

FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: **TERBUT 500 SC**

Product names: **TERBUT 500 SC/
TAZOPRYM 500 SC / CORNAO 500 SC**

Chemical active substance:

Terbuthylazine, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: 04/2020

MS Finalisation date: 01.2021; 03.2022: updated 06.2022

Version history

When	What
04/2020	Submission dossier by applicant
01.2021	Supplement calculations – section 8.9
01.2021	Draft evaluation by RMS
03. 2022	Final Registration Report
06.2022	Updated Registration Report

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8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

PPP (product name/code): Terbut 500 SC, Tazoprym 500 SC, Cornao 500 SC/ Terbut 500 SC Formulation type: suspension concentrate (SC)
Active substance 1: terbuthylazine Conc. of as 1: 500 g/L
Applicant: Synthos Agro sp. Z o.o. Professional use: ☒
Zone(s): central Non professional use: ☐
Verified by MS: no
Field of use: herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergis t per ha ^(f)	Conclu- sions Ground water*
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica- tions (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			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Maize (post-emergence)	F	Sensitive: <i>Capsella bursa-pastoris</i> <i>Viola arvensis</i> <i>Chenopodium album</i> <i>Amaranthus retroflexus</i> <i>Galium aparine</i> <i>Tripleurospermum inodorum</i> <i>Veronica arvensis</i> <i>Fallopia convolvulus</i> <i>Solanum nigrum</i> <i>Matricaria Chamomilla</i> Medium sensitive: <i>Cyanus segetum</i> <i>Stellaria media</i>	Fine spraying	BBCH 12-16	1	-	1 l/ha	500 g as/ha	200 l/ha			R Using once every third year on the same field
				Sensitive:	Fine spraying	BBCH	1	-	1 l/ha + 0,2	500 g as/ha	200-300			R

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergis t per ha (i)	Conclu- sions Ground water*
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica- tions (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			
				<i>Chenopodium album</i> <i>Viola arvensis</i> <i>Amaranthus retroflexus</i> <i>Galium aparine</i> <i>Tripleurospermum inodorum</i> <i>Capsella bursa-pastoris</i> <i>Veronica arvensis</i> <i>Fallopia convolvulus</i> <i>Solanum nigrum</i> <i>Matricaria Chamomilla</i> <i>Stellaria media</i> Medium sensitive: <i>Cyanus segetum</i>		12-16			(adiuwant)		l/ha			Using once every third year on the same field
2	PL	Maize (pre- emergence)	F	Sensitive: <i>Chenopodium album</i> <i>Viola arvensis</i> <i>Amaranthus retroflexus</i> <i>Tripleurospermum inodorum</i> <i>Matricaria Chamomilla</i> Medium sensitive: <i>Stellaria media</i> <i>Cyanus segetum</i>	Fine spraying	BBCH 00	1	-	1 l/ha	500 g as/ha	200-300 l/ha			R Using once every third year on the same field
				Sensitive: <i>Viola arvensis</i> <i>Amaranthus retroflexus</i> <i>Tripleurospermum inodorum</i> <i>Capsella bursa-pastoris</i> <i>Matricaria Chamomilla</i> Medium sensitive: <i>Fallopia convolvulus</i> <i>Geranium pusillum</i> <i>Galium aparine</i> <i>Cyanus segetum</i>	Fine spraying	BBCH 00	1	-	1 l/ha + 0,2 l/ha (adiuwant)	500 g as/ha	200- 300 l/ha			R Using once every third year on the same field

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergis t per ha (i)	Conclu- sions Ground water*
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica- tions (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			
				<i>Stellaria media</i>										

* **R Restriction of use: Use once every third year on the same field (according to the Regulation (EU) 2021/824 amending Regulations (EU) No 540/2011 and (EU) No 820/2011)**

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

Explanation for column 15 "Conclusion"

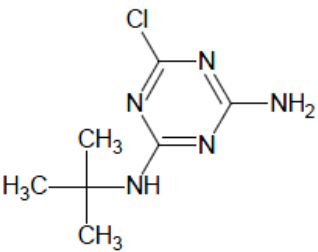
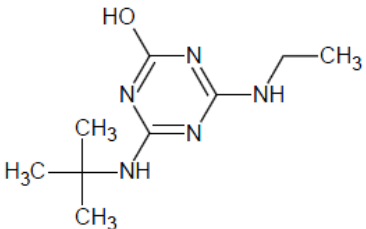
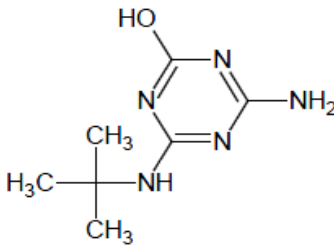
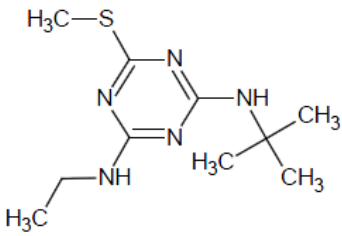
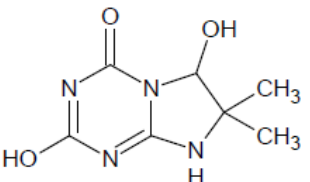
A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

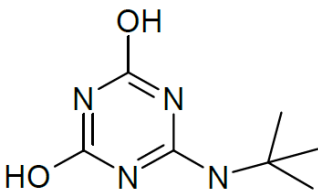
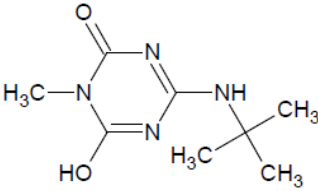
zRMS comments:

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 informations are highlighted in blue.**

8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
Desethyl-terbutylazine (MT1) N-tert-butyl-6-chloro-1,3,5-triazine-2,4-diamine	201.7		Soil: 32.9% Water/sediment: 7.3%	PEC _{gw} : leaching potential to groundwater PEC _{soil} : risk for soil organisms PEC _{sw/sed} : risk for aquatic organism
Hydroxy-terbutylazine (MT13) 4-(tert-butylamino)-6-(ethylamino)-1,3,5-triazin-2-ol	211.3		Soil: 34.5% Water/sediment: 20.0%	PEC _{gw} : leaching potential to groundwater PEC _{soil} : risk for soil organisms PEC _{sw/sed} : risk for aquatic organism
Desethyl hydroxy-terbutylazine (MT14) 4-amino-6-(tert-butylamino)-1,3,5-triazin-2-ol	183.2		Soil: 28%	PEC _{gw} : leaching potential to groundwater PEC _{soil} : risk for soil organisms
Terbutryn (MT26) N ² -tert-butyl-N ⁴ -ethyl-6-methylthio-1,3,5-triazine-2,4-diamine	241.4		Soil: 0.001% Water/sediment: 7.4%	PEC _{gw} : leaching potential to groundwater PEC _{soil} : risk for soil organisms PEC _{sw/sed} : risk for aquatic organism
LM3 2,6-dihydroxy-7,7-dimethyl-7,8-dihydroimidazo[1,2-a][1,3,5]triazin-4(6H)-one	198.2		lysimeter metabolite	PEC _{gw} : leaching potential to groundwater

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
LM5 6-(<i>tert</i> -butylamino)-1,3,5-triazine-2,4-diol	184.2		lysimeter metabolite	PEC _{gw} : leaching potential to groundwater
LM6 4-(<i>tert</i> -butylamino)-6-hydroxy-1-methyl-1,3,5-triazin-2(1 <i>H</i>)-one	198.2		lysimeter metabolite	PEC _{gw} : leaching potential to groundwater

Metabolites LM1, LM2 and LM 4 are considered as toxicologically relevant. However, according to lysimeter studies and groundwater monitoring, their concentration do not occur above trigger value of 0.1 µg/L. Therefore they are not included in further calculations.

zRMS comments:

Metabolites of terbuthylazine are in line with EU agreed endpoints as reported in EFSA Journal 2011; 9(1):1969. 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.

According to the Regulation (EU) 2021/824 amending Regulations (EU) No 540/2011 and (EU) No 820/2011 the active substance terbuthylazine should be restricted to once every third year on the same field at a maximum rate of 850 g/ha.

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)

Reference to:

- Peer review of the pesticide risk assessment of the active substance terbuthylazine (EFSA Journal EFSA Journal 2011; 9(1):1969);

8.3.1.1 Terbutylazine and its metabolites

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

terbutylazine, laboratory studies, aerobic conditions									
Soil type	%OM	pH (KCl or CaCl ₂)	temp. °C/soil moisture for study (%w/w)	Soil moisture at pF2 (%w/w)	DT _{50,actual} (d)	DT _{50,ref} 20°C pF2 (d)	Min. Chi ² error (%)	Method of calculation	Evaluated on EU level y/n/ Reference
Gartenacker Sandy Loam	3.79	7.25	20 / 26.73	48.92	78.7	51.6	1.7	SFO	Yes / EFSA Journal 2011; 9(1):1969
Pappelacker Loamy Sand	1.9	7.6	20 / 15.8	29.3	93.1	60.4	2.9	SFO	
Weide Sandy Loam	2.24	7.5	20 / 18.96	36.6	65.0	41.0	2.5	SFO	
Speyer 2.2 Loamy Sand	3.91	6.1	20 / 19.2	12.1	167	167	2.1	SFO	
Borstel Loamy Sand	2.59	5.8	20 / 10.88	14 ^b	143	120	1.0	SFO	
Lorsch Sandy Clay Loam	3.1	5.3	20 / 19.92	22 ^b	110	103	1.4	SFO	
Gartenacker Silt Loam 1.57 kg/ha	3.59	7.32	20 / 29.17	48.61	77.0	53.9	4.4	SFO	
Gartenacker Silt Loam 0.15 kg/ha	3.59	7.32	20 / 29.17	48.61	59.7	41.8	4.9	SFO	
Collombey Sand	2.29	7.7	20 / 16.8	25.31	80.0	60.0	5.9	SFO	
Les Evouettes Silt Loam	2.41	6.1	20 / 22.12	40.21	58.4	38.2	7.7	SFO	
Speyer 2.2 Loamy Sand	4.4	6.0	20 / 16.16	21.21	122	101	2.2	SFO	
Speyer 2.3 Sandy Loam	1.28	6.6	20 / 12.56	18.61	112	85.2	2.4	SFO	
Les Evouettes Loam	6.4	6.8	20 / 35.85	47.8	69.7	57.0	4.3	SFO	
Speyer 2.2 Loamy Sand	3.95	6.18	20 / 17.72	14 ^b	136	138	5.6	SFO	
Sisseln Sandy Loam	2.71	7.16	20 / 20.96	19 ^b	83.7	83.7	4.1	SFO	
Collombey Loamy Sand	2.02	7.45	20 / 16.12	14 ^b	73.6	73.6	4.2	SFO	
Diegten Clay Loam	2.74	6.9	20 / 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 different 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 - laboratory studies (where metabolite applied as starting material)

desethyl-terbuthylazine, laboratory studies, aerobic conditions (where metabolite applied as starting material)									
Soil type	%OM	pH (KCl or CaCl ₂)	temp. °C/soil moisture for study (%w/w)	Soil moisture at pF2 (%w/w)	DT _{50,actual} (d)	DT _{50,ref} 20°C pF2 (d)	Min. Chi ² error (%)	Method of calculation	Evaluated on EU level y/n/ Reference
Borstel – Loamy Sand	2.63	5.79	20 / 10.9	14 ^a	83.9	70.3	1.9	SFO	Yes / EFSA Journal 2011; 9(1):1969
Gartenacker* - Loam	3.20	7.28	20 / 26.7	25 ^a	61.8	61.8	3.1	SFO	
Lorsch – Sandy Clay Loam	3.16	5.25	20 / 19.9	22 ^a	40.7	38.0	3.3	SFO	
Speyer 2.3 – Sandy Loam	2.10	6.40	20 / 15.6	19 ^a	61.8	53.8	6.7	SFO	
Speyer 2.1 – Sand	1.07	5.90	20 / 12.4	12 ^a	45.2	45.2	4.9	SFO	
Speyer 2.2 – Loamy Sand	4.00	5.60	20 / 19.2	14 ^a	50.7	50.7	4.1	SFO	
Westmaas – Silt Loam	2.41	7.40	20 / 15.6	26 ^a	93.8	65.6	6.0	SFO	
Geometric mean					60.0	54.0	-	-	
Median					61.8	53.8	-	-	

*NB. Significant volatiles observed for Gartenacker soil

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

Table 8.3-3: Summary of aerobic degradation rates for desethyl-terbuthylazine - laboratory studies (where metabolite formed from parent terbuthylazine during the study)

desethyl-terbuthylazine, laboratory studies, aerobic conditions (where metabolite formed from parent ter- buthylazine during the study)										
Soil type	%OM	pH (KCl or CaCl ₂)	temp. °C/soil moisture for study (%w/w)	Soil mois- ture at pF2 (%w/w)	DT _{50,act} ual (d)	Form frac. (ffm)	DT _{50,ref} 20°C pF2 (d)	Min. Chi ² error (%)	Method of calcu- lation	Evaluated on EU level y/n/ Reference
Gartenacker Sandy Loam	3.79	7.25	20 / 26.73	48.92	66.0	0.606	43.2	5.8	SFO	Yes / EFSA Journal 2011; 9(1):1969
Pappelacker Loamy Sand	1.90	7.60	20 / 15.80	29.3	105.7	0.591	68.6	6.2	SFO	
Weide San- dy Loam	2.24	7.50	20 / 18.96	36.6	87.4	0.536	55.2	4.6	SFO	
Borstel Loamy Sand	2.59	5.80	20 / 10.88	14 ^b	53.8	0.357	45.1	2.3	SFO	
Gartenacker Silt Loam 1.57 kg/ha	3.59	7.32	20 / 29.17	48.61	112.8	0.430	78.9	11.3	SFO	
Gartenacker	3.59	7.32	20 / 29.17	48.61	42.9	0.575	30.0	9.3	SFO	

desethyl-terbuthylazine, laboratory studies, aerobic conditions (where metabolite formed from parent terbuthylazine during the study)										
Soil type	%OM	pH (KCl or CaCl ₂)	temp. °C/soil moisture for study (%w/w)	Soil moisture at pF2 (%w/w)	DT _{50,actual} (d)	Form frac. (ffm)	DT _{50,ref} 20°C pF2 (d)	Min. Chi ² error (%)	Method of calculation	Evaluated on EU level y/n/ Reference
Silt Loam 0.15 kg/ha										
Collombey Sand	2.29	7.70	20 / 16.80	25.31	26.9	0.498	20.2	18.1	SFO	
Les Evouettes Silt Loam	2.41	6.10	20 / 22.12	40.21	21.7	0.594	14.3	13.7	SFO	
Speyer 2.3 Sandy Loam	1.28	6.60	20 / 12.56	18.61	91.6	0.346	69.6	11.7	SFO	
Sisseln Sandy Loam	2.71	7.16	20 / 20.96	19 ^b	76.6	0.536	76.6	6.0	SFO	
Collombey Loamy Sand	2.02	7.45	20 / 16.12	14 ^b	60.4	0.580	60.4	3.5	SFO	
Diegten Clay Loam	2.74	6.90	20 / 20.76	28 ^b	63.5	0.323	51.5	7.7	SFO	
Arithmetic mean ^a					-	0.484	-	-	-	
Geometric mean ^a					61.8	-	46.9	-	-	
Median ^a					68.4	0.536	51.5	-	-	

(a) Average formation fraction and geometric mean DT₅₀ for replicate soil values calculated first

(b) FOCUS default moisture content based on soil texture

Note that the t-test result was >99% for all soils except Collombey (>95%), Les Evouettes (>98%) and Speyer 2.3 (>92%)

Table 8.3-4: Summary of aerobic degradation rates for hydroxy-terbuthylazine - laboratory studies (where metabolite applied as starting material)

hydroxy-terbuthylazine, laboratory studies, aerobic conditions (where metabolite applied as starting material)									
Soil type	%OM	pH (KCl)	temp. °C/soil moisture for study (%w/w)	Soil moisture at pF2 (%w/w)	DT _{50,actual} (d)	DT _{50,ref} 20°C pF2 (d)	Min. Chi ² error (%)	Method of calculation	Evaluated on EU level y/n/ Reference
Borstel – Loamy Sand	2.6	5.8	20 / 10.88	14 ^a	207	173	4.7	SFO	Yes / EFSA Journal 2011; 9(1):1969
Gartenacker – Loam	2.8	7.6	20 / 25.08	25 ^a	298	298	2.2	SFO	
Vetroz – Silt Loam	3.1	7.7	20 / 23.56	26 ^a	281	278	2.9	SFO	
Cranfield 115 – Clay Loam	2.9	7.4	20 / 22.10	28 ^a	>1000	>1000	3.3	SFO	

hydroxy-terbuthylazine, laboratory studies, aerobic conditions (where metabolite applied as starting material)									
Soil type	%OM	pH (KCl)	temp. °C/soil moisture for study (%w/w)	Soil moisture at pF2 (%w/w)	DT _{50,actual} (d)	DT _{50,ref} 20°C pF2 (d)	Min. Chi ² error (%)	Method of calculation	Evaluated on EU level y/n/Reference
Cranfield 164 – Silt Loam	5.2	6.5	20 / 29.12	26 ^a	>1000	>1000	3.7	SFO	
Cranfield 243 – Sandy Loam	1.9	4.3	20 / 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 DT_{50, actual} = 325 d, DT_{50, ref} = 305d))

Table 8.3-5: Summary of aerobic degradation rates for hydroxy-terbuthylazine - laboratory studies (where metabolite formed from parent terbuthylazine during the study)

hydroxy-terbuthylazine, laboratory studies, 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 calculation	Evaluated on EU level y/n/ Reference
Gartenacker Sandy Loam	3.79	7.25	Acceptable	0.080	12.1	SFO using a fixed DT ₅₀ of 325 d	Yes / EFSA Journal 2011; 9(1):1969
Pappelacker Loamy Sand	1.90	7.60	Acceptable	0.065	28.0	SFO using a fixed DT ₅₀ of 325 d	
Weide Sandy Loam	2.24	7.50	Acceptable	0.059	28.6	SFO using a fixed DT ₅₀ of 325 d	
Speyer 2.2 Loamy Sand	3.91	6.10	Acceptable	0.313	26.4	SFO using a fixed DT ₅₀ of 325 d	
Borstel Loamy Sand	2.59	5.80	Very good	0.219	3.00	SFO using a fixed DT ₅₀ of 325 d	
Lorsch Sandy Clay Loam	3.10	5.30	Very good	0.379	7.00	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	7.70	Acceptable	0.301	18.2	SFO using a fixed DT ₅₀ of 325 d	
Les Evouettes Silt Loam	2.41	6.10	Good	0.381	9.60	SFO using a fixed DT ₅₀ of 325 d	
Speyer 2.2 Loamy Sand	4.40	6.00	Good	0.379	12.0	SFO using a fixed DT ₅₀ of 325 d	
Speyer 2.3 Sandy Loam	1.28	6.60	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	6.90	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 8.3-6: Summary of aerobic degradation rates for desethyl hydroxy-terbuthylazine - laboratory studies (where metabolite applied as starting material)

desethyl hydroxy-terbuthylazine, laboratory studies, aerobic conditions (where metabolite applied as starting material)									
Soil type	%OM	pH (KCl)	temp. °C/soil moisture for study (%w/w)	Soil moisture at pF2 (%w/w)	DT _{50,actual} (d)	DT _{50,ref} 20°C pF2 (d)	Min. Chi ² error (%)	Method of calculation	Evaluated on EU level y/n/ Reference
Borstel – Loamy Sand	2.6	5.8	20 / 10.88	14a	135	113	7.7	SFO	Yes / EFSA Journal 2011; 9(1):1969
Gartenacker – Loam	2.8	7.6	20 / 25.08	25a	50.1	50.1	5.3	SFO	
Lorsch – sandy clay loam	3.1	5.3	20 / 19.92	22a	377	351	5.1	SFO	
Vetroz – Silt Loam	3.1	7.7	20 / 23.56	26a	69.7	65.1	4.0	SFO	
Geometric mean					115	107	-	-	

(a) FOCUS default moisture content based on soil texture
 t-test result was >99% for every soil except Lorsch where it was >97%

Table 8.3-7: Summary of aerobic degradation rates for desethyl hydroxy-terbuthylazine - laboratory studies (where metabolite formed from parent terbuthylazine during the study)

desethyl hydroxy-terbuthylazine, laboratory studies, aerobic conditions (where metabolite formed from parent desethyl-terbuthylazine during the study)							
Soil type	%OM	pH (KCl or CaCl ₂)	Visual inspection	Form frac. (ffm)	Min. Chi ² error (%)	Method of calculation	Evaluated on EU level y/n/ Reference
Borstel – Loamy Sand	2.6	5.8	Very good	0.203	2.7	SFO using a fixed DT ₅₀ of 135 d	Yes / EFSA Journal 2011; 9(1):1969
Gartenacker – Loam	2.8	7.6	Very good	0.179	9.1	SFO using a fixed DT ₅₀ of 50.1 d	
Lorsch – sandy clay loam	3.1	5.3	Very good	0.458	3.5	SFO using a fixed DT ₅₀ of 377 d	
Arithmetic mean				0.280	-	-	

All studies performed at 20°C

zRMS comments:

Soil degradation data for of terbuthylazine and its metabolites are in line with EU agreed endpoints as reported in EFSA Journal 2011; 9(1):1969.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Studies on the anaerobic degradation in soil have previously been evaluated within an EU peer review process. Under anaerobic conditions, the route of terbuthylazine breakdown is similar to the aerobic route of metabolism, forming no novel metabolites.

Table 8.3-8: Summary of anaerobic degradation rates for terbuthylazine - laboratory studies

Soil type	%OM	pH	t.°C /%MWH C	DT ₅₀ / DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi² (%)	Method of calcu- lation	Evaluated on EU level y/n/ Refer- ence
Gartenacker – Sandy loam - SYN	3.79	7.25	20 / flooded soil	108.3 / 359.9	N/A	0.981	SFO	Yes / EFSA Journal 2011; 9(1):1969
Speyer 2.3 – Sandy Loam - SYN	2.07	6.3	20 / flooded soil	131 / 436	N/A	0.966	SFO	
Geometric mean				119.1	-	-	-	

8.4 Field studies (KCP 9.1.1.2)

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

8.4.1.1 Terbuthylazine and its metabolites

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

Soil type	Location (country or USA state)	% OM	pH	Depth (cm)	DT _{50, ref} 20°C pF2 (d)	DT _{90, ref} 20°C pF2 (d)	Min. χ² error (%)	t-test (%)	Method of cal- culation ^a	Evaluated on EU level y/n/ Refer- ence
Loam – Bare soil	St Aubin, Switzerland	3.1	7.2	0-10	18.0	59.8	5.4	>99	SFO	Yes / EFSA Journal 2011; 9(1):1969
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	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	1.0	8.6	0-10	12.1	40.2	9.1	>99	SFO	

Soil type	Location (country or USA state)	% OM	pH	Depth (cm)	DT _{50, ref} 20°C pF2 (d)	DT _{90, ref} 20°C pF2 (d)	Min. χ^2 error (%)	t-test (%)	Method of cal- culation ^a	Evaluat- ed on EU level y/n/ Refer- ence
	(North) (1.0)									
Sand – Bare soil	Nevoy, France (North) (1.5)	1.0	8.6	0-10	18.9	62.7	7.3	>99	SFO	
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	>99	SFO	
Sandy silt loam – Bare soil	Eraclea, Italy (1.0) ^b	3.4	7.6	0-10	10.0	33.3	20.9	>99	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 ^e	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	-	-	-	

NK – not known

(a) soils were normalised for temperature assuming a Q10 of 2.2 using a time step normalisation procedure. Soil moisture content was assumed to be at pF2 and not corrected for.

(b) Excluded from statistical evaluations due to poor fits

(c) Geometric mean of replicate trials calculated first; median based on n = 16

(d) The un-normalised SFO DT₅₀ at the Molinella field site (SEU) was 149.9 d (chi² error level = 12.8%, acceptable visual fit)

(e) The un-normalised SFO DT₅₀ at the Hilgermissen field site (NEU) was 46.6 d (chi² error level = 17.2%, acceptable visual fit up to approximate DT₉₀)

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

Aerobic conditions (where metabolite formed from parent terbuthylazine during the study)										
Soil type	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. χ^2 error (%)	t-test (%)	Method of cal- culation ^d	Evaluat- ed on EU level y/n/ Refer- ence
Loam – Bare soil	St Aubin, Switzerland	3.1	7.2	16.5	54.9	0.298	17.1	>99	SFO	Yes /

Aerobic conditions (where metabolite formed from parent terbuthylazine during the study)										
Soil type	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. χ^2 error (%)	t-test (%)	Method of cal- culation^d	Evaluated on EU level y/n/ Refer- ence
Silt loam – Bare soil	Pleidsheim, Germany	2.1	6.0	30.9	103	0.117	13.7	>77	SFO	EFSA Journal 2011; 9(1):1969
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	-	-	-	-	

(a) only valid datasets considered

(b) arithmetic mean of replicate soils calculated first

(c) geometric mean of replicate soils calculated first

(d) soils were normalised for temperature assuming a Q10 of 2.2 using a time step normalization procedure. Soil moisture content was assumed to be at pF2 and not corrected for.

NB the applicant proposed a geometric mean of 29.6 d based on a marginally different set of soils considered acceptable

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

Soil type	Location (country or USA state)	% OM	pH	Visual in- spection	Form. frac. (ffm)	Min. χ^2 error (%)	Method of calculation	Evaluated on EU level y/n/ Refer- ence
Loam – Bare soil	St Aubin, Switzerland	3.1	7.2	Reasonable	0.079	22.7	SFO using a fixed DT ₅₀ of 305 d	Yes / EFSA Journal 2011; 9(1):1969
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	

Soil type	Location (country or USA state)	% OM	pH	Visual in- spection	Form. frac. (ffm)	Min. χ^2 error (%)	Method of calculation	Evaluated on EU level y/n/ Refer- ence
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	-	-	

(a) arithmetic mean of replicate soils calculated first

zRMS comments:

Field soil degradation data for of terbuthylazine is in line with EU agreed endpoints as reported in EFSA Journal 2011; 9(1):1969.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

There is no evidence of accumulation in soil of terbuthylazine, desethyl-terbuthylazine, hydroxy terbuthylazine or desethyl-hydroxy terbuthylazine after repeated applications at 7 locations in Northern Italy.

8.5 Mobility in soil (KCP 9.1.2)

Terbuthylazine shows medium mobility in soils and desethyl-terbuthylazine, hydroxy terbuthylazine and desethyl-hydroxy terbuthylazine show high to very high, medium and low to very high mobility in soil respectively.

8.5.1 Terbuthylazine and its metabolites

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

Terbuthylazine – active substance								
Soil type	OC (%)	Soil pH (-)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Refer- ence
Speyer 2.2 Loamy Sand – OXON	2.29	6.6	N/A	N/A	5.34	233	0.98	Yes / EFSA Journal 2011; 9(1):1969
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	4.10	7.3	N/A	N/A	8.18	200	0.90	
Pappelacker Loamy Sand – SYN	1.10	7.6	N/A	N/A	2.10	191	0.92	

Terbuthylazine – active substance								
Soil type	OC (%)	Soil pH (-)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Lorsch Sandy Clay Loam – SYN	1.80	5.3	N/A	N/A	5.86	318	0.94	
Gartenacker Loam – SYN	2.00	7.1	N/A	N/A	3.74	187	0.88	
Vetroz Silt Loam - SYN	4.70	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-dependency		Possible weak negative correlation between sorption and soil pH ($r^2 = 0.5456$)						

N/A = not recorded

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

Metabolite desethyl-terbuthylazine								
Soil Type	OC (%)	pH (-)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Collombey Loamy Sand - SYN	0.80	7.3	N/A	N/A	0.594	74.0	0.85	Yes / EFSA Journal 2011; 9(1):1969
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	0.60	5.9	N/A	N/A	0.43	67.2	0.95	
Speyer 2.2 Loamy Sand – OXON	2.30	5.6	N/A	N/A	1.90	81.7	0.91	
Beek Silt Loam – OXON	0.60	6.6	N/A	N/A	0.28	43.8	0.94	
Marknesse Silt Loam - OXON	1.30	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-dependency		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 hydroxy-terbuthylazine

Metabolite hydroxy-terbuthylazine								
Soil Type	OC (%)	Soil pH (-)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Cranfield 115 Clay Loam – OXON	1.7	7.9	N/A	N/A	3.51	208.6	0.82	Yes / EFSA Journal 2011; 9(1):1969
Cranfield 164 Silt Loam – OXON	3.0	7.1	N/A	N/A	5.94	196.9	0.80	
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	0.8	7.3	N/A	N/A	1.19	149	0.91	
Les Evouettes Silt Loam - SYN	2.4	7.2	N/A	N/A	2.49	104	0.79	
Vetroz Silt Loam - SYN	4.7	7.2	N/A	N/A	8.36	178	1.31	
Arithmetic mean					3.90	187	0.91	
pH-dependency		no						

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

Metabolite desethyl hydroxy-terbuthylazine								
Soil Type	OC (%)	pH (-)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Borstel Loamy Sand	1.30	5.00	1.80	136	1.44	111	0.9300	Yes / EFSA Journal 2011; 9(1):1969
Lorsch Sandy Clay Loam	1.80	5.30	3.80	211	3.39	188	0.9700	
Gartenacker Loam/Silt Loam	2.00	7.10	1.20	59	1.10	55	0.9800	
Vetroz Silt Loam	4.70	7.20	2.80	60	2.67	57	0.9800	
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	

Metabolite desethyl hydroxy-terbuthylazine								
Soil Type	OC (%)	pH (-)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
pH-dependency		no						

Table 8.5-5: Summary of soil adsorption/desorption for terbutryn

Metabolite terbutryn								
Soil Type	OC (%)	pH (-)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Pappelacker - Sandy Loam	1.1	7.6	N/A	N/A		392	1.01	Yes / EFSA Journal 2011; 9(1):1969
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-dependency		No evidence from narrow pH range studied						

8.5.2 Column leaching (KCP 9.1.2.1)

Table 8.5-6: Summary of column leaching studies for terbuthylazine

Elution (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)

Table 8.5-7: Summary of lysimeter studies for terbuthylazine

Lysimeter/ field leaching studies (SYN) Summary of metabolite codes:- MT1 = GS26379 MT13 = GS23158 MT14 = GS28620 MT19 = GS17792 MT20 = GS28273	Location: Schmallingenberg/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
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<p>MT22 = G28279 LM1 = MT24 = G35713 LM2 = MT28 = CSAA036479 LM3 = SM9 = CSCD692760 LM4 = CSAA404949 LM5 = MT23 = SM12 = GS16984 LM6 = SM6 = CSCD648241</p>	<p>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, 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: < 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 desethylter-</p>

	<p>buthylazine (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)</p> <p>*= structures tentatively assigned to peaks</p> <p>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)</p> <p>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>
Lysimeter/ field leaching studies (OXON)	<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</p> <p>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)</p>

	<p>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)</p> <p>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>
Lysimeter/ field leaching studies (OXON)	<p>Location: Itingen, Switzerland Study type (e.g.lysimeter, field): lysimeter (x2) Soil properties (0 – 30 cm): Neustadt Sandy loam, pH = 6.18, OC= 1.43, MWHC = 45.35 % Dates of application : 10/05/05 Crop : bare soil followed by plot being split and one of the following crops being sown: radish, spinach, wheat Interception estimated: 0 % (based on application to bare soil) Annual rainfall during first year May 2005 to April 2006 (mm): 798.5 mm Number of applications: 1 application to bare soil Duration: 1 year Application rate: 972 g/ha (Lysimeter 4); 980 g/ha (Lysimeter 6) Average annual leachate volume (mm): 731 mm % radioactivity in leachate (maximum/year): 1.60 - 1.70 % AR Annual average concentrations (e.g. 1st yr, Lysimeter 4 or 6): not detected – terbuthylazine, desethyl terbuthylazine, hydroxy terbuthylazine</p> <p>0.03/0.02µg/l LM1 (lysimeter 4/6, 1st year); 0.07/0.08µg/l LM2 (lysimeter 4/6, 1st year); 0.24/0.23µg/l LM3 (lysimeter 4/6, 1st year); 0.11/0.21µg/l LM4 (lysimeter 4/6, 1st year); 0.68/0.78µg/l LM5 (lysimeter 4/6, 1st year); 0.18/0.19µg/l LM6 (lysimeter 4/6, 1st year); 0.08/0.08µg/l LM7 (lysimeter 4/6, 1st year);</p> <p>All concentrations are in µg metabolite/l. Amount of radioactivity in the soils at the end of the study = not reported</p>
Lysimeter/ field leaching studies (SYN)	<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.:</p> <p>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.</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): < 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, 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</p> <p>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.</p> <p>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. 2-hydroxy terbuthylazine: 2 detections out of 144 samples, 0%(0 samples) >0.1µg/l; maximum concentration = 0.05µg/l. LM5: 11 detections out of 21 samples; 29% (~6 samples) > 0.1µg/l; maximum concentration = 0.68µg/l. LM6: 9 detections out of 21 samples; 38% (~8 samples) >0.1µg/l; maximum concentration = 1.58µg/l.</p> <p>Annual average concentrations: 0.03 – 0.58 µg/L terbuthylazine (basin irrigation) <0.01 – 0.07 µg/L terbuthylazine (sprinkler or border irrigation) 0.07 – 0.73 µg/L desethyl terbuthylazine (basin irrigation) <0.01 – 0.22 µg/L desethyl terbuthylazine (sprinkler or border irrigation) < 0.05 – 0.05 µg/L (single sample) 2-hydroxy terbuthylazine (analysed for 2007 only) 0.04 – 0.37 µg/L desethyl hydroxy-terbuthylazine (analysed for the 2007 season only) <0.05 – 0.48 µg/L GS16984 (LM5) (analysed for the 2007 season only) <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</p>

	derive from previous usage following several years of commercial application in the upstream areas.
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zRMS comments:

Soil mobility data for terbuthylazine and its metabolites are in line with EU agreed endpoints as reported in EFSA Journal 20119(1):1969.

8.5.4 Field leaching studies (KCP 9.1.2.3)

Table 8.5-8: Summary of field leaching studies for terbuthylazine

Location	Date of application	Tested substances	Reference
Northern Italy (8 field leaching study*, 395 samples)	2005 to 2007	terbuthylazine, hydroxy terbuthylazine (analysed for 2007 only), desethyl hydroxy- terbuthylazine (analysed for 2007 only), LM5 (analysed for the 2007 season only), LM6 (analysed for the 2007 season only)	Sapiets (2009) and Baravelli (2009), as summarised in UK (2010)
Germany (targeted monitoring, 25 wells, 29 samples)	1990 to 2000	terbuthylazine desethyl-terbuthylazine, hydroxy-terbuthylazine, desethylhydroxy- terbuthylazine	Ressler (2004) and annual reports, as summarised in UK (2007)

* two additional sites with basin irrigation are not considered here, as basin irrigation is not supported

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

8.6.1 Terbuthylazine and its metabolites

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

Water/sediment system	pH water phase	pH sed.	t. °C	DT ₅₀ -DT ₉₀ whole syst. (d)	χ^2 %	DT ₅₀ -DT ₉₀ water (d)	χ^2 %	DT ₅₀ -DT ₉₀ sed. (d)	χ^2 %	Method of calculation	Evaluated on EU level y/n/ Reference
Distribution: max. in sed. 51.8 % AR after 14 d											
River Rhine sandy loam -SYN	8.3	7.7	20	73 - 242	0.9917	6 - 131	0.9994	NC	-	SFO – whole system DFOP – water phase	Yes / EFSA Journal 2011; 9(1):1969
Pond Ormalingen silt loam - SYN	8.1	7.5	20	33 - 110	0.9994	6 - 47	0.9991	NC	-	SFO – whole system	

Water/sediment system	pH water phase	pH sed.	t. °C	DT ₅₀ -DT ₉₀ whole syst. (d)	χ ² %	DT ₅₀ -DT ₉₀ water (d)	χ ² %	DT ₅₀ -DT ₉₀ sed. (d)	χ ² %	Method of calculation	Evaluated on EU level y/n/Reference
Distribution: max. in sed. 51.8 % AR after 14 d											
										DFOP – water phase	
River Rhine Loamy sand – OXON	8.2	7.3	20	83.5 - 277.5	0.9991	31.4 - 104.4	0.8500	NC	-	SFO	
Pond Anwil clay loam - OXON	8.3	6.6	20	118.5 - 393.8	0.9670	32.1 - 106.7	0.8700	NC	-	SFO	
Geometric mean				69.9 days - 232.2 days		NC – not all SFO		-		SFO	

NC = not calculated

Table 8.6-2: Summary of observed metabolites

desethyl-terbuthylazine (MT1) Water/sediment system	Max. in whole system 8.8 % AR fter 110 d Max. in water 8.0 % AR after 365 d Max. in sediment 2.8 % AR after 110 d	Evaluated on EU level: YES Reference: EFSA Journal 2011; 9(1):1969
hydroxy-terbuthylazine (MT13) Water/sediment system	Max. in whole system 20.0 % AR fter 365 d Max. in water 5.7 % AR after 365 d Max. in sediment 14.5 % AR after 272 d	
terbutryn (MT26) Water/sediment system	Max. in whole system 7.4 % AR fter 365 d Max. in water 0.3 % AR after 118 d Max. in sediment 7.4 % AR after 272 d	

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

8.7.1 Justification for new endpoints

There are no deviations from the EU agreed endpoints.

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

Calculations of PEC_{soil} were performed using: “Soil persistence models and EU registration” (The final report of the work of the Soil Modelling Work group of FOCUS).

The PEC of terbuthylazine and its metabolites in soil has been assessed with the FOCUS model, FOCUS groundwater interception values and the maximum DT₅₀ values established in the EU review i.e. EFSA Journal 2011; 9(1):1969. Metabolites listed as being relevant for soil risk assessment are desethyl-terbuthylazine (max. 32.9 %) and hydroxy-terbuthylazine (max. 34.5 %).

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

Crop	Applica- tion rate (g a.s./ha)	Number of appli- cations/interval	Crop interception (%) – worst case ¹	Depth of soil layer (cm)	Soil bulk density (g/cm ³)
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Maize (pre-emergence, BBCH 00)	500	1/n.a.	0	5	1.5
Maize (post-emergence, BBCH 12-16)	500	1/n.a.	25	5	1.5

¹ values based on the FOCUS guidance (*Generic Guidance for Tier 1 FOCUS Ground Water Assessments (version: 2.2, May 2014)*)

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
Terbuthylazine	229.7	-	46.6	Yes / EFSA Journal 2011; 9(1):1969
Desethyl-terbuthylazine MT1	201.7	32.9	30.9	Yes / EFSA Journal 2011; 9(1):1969
Hydroxy-terbuthylazine MT13	211.3	34.5	1000 (worst case default)	Yes / EFSA Journal 2011; 9(1):1969
Desethyl hydroxy- terbythylazine (MT14)	183.2	28	135	Yes / EFSA Journal 2011; 9(1):1969

Table 8.7-3: PEC_{soil} for terbuthylazine on maize – pre-emergence use

PEC _{soil} (mg/kg)		maize	
		Single application	
		Actual	TWA
Initial		0.667	0.667
Short term	24h	0.657	0.662
	2d	0.647	0.657
	4d	0.628	0.647
Long term	7d	0.601	0.633
	14d	0.541	0.602
	21d	0.488	0.573
	28 d	0.440	0.545
	50d	0.317	0.470
	100d	0.151	0.347
Plateau concentration		Not required since DT ₅₀ in soil is <90d	
PEC _{accumulation} (PEC _{act} +PEC _{soil plateau})			

Table 8.7-4: PEC_{soil} for terbuthylazine on maize – post-emergence use

PEC _{soil} (mg/kg)		maize	
		Single application	
		Actual	TWA
Initial		0.500	0.500
Short term	24h	0.493	0.496
	2d	0.485	0.493
	4d	0.471	0.485
Long term	7d	0.451	0.475
	14d	0.406	0.451
	21d	0.366	0.429
	28 d	0.330	0.409
	50d	0.238	0.353
	100d	0.113	0.260
Plateau concentration		Not required since DT ₅₀ in soil is <90d	
PEC _{accumulation} (PEC _{act} +PEC _{soil plateau})			

PEC_{soil} of metabolites

Desethyl-terbuthylazine (MT1)

Table 8.7-5: PEC_{soil} for MT1 on maize – pre-emergence

PEC _{soil} (mg/kg) 144.4 g/ha		maize	
		Single application	
		Actual	TWA
Initial		0.193	0.193
Short term	24h	0.188	0.190
	2d	0.184	0.188
	4d	0.176	0.184
Long term	7d	0.165	0.178
	14d	0.141	0.165
	21d	0.120	0.154
	28 d	0.103	0.143
	50d	0.063	0.116
	100d	0.020	0.077
Plateau concentration		Not required	

PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})	Not relevant since DT ₅₀ < 90 used
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Table 8.7-6: PEC_{soil} for MT1 on maize – post-emergence

PEC _{soil} (mg/kg) 144.4 g/ha		maize	
		Single application	
		Actual	TWA
Initial		0.144	0.144
Short term	24h	0.141	0.143
	2d	0.138	0.141
	4d	0.132	0.138
Long term	7d	0.123	0.134
	14d	0.105	0.124
	21d	0.090	0.115
	28 d	0.077	0.107
	50d	0.047	0.087
	100d	0.015	0.058
Plateau concentration		Not required	
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Not relevant since DT ₅₀ < 90 used	

Hydroxy-terbuthylazine (MT13)

Table 8.7-7: PEC_{soil} for MT13 on maize – pre-emergence

PEC _{soil} (mg/kg) 158.7 g/ha		maize	
		Single application	
		Actual	TWA
Initial		0.212	0.212
Short term	24h	0.211	0.212
	2d	0.211	0.211
	4d	0.211	0.211
Long term	7d	0.211	0.211
	14d	0.210	0.211
	21d	0.209	0.210
	28 d	0.208	0.210
	50d	0.204	0.208
	100d	0.197	0.204

Plateau concentration	0.729
$\frac{PEC_{\text{accumulation}}}{(PEC_{\text{act}} + PEC_{\text{soil plateau}})}$	0.941

Figure 1 Saw-teeth curve showing PEC_s concentrations of MT13 following subsequently single annual applications of TERBUT 500 SC on Maize.

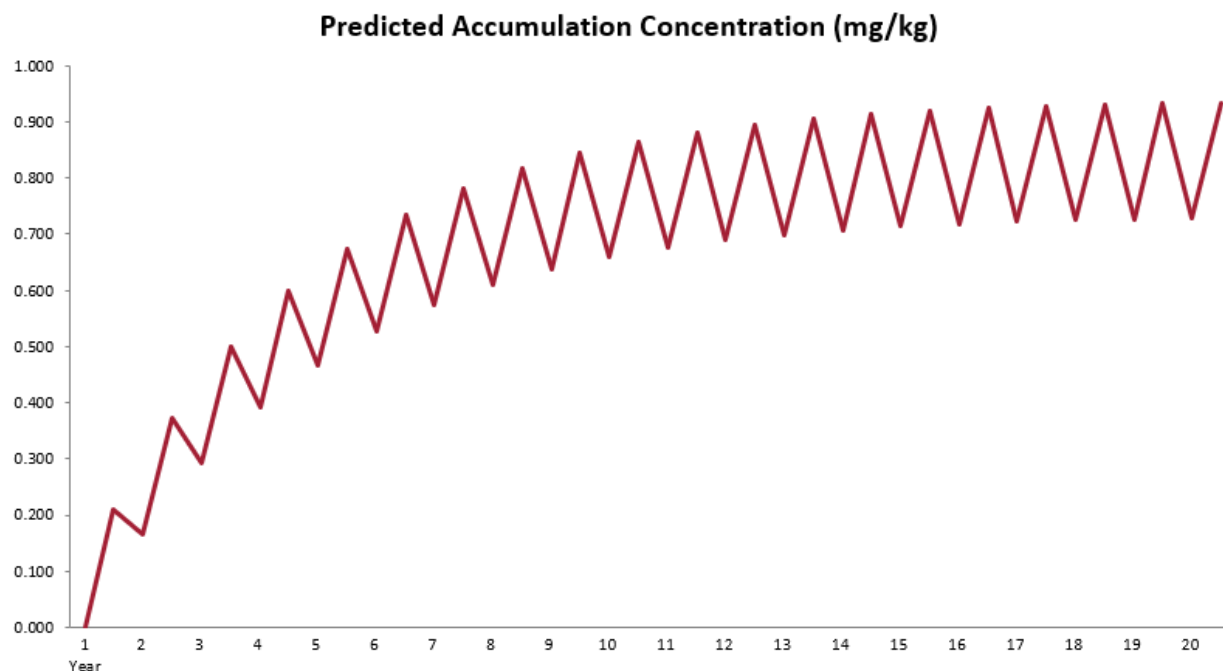
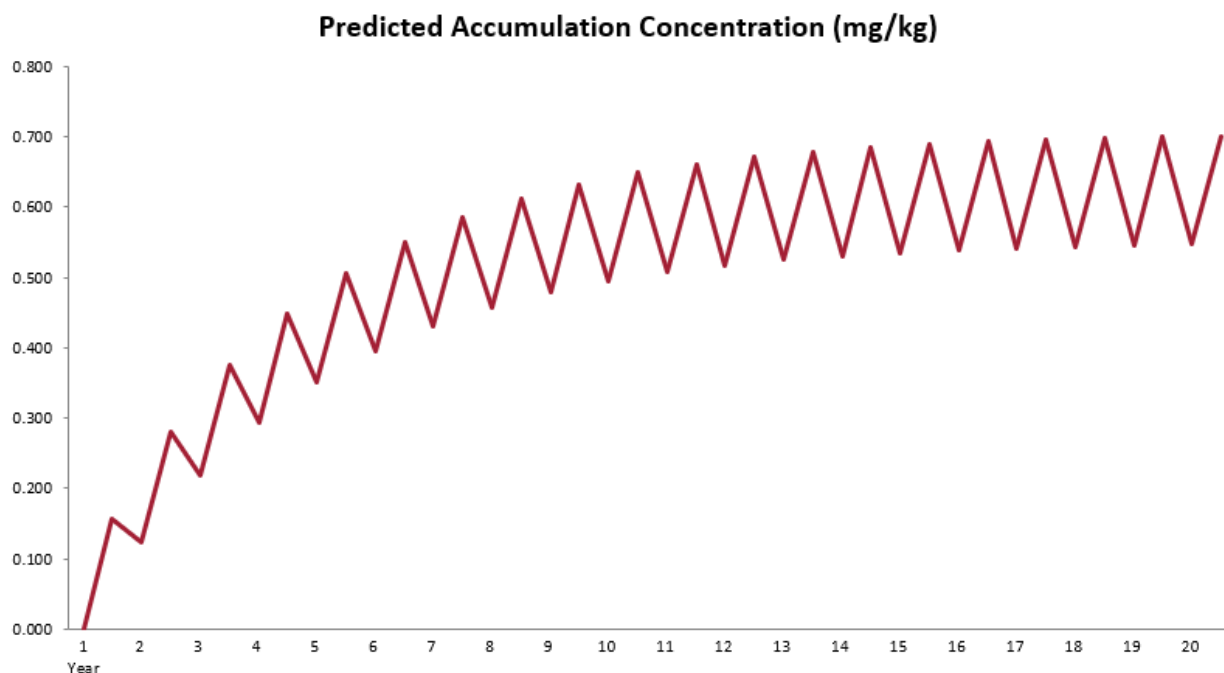


Table 8.7-8: PEC_{soil} for MT13 on maize – post-emergence

PEC _{soil} (mg/kg) 158.7 g/ha		maize	
		Single application	
		Actual	TWA
Initial		0.159	0.159
Short term	24h	0.159	0.159
	2d	0.158	0.159
	4d	0.158	0.158
Long term	7d	0.158	0.158
	14d	0.157	0.158
	21d	0.156	0.158
	28 d	0.156	0.157
	50d	0.153	0.156
	100d	0.148	0.153
Plateau concentration		0.547	
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.706	

Figure 2 Saw-teeth curve showing PEC_s concentrations of MT13 following subsequently single annual applications of TERBUT 500 SC on Maize.



Desethyl hydroxy-terbuthylazine (MT14)

Table 8.7-9: PEC_{soil} for MT14 on maize – pre-emergence

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	

Figure 3 Saw-teeth curve showing PEC_s concentrations of MT14 following subsequently single annual applications of TERBUT 500 SC on Maize.

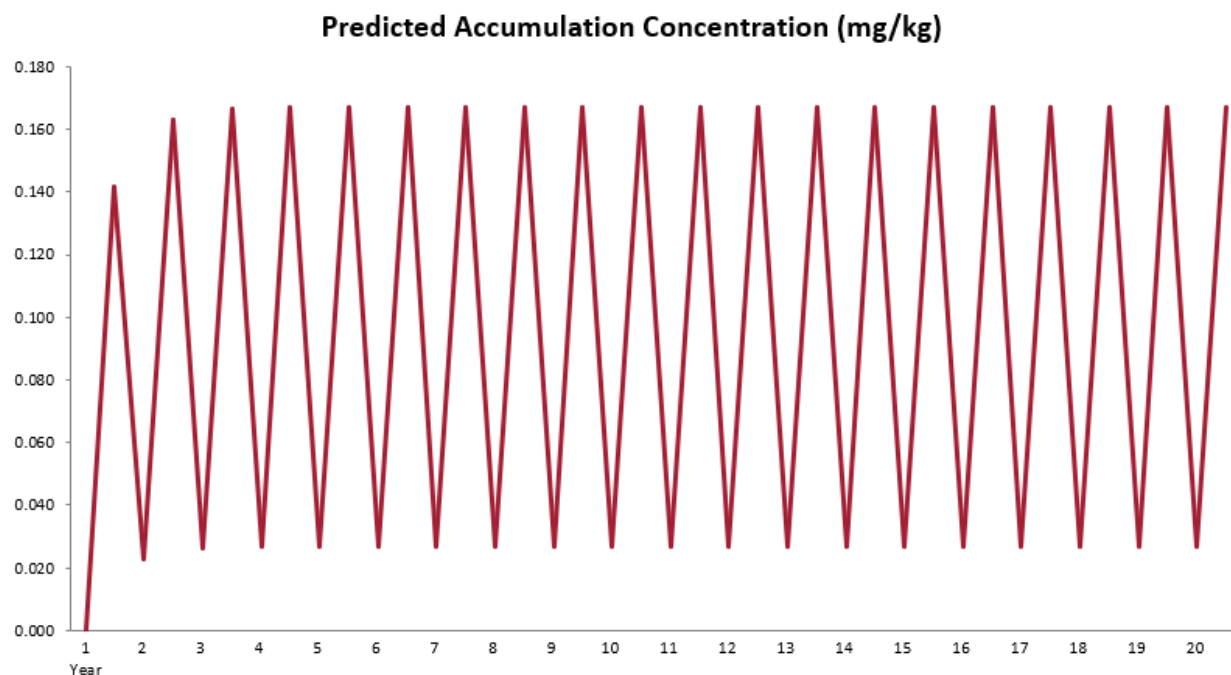
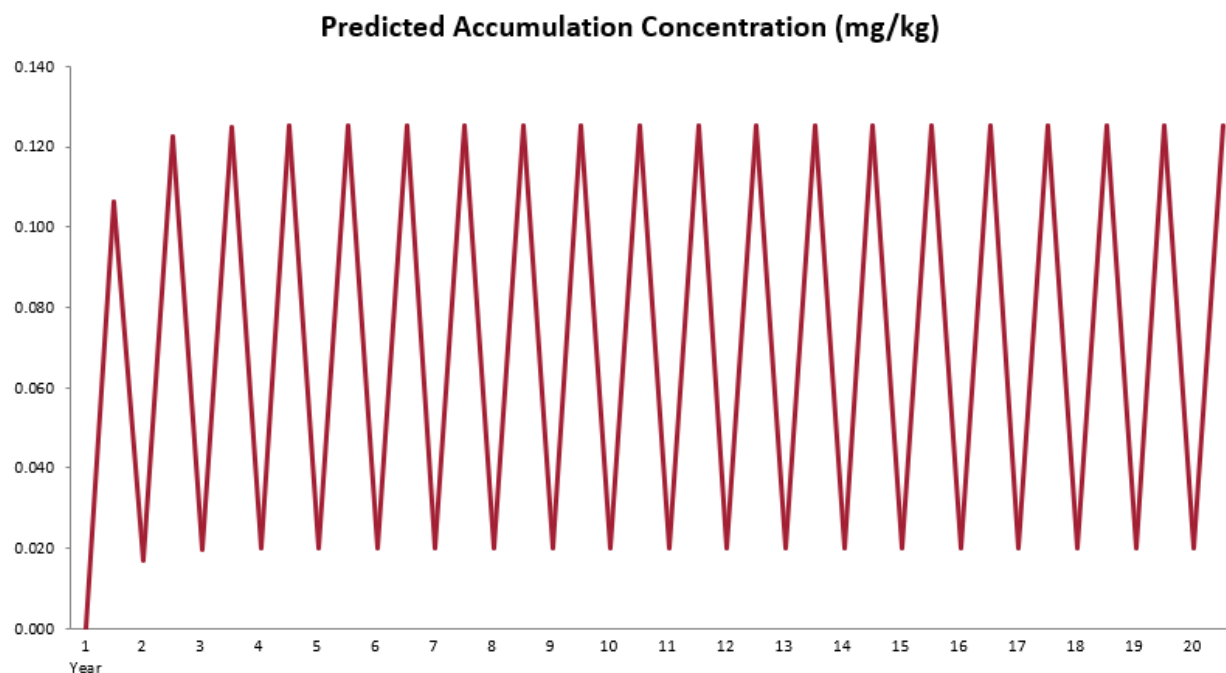


Table 8.7-10: PEC_{soil} for MT14 on maize – post-emergence

PEC _{soil} (mg/kg) 111.7 g/ha		maize	
		Single application	
		Actual	TWA
Initial		0.112	0.112
Short term	24h	0.111	0.111
	2d	0.111	0.111
	4d	0.109	0.111
Long term	7d	0.108	0.110
	14d	0.104	0.108
	21d	0.100	0.106
	28 d	0.097	0.104
	50d	0.086	0.099
	100d	0.067	0.087
Plateau concentration		0.020	
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.132	

Figure 4 Saw-teeth curve showing PEC_s concentrations of MT14 following subsequently single annual applications of TERBUT 500 SC on Maize.



8.7.2.1 PEC_{soil} of TERBUT 500 SC

Table 8.7-11: PEC_{soil} for TERBUT 500 SC on Maize

Active substance/ reparation	Application rate (g/ha)	PEC _{act} (mg/kg)	Tillage depth (cm)	PEC _{soil,plateau} (mg/kg)	PEC _{accu} = PEC _{act} + PEC _{soil,plateau} (mg/kg)
Maize – pre-emergence	1102	1.469	n/a	Not required	
Maize – post-emergence	1102	1.102	n/a	Not required	

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 for proposed of uses in GAP.

The PEC_{soil} results was presented in Table 8.7-12 -8.7-13.

TERBUT 500 SC:

PEC_{soil initial} = 1.469 mg/kg for maize – pre-emergence

PEC_{soil initial} = 1.102 mg/kg for maize – post-emergence

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

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

9.2.4)

8.8.1 Justification for new endpoints

There are no deviations from the EU agreed endpoints.

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

TERBUT 500 SC was not assessed as representative formulation. PEC_{GW} was calculated, using PEARL 4.4.4 and PELMO 5.5.3, according to endpoints for terbuthylazine and its metabolites and submitted for TERBUT 500 SC.

In two monitoring studies considered by experts to provide reliable information on leaching potential, LM3, LM5 and LM6 were frequently detected in groundwater in concentrations exceeding 0.1 µg/l. Frequency of exceedance of 0.1 µg/l reached 29%, 38% and 34% for LM3, LM5 and LM6 respectively. Similar monitoring data on the other metabolites LM1, LM2 and LM4 were not available. Therefore PEC_{gw} for LM3, LM5, LM6, MT1, MT13, MT14 and terbuthylazine is calculated.

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

Use No.	1	1
Crop	Maize – pre-emergence	Maize – post-emergence
Application rate (g as/ha)	Terbuthylazine 500	Terbuthylazine 500
Number of applications/interval (d)	1/0	1/0
Application date	14 days before emergence	14 days after emergence
Crop interception (%)	0	25
Frequency of application	annual	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3

8.8.2.1 Terbuthylazine and its metabolites

Table 8.8-2: Input parameters related to active substance Terbuthylazine and metabolites for PEC_{gw} calculations

Compound	Terbuthylazine	MT1	MT13	MT14	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	229.7	201.7	211.3	183.2	Y/EFSA Journal 2011; 9(1):1969
Water solubility (mg/L):	8.5	327.1	7.19	18.0	Y/EFSA Journal 2011; 9(1):1969
Saturated vapour pressure (Pa):	0	0	0	0	Worst case
DT ₅₀ in soil (d)	19.4	29.6	453	107.0	Y/EFSA Journal

Compound	Terbuthylazine	MT1	MT13	MT14	Value in accordance with EU endpoint y/n/ Reference*
					2011; 9(1):1969 Confirmatory Data 2015
K _{fom} (mL/g)	87.6	45.2	108.5	70.2	Y/EFSA Journal 2011; 9(1):1969
1/n	0.93	0.895	0.91	0.9	Y/EFSA Journal 2011; 9(1):1969
Plant uptake factor	0	0	0	0	Worst case
Soil Formation Factor		32.9	34.5	28	Y/EFSA Journal 2011; 9(1):1969

Table 8.8-3: Input parameters related to active substance Terbuthylazine and metabolites for PEC_{gw} calculations

Compound	LM3	LM5	LM6	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	198.2	184.2	198.2	Additional Report to the DAR, Volume 3, part 4, B.8
Water solubility (g/mol):	18	18	18	Additional Report to the DAR, Volume 3, part 4, B.8
Saturated vapour pressure (Pa):	0	0	0	Additional Report to the DAR, Volume 3, part 4, B.8
DT ₅₀ in soil (d)	305	128	305	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	0.9	0.9	0.9	Additional Report to the DAR, Volume 3, part 4, B.8
Plant uptake factor	0	0	0	Worst case
Soil Formation Factor	20.1	45	20.1	Additional Report to the DAR, Volume 3, part 4, B.8

Table 8.8-4: PEC_{gw} for terbuthylazine and metabolites on maize (with FOCUS PEARL 4.4.4.) – pre-emergence use

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)			
		Terbuthylazine	MT1	MT13	MT14
Maize	Châteaudun	< 0.001	0.531	7.178	2.125
	Hamburg	0.002	1.240	8.717	2.773

	Kremsmünster	< 0.001	0.943	6.722	2.139
	Okehampton	0.002	1.225	7.063	2.455
	Piacenza	0.001	0.819	6.242	1.872
	Porto	< 0.001	0.363	4.274	1.216
	Sevilla	< 0.001	0.167	1.423	0.198
	Thiva	< 0.001	0.171	6.746	1.56

Table 8.8-5: PEC_{gw} for terbuthylazine and metabolites on maize (with FOCUS PEARL 4.4.4.) – pre-emergence use

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		LM3	LM5	LM6
Maize	Châteaudun	1.715	1.882	0.498
	Hamburg	1.899	2.290	0.510
	Kremsmünster	1.570	1.704	0.455
	Okehampton	1.088	1.431	0.271
	Piacenza	1.865	1.953	0.595
	Porto	0.779	0.911	0.216
	Sevilla	0.743	0.422	0.292
	Thiva	2.758	2.319	1.001

Table 8.8-6: PEC_{gw} for terbuthylazine and metabolites on maize (with FOCUS PELMO 5.5.3) – pre-emergence use

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)			
		Terbuthylazine	MT1	MT13	MT14
Maize	Châteaudun	< 0.001	< 0.001	14.598	0.016
	Hamburg	< 0.001	< 0.001	16.593	0.133
	Kremsmünster	< 0.001	< 0.001	13.008	0.100
	Okehampton	< 0.001	< 0.001	12.722	0.162
	Piacenza	< 0.001	< 0.001	11.382	0.162
	Porto	< 0.001	< 0.001	7.833	0.051
	Sevilla	< 0.001	< 0.001	5.453	< 0.001
	Thiva	< 0.001	< 0.001	18.305	0.006

Table 8.8-7: PEC_{gw} for terbuthylazine and metabolites on maize (with FOCUS PELMO 5.5.3) – pre-emergence use

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		LM3	LM5	LM6
Maize	Châteaudun	11.481	0.307	5.311

	Hamburg	13.331	0.954	6.114
	Kremsmünster	10.665	0.670	4.738
	Okehampton	9.619	0.918	4.486
	Piacenza	8.707	0.824	4.184
	Porto	6.245	0.462	2.822
	Sevilla	5.533	0.008	1.870
	Thiva	15.344	0.185	6.377

Table 8.8-8: PEC_{gw} for terbuthylazine and metabolites on maize (with FOCUS PEARL 4.4.4.) – post-emergence use

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)			
		Terbuthylazine	MT1	MT13	MT14
Maize	Châteaudun	< 0.001	0.586	7.282	2.200
	Hamburg	0.003	1.437	8.847	2.884
	Kremsmünster	< 0.001	0.947	6.700	2.165
	Okehampton	0.003	1.382	7.119	2.509
	Piacenza	0.001	0.905	6.460	1.984
	Porto	< 0.001	0.433	4.198	1.259
	Sevilla	< 0.001	0.021	1.389	0.219
	Thiva	< 0.001	0.205	7.006	1.686

Table 8.8-9: PEC_{gw} for terbuthylazine and metabolites on maize (with FOCUS PEARL 4.4.4.) – post-emergence use

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		LM3	LM5	LM6
Maize	Châteaudun	1.729	1.913	0.498
	Hamburg	1.901	2.325	0.508
	Kremsmünster	1.586	1.734	0.457
	Okehampton	1.089	1.443	0.268
	Piacenza	1.893	2.012	0.598
	Porto	0.795	0.926	0.926
	Sevilla	0.762	0.422	0.296
	Thiva	2.841	2.404	1.019

Table 8.8-10: PEC_{gw} for terbuthylazine and metabolites on maize (with FOCUS PELMO 5.5.3) – post-emergence use

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)			
		Terbuthylazine	MT1	MT13	MT14
Maize	Châteaudun	< 0.001	< 0.001	11.917	0.014
	Hamburg	< 0.001	< 0.001	13.363	0.122
	Kremsmünster	< 0.001	< 0.001	10.776	0.076
	Okehampton	< 0.001	< 0.001	10.397	0.142
	Piacenza	< 0.001	< 0.001	9.855	0.151
	Porto	< 0.001	< 0.001	6.733	0.049
	Sevilla	< 0.001	< 0.001	4.319	< 0.001
	Thiva	< 0.001	< 0.001	16.603	0.007

Table 8.8-11: PEC_{gw} for terbuthylazine and metabolites on maize (with FOCUS PELMO 5.5.3) – post-emergence use

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		LM3	LM5	LM6
Maize	Châteaudun	9.696	0.257	4.407
	Hamburg	10.684	0.810	4.926
	Kremsmünster	8.877	0.551	3.969
	Okehampton	8.075	0.786	3.717
	Piacenza	7.668	0.719	3.633
	Porto	5.262	0.410	2.409
	Sevilla	4.394	0.005	1.437
	Thiva	13.741	0.181	5.824

The Predicted Environmental Concentrations (PEC_{gw}) of terbuthylazine and its major metabolites were calculated with FOCUS PEARL and FOCUS PELMO on the basis of EU agreed endpoints which were summarized in EFSA Scientific Report (2009) 296, 63-90; Addendum to DAR (2006). Nine scenarios were taken into consideration: Châteaudun, Hamburg, Okehampton, Kremsmünster, Jokioinen, Piacenza, Porto, Sevilla and Thiva.

Obtained PEC_{gw} of terbuthylazine in each scenario and for the recommended uses of TERBUT 500 SC are significant below the trigger value of 0.1 µg/L and therefore the use of this plant protection product according to recommendations does not pose a risk of groundwater contamination.

Obtained PEC_{gw} of metabolites in each scenario and for the recommended uses of TERBUT 500 SC are over the trigger value of 0.1 µg/L and therefore the use of this plant protection product according to recommendations may pose a risk of groundwater contamination. Therefore, further justifications are summarised in dRR Section 10 – Assessment of the relevance of metabolites in groundwater.

Comments zRMS:

The calculations of PEC_{gw} 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 < 0, 1 µg/L, below the trigger value, therefore the use of this plant protection product according to recommendations does not pose a risk of groundwater contamination.

The metabolites are predicted to occur above 0.75 µg/L in all or almost all FOCUS scenarios, a refined consumer assessment is necessary. The PPR Panel derived reference values for MT1, MT13, MT14, LM2, LM4 and LM5 and EFSA (*Updated peer review of the pesticide risk assessment for the active substance terbuthylazine in light of confirmatory data* EFSA Journal 2019;17(9):5817) carried out a risk assessment taking into account exposure to those metabolites through drinking water and food intake combined.

According the Regulation (EU) 2021/824 amending Regulations (EU) No 540/2011 and (EU) No 820/2011 the active substance terbuthylazine should be restricted to once every third year on the same field at a maximum rate of 850 g/ha.

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.

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

8.9.2 Active substances, relevant metabolites 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	TERBUT 500 SC
Use No.	1	2
Crop	Maize pre-emergence	Maize post-emergence
Application rate (kg as/ha)	Terbuthylazine: 0.500	Terbuthylazine: 0.500
Number of applications/interval (d)	1/0	1/0
Application window	Mar - May (relevant for STEP 1 and 2 only)	Mar – May/ Jun - Sep (relevant for STEP 1 and 2 only)
Application method	Ground spray	Ground spray
Models used for calculation	FOCUS SWASH v3.1, FOCUS PRZM v3.3.1, FOCUS MACRO v5.5.3, FOCUS TOXWA v3.3.1 FOCUS SWAN 5.1	FOCUS SWASH v3.1, FOCUS PRZM v3.3.1, FOCUS MACRO v5.5.3, FOCUS TOXWA v3.3.1 FOCUS SWAN 5.1

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*	
		Pre-emergence used	Post-emergence used
Maize	D3	25 April – 25 May	12 May – 24 June
	D4	30 April – 30 May	18 May – 30 June
	D5	30 April – 30 May	15 May – 23 June
	D6	10 April – 10 May	25 April – 1 June
	R1	23 April – 23 May	10 May – 22 June
	R2	21 April – 21 May	9 May – 22 June
	R3	21 April – 21 May	8 May – 18 June
	R4	31 March – 30 April	15 April – 24 May

*Date adjusted according to AppDate (3.06)

Table 8.9-3: Input parameters related to active substance Terbutylazine and MT1, MT13 and MT26 for PEC_{sw/sed} calculations STEP 1/2 and 3/4

Compound	Terbutylazine	MT1	MT13	MT26	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	229.7	201.7	211.3	241.4	Y/ EFSA Journal 2011; 9(1):1969
Saturated vapour pressure (Pa)	not required for Step 1+2/0	not required for Step 1+2	not required for Step 1+2/0	not required for Step 1+2/0	Worst case
Water solubility (mg/L)	8.5	327.1	7.19	8.5	Y/ EFSA Journal 2011; 9(1):1969
Diffusion coefficient in water (m ² /d)	not required for Step 1+2/ 4.3 x 10 ⁻⁵	not required for Step 1+2	not required for Step 1+2/ 4.3 x 10 ⁻⁵	not required for Step 1+2/ 4.3 x 10 ⁻⁵	default
Diffusion coefficient in air (m ² /d)	not required for Step 1+2/0.43	not required for Step 1+2	not required for Step 1+2/0.43	not required for Step 1+2/0.43	default
K _{foc} (mL/g)	151	78	187.1	518	Y/ EFSA Journal 2011; 9(1):1969
Freundlich Exponent 1/n	0.93	0.895	0.91	1.0	Y/ EFSA Journal 2011; 9(1):1969
Plant Uptake	not required for Step 1+2/0	not required for Step 1+2	not required for Step 1+2/0	not required for Step 1+2/0	Worst case
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/ 0.05 (MACRO)	not required for Step 1+2	not required for Step 1+2/ 0.05	not required for Step 1+2/ 0.05	default

Compound	Terbuthylazine	MT1	MT13	MT26	Value in accordance to EU endpoint y/n/ Reference
	0.50 (PRZM)		(MACRO) 0.50 (PRZM)	(MACRO) 0.50 (PRZM)	
DT _{50,soil} (d)	19.4	26.9	453	0.1	Y/ EFSA Journal 2011; 9(1):1969
DT _{50,water} (d)	1000	1000	1000	1000	Y/ EFSA Journal 2011; 9(1):1969
DT _{50,soil} (d)	69.9	1000	1000	190	Y/ EFSA Journal 2011; 9(1):1969
DT _{50,whole system} (d)	1000	1000	1000	190	Y/ EFSA Journal 2011; 9(1):1969
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil:54% Total system: 7.3%	Soil:34.5% Total system: 20.0%	Total system:7.4%	Y/ EFSA Journal 2011; 9(1):1969

PEC_{sw/sed}

Table 8.9-4 Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (EFSA Journal)

Compound	Ecotoxicology lowest regulatory acceptable concentration
Terbuthylazine	1.0 µg/L (<i>Navicula pelliculosa</i>)
MT1	38 µg/L (<i>Selenastrum capricornutum</i>)
MT13	25 µg/L (<i>O.mykiss</i>)
MT26	0.36 µg/L (<i>Pseudokirchneriella subcapitata</i>)

Table 8.9-5: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Terbuthylazine following single application of TERBUT 500 SC to maize post-emergence use

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
RAC = 1.0 µg/L					
Step 1	---	143.3	0	128.72	213.15
Step 2					
Northern Europe	March-May and Jun-Sep	22.07	4	21.37	32.65
Southern Europe	March-May / Jun - Sep	40.11 / 31.09	4 / 4	39.02 / 30.20	59.62 / 46.14
Step 3					

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
D3	ditch	2.624	135	0.1512	0.7068
D4	pond	0.1581	356	0.1536	0.5158
D4	stream	2.252	150	0.08141	0.1565
D5	pond	0.1753	147	0.1640	0.4692
D5	stream	2.364	147	0.03988	0.2006
D6	ditch	2.631	115	0.1381	0.6899
R1	pond	0.9372	113	0.8430	1.642
R1	stream	13.85	113	0.5666	4.184
R2	stream	6.683	74	0.2104	1.741
R3	stream	16.94	84	0.6598	3.568
R4	stream	18.05	58	0.8106	4.805

** twa-time as required by ecotox
 RAC: Regulatory acceptable concentration

For the intended uses of TERBUT 500 SC, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (diatoms) in most of FOCUS Steps 1-3 scenarios. Therefore, risk mitigation assessment is necessary and PEC/RAC ratios were calculated considering reduced exposure of surface water bodies.

FOCUS Step 4

Table 8.9-6: Global maximum PEC_{sw} values for Terbutylazine, following single application of TERBUT 500 SC to maize post-emergence use, according to surface water Step 4 calculations and toxicity data for aquatics organisms with mitigation of spray drift and run-off (FOCUS SWAN)

PEC _{sw} (µg/L)	Scenario	STEP 4 Terbutylezine		
Nozzle reduction	Vegetative strip (m)	0	5	10
	No spray buffer (m)	10	5	10
None	D3 ditch	0.4559	0.8598	0.4559
50 %		0.2280	0.4299	0.2280
None	D4 pond	0.1503	0.1557	0.1503
50 %		0.1433	0.1460	0.1433
None	D 4 stream	0.5071	0.9515	0.5071
50 %		0.2564	0.4784	0.2564
None	D5 pond	0.1374	0.1640	0.1374
50 %		0.1034	0.1167	0.1034
None	D5 stream	0.5434	1.007	0.5434
50 %		0.2818	0.5135	0.2818

PEC _{sw} (µg/L)	Scenario	STEP 4 Terbutylezine		
Nozzle reduction	Vegetative strip (m)	0	5	10
	No spray buffer (m)	10	5	10
None	D6 ditch	0.4674	0.8705	0.4674
50 %		0.2400	0.4415	0.2400
None	R1 pond	0.9034	0.1364	0.0680
50 %		0.8730	0.0938	0.0340
None	R1 stream	13.85	0.9773	0.4057
50 %		13.85	0.9773	0.2029
None	R2 Stream	6.683	1.024	0.5427
50 %		6.683	0.5117	0.2714
None	R3 Stream	16.94	1.074	0.5969
50 %		16.94	0.5370	0.2848
None	R4 Stream	18.05	0.7630	0.4045
50 %		18.05	0.3814	0.2023

RAC: Regulatory acceptable concentration

PEC/RAC ratios below the relevant trigger of 1 are shown in bold

Since the scenario R1 stream represents the worst case, results only for this scenario are presented.

Table 8.9-7: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Terbutylazine following single application of TERBUT 500 SC to maize pre-emergence use

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
RAC = 1.0 µg/L					
Step 1	---	143.3	0	128.72	213.15
Step 2					
Northern Europe	March-May	28.08	4	27.26	41.64
Southern Europe	March-May	52.13	4	50.79	77.60
Step 3					
D3	ditch	2.623	125	0.1474	0.6978
D4	pond	0.1523	355	0.1479	0.4881
D4	stream	2.250	150	0.07901	0.1442
D5	pond	0.1538	131	0.1426	0.3894
D5	stream	2.255	131	0.0262	0.1375
D6	ditch	2.631	100	0.1923	0.7918
R1	pond	0.2334	81	0.2251	0.5071

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	7.123	68	0.2506	1.379
R2	stream	5.340	66	0.2099	1.178
R3	stream	2.564	53	0.06643	0.3906
R4	stream	17.37	49	0.8221	4.625

** twa-time as required by ecotox

RAC: Regulatory acceptable concentration

For the intended uses of TERBUT 500 SC, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (diatoms) in most of FOCUS Steps 1-3 scenarios. Therefore, risk mitigation assessment is necessary and PEC/RAC ratios were calculated considering reduced exposure of surface water bodies.

FOCUS Step 4

Table 8.9-8: Global maximum PEC_{sw} values for Terbutylazine, following single application of TERBUT 500 SC to maize pre-emergence use, according to surface water Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off (FOCUS SWAN)

PEC _{sw} (µg/L)	Scenario	STEP 4 Terbutylazine			
Nozzle reduction	Vegetative strip (m)	0	0	5	10
	No spray buffer (m)	5	10	5	10
None	D3 ditch	0.8597	0.4558	0.8598	0.4558
50 %		0.4298	0.2280	0.4298	0.2280
None	D4 pond	0.1500	0.1445	0.1500	0.1445
50 %		0.1403	0.1376	0.1403	0.1376
None	D 4 stream	0.9495	0.5051	0.9495	0.5051
50 %		0.4764	0.2544	0.4764	0.2544
None	D5 pond	0.1425	0.1160	0.1425	0.1160
50 %		0.09525	0.08195	0.09525	0.08195
None	D5 stream	0.9589	0.5160	0.9589	0.5160
50 %		0.4874	0.2662	0.4874	0.2662
None	D6 ditch	0.8669	0.4629	0.8669	0.4629
50 %		0.4369	0.2350	0.4369	0.2350
None	R1 pond	0.2246	0.2040	0.09458	0.0680
50 %		0.1879	0.1786	0.04729	0.0340
None	R1 stream	7.123	7.123	0.7631	0.4046
50 %		7.123	7.123	0.3814	0.2023
None	R2 Stream	5.340	5.340	1.015	0.5378

PEC _{sw} (µg/L)	Scenario	STEP 4 Terbuthylazine			
Nozzle reduction	Vegetative strip (m)	0	0	5	10
	No spray buffer (m)	5	10	5	10
50 %		5.340	5.340	0.5071	0.2690
None	R3 Stream	1.199	1.199	1.080	0.5724
50 %		1.199	1.199	0.5396	0.2862
None	R4 Stream	17.37	17.37	0.7630	0.4045
50 %		17.37	17.37	0.3814	0.2023

RAC: Regulatory acceptable concentration

PEC/RAC ratios below the relevant trigger of 1 are shown in bold

Metabolites of terbuthylazine

Table 8.9-9: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for MT1 following single application to maize post-emergence use

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, tva} (µg/L)**	Max PEC _{sed} (µg/kg)*
Rac = 38 µg/L					
Step 1	---	81.81	0	81.19	63.74
Step 2					
Northern Europe	March-May and Jun-Sep	11.25	4	11.16	8.76
Southern Europe	March-May / Jun-Sep	22.22 / 16.74	4	22.05 / 16.61	17.32 / 13.04

** two-time as required by ecotox

RAC: Regulatory acceptable concentration

Table 8.9-10: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for MT1 following single application to maize pre-emergence use

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, tva} (µg/L)**	Max PEC _{sed} (µg/kg)*
Rac = 38 µg/L					
Step 1	---	81.81	0	81.19	63.74
Step 2					
Northern Europe	March-May	14.91	4	14.79	11.61
Southern Europe	March-May	29.54	4	29.32	23.54

** two-time as required by ecotox

RAC: Regulatory acceptable concentration

Table 8.9-11: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for MT13 following single application of TEBUT 500 SC to maize post-emergence use

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Rac = 25 µg/L					
Step 1	---	67.93	0	67.28	126.63
Step 2					
Northern Europe	March-May and Jun-Sep	10.25	4	10.13	19.06
Southern Europe	March-May / Jun-Sep	19.77 / 15.01	4	19.58 / 14.85	36.86 / 27.96

** two-time as required by ecotox

RAC: Regulatory acceptable concentration

Table 8.9-12: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for MT13 following single application of TEBUT 500 SC to maize pre-emergence use

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Rac = 25 µg/L					
Step 1	---	67.93	0	67.28	126.63
Step 2					
Northern Europe	March-May	13.42	4	13.28	24.99
Southern Europe	March-May	26.12	4	25.88	48.72

** two-time as required by ecotox

RAC: Regulatory acceptable concentration

Since calculated PEC_{sw} for southern Europe is barely over the RAC value, no further calculations are needed.

Table 8.9-13: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for MT26 following single application of TEBUT 500 SC to maize post-emergence use

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Rac = 0.36 µg/L					
Step 1	---	8.05	0	7.61	40.79
Step 2					
Northern Europe	March-May and Jun-Sep	1.24	4	1.19	6.23
Southern Europe	March-May / Jun-Sep	2.24 / 1.74	4	2.16 / 1.68	11.38 / 8.81
Step 3					

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
D3	ditch	0.205	125	0.011	0.076
D4	pond	0.008	150	0.007	0.025
D4	stream	0.175	150	0.001	0.010
R1	pond	0.008	64	0.007	0.021
R1	stream	0.139	64	0.001	0.0122

** two-time as required by ecotox

RAC: Regulatory acceptable concentration

Table 8.9-14: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for MT26 following single application of TERBUT 500 SC to maize pre-emergence use

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Rac = 0.36 µg/L					
Step 1	---	8.05	0	7.61	40.79
Step 2					
Northern Europe	March-May	1.57	4	1.51	7.95
Southern Europe	March-May	2.90	4	2.82	14.81
Step 3					
D3	ditch	0.204	95	0.0095	0.068
D4	pond	0.0083	108	0.0066	0.024
D4	stream	0.164	108	0.0004	0.0055
R1	pond	0.0083	57	0.0072	0.0215
R1	stream	0.141	57	0.0013	0.0163

** two-time as required by ecotox

RAC: Regulatory acceptable concentration

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 & 4 were used for PEC_{sw} and PEC_{sed} assessment. All parameters have been taken according to List of Endpoints EFSA Journal 2011; 9(1):1969.

For PEC_{sw/sed} calculations at STEP 4, the values used for reduction in run off volume and flux and erosion mass 0.5 and 0.8 for 5 meters of vegetative buffer strip according to the Austrian Environmental Agency (AGES) should be considered at national level.

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.

8.9.2.1 PEC_{sw/sed} of TERBUT 500 SC

TERBUT 500 SC was not assessed as representative formulation. PEC_{sw} was calculated according to endpoints for terbuthylazine and submitted for TERBUT 500 SC.

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

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Terbuthylazine
Direct photolysis in air	No data
Quantum yield of direct phototransformation	No data
Photochemical oxidative degradation in air	DT50 (h): 13.55 derived by the Atkinson model OH (12h) concentration assumed = 1.5×10^6
Volatilisation	Vapour pressure (Pa): 9.0×10^{-5} Henry's Law Constant (Pa.m ³ /mol): 2.3×10^{-3}
Metabolites	None

The vapour pressure at 20 °C of the active substance terbuthylazine is between 10^{-5} and 10^{-4} Pa. Hence the active substance terbuthylazine is regarded as volatile (volatilisation from soil and plant surfaces). However due to rapid photochemical degradation, exposure of adjacent surface waters and terrestrial ecosystems by the terbuthylazine due to volatilization with subsequent deposition is not considered.

Comments zRMS:

Accepted.

Appendix 1 Lists of data considered in support of the evaluation

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

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	Owner
KCP 9.1	Anon	2002	Groundwater Survey 2002, Part 5: Pesticides and Degradation Products Pages 57-74 Syngenta Crop Protection AG, Syngenta File No ICI224/0922 Non-GLP, Published	Syngenta
	Bader, U.	1990	GS 13529, Report on the teste for ready biodegradability in the Modified Sturm Test Novartis Crop Protection AG, Basel Report No 901360 GLP, Unpublished	Syngenta
	Glaenzel, A.	1998	Rate of degradation S135ne under various conditions Novartis Crop Protection AG, Basel Report No 97RP02 GLP, Unpublished	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Owner
KCP 9.1	James, T., et al.	1998	Degradation and movement of terbuthylazine in soil Published Syngenta File No GS13529/1683	---
	Kjaer, J.	2003	The Danish Pesticide Leaching Assesment Programme. Monitoring Results May 1999 – June 2002. Third Repot Geological Survey of Denmark and Greenland, the Danish Institute of Agricultural Science and the National Environmental Research Institute Non GLP, Published	Published Reference
	Kjaer, J.	2004	The Danish Pesticide Leaching Assesment Programme. Monitoring Results May 1999 – June 2003. Geological Survey of Denmark and Greenland, the Danish Institute of Agricultural Science and the National Environmental Research Institute Non GLP Published	Published Reference
	Schmidt, B., Zietz, E.	2000	Monitoring site-related evaluation of terbuthylazine findings in Groundwater Novartis Crop Protection AG, Basel Report No 100-1522-1738 Non GLP, Unpublished	Syngenta
KCP 9.1.1	Abildt, U.	1991	Aerobic degradation of GS 13529 in soil under various test conditions Novartis Crop Protection AG, Basel Report No 38-90 GLP, Unpublished	Syngenta
	Galia, H., Margenroth, U.	1993	Degradation of 14C-Terbuthylazin Technical (GS 13529): in Four Soils Incubated under Aerobic Conditions Novartis Crop Protection AG, Basel Report No 243224 GLP, Unpublished	Syngenta
	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 Report No 99AG05 GLP, Unpublished	Syngenta
	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 Report No 99MO06 GLP, Unpublished	Syngenta
	Offizorz, P.,	1990a	Dissipation rate determination of terbuthylazine	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Owner
	Ressler, H.		Novartis Crop Protection AG, Basel Report No 170425 Not GLP, Unpublished	
KCP 9.1.1	Phaff, R.	2000a	Degradation of ¹⁴ C-triazine labelled GS 28620 in four soils under aerobic conditions at 20°C Novartis Crop Protection AG, Basel Report No 99RP05 GLP, Unpublished	Syngenta
	Purghart, V.	2000	Terbuthylazine (GS 13529): soil photolysis Novartis Crop Protection AG, Basel Report No 1047.102.720 GLP, Unpublished	Syngenta
	Reischmann, F.	2000a	Rate of degradation of Triazine-U- ¹⁴ C) labelled GS 26379 in three soils under aerobic laboratory conditions at 20°C Novartis Crop Protection AG, Basel Report No 99RF04 GLP, Unpublished	Syngenta
	Schaffer, A. and 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, Unpublished	Syngenta
	Schaffer, A. and Nicollier, G.	1997b	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, Unpublished	Syngenta
KCP 9.1.1.2	Edwards, P., Evans, P.	2004	Terbuthylazine: Residue Stability Study for Terbuthylazine (GS13529) and its Metabolites (GS26379, GS23158 and GS28620) in Soil under Freezer Storage Conditions – Interim Report Syngenta Crop Protection AG, Report No RJ3492B GLP, Unpublished	Syngenta
	Evans, P.	2004a	Terbuthylazine (GS13529) and S-Metolachlor (CGA77102): Dissipation Study with Terbuthylazine (GS13529) and Metolachlor (CGA77102) in or on Cultivated Soil in France (South) Syngenta Crop Protection AG, Report No RJ3521B GLP, Unpublished	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Owner
KCP 9.1.1.2	Evans, P.	2004b	Terbuthylazine (GS13529) and S-Metolachlor (CGA77102): Dissipation Study with Terbuthylazine and Metolachlor (CGA77102) in or on Cultivated Soil in Italy Syngenta Crop Protection AG, Report No RJ3522B GLP, Unpublished	Syngenta
	Klosowski, R., Siebes, J., Nolting, H.	1990	Investigations into the infiltration behaviour of active ingredient Terbuthylazine and the metabolite Desethyl-Terbuthylazine. GLP, Published	Published reference
	Offizorz, P., Ressler, H.	1990b	Field soil, Dissipation rate determination of terbuthylazine Novartis Crop Protection AG, Basel Report No 170414 Not GLP, Unpublished	Syngenta
	Offizorz, P., Ressler, H.	1991a	Field soil, dissipation rate determination of terbuthylazine (Exp.-No. 51-90B) Novartis Crop Protection AG, Basel Report No 223740 Not GLP, Unpublished	Syngenta
	Offizorz, P., Ressler, H.	1991b	Field soil, dissipation rate determination of terbuthylazine (Exp.-No. 25-90B) Novartis Crop Protection AG, Basel Report No 223727 Not GLP, Unpublished	Syngenta
	Offizorz, P., Ressler, H.	1991c	Field soil, dissipation rate determination of terbuthylazine (Exp.-No. 24-90B) Novartis Crop Protection AG, Basel Report No 223716 Not GLP, Unpublished	Syngenta
	Offizorz, P., Ressler, H.	1991d	Field soil, dissipation rate determination of terbuthylazine (Exp.-No. 50-90B) Novartis Crop Protection AG, Basel Report No 223738 Not GLP, Unpublished	Syngenta
	Nicollier, G.	1997	Field dissipation of GS 13529 after bareground application of [triazine-(U)-14C] labelled material Novartis Crop Protection AG, Basel Report No CMR 08/97 GLP, Unpublished	Syngenta
KCP 9.1.2	Adam, D.	2000a	Adsorption/desorption of GS 23158 in Borstel soil Novartis Crop Protection AG, Basel Report No 99DA11 GLP, Unpublished	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Owner
KCP 9.1.2	Ellgenhausen, H.	1988	Leaching model study with GS 13529 in four soil types Novartis Crop Protection AG, Basel Report No 14-88 GLP, Unpublished	Syngenta
	Haamann, H., Gramatte, A., Brodsky, J.	1993	Experimental examinations of the behaviour of terbuthylazine in soil Novartis Crop Protection AG, Basel Report No BE-FLA-20-89-1 GLP, Unpublished	Syngenta
	Hassink, J.	1992	Outdoor lusimeter study on Terbuthylazine Novartis Crop Protection AG, Basel Report No CIB-04/7-11 GLP, Unpublished	Syngenta
	Luetolf, W., Haamann, H.	1998	Experimental studies on the behaviour of terbuthylazine in soil – study on potential leaching into groundwater – 1994/95 Novartis Crop Protection AG, Basel Report No 3053/94 GLP, Unpublished	Syngenta
	Luetolf, W.	1999	Experimental studies on the behaviour of terbuthylazine in soil – study on potential leaching into groundwater – 1994/95 Novartis Crop Protection AG, Basel Report No 3060/95 GLP, Unpublished	Syngenta
	Luetolf, W.	2000a	Experimental studies on the behaviour of terbuthylazine in soil – study on potential leaching into groundwater – 1996/97 Novartis Crop Protection AG, Basel Report No 3070/96 GLP, Unpublished	Syngenta
	Luetolf, W.	2000b	Experimental studies on the behaviour of terbuthylazine in soil – study on potential leaching into groundwater – 1997/98 Novartis Crop Protection AG, Basel Report No 3140/97 GLP, Unpublished	Syngenta
	McLaughlin, S., Galicia, H.	1996a	GS 26379: Determination of adsorption and desorption in three soils Novartis Crop Protection AG, Basel Report No 95-058-1008 GLP, Unpublished	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Owner
KCP 9.1.2	McLaughlin, S., Galicia, H.	1996b	GS 23158: Determination of adsorption and desorption in three soils Novartis Crop Protection AG, Basel Report No 95-059-1008 GLP, Unpublished	Syngenta
	Morgenroth, U.	2000b	Adsorption/desorption of Triazine-U-14C labelled GS 28620 in various soils Novartis Crop Protection AG, Basel Report No 00MO01 GLP, Unpublished	Syngenta
	Mueller, J.	1991a	Determination the adsorption and desorption of terbuthylazine. Novartis Crop Protection AG, Basel Report No CIB-004/7-13 GLP, Unpublished	Syngenta
	Mueller, J.	1991b	Determination of adsorption/desorption of desethyl-terbuthylazine. Novartis Crop Protection AG, Basel Report No GS26379/0006 GLP Unpublished	Syngenta
	Phaff, R.	2000b	Adsorbition/Desorbition of GS 13529 in various soils Novartis Crop Protection AG, Basel Report No 99RP04 GLP, Unpublished	Syngenta
	Reischmann, F.	2000b	Adsorbition/Desorbition of Triazine-U-14C-labelled GS 26379 in soil lorsh Novartis Crop Protection AG, Basel Report No 00RF04 GLP, Unpublished	
	Ricker, I., Haamann, H.	1993	Experimental studies on the behaviour of terbuthylazine in soil – 1992 Novartis Crop Protection AG, Basel Report No BE-FLA-20-89-1 GLP, Unpublished	Syngenta
KCP 9.1.2.3	Burgener, A.	1995	14C-Terbuthylazine/14C-Atrazine: Mobility and Degradation in Soil in Outdoor Lysimeters Novartis Crop Protection AG, Basel Report No 321581 GLP, Unpublished	Syngenta
	Luetolf, W.	2002	Study on potential leaching into groundwater – 1999/2000 – Field experiment section. Novartis Crop Protection AG, Basel Report No 3091/99 GLP, Unpublished	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Owner
KCP 9.1.2.3	Mamouni, A.	1996	14C-Terbuthylazine: mobility and Degradation in Soil in Outdoor Lysimeters RCC AG, Itingen, Switzerland, Report No. 348794 GLP Unpublished	OXON
	Ressler, H.	2004	Leaching behaviour of terbuthylazine in a long term field experiment from 1990 to 2001 in Germany Syngenta Crop Protection AG, Report No HR012004 Non-GLP, Unpublished	Syngenta
	Tribolet, R.	2003	Study on potential leaching into groundwater – 1999/2000 – Field experiment section. Novartis Crop Protection AG, Basel Report No 3040/00 GLP, Unpublished	Syngenta
	Zietz, E.	2000	Monitoring of GS13529 (Terbuthylazine) in Surface Water adjacent Field susceptible to run-off. Trial Sites Ramholz (Hesse) and Kemading (Bavaria) Novartis Agro, Report No IF-99/07972-00 GLP, Unpublished	Syngenta
KCP 9.2	Adam, D.	2000b	Hydrolysis of [triazine-U-14C]-labelled GS 26379 under laboratory conditions Novartis Crop Protection AG, Basel Report No 00DA01 GLP, Unpublished	Syngenta
	Bourry, R.	2003	Stability of Residues of GS 28620 and GS 23158 (Metabolites of Terbuthylazine) in Deep Freeze Stored Analytical Specimens of Potable Water Syngenta Crop Protection AG, Report No 301/01 Non-GLP, Unpublished	Syngenta
	Doyle, R.	1991	Hydrolysis of 14C-Terbuthylazine Novartis Crop Protection AG, Basel Report No IITRI-VTC-9004 GLP, Unpublished	Syngenta
	Glaenzel, A.	2000b	Aqueous photolysis of 14C-triazine labelled GS 26379 under laboratory conditions Novartis Crop Protection AG, Basel Report No 99AG06 GLP, Unpublished	Syngenta
	Mamouni, A.	1998	14C-Terbuthylazine: degradation and metabolism in aquatic systems	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Owner
			Novartis Crop Protection AG, Basel Report No 608207 GLP, Unpublished	
KCP 9.2	Mamouni,A.	2002	Aqueous Photolysis of 14C-Triazine Ring Labelled GS 13529 under :aboratory Conditions Syngenta Crop Protection AG, Syngenta File No 820642 Non-GLP, Unpublished	Syngenta
	Reese-Staehler, G.	2000	Monitoring of GS13529 (Terbuthylazine) in Surface Water in the Area of Fields Endangered by Run off. Sites: Adenstedt (Lower Saxony) and Suplingen (Sachsen Anhalt) Novartis Crop Protection AG, Basel Report No OC9902 GLP, Unpublished	Syngenta
	Van, der Gaaw A.	2002	14C-Triazine Ring labelled GS23158 Hydrolysis at three different pH values Syngenta Crop Protection AG, Syngenta File No GS13529/1732 Non-GLP, Unpublished	Syngenta
	Zetzsch, C., Palm, W.	1993	GS 13529 UV – Absorption sprectra of Terbuthylazin – estimation of aqueous photolysis maximum rate constant and minimum half-life in sunlight Novartis Crop Protection AG, Basel Report No PC91-3 GLP ,Unpublished	Syngenta
KCP 9.3	Reischmann, F.	1992	Volatilization of GS 13529 from soil surface under controlled laboratory conditions Novartis Crop Protection AG, Basel Report No 95RF14 GLP, Unpublished	Syngenta
	Reischmann, F.	1995	Volatilization of GS 13529 from water (calculation) Novartis Crop Protection AG, Basel Report No 95RF14 GLP, Unpublished	Syngenta
	Sandmeier, P.	1992	GS 13529 Volatility from plant and soil surfaces Novartis Crop Protection AG, Basel Report No 92PSA06 GLP, Unpublished	Syngenta
	Sandmeier, P.	1993	Volatilization of GS 13529 from Plant and Soil ofter Posemergent Spray Application of 14C-labelled Material on Maize under Indoor Conditions Novartis Crop Protection AG, Basel Report No 93PSA17	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Owner
			GLP, Unpublished	
KCP 9.3	Stamm, E.	1997	Atmosphere oxidation of terbuthylazine GS 13529 by hydroxyl radicals; rate estimation Novartis Crop Protection AG, Basel Report No 95A97007SM GLP, Unpublished	Syngenta
	Zetsch, C., Palm, W.	1994	Determination of the OH-rate constant of terbuthylazine adsorbed on aerosols Novartis Crop Protection AG, Basel Report No PC92-4 GLP, Unpublished	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

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

Appendix 2 Detailed evaluation of the new Annex II studies

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