if they may have been evaluated previously, e.g. in the EU peer review of the active substance(s), and thus, are not summarised in this document in detail. New data evaluated for the active substance(s) should be included as well.

Please sort by data points and within one data point by names of authors.

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.3	K. Florynski	2019	TERBUT 500 SC 500 SC Predicted environmental concentration of terbuthylazine and its metabolites in soil, ground water and surface water. PUH Chemirol Sp. z o.o. Study code: TERBU-B8 Non GLP Unpublished	N	Chemirol
KCP 9.2.4	K. Florynski	2016	TERBUT 500 SC 500 SC Predicted environmental concentration of terbuthylazine and its metabolites in soil, ground water and surface water. PUH Chemirol Sp. z o.o. Study code: TERBU-B8 Non GLP Unpublished	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.5	K. Florynski	2016	TERBUT 500 SC 500 SC Predicted environmental concentration of terbuthylazine and its metabolites in soil, ground water and surface water. PUH Chemirol Sp. z o.o. Study code: TERBU-B8 Non GLP Unpublished	N	Chemirol

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/01	Schaffer A. Nicollier G.	1997a	Degradation of ¹⁴ C-labelled GS13529 in Gartenacker loam soil under aerobic conditions at 10 and 20 C and under anaerobic/sterile conditions at 20 C. Syngenta Crop Protection AG. Study No. 96AS01. GLP: Yes Published: No Report No. GS135239/1475.	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/02	Schaffer A. Nicollier G.	1997a	Degradation of ¹⁴ C-labelled GS13529 in Gartenacker loam soil under aerobic conditions at 10 and 20 C and under anaerobic/sterile conditions at 20 C. Syngenta Crop Protection AG. Study No. 96AS05. GLP: Yes Published: No Report No. GS135239/1475.	N	Syngenta
KCP 9.1.1/03	Morgenroth, U	2000a	Degradation of [triazine-U-14C]-labelled GS 13529 in two soils under aerobic conditions at 20°C Novartis Crop Protection AG, Basel, Switzerland, Report No 99MO06 GLP Not Published Syngenta File N° GS13529/1673	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/04	Glaenzel, A.	1998	Rate of degradation of GS 13529 in one soil under various conditions Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 97RP02 GLP Not Published Syngenta File N° GS13529/1582	N	Syngenta
KCP 9.1.1/05	Galicia H., Morgenroth, U.	1993	Degradation of 14C-Terbuthylazin Technical (GS 13529): in Four Soils Incubated under Aerobic Conditions Novartis Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, Report No 243224 GLP Not Published Syngenta File N° GS13529/1219	N	Syngenta

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/06	Purghart, V.	2000	Terbutylazine (GS 13529): soil photolysis Novartis Crop Protection AG, Basel, Switzerland Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland, Report No 1047.102.720 GLP Not Published Syngenta File N° GS13529/1706	N	Syngenta
KCP 9.1.1/07	Abildt, U.	1991	Aerobic degradation of GS 13529 in soil under various test-conditions Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 38-90 GLP Not Published Syngenta File N° GS13529/0855	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/08	Reischmann, F.	2000a	Rate of degradation of Triazine-U-14C) labelled GS 26379 in three soils under aerobic laboratory conditions at 20° C Novartis Crop Protection AG, Basel, Switzerland, Report No 99RF04 GLP Not Published Syngenta File N° GS26379/0008	N	Syngenta
KCP 9.1.1/09	Glaenzel, A.	2000a	Rate of degradation of 14C-triazine labelled GS 23158 in three soils under laboratory conditions at 20°C Novartis Crop Protection AG, Basel, Switzerland, Report No 99AG05 GLP Not Published Syngenta File N° GS23158/0006	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/10	Phaff,R.	2000a	Degradation of 14C-triazine labelled GS 28620 in four soils under aerobic conditions at 20°C Novartis Crop Protection AG, Basel, Switzerland, Report No 99RP05 GLP Not Published Syngenta File N° GS28620/0008	N	Syngenta
KCP 9.1.1/11	Nicollier,G.	1997	Field dissipation of GS 13529 after bareground application of [triazine-(U)-14C] labelled material Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No CMR.08/97 GLP Not Published Syngenta File N° GS13529/1485	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/12	Offizorz, P., Ressler, H.	1990a	Dissipation rate determination of terbuthylazine Novartis Crop Protection AG, Basel, Switzerland RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany, Report No 170425 Not GLP Not Published Syngenta File N° GS13529/0924	N	Syngenta
KCP 9.1.1/13	Offizorz, P., Ressler, H.	1990b	Field soil, Dissipation rate determination of terbuthylazine Novartis Crop Protection AG, Basel, Switzerland RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany, Report No 170414 Not GLP Not Published Syngenta File N° GS13529/0926	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/14	Offizorz, P., Resseler, H.	1991a	Field soil dissipation rate determination of terbuthylazine (Exp.-No. 51-90B) Novartis Crop Protection AG, Basel, Switzerland RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany, Report No 223740 GLP Not Published Syngenta File N° GS13529/0925	N	Syngenta
KCP 9.1.1/15	Offizorz, P., Resseler, H.	1991b	Field soil dissipation rate determination of terbuthylazine (Exp.-No. 25-90B) Novartis Crop Protection AG, Basel, Switzerland RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany, Report No 223727 GLP Not Published Syngenta File N° GS13529/0927	N	Syngenta
KCP 9.1.1/16	Offizorz, P., Resseler, H.	1991c	Field soil dissipation rate determination of terbuthylazine (Exp.-No. 24-90B) Novartis Crop Protection AG, Basel, Switzerland RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany, Report No 223716 GLP Not Published Syngenta File N° GS13529/0928	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/17	Offizorz, P., Ressler, H.	1991d	Field soil dissipation rate determination of terbuthylazine (Exp.-No. 50-90B) Novartis Crop Protection AG, Basel, Switzerland RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany, Report No 223738 GLP Not Published Syngenta File N° GS13529/0929	N	Syngenta
KCP 9.1.1/18	Evans, P.	2004a	Terbuthylazine (GS13529) and S-Metolachlor (CGA77102): Dissipation Study with Terbuthylazine (GS13529) and S-Metolachlor (CGA77102) in or on Cultivated Soil in France (South) Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, Report No RJ3521B GLP Not Published Syngenta File N° CGA77102/0806	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/19	Evans, P.	2004b	Terbutylazine (GS13529) and S-Metolachlor (CGA77102) : Dissipation Study with Terbutylazine and S-Metolachlor (CGA77102) in or on Cultivated Soil in Italy Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, Report No RJ3522B GLP Not Published Syngenta File N° CGA77102/0807	N	Syngenta
KCP 9.1.1/20	Edwards,P., Evans, P.	2004	Terbutylazine: Residue Stability Study for Terbutylazine (GS13529) and its Metabolites (GS26379, GS23158 and GS28620) in Soil under Freezer Storage Conditions - Interim Report Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, Report No RJ3492B GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/21	Mamouni A., Morgenroth U.	1995	METABOLISM AND DEGRADATION OF 14C-TERBUTHYLAZINE IN FOUR SOILS INCUBATED UNDER AEROBIC CONDITIONS RCC AG., Itingen, Switzerland Oxon Italia S.P.A, Pero, Italy Report-no. 324505 GLP: yes published: no	N	Oxon
KCP 9.1.1/22	Wonders J.,van Noorloos.B.	2003	ANAEROBIC SOIL METABOLISM OF TERBUTHYLAZINE Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 356906 GLP: yes published: no	N	Oxon
KCP 9.1.1/23	Willems H., Wonders J.	2001	PHOTODEGRADATION OF TERBUTHYLAZINE ON SOIL SURFACES Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 308148 GLP: yes published: no	N	Oxon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/24	Willems H.	1998a	DETERMINATION OF THE METABOLISM AND DEGRADATION RATE OF DESETHYLTERBUTHYLAZINE IN SOIL Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 197786 GLP: yes published: no	N	Oxon
KCP 9.1.1/25	Willems H.	1998b	DETERMINATION OF THE DEGRADATION RATE OF DESETHYLTERBUTHYLAZINE IN THREE SOILS Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 197775 GLP: yes published: no	N	Oxon
KCP 9.1.1/26	Slangen P.J.	2001a	DETERMINATION OF THE DEGRADATION RATE OF 2-HYDROXYTERBUTHYLAZINE IN THREE SOILS Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 308251 GLP: yes published: no	N	Oxon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/26	Glanzel A.	2000	RATE OF DEGRADATION OF 14C-TRIAZINE LABELLED GS 23158 IN THREE SOILS UNDER LABORATORY CONDITIONS AT 20°C. Novartis Crop Protection AG, Basel, Switzerland. Unpublished report No. 99AG05. Study dates: 11 October 1999 – 15 March 2000 Syngenta File N° GS 23158/0006	N	Oxon
KCP 9.1.1/27	Roberts N.L.	1999	CLICK 50 SC: SOIL DISSIPATION WITH TERBUTHYLAZINE IN FRANCE Huntingdon Life Sciences Ltd., Cambridgeshire, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 162/983485 GLP: yes published: no	N	Oxon
KCP 9.1.1/28	Roberts N.L.	2000	CLICK 50 SC: SOIL DISSIPATION WITH TERBUTHYLAZINE IN ITALY Huntingdon Life Sciences Ltd., Cambridgeshire, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 162/984733 GLP: yes published: no	N	Oxon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/29	Blaschke U.G.	1998	CLICK 50 SC: SOIL DISSIPATION WITH TERBUTHYLAZINE IN GERMANY Huntingdon Life Sciences Ltd., Suffolk, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 188/983486 GLP: yes published: no	N	Oxon
KCP 9.1.1/30	Todd M.	1999	2 HYDROXY TERBUTHYLAZINE: VALIDATION AND DETERMINATION OF RESIDUES IN SOIL SAMPLES GENERATED FROM FIELD DISSIPATION TRIALS HELD IN NORTHERN EUROPE Huntingdon Life Sciences Ltd., Suffolk, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 227/993260 GLP: yes published: no	N	Oxon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/31	Lucini L.	2006	LUCINIL FREEZER STORAGE STABILITY OF TERBUTHYLAZINE AND ITS METABOLITES DESETHYL-TERBUTHYLAZINE AND 2-HYDROXY-TERBUTHYLAZINE IN SOIL INTERIM REPORT 2 YEARS Research Centre “E. Gagliardini” – SIPCAM S.p.A. 26857 Salerano sul Lambro (LO) ITALY Oxon Italia S.P.A, Pero, Italy Report-no. SIP 1433 GLP: yes published: no	N	Oxon
KCP 9.1.1/32	Willems H	2007	Amendment to: Determination of the metabolism and degradation rate of desethylterbutylazine in soil Oxon Italia, S.p.a, Pero, Italy NOTOX B.V., Hertogenbosch, Netherlands, 197786 GLP, not published	N	Oxon
KCP 9.1.1/33	Hardy I	2007	<i>Terbutylazine - Overview of FOCUS Kinetic Modelling of Laboratory and Field Soil Studies and Selection of Modelling Endpoints</i> Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Battelle UK Ltd., Ongar, United Kingdom, NC/08/006F Not GLP, not published	N	Syn/Oxn
KCP 9.1.1/34	Hardy I	2008a	Terbutylazine - Kinetic Modelling Analysis of Data from Aerobic Soil Degradation Studies in Order to Derive DT50 Values and Formation Fractions for Use as Modelling Endpoints Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Battelle UK Ltd., Ongar, United Kingdom, NC/08/006A Not GLP, not published	N	Syn/Oxn
KCP 9.1.1/35	Hardy I	2008b	Terbutylazine - Kinetic Modelling Analysis of Data from Aerobic Soil Degradation Studies	N	Syn/Oxn

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			With the Metabolite MT1 (GS26379) in Order to Derive DT50 Values and Formation Fractions for Use as Modelling Endpoints Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Battelle UK Ltd., Ongar, United Kingdom, NC/08/006B Not GLP, not published		
KCP 9.1.1/36	Hardy I	2008c	Terbutylazine - Kinetic Modelling Analysis of Data from Aerobic Soil Degradation Studies With the Metabolite MT13 (GS23158) in Order to Derive DT50 Values for Use as Modelling Endpoints Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia S.p.a., Pero, Italy. Battelle UK Ltd., Ongar, United Kingdom, NC/08/006C Not GLP, not published	N	Syn/Oxn
KCP 9.1.1/37	Hardy I	2008d	Terbutylazine - Kinetic Modelling Analysis of Data from Aerobic Soil Degradation Studies With the Metabolite MT14 (GS28620) in Order to Derive DT50 Values for Use as Modelling Endpoints Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Battelle UK Ltd., Ongar, United Kingdom, NC/08/006D Not GLP, not published	N	Syn/Oxn
KCP 9.1.1/38	Hardy I	2008e	Terbutylazine - Kinetic Modelling Analysis of Data from Field Soil Dissipation Studies in Order to Derive Normalised DT50 Values and Formation Fractions for Use as Modelling Endpoints Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Battelle UK Ltd., Ongar, United Kingdom, NC/08/006E Not GLP, not published	N	Syn/Oxn
KCP 9.1.1/39	Lucini L	2007	Characterisation of soils tested in field dissipation studies with Click 50 SC Oxon Italia S.p.a., Pero, Italy , OXO - TBA - AII -0701010202 GLP, not published	N	Oxon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/40	Trevisan M	2009	Terbutylazine - Multi-site Study for the Monitoring of Terbutylazine and its Metabolites in Soil Syngenta CP S.p.A, Milano, Italy; Oxon Italia S.p.a., Pero, Italy. CERZOO, Piacenza, Italy, CZ/07/020/UCSC/TBASOI/RF, T008420-07 GLP, not published	N	Syn/Oxn
KCP 9.1.2/01	Phaff,R.	2000b	Adsorption / Desorption of GS 13529 in various soils Novartis Crop Protection AG, Basel, Switzerland, Report No 99RP04 GLP Not Published	N	Syngenta
KCP 9.1.2/02	Mueller J.	1991a	Determining the adsorption and desorption of terbuthylazine. Novartis Crop Protection AG. Fraunhofer Institute for Environmental Chemistry and Ecotoxicology. Report No CIB-004/7-13. GLP: Yes Published: No	N	Syngenta
KCP 9.1.2/03	Reischamnn F.	2000b	Adsorption / desorption of Triazine-U-14C-labelled GS 26379 in soil lorsch Novartis Crop Protection AG, Basel, Switzerland, Report No 00RF04 GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2/04	McLaughlin, S., Galicia,H.	1996a	GS 26379: Determination of adsorption and desorption in three soils Novartis Crop Protection AG, Basel, Switzerland Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland, Report No 95-058-1008 GLP Not Published	N	Syngenta
KCP 9.1.2/05	Mueller,J.	1991b	Determination of adsorption/desorption of desethyl-terbuthylazine. Fraunhofer-Institut für Umweltchemie und Ökotoxikologie. Report No. CIB-05/7-13. GLP: Yes Published: No	N	Syngenta
KCP 9.1.2/06	Adam, D.	2000a	Adsorption / desorption of GS 23158 in Borstel soil Novartis Crop Protection AG, Basel, Switzerland, Report No 99DA11 GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2/07	Mclaughlin,S., Galicia,H.	1996b	GS 23158: Determination of adsorption and desorption in three soils Novartis Crop Protection AG, Basel, Switzerland Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland, Report No 95-059-1008 GLP Not Published	N	Syngenta
KCP 9.1.2/08	Morgenroth,U.	2000b	Adsorption / Desorption of Triazine-U-14C labelled GS 28620 in various soils Novartis Crop Protection AG, Basel, Switzerland, Report No 00MO01 GLP Not Published	N	Syngenta
KCP 9.1.2/09	Morgenroth,U.	1995	ADSORPTION/DESORPTION OF 14C-TERBUTHYLAZINE ON FOUR SOILS RCC AG., Itingen, Switzerland Oxon Italia S.P.A, Pero, Italy Report-no. 385582 GLP: yes published: no	N	Oxon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2/10	Willems H.	1997	ADSORPTION/DESORPTION OF DESETHYLTERBUTHYLAZINE ON SOIL Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 197797 GLP: yes published: no	N	Oxon
KCP 9.1.2/11	Slangen P.J.	2001b.	ADSORPTION/DESORPTION OF 2- HYDROXYTERBUTHYLAZINE ON SOIL Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 308238 GLP: yes published: no	N	Oxon
KCP 9.1.2/12	McLaughlin S, Lentz N	2008	14C-GS28620 (Desethyl-hydroxy-terbuthylazine). Adsorption of 14C-GS28620 (Desethyl-hydroxy- terbuthylazine) on Multiple Soils. Syngenta - Jealott's Hill, Bracknell, United Kingdom; ; Oxon Italia S.p.a., Pero, Italy. Springborn Laboratories Inc., Wareham, USA, 1781.6712, T001654-08 GLP, not published	N	OXON/SYN
KCP 9.1.2/13	Ulbrich R.	1998	Adsorption / desorption of GS 14260 in various soils Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 97UL03 GLP, not published	N	OXON/SYN
KCP 9.1.2/14	Simmonds M, Burgess M	2009	Terbuthylazine - Estimation of Adsorption Coefficient (Koc) on Soil of CSCD648241, a Soil Metabolite, by HPLC (OECD 121)	N	OXON/SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Syngenta - Jealott's Hill, Bracknell, United Kingdom; ; Oxon Italia S.p.a., Pero, Italy. Battelle UK Ltd., Ongar, United Kingdom, NC/09/009, T000357-09 GLP, not published		
KCP 9.1.2/15	Simmonds M, Burgess M	2009a	Terbuthylazine - Estimation of Adsorption Coefficient (Koc) on Soil of CSCD692760, a Soil Metabolite, by HPLC (OECD 121) Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia S.p.a., Pero, Italy. Battelle UK Ltd., Ongar, United Kingdom, NC/09/008, T000514-09 GLP, not published	N	OXON/SYN
KCP 9.1.2/16	Simmonds M, Burgess M	2009b	Terbuthylazine - Estimation of Adsorption Coefficient (Koc) on Soil of CSCD692760, a Soil Metabolite, by HPLC (OECD 121) Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia S.p.a., Pero, Italy. Battelle UK Ltd., Ongar, United Kingdom, NC/09/008, T000514-09 GLP, not published	N	OXON/SYN
KCP 9.1.2/17	Ellgehausen, H.	1988	Leaching model study with GS 13529 in four soil types Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 14-88 GLP Not Published	N	Syngenta
KCP 9.1.2/18	Hassink,J.	1992	Outdoor lysimeter study on Terbuthylazine Novartis Crop Protection AG, Basel, Switzerland ITA Fraunhofer-Inst., Hannover, Germany, Report No CIB-04/7-11 GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2/19	Burgener A.	1995	14C-Terbuthylazine/14C-Atrazine: Mobility and Degradation in Soil in Outdoor Lysimeters Novartis Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, Report No 321581 GLP Not Published	N	Syngenta
KCP 9.1.2/20	Ressler, H.	2004	Leaching behaviour of terbuthylazine in a long term field experiment from 1990 to 2001 in Germany Syngenta Crop Protection AG, Basel, Switzerland C.A.U. GmbH, Dreieich, Germany, Report No HR012004 Not GLP Not Published	N	Syngenta
KCP 9.1.2/21	Haaman, H., Gramatte, A. Brodsky.J.	1993	Experimental examinations of the behaviour of terbuthylazine in soil Novartis Crop Protection AG. Battelle Institut, Frankfurt Germany. Report No BE-FLA-20-89-1 GLP: Yes Published: No	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2/22	Ricker, I., Haamann H.	1993	Experimental studies on the behaviour of terbuthylazine in soil – 1992. Battelle Europe, Battelle Institut e.V. Frankfurt/M Germany & C.A.U. GmbH, Frankfurt/M Germany. Report No. T01 FR01. GLP: Yes Published: No	N	Syngenta
KCP 9.1.2/23	Lutolf, W. Haamann, H.	1998	Behaviour of terbuthylazine in soil after application of formulation SC 500 (A-6144C) and potential leaching to groundwater – Determination of terbuthylazine and GS26379. C.A.U. GmbH, Dreieich Germany (field part) & Novartis Crop Protection AG (Laboratory part). Report No. 3053/94. GLP: Yes Published: No	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2/24	Lutolf, W	1999	Behaviour of terbuthylazine and metolachlor in soil after application of formulation SC 500 (A-6144C) and potential leaching to groundwater. C.A.U. GmbH, Dreieich Germany (field part) & Novartis Crop Protection AG, (Laboratory part). Report No. 3060/95. GLP: Yes Published: No	N	Syngenta
KCP 9.1.2/25	Lutolf, W	2000	Behaviour of terbuthylazine and metolachlor in soil after application of formulation SC 500 (A-6144C) and potential leaching to groundwater. C.A.U. GmbH, Dreieich Germany (field part) & Novartis Crop Protection AG. Report No. 3070/96. GLP: Yes Published: No	N	Syngenta
KCP 9.1.2/26	Lutolf, W	2000b	Study on the leaching of terbuthylazine and metolachlor in a long term field experiment. C.A.U. GmbH, Dreieich Germany (field part) & Novartis Crop Protection AG. Report No. 3140/97. GLP: Yes Published: No	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2/27	Lutolf, W	2002	Study on the leaching of terbuthylazine and metolachlor in a long term field experiment. C.A.U. GmbH, Dreieich Germany (field part) & Novartis Crop Protection AG. Report No. 3091/99. GLP: Yes Published: No	N	Syngenta
KCP 9.1.2/28	Tribolet, R.	2003	Study on the leaching of terbuthylazine and metolachlor in a long term field experiment. C.A.U. GmbH, Dreieich Germany (field part) & Novartis Crop Protection AG. Report No. 3040/00. GLP: Yes Published: No	N	Syngenta
KCP 9.1.2/29	Zietz, E.	2000	Monitoring of GS13529 (Terbuthylazine) in Surface Water adjacent Fields susceptible to run-off. Trial Sites Ramholz (Hesse) and Kemading (Bavaria) Novartis Agro GmbH, Frankfurt, Germany Institut Fresenius, Taunusstein, Germany, Report No IF-99/07972-00 GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2/30	Mamouni, A.	1996	14C-Terbuthylazine: Mobility and Degradation in Soil in Outdoor Lysimeters. RCC AG., Itingen, Switzerland, Report No. 348794, GLP: Yes Published: No	N	Syngenta
KCP 9.1.2/31	Mamouni, A Burgener A.	1996	14C-TERBUTHYLAZINE: MOBILITY AND DEGRADATION IN SOIL IN OUTDOOR LYSIMETERS RCC AG., Itingen, Switzerland Oxon Italia S.P.A, Pero, Italy Report-no. 348794 GLP: yes	N	Oxon
KCP 9.1.2/32	Mamouni, A	2006	TERBUTHYLAZINE:IDENTIFICATION OF LEACHATE METABOLITES AFTER TREATMENT OF SOIL IN OUTDOOR LYSIMETERS RCC AG., Itingen, Switzerland Oxon Italia S.p.A. Pero, Italy Report-no. A04858 GLP: yes	N	Oxon
KCP 9.1.2/33	Hassink J.	1992	OUTDOOR LYSIMETER STUDY ON TERBUTHYLAZINE. Fraunhofer Institut für Umweltchemie und Ökotoxikologie, Germany, CIB-04/7-11, November 1992	N	Oxon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2/34	Burgener A.	1995	¹⁴ C-TERBUTHYLAZINE/ ¹⁴ C-ATRAZINE: MOBILITY AND DEGRADATION IN SOIL IN OUTDOOR LYSIMETERS, RCC Umweltchemie AG, Itingen, Switzerland, 321581, 06.07.1995	N	Oxon
KCP 9.1.2/35	Ressler, H.	2004	LEACHING BEHAVIOUR OF TERBUTHYLAZINE (GS 13529) AND METABOLITES IN A LONG TERM FIELD EXPERIMENT FROM 1990 TO 2001 IN GERMANY. Syngenta Agro GmbH, Maintal, Germany Summary Report No. HR012004, 13.01.2004 non GLP, not published	N	Oxon
KCP 9.1.2/36	Mamouni A	2008	SECOND AMENDMENT TO REPORT Terbutylazine: Identification of leachate metabolites after treatment of soil in outdoor lysimeters Oxon Italia S.p.A. RCC Ltd., Itingen, Switzerland, A05848 GLP, not published	N	Oxon/Syngenta
KCP 9.1.2/37	Saeed M	2009	Confirmation of identity of 14C-labelled Leachate components LM1, LM2 and LM4 in Leachate water sample extract J7357/03/01 Syngenta; Oxon Italia S.p.a., Pero, Italy. Syngenta - Jealott's Hill, Bracknell, United Kingdom, REP_GLP 10376902, 09AS001 GLP, not published	N	Oxon/Syngenta
KCP 9.1.2/38	Saeed M	2009a	Confirmation of the identity of the 14C-labelled Leachate component LM3 in Leachate Water sample extract J7357/03/01 Syngenta; Oxon Italia S.p.a., Pero, Italy. Syngenta - Jealott's Hill, Bracknell, United Kingdom, REP_GLP 10372116, 08AS064	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP, not published		
KCP 9.1.2/39	Saeed M	2009b	Confirmation of identity and estimate the quantity of 14C-labelled Leachate components in Leachate water sample extract J7357/03/01 Syngenta; Oxon Italia S.p.a., Pero, Italy. Syngenta - Jealott's Hill, Bracknell, United Kingdom, REP_GLP 10387599, 09AS006 GLP, not published	N	Oxon/Syngenta
KCP 9.1.2/40	Hand L.	2009	Review of the Separation and Identification of Terbutylazine Metabolites Detected in Lysimeter Leachate Samples Syngenta; Oxon Italia S.p.a., Pero, Italy. Syngenta - Jealott's Hill, Bracknell, United Kingdom, T000412-09/3Not GLP, not published	N	Oxon/Syngenta
KCP 9.1.2/41	Sapiets A	2009	Field leaching study to investigate the movement of terbuthylazine and its metabolites to shallow groundwater in Northern Italy Syngenta; Oxon Italia S.p.a., Pero, Italy. Syngenta - Jealott's Hill, Bracknell, United Kingdom, T000412-09/3 Not GLP, not published	N	Oxon/Syngenta
KCP 9.1.2/42	Baravelli P L	2009	Terbutylazine - Determination of Residues of Terbutylazine Metabolites GS26379, CSCD648241 and GS16984 in Groundwater Samples Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia S.p.a., Pero, Italy. AgriParadigma S.r.l. Ravenna, Italy, AGRI 039/08 GLP, T000450-08 GLP, not published	N	Oxon/Syngenta
KCP 9.2/01	Doyle R	1991	Hydrolysis of 14C-Terbutylazine Novartis Crop Protection AG, Basel, Switzerland IIT Research Institute, Newington, United States, Report No IITRI-VTC-9004 GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/02	Adam D.	2000b	Hydrolysis of [triazine-U-14C]-labelled GS 26379 under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland, Report No 00DA01 GLP Not Published	N	Syngenta
KCP 9.2/03	Van der Gaauw A.	2002	14C-Triazine Ring labelled GS23158: Hydrolysis at three different pH values Syngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, Report No 815668 GLP Not Published	N	Syngenta
KCP 9.2/04	Zetsch, C., Palm, W.	1993	GS 13529 UV-Absorption spectra of Terbutylazin - estimation of aqueous photolysis maximum rate constant and minimum half-life in sunlight Novartis Crop Protection AG, Basel, Switzerland ITA Fraunhofer-Inst., Hannover, Germany, Report No PC91-3 GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/05	Mamouni, A.	2002	Aqueous Photolysis of 14C-Triazine Ring Labelled GS 13529 under Laboratory Conditions Syngenta Crop Protection AG, Basel, Switzerland, Report No 820642 GLP Not Published	N	Syngenta
KCP 9.2/06	Glaenzel	2000b	Aqueous photolysis of 14C-triazine labelled GS 26379 under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland, Report No 99AG06 GLP Not Published	N	Syngenta
KCP 9.2/07	Bader,U.	1990	GS 13529, Report on the test for ready biodegradability in the Modified Sturm Test Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 901360 GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/08	Mamouni, A,	1998	14C-Terbuthylazine: degradation and metabolism in aquatic systems Novartis Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, Report No 608207 GLP Not Published	N	Syngenta
KCP 9.2/09	Reischmann, F.	1995	volatilization of GS 13529 from water (calculation) Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 95RF14 GLP Not Published	N	Syngenta
KCP 9.2/10	Reischmann, F.	1992	Volatilization of GS 13529 from soil surface under controlled laboratory conditions Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 17/92 GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/11	Sandmeier, P.	1992	GS 13529 Volatility from plant and soil surfaces Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 92PSA06 GLP Not Published	N	Syngenta
KCP 9.2/12	Sandmeier, P.	1993	Volatilization of GS 13529 from Plant and Soil after Postemergent Spray Application of 14C-labelled Material on Maize under Indoor Conditions Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 93PSA17 GLP Not Published	N	Syngenta
KCP 9.2/13	Stamm, E.	1997	Atmospheric oxidation of terbuthylazine GS 13529 by hydroxyl radicals; rate estimation Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 95A97007SM GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/14	Reese-Staehler,G.	2000	Monitoring of GS13529 (Terbutylazine) in Surface Water in the Area of Fields Endangered by Run off. Sites: Adenstedt (Lower Saxony) and Süplingen (Sachsen Anhalt) Novartis Agro GmbH, Frankfurt, Germany Biologische Bundesanstalt für Land- und Forstwirtschaft, Braunschweig, Germany, Report No OC9902 GLP: Yes Published: No	N	Syngenta
KCP 9.2/15	Schmidt, B., Zietz,E.	2000	Monitoring site-related evaluation of terbuthylazine findings in Groundwater. Novartis Agro GmbH, Frankfurt, Germany Institut Fresenius Taunusstein, Germany. Report No. 100-1522-1738 Not GLP Not published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/16	Anon	2002	Groundwater Survey 2002. Part 5: Pesticides and Degradation Products Pages 57-74 Syngenta Crop Protection AG, Basel, Switzerland Not GLP Published	N	Syngenta
KCP 9.2/17	Kjaer,J.	2003	The Danish Pesticide Leaching Assessment Programme. Monitoring Results May 1999 - June 2002. Third Report Geological Survey of Denmark and Greenland, the Danish Institute of Agricultural Science and the National Environmental Research Institute http://pesticidvarsling.dk/monitor_uk/2002_uk/index.html Not GLP Published	N	Published reference

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/18	Kjaer,J.	2003	The Danish Pesticide Leaching Assessment Programme. Monitoring Results May 1999 - June 2002. Third Report Geological Survey of Denmark and Greenland, the Danish Institute of Agricultural Science and the National Environmental Research Institute http://pesticidvarsling.dk/monitor_uk/2002_uk/index.html Not GLP Published	N	Published reference
KCP 9.2/19	Hennecke D.	2004a	AQUATIC PHOTODEGRADATION AND QUANTUM YIELD OF DESETHYL-TERBUTHYLAZINE Fraunhofer Institut, 57392 Schmallenberg-Grafschaft, Germany Oxon Italia S.P.A, Pero, Italy Report-no. GAB-006/7-05 GLP: yes published: no	N	Oxon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/20	Hennecke D.	2004b	AQUATIC PHOTODEGRADATION AND QUANTUM YIELD OF 2-HYDROXY-TERBUTHYLAZINE Fraunhofer Institut, 57392 Schmallenberg-Grafschaft, Germany Oxon Italia S.P.A, Pero, Italy Report-no. GAB-007/7-05 GLP: yes published: no	N	Oxon
KCP 9.2/21	Desmares-Koopmans M.J.E	2001	DETERMINATION OF 'READY' BIODEGRADABILITY: CARBON DIOXIDE (CO ₂) EVOLUTION TEST (MODIFIED STURM TEST) WITH TERBUTHYLAZINE TECHNICAL Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 308115 GLP: yes published: no	N	Oxon
KCP 9.2/22	Mamouni A.	1995	[14C]-TERBUTHYLAZINE DEGRADATION AND METABOLISM IN WATER/SEDIMENT SYSTEMS RCC AG., Itingen, Switzerland Oxon Italia S.P.A, Pero, Italy Report-no. 385593 GLP: yes published: no	N	Oxon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/23	Burgener	1995	INVESTIGATION OF THE VOLATILIZATION OF [14C]-TERBUTHYLAZINE FROM SOIL AND DWARF RUNNER BEAN RCC, Itingen, Switzerland Oxon Italia S.P.A, Pero, Italy Report-no. 385604 GLP: yes published: no	N	Oxon
KCP 9.2/24	Zietz E	2009	Terbuthylazine - Storage Stability Investigation of the Terbuthylazine Metabolites CSCD648241, CSAA404791 and CSCD692760 in Water by Re Analysis of Selected Groundwater Samples Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia S.p.a., Pero, Italy. SGS Institut Fresenius GmbH, Geneva, Switzerland, IF-09/01345520, T000403-09 GLP, not published	N	Oxon/Syngenta
KCP 9.2/25	Phaff R.	2000	Degradation and metabolism of 14C-triazine ring-labelled GS 14260 in two aerobic aquatic systems under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 97RP07 GLP, not published	N	Oxon/Syngenta
KCP 9.2/26	Adam D.	2010	SYN545666/LM6(Terbuthylazine Metabolite) - Rate of Degradation under aerobic laboratory conditions in three soils at 20°C Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Innovative Environmental Services (IES) Ltd., Switzerland. 115 10 023 GLP, not published	N	Oxon/Syngenta
KCP 9.2/27	Schmidt B.	2003	Description of selected groundwater monitoring wells and the local hydrogeological situation in Schleswig-Holstein, Germany Syngenta Agro GmbH, Maintal, Germany Institut Fresenius, Taunusstein, Germany, 1688503 Not GLP, not published	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/28	Schmidt B.	2003a	Description of selected groundwater monitoring wells and the local hydrogeological situation in Mecklenburg-West Pomerania, Germany Syngenta Agro GmbH, Maintal, Germany Institut Fresenius, Taunusstein, Germany, 1688504 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/29	Schmidt B. Klaas P.	2004	Description of Groundwater Monitoring Wells and the Local Hydrogeological Conditions in the Southern Upper Rhine Valley (Ortenau und Breisgau), Germany [translated version] Syngenta Crop Protection AG, Basel, Switzerland Institut Fresenius, Taunusstein, Germany, 1488606 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/30	Schmidt B.	2005	Description of Groundwater Monitoring Wells and the Local Hydrogeological Conditions in the Rottal, Germany [translated version] Syngenta Crop Protection AG, Basel, Switzerland Institut Fresenius, Taunusstein, Germany, 1488602 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/31	Schmidt B., Klaas P.	2005	Description of Groundwater Monitoring Wells and the Local Hydrogeological Conditions in the Hessian Ried, Germany [translated version] Syngenta Crop Protection AG, Basel, Switzerland Institut Fresenius, Taunusstein, Germany, 1488604 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/32	Schneider M., Klaas P.	2005a	Description of selected groundwater monitoring wells and the local hydrogeological situation in the region Muensterland/ Emsland, Germany Syngenta Crop Protection AG, Basel, Switzerland Institut Fresenius, Taunusstein, Germany, 1488607 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/33	Ressler H	2009a	Terbuthylazine: Results of farmer interviews on the use of terbuthylazine (GS13529) in the vicinity of groundwater monitoring wells in Germany in 2004 - 2006 including characterisation of the monitoring regions Syngenta Agro GmbH, Maintal, Germany	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			, HR 02 2009 Not GLP, not published		
KCP 9.2/34	Glaenzel A.	2005	Determination of Terbutylazine (GS 13529), GS 26379, GS 28260 and GS 23158 in Water Samples from Ground Water Monitoring in Schleswig-Holstein and Bavaria in Germany Syngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, 856134 GLP, not published	N	Oxon/Syngenta
KCP 9.2/35	Schmidt B	2009	Terbutylazine: Analysis of terbutylazine (GS13529) and its metabolites CSCD648241 (LM6), GS16984 (LM5), GS26379, GS23158 and GS28620 in groundwater samples from wells with documented uses of terbutylazine on upstream fields in Germany Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia S.p.a., Pero, Italy. SGS Institut Fresenius GmbH, Geneva, Switzerland , IF-08/01230035 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/36	Zietz E	2009a	Terbutylazine: Analysis of CSCD692760 (LM3) in groundwater samples from wells with documented uses of terbutylazine on upstream fields in Germany Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia S.p.a., Pero, Italy. SGS Institut Fresenius GmbH, Geneva, Switzerland, IF-09/01393295, T0001794-09 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/37	Maroni M, Bersani M	1997	Weed Control in Maize Areas of the Po Plain Impact Assessment for Triazines in the Groundwater Table Novartis SpA Italy Syngenta - Jealott's Hill, Bracknell, United Kingdom International Centre for Pesticide Safety, Busto Garolfo, Milano, Italy GLP, not published	N	Oxon/Syngenta
KCP 9.2/38	Auteri	2007	Assessment of the Contamination of Groundwater Table by Terbutylazine, Hydroxyterbutylazine and Desethylterbutylazine in the Po Plain Novartis SpA Italy Syngenta - Jealott's Hill, Bracknell, United Kingdom International Centre for Pesticide Safety, Busto Garolfo, Milano, Italy. T019446-04 Not GLP, not published	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/39	Seville A	2009	Water Monitoring Study in the Ribatejo, Beira Litoral, Oeste and Douro Regions of Portugal, 1999-2007 Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom T004961-02-REG Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/40	Various	2000	Groundwater Monitoring Portugal, Hydrogeological Assessment Report: Ribatejo Syngenta Crop Protection AG, Basel, Switzerland Universidade de Lisboa, Lisboa, Portugal, Ribatejo, Portugal Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/41	Various	2000a	Groundwater Monitoring Portugal, Hydrogeological Assessment Report: Oeste and Douro, Portugal Syngenta Crop Protection AG, Basel, Switzerland Universidade de Lisboa, Lisboa, Portugal, Oeste and Douro Portugal Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/42	Various	2000b	Groundwater Monitoring Portugal, Hydrogeological Assessment Report: Biera Litoral, Portugal Syngenta Crop Protection AG, Basel, Switzerland Hidrogeo, Consultores de Hidrogeologia e Ambiente Lda., Lisboa, Portugal, Biera Litoral Portugal Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/43	Various	2003	Annex 1, Monitoring Network, Hydrogeological Assessment Report: Biera Litoral, Portugal Syngenta Crop Protection AG, Basel, Switzerland Hidrogeo, Consultores de Hidrogeologia e Ambiente Lda., Lisboa, Portugal, Annex 1 Biera Litoral Portugal Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/44	Seville A	2009a	Terbuthylazine (GS13529) - Retrospective Groundwater Monitoring in Southern Spain 2000 to 2003 Syngenta - Jealott's Hill, Bracknell, United Kingdom , T004964-02-REG, T004964-02 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/45	Pulido A	2000	Groundwater Monitoring South Spain ? Hydrological Assessment Syngenta - Jealott's Hill, Bracknell, United Kingdom Not GLP, not published	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/46	Cornejo J	2002	Ground and Surface Water Monitoring in Major Olive Regions in Andalucia Syngenta - Jealott's Hill, Bracknell, United Kingdom Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/47	Cornejo J	2004	Ground and Surface Water Monitoring in Major Olive Regions in Andalucia Syngenta - Jealott's Hill, Bracknell, United Kingdom Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/48	Seville A	2009b	Terbutylazine (GS13529) - Retrospective Groundwater Monitoring in South Eastern Regions of Spain 2000 to 2001 Syngenta - Jealott's Hill, Bracknell, United Kingdom , T005761-04-REG, T005761-04 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/49	Ruiz A, de Barreda Diego G	2001	Monitoring Surface Water and Groundwater in Eastern Spain Sampling and Analytical Results Syngenta - Jealott's Hill, Bracknell, United Kingdom Diego Gomez de Barreda Castillo; (2001); I.V.I.A-L.A., Moncada, Valencia, Spain Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/50	Robinson N, Wallace D	2009	Terbutylazine (GS13529) - Retrospective Groundwater Monitoring in Northern Spain, 2000 to 2004 Syngenta - Jealott's Hill, Bracknell, United Kingdom , T004962-02-REG, T004962-02 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/51	Candela L	2000	Regional Hydrological and Hydrogeological Studies Aimed at Monitoring Pesticide Residues Final Report 2000 Syngenta - Jealott's Hill, Bracknell, United Kingdom Department of Geotechnical and Geoscience, Technical University of Catalonia-UPC, Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/52	Candela L	2000a	Regional Hydrological and Hydrogeological Studies Aimed at Monitoring Pesticide Residues Appendices Syngenta - Jealott's Hill, Bracknell, United Kingdom Department of Geotechnical and Geoscience, Technical University of Catalonia-UPC, Not GLP, not published	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/53	Candela L	2003	Regional Hydrological and Hydrogeological Studies Aimed at Monitoring Pesticide Residues Addendum 2003 Syngenta - Jealott's Hill, Bracknell, United Kingdom Department of Geotechnical and Geoscience, Technical University of Catalonia-UPC, Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/54	Barcelo D, Lacorte S	2001	Water Monitoring Study in Northern Spain Syngenta - Jealott's Hill, Bracknell, United Kingdom Department of Environmental Chemistry, IIQAB-CSIC, Jordi Girona 18-26, 08034 Barcelona, Spain, Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/55	Schmidt B	2009a	Terbuthylazine - Retrospective Groundwater Monitoring in the Fricktal Region (Switzerland) Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS Institut Fresenius GmbH, Geneva, Switzerland, T008940-08-REG2, T008940-08 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/56	Schmidt B	2009b	Terbuthylazine - Retrospective Groundwater Monitoring in the Region Stein-Sisseln-Kaisten (Switzerland) Final Study Report Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS Institut Fresenius GmbH, Geneva, Switzerland, T008940-08-REG1, T008940-08 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/57	Schmidt B	2006	Clarification of Monitoring Point related Findings of Terbuthylazine in the Groundwater in Germany. Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS Institut Fresenius GmbH, Taunusstein, Germany. Final Study Report No. IF-06/00639090. GLP, not published	N	Oxon/Syngenta
KCP 9.2/58	Schmidt B	2009c	Clarification of Monitoring Point related Findings of Terbuthylazine / Desethyl terbuthylazine in the Groundwater in Germany 2005-2008. Syngenta Agro GmbH, Maintal, Germany SGS Institut Fresenius GmbH, Taunusstein, Germany. Final Study Report No. IF-08/01287363. Syngenta Ltd, Bracknell, UK GLP, not published	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/59	Zietz E.	2007	Monitoring of GS 13529 (terbuthylazine) in surface water adjacent to fields susceptible to run-off Syngenta Agro GmbH, Maintal, Germany SGS Institut Fresenius GmbH, Taunusstein, Germany. Final Study Report No. IF-99/07972-00 GLP, not published	N	Oxon/Syngenta
KCP 9.2/60	Bischoff G	2006	MONITORING OF GS 13529 (TERBUTHYLAZINE) IN SURFACE WATER ADJACENT TO FIELDS PRONE TO RUNOFF Sites Adenstedt (Lower Saxony) and Suplingen (Saxony-Anhalt) Syngenta Agro GmbH, Maintal, Germany Federal Biological Research Centre for Agriculture and Forestry, Berlin, Germany, OC9902 GLP, not published	N	Oxon/Syngenta

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the new Annex II studies

Present the authority's comment on the study in a box above each individual study. If there is more than one fate study available, list each one separately, i.e., A.7.1.1 Study 1, A.7.1.2 Study 2 etc.

A 2.1 Study 1

Comments of zRMS:	Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information
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Reference:	Data point
Report	Title, author(s), year, report No, document No, Authority registration No
Guideline(s):	Yes/No (If yes, give guidelines; If no, give justification, e.g., “ no guidelines available” or “ methods used comparable to guideline(s) xxx”)
Deviations:	Yes/No (If yes, describe deviations from test guidelines)
GLP:	Yes/No (If no, give justification, e.g., state that GLP was not compulsory at the time the study was performed)
Acceptability:	Yes/No/Supplementary

Materials and methods

Results and discussions

Conclusion

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

Additional appendices may be added to include further information such as the table of metabolites. This Appendix can be deleted if not needed.