FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: H-01-2022

Product name(s): Terbutylazyna 500 SC

Chemical active substance:

terbuthylazine, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: ProAgri International Sp. z o.o.

Submission date: April 2024

MS Finalisation date: 11.2024; 03.2025

Version history

When	What
April 2024	Submission dRR by Applicant
November 2024	Assessment by zRMS
March 2025	The final Registration Report

Table of Contents

8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I***	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:** **e.g. safen-er/synergist per ha** **e.g. recommended or mandatory tank mixtures**	**PECgw** **Conclusion**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**L product / ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**			
1	Poland	Maize	F	weeds (for details please refer to dRR B3)	broadcast spraying	BBCH 00	a) 1 b) 1	a) 1.0-1.5 L/ha b) 1.0-1.5 L/ha	a) 500 - 750 g as/ha	100-400 L/ha	N/A	Targeted range: 1.0-1.5 L/ha every 3 years	R
2	Poland	Maize	F	weeds (for details please refer to dRR B3)	broadcast spraying	BBCH 12-16	a) 1 b) 1	a) 1.0-1.5 L/ha b) 1.0-1.5 L/ha	a) 500 - 750 g as/ha	100-400 L/ha	N/A	Targeted range: 1.0-1.5 L/ha every 3 years	R

* F: professional field use, G: professional greenhouse use, I: indoor application

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

Table 8.1-2: Assessed (critical) uses during approval of terbuthylazine concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use No.	**Member state(s)**	**Crop and/ or situation (crop desti- nation / purpose of crop)**	**F, Fn, Fnp G, Gn, Gnp or I**	**Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)**	**Application**				**Application rate**			**PHI (days)**	**Remarks: e.g. g safen- er/synergist per ha**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number per use per crop/ season**	**Min. interval between applica- tions (days)**	**kg as/ hL max. rate per appl. max. total rate per crop/season**	**kg as/ha max. rate per appl. max. total rate per crop/season**	**Water L/ha min - max**		
1	N.EU	Maize	F	Dicot and monocot weeds	Tractor - mounted sprayer	Pre emergence - 8 leaf	1 1	N/A	a) 0.375 Terbuthylazine, 0.614 S-metolachlor b) 0.375 Terbuthylazine, 0.614 S-metolachlor	a) 0.750 Terbuthylazine, 1.228 S-metolachlor b) 0.750 Terbuthylazine, 1.228 S- metolachlor	200-500	N/A	[1] [2] [3] [4] [5] [6]
2	S.EU	Maize	F	Dicot and monocot weeds	Tractor - mounted sprayer	Pre emergence - 8 leaf	1 1	N/A	a) 0.375 Terbuthylazine, 0.614 S-metolachlor b) 0.375 Terbuthylazine, 0.614 S-metolachlor	a) 0.844 Terbuthylazine, 1.415 S-metolachlor b) 0.844 Terbuthylazine, 1.415 S- metolachlor	200-500	N/A	[1] [2] [3] [4] [5] [6]
1	France (N) Germany (N) The Nether- lands (N) ---------------- France(S) Italy (S) Spain (S)	Maize	F	Annual and perenni- al broad leaved weeds	spray	Pre emergence Early post emergence (12- 16)	1 1	N/A	a) 0.500 b) 0.500	a) 0.844 b) 0.844	200-500	N/A	[1] [3] [4] [6]
2	Italy (S) Spain (S)	Sorghum	F	Annual and perenni- al broad leaved weeds	spray	Pre emergence Early post emergence (14)	1 1	N/A	a) 0.500 b) 0.500	a) 0.844 b) 0.844	200-500	N/A	[1] [3] [4] [6]

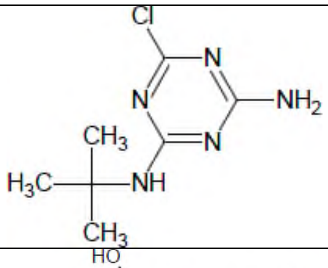
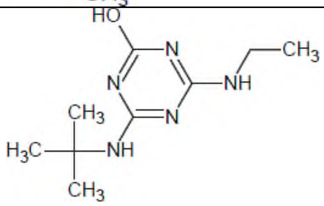
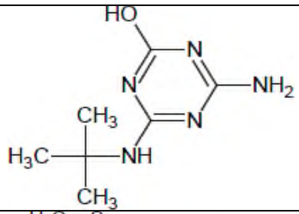
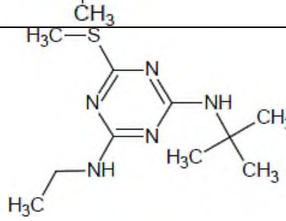
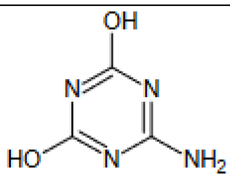
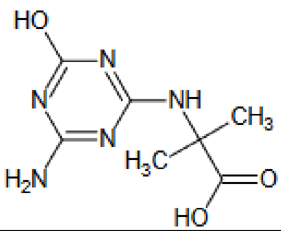
[1] A critical area of concern is identified because a high long-term risk and a high risk from secondary poisoning were indicated for mammals in section 5.
[2] A high long-term risk to earthworms was indicated in the risk assessment for the representative uses of the formulation 'Gardo® Gold®'.
[3] A critical area of concern is identified for groundwater contamination of toxicologically relevant metabolites and a herbicidally relevant metabolite over a wide range ofgeoclimatic conditions.
[4] For the metabolites LM1, LM2, LM3, LM4, LM5 and LM6 the groundwater exposure assessment cannot be finalised.
[5] A high long-term risk to birds was indicated.
[6] The batches used in the toxicological studies do not support the technical specification from either the Syngenta or the Oxon source.

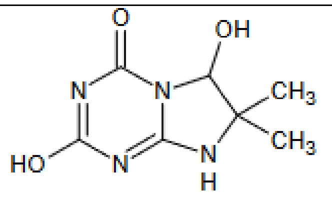
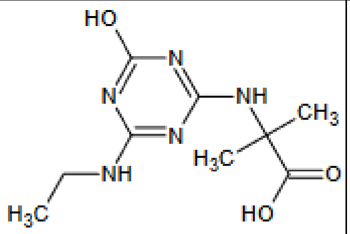
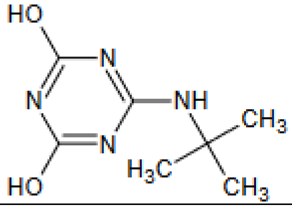
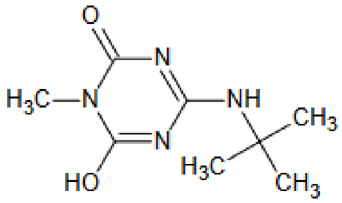
Remarks table:

(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(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 <u>and</u> 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

8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass [g/mol]	Chemical name	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
Desethyl-terbuthylazine (MT1)	201.7	N-tert-butyl-6-chloro- 1,3,5-triazine-2,4- diamine		Soil: 32.9% Water/sediment: 7.3%	PECsoil PECsw/sed PECgw
Hydroxy-terbuthylazine (MT13)	211.3	4-(tert-butylamino)-6-(ethylamino)-1,3,5- triazin-2-ol		Soil: 34.5% Water/sediment: 20.0%	PECsoil PECsw/sed PECgw
Desethyl hydroxy-terbuthylazine (MT14)	183.2	4-amino-6-(tert-butylamino)-1,3,5- triazin-2-ol		Soil: 28% Water/sediment: n/a*	PECsw/sed PECgw
Terbutryn (MT26)	241.4	N^2-tert-butyl-N^4-ethyl-6-methylthio- 1,3,5-triazine-2,4-diamine		Soil: n/a* Water/sediment: 7.4%	PECsw/sed
LM1	128.1	6-amino-1,3,5-triazine-2,4-diol		lysimeter metabolite	PECgw
LM2	213.2	N-(4-amino-6-hydroxy-1,3,5-triazin-2-yl)-2-methylalanine		lysimeter metabolite	PECgw

LM3	198.2	2,6-dihydroxy-7,7- dimethyl-7,8-dihydroimid-azo[1,2-*a*][1,3,5]triazin-4(*6H*)-one		lysimeter metabo-lite	PECgw
LM4	241.2	N-[4-(ethylamino)-6-hydroxy-1,3,5-triazin-2-yl]-2-methylalanine		lysimeter metabo-lite	PECgw
LM5	184.2	6-(tert-butylamino)-1,3,5-triazine-2,4-diol		lysimeter metabo-lite	PECgw
LM6	198.2	4-(tert-butylamino)-6-hydroxy-1-methyl-1,3,5-triazin-2(1H)-one		lysimeter metabo-lite	PECgw

8.3 Rate of degradation in soil (KCP 9.1.1)

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

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

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

Terbuthylazine	**Aerobic conditions**									
Soil name and classification	**% OM**	**pH (KCl or $CaCl_2$)**	**temp. °C / soil moisture for study (% w/w)**	**Soil moisture at pF2 (% w/w)**	**DT_{50} actual (d)**	**DT_{50}, 20 °C pF2 (d)**	**Min chi² error (%)**	**Method of calc.**	**Evaluated on EU level y/n/ Reference**
Gartenacker Sandy Loam	3.79	7.25	20°C/26.73 %	48.92	78.7	51.6	1.7	SFO	Yes, EFSA Journal 2017; 15(6):4868
Pappelacker Loamy Sand	1.9	7.6	20°C / 15.8 %	29.3	93.1	60.4	2.9	SFO	
Weide Sandy Loam	2.24	7.5	20°C/18.96 %	36.6	65.0	41.0	2.5	SFO	
Speyer 2.2 Loamy Sand	3.91	6.1	20°C / 19.2 %	12.1	167	167	2.1	SFO	
Borstel Loamy Sand	2.59	5.8	20°C/10.88 %	14[b]	143	120	1.0	SFO	
Lorsch Sandy Clay Loam	3.1	5.3	20°C/19.92 %	22[b]	110	103	1.4	SFO	
Gartenacker Silt Loam 1.57 g/ha	3.59	7.32	20°C/29.17 %	48.61	77.0	53.9	4.4	SFO	
Gartenacker Silt Loam 0.15 g/ha	3.59	7.32	20°C/29.17 %	48.61	59.7	41.8	4.9	SFO	
Collombey Sand	2.29	7.7	20°C / 16.8 %	25.31	80.0	60.0	5.9	SFO	
Les Evouettes Silt Loam	2.41	6.1	20°C/22.12 %	40.21	58.4	38.2	7.7	SFO	
Speyer 2.2 Loamy Sand	4.4	6.0	20°C/16.16 %	21.21	122	101	2.2	SFO	
Speyer 2.3 Sandy Loam	1.28	6.6	20°C/12.56 %	18.61	112	85.2	2.4	SFO	
Les Evouettes Loam	6.4	6.8	20°C/35.85 %	47.8	69.7	57.0	4.3	SFO	
Speyer 2.2 Loamy Sand	3.95	6.18	20°C/17.72 %	14[b]	136	138	5.6	SFO	
Sisseln Sandy Loam	2.71	7.16	20°C/20.96 %	19[b]	83.7	83.7	4.1	SFO	
Collombey Loamy Sand	2.02	7.45	20°C/16.12 %	14[b]	73.6	73.6	4.2	SFO	
Diegten Clay Loam	2.74	6.9	20°C/20.76 %	28[b]	117	94.9	1.9	SFO	
Geometric mean[a]				**91.1**			**72.0**	-	

Median	**88.4**	**75.1**	-	

[a] Geometric mean for replicate soil values calculated first (excluding the two Les Evouettes soils that were considered to be substantially 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 (MT1) - laboratory studies

Desethyl-ter-buthylazine (MT1)	**Aerobic conditions (where metabolite applied as starting material)**								
Soil type	**% OM**	**pH (KCl or $CaCl_2$)**	**temp. ºC / soil moisture for study (%w/w)**	**Soil moisture at pF2 (%w/w)**	**DT_{50} actual (d)**	**DT_{50}, ref 20ºC pF2 (d)**	**Min chi² error (%)[b]**	**Method of calc.**	**Evaluated on EU level y/n/ Reference**
Borstel Loamy Sand	2.63	5.79	20°C / 10.9%	14[a]	83.9	70.3	1.9	SFO	Yes, EFSA Journal 2017; 15(6):4868
Gartenacker* Loam	3.20	7.28	20ºC / 26.7 %	25[a]	61.8	61.8	3.1	SFO	
Lorsch Sandy Clay Loam	3.16	5.25	20ºC / 19.9 %	22[a]	40.7	38.0	3.3	SFO	
Speyer 2.3 Sandy Loam	2.1	6.4	20ºC / 15.6%	19[a]	61.8	53.8	6.7	SFO	
Speyer 2.1 Sand	1.07	5.9	20ºC / 12.4%	12[a]	45.2	45.2	4.9	SFO	
Speyer 2.2 Loamy Sand	4.00	5.6	20ºC / 19.2%	14[a]	50.7	50.7	4.1	SFO	
Westmaas Silt Loam	2.41	7.4	20ºC / 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
[b] t-test result was >99% for every soil

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

Hydroxy-ter-buthylazine (MT13)	**Aerobic conditions (where metabolite applied as starting material)**								
Soil type	**% OM**	**pH (KCl)**	**temp. ºC / soil moisture for study (%w/w)**	**Soil moisture at pF2 (%w/w)**	**DT_{50} actual (d)**	**DT_{50},ref 20 ºC pF2 (d)**	**Min chi² error (%)[b]**	**Method of calc.**	**Evaluated on EU level y/n/ Reference**
Borstel Loamy Sand	2.6	5.8	20°C / 10.88 %	14[a]	207	173	4.7	SFO	Yes, EFSA Journal 2017;
Gartenacker Loam	2.8	7.6	20ºC / 25.08 %	25[a]	298	298	2.2	SFO	

Vetroz Silt Loam	3.1	7.7	20°C / 23.56 %	26[a]	281	278	2.9	SFO	15(6):4868
Cranfield 115 Clay Loam	2.9	7.4	20°C / 22.1 %	30.4[c]	>1000	>1000	3.3	SFO	
Cranfield 164 Silt Loam	5.2	6.5	20°C / 29.12 %	41.2[c]	>1000	>1000	3.7	SFO	
Cranfield 243 Sandy Loam	1.9	4.3	20°C / 20.44 %	22.7[a]	645	600	1.7	SFO	
Geometric mean					**473[b]**	**453[b]**	-	-	

[a] FOCUS default moisture content based on soil texture
[b] the geomean was calculated assuming a default DT50 of 1000 d for Cranfield 115 and Cranfield 164 soils
[c] measured pF2.5 value was above the FOCUS default pF2 and the measured pF2.5 was used as a worst-case assessment.

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

Desethyl- hydroxy- terbuthylazine (MT14)	**Aerobic conditions (where metabolite applied as starting material)**								
Soil type	**% OM**	**pH (KCl)**	**temp. ºC / soil moisture for study (%w/w)**	**Soil moisture at pF2 (%w/w)**	**DT50actual (d)**	**DT50ref 20 ºC pF2 (d)**	**Min chi² error (%)[b]**	**Method of calc.**	**Evaluated on EU level y/n/ Reference**
Borstel Loamy Sand	2.6	5.8	20ºC / 10.88%	14[a]	135	113	7.7	SFO	Yes, EFSA Journal 2017; 15(6):4868
Gartenacker Loam	2.8	7.6	20ºC / 25.08%	25[a]	50.1	50.1	5.3	SFO	
Lorsch Sandy Clay loam	3.1	5.3	20ºC / 19.92%	22[a]	377	351	5.1	SFO	
Vetroz Silt loam	3.1	7.7	20ºC / 23.56%	26[a]	69.7	65.1	4.0	SFO	
Geometric mean					**115**	**107**	-	-	

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

Table 8.3-5: Summary of aerobic degradation rates for LM1 - laboratory studies

LM1 (MT24)	**Aerobic conditions (where metabolite applied as parent)**								
Soil type	**% OM**	**pH (water)**	**temp. ºC / soil moisture for study (%w/w)**	**Soil moistureat pF2 (% w/w)**	**DT50, actual (d)**	**DT50, ref, 20 ºC, pF2 (d)**	**Min chi² error(%)**	**Method of calc.**	**Evaluated on EU level y/n/ Reference**
Gartenacker Loam	1.96	7.5	20°C / pF2	35.3	0.41	0.41	4.1 (p=5.3E-009)	SFO	Yes, EFSA Journal 2017; 15(6):4868
18 Acres	2.88	7	20ºC / pF2	29.8	0.48	0.48	10.1 (p=1.5E-006)	SFO	
Vetroz Silt Loam	2.36	7.6	20ºC / pF2	26.4	0.33	0.33	24.2 (p=2.8E-004)	SFO	
Geometric mean					**0.4**	**0.4**	-	-	

Table 8.3-6: Summary of aerobic degradation rates for LM2 - laboratory studies

LM2 (MT28)	Aerobic conditions (where metabolite applied as parent)								
Soil type	% OM	pH (water)	temp. ºC / soil moisture for study (%w/w)	Soil moisture at pF2 (% w/w)	DT50, actual (d)	DT50, ref 20 ºC pF2 (d)	Min chi² error (%)	Method of calc.	Evaluated on EU level y/n/ Reference
Gartenacker Loam	3.1	7.5	20ºC / pF2	35.3	19.1	19.1	8.8 (p=1.9E-009)	SFO	Yes, EFSA Journal 2017; 15(6):4868
18 Acres	3.4	6.5	20ºC / pF2	29.8	11.5	11.5	7.9 (p=2.2E-008)	SFO	
Vetroz Silt Loam	3.9	7.8	20ºC / pF2	26.4	20.5	20.5	6.3 (p=3.1E-011)	SFO	
Geometric mean					**16.5**	**16.5**		-	

Table 8.3-7: Summary of aerobic degradation rates for LM3 - laboratory studies

LM3	Aerobic conditions (where metabolite applied as parent)								
Soil type	% OM	pH (water)	temp. ºC / soil moisturefor study (%w/w)	Soil moistureat pF2 (% w/w)	DT50, actual (d)	DT50, ref 20 ºC pF2 (d)	Min chi² error (%)	Method of calc.	Evaluated on EU level y/n/ Reference
Gartenacker Loam	3.1	7.5	20ºC / pF2	35.3	7.3	7.3	7.2 (p=.4E-009)	SFO	Yes, EFSA Journal 2017; 15(6):4868
18 Acres	3.4	6.5	20ºC / pF2	29.8	38.7	38.7	13.2 (p=1.3E-006)	SFO	
Vetroz Silt Loam	3.9	7.8	20ºC / pF2	26.4	6.5	6.5	5.1 (p=1.6E-010)	SFO	
Geometric mean					**12.2**	**12.2**			

Table 8.3-8: Summary of aerobic degradation rates for LM4- laboratory studies

LM4	Aerobic conditions (where metabolite applied as parent)								
Soil type	% OM	pH (water)	temp. ºC / soil moisturefor study (%w/w)	Soil moisture at pF 2 (% w/w)	DT50 actual (d)	DT50 ref 20ºC pF2 (d)	Min chi² error (%)	Method of calc.	Evaluated on EU level y/n/ Reference
Gartenacker –Loam	3.1	7.5	20ºC/pF2	35.3	49.9	49.9	2.5 (p=1.1E-013)	SFO	Yes, EFSA Journal 2017; 15(6):4868
18 Acres	3.4	6.5	20ºC/pF2	29.8	65.2	65.2	6.8 (p=2.0E-008)	SFO	
Vetroz – Silt Loam	3.9	7.8	20ºC/pF2	26.4	47.4	47.4	3.1 (p=1.7E-012)	SFO	
Geometric mean					**53.6**	**53.6**	-	-	

Table 8.3-9: Summary of aerobic degradation rates for LM5 - laboratory studies

LM5	Aerobic conditions (where metabolite applied as parent)								
Soil type	**% OM**	**pH (water)**	**temp. ºC / soil mois-turefor study (% w/w)**	**Soil mois-ture at pF2 (% w/w)**	**DT_{50} actual (d)**	**DT_{50} ref 20 ºC pF2 (d)**	**Min chi² error (%)**	**Method of calc.**	**Evaluated on EU level y/n/ Reference**
18 Acres	4.7	6.5	20ºC / pF2	29.8	70.6	70.6	5.9 (p=1.4E-008)	SFO	Yes, EFSA Journal 2017; 15(6):4868
Vetroz Silt Loam	4.1	8.0	20ºC / pF2	26.4	36.5	36.5	7.1 (p=4.2E-009)	SFO	
Geometric mean					**47.0**	**47.0**	-	-	

Table 8.3-10: Summary of aerobic degradation rates for LM6 - laboratory studies

LM6	Aerobic conditions (where metabolite applied as parent)								
Soil type	**% OM**	**pH (wa-ter)**	**temp. ºC / soil mois-turefor study (% w/w)**	**Soil mois-tureat pF2 (% w/w)**	**DT_5 actual (d)**	**DT_{50} ref 20ºC pF2 (d)**	**Min chi² error (%)**	**Method of calc.**	**Evaluated on EU level y/n/ Reference**
Gartenacker Loam	3.0	7.5	20ºC / pF2	35.3	211	211	3.3 (p=2.5E-007)	SFO	Yes, EFSA Journal 2017; 15(6):4868
18 Acres	4.7	6.5	20ºC / pF2	29.8	390	390	2.1 (p=2.2E-006)	SFO	
Vetroz SiltLoam	4.1	8.0	20ºC / pF2	26.4	171	171	2.6 (p=1.7E-009)	SFO	
Geometric mean					**241**	**241**	-	-	

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Under anaerobic conditions, the route of terbuthylazine breakdown is similar to the aerobic route of metabolism, forming no novel metabolites.

Table 8.3-11: Summary of anaerobic degradation rates for terbuthylazine - laboratory studies

Terbuthylazine	Anaerobic conditions							
Soil type	**% OM**	**pH (water)**	**temp. ºC / % MWHC**	**DT_{50}/DT90 (d)**	**DT_{50} 20ºC pF2/ 10kPa (d)**	**St. (r^2)**	**Method of calc.**	**Evaluated on EU level y/n/ Reference**
Gartenacker Sandy loam SYN	3.79	7.25	20ºC / flooded soil	108.3/359.9	N/A	0.981	SFO	Yes, EFSA Journal 2017;
Speyer 2.3	2.07	6.3	20ºC /	131/ 436	N/A	0.966	SFO	

Sandy Loam SYN			flooded soil					15(6):4868
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)

Field studies with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

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

Terbuthylazine	**Aerobic conditions**									
Soil type (indicate if bare or cropped soil was used)	**Location (countryor USA state)**	**% OM**	**pH**	**Depth (cm)**	**DT50, ref 20°C pF2 (d)**	**DT90, ref 20°C pF2 (d)**	**Min chi² error (%)**	**t-test (%)**	**Method of calc.[a]**	**Evaluated on EU level y/n/ Reference**
Loam – Bare soil	St Aubin, Switzerland	3.1	7.2	0 – 10	17.4	58	5.2	> 99%	SFO	Yes, EFSA Journal 2017; 15(6):4868
Silt loam – Bare soil	Eschwege, Germany	4.0	6.2	0 – 20	16.9	56.1	16.7	> 99%	SFO	
Silt loam – Bare soil	Goch, Germany	6.4	6.25	0 – 20	28.8	95.8	8.2	> 99%	SFO	
Silty clay loam – Bare soil	Keeken, Germany	7.6	6.1	0 – 20	24.3	80.9	17.7	> 99%	SFO	
Silt loam – Bare soil	Pleidsheim, Germany	2.1	6	0 – 20	15.4	51.1	19.2	> 99%	SFO	
Loamy sand – Bare soil	Lorsch Helming, Germany	1.4	5.25	0 – 20	6.43	21.4	21	> 99%	SFO	
Loamy sand – Bare soil	WeezeWemb, Germany	3.8	6.2	0 – 20	11.1	36.8	17.7	> 99%	SFO	
Clay loam – Bare soil	Grisolles, Southern France	1.62	7.3	0 – 30	52.5	175	13.2	> 99%	SFO	
Silt loam – Bare soil	Molinella, Italyd	1.31	7.6	0 - 30	149	497	12.9	> 99%	SFO	
Silt loam – Bare soil	St Firmin, France (North) (1.0)[c]	1.6	8.4	0 – 10	24.8	82.3	8.7	> 99%	SFO	
Silt loam – Bare soil	St Firmin, France (North) (1.5)	1.6	8.4	0 – 10	21.2	70.5	9.5	> 99%	SFO	
Sand – Bare soil	Nevoy, France (North) (1.0)	1.0	8.6	0 – 10	12.5	41.5	8.8	> 99%	SFO	
Sand – Bare soil	Nevoy, France (North) (1.5)	1.0	8.6	0 – 10	19.4	64.4	6.5	> 99%	SFO	
Silt loam – Bare	Charny,	1.0	5.9	0 – 10	12.5	41.5	8.8	> 99%	SFO	

soil	France (North) (1.0)									
Silt loam – Bare soil	Charny, France (North) (1.0)	1.0	5.9	0 – 10	17.6	58.5	9.4	> 99%	SFO	
Silty sand – Bare soil	Ports sur Vienne,France (North) (1.0) [c]	1.9	6.6	0 – 10	13.9	46.3	4.9	> 99%	SFO	
Silty sand – Bare soil	Ports sur Vienne,France (North) (1.5)	1.9	6.6	0 – 10	27.9	92.8	13.7	> 99%	SFO	
Sandy silt loam – Bare soil	Eraclea, Italy (1.0)[b]	3.4	7.6	0 – 10	67.7	225	39.6	>81%	SFO	
Sandy silt loam – Bare soil	Eraclea, Italy (1.0)[b]	3.4	7.6	0 – 10	9.51	31.6	20.2	>98%	SFO	
Clay – Bare soil	Emilia, Italy	3.3	7.5	0 – 10	32.6	1.8	7	> 99%	SFO	
Clay – Bare soil	Emilia Italy [c]	3.3	7.5	0 – 10	31.8	1.6	5.3	> 99%	SFO	
Soft clayey sand –Bare soil	Hilgermissen, Germany[e]	1.5	5.9	0 – 10	33.5	111	11.8	> 99%	SFO	
Clayey sand – Bare Soil	Leutzke, Germany	2.9	5.5	0 – 10	9.72	32.3	25.7	> 99%	SFO	
Geometric mean[c]					**21.8**	**72.6**	-	-	-	
Median mean[c]					**20.0**	**66.5**	-	-	-	

NK – not known
[a] soils were normalised for temperature assuming a Q10 of 2.58 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

Desethyl- terbuthylazine (MT1)	**Aerobic conditions (where metabolite formed from parent terbuthylazine during the study)**									
Soil type (indicate if bare or cropped soil was used)	**Location (countryor USA state)**	**% OM**	**pH**	**DT50 ref 20°C pF2(d)**	**DT90ref 20°C pF2 (d)**	**Form. Frac. (ffm)**	**Minchi² error (%)**	**t-test (%)**	**Method of calc.[a]**	**Evaluated on EU level y/n/ Reference**
Loam – Bare soil	St Aubin, Switzerland	3.1	7.2	16.6	55.3	0.292	17.6	>99%	SFO	Yes, EFSA Journal 2017; 15(6):4868
Silt loam – Bare soil	Pleidsheim, Germany	2.1	6	31	103	0.112	17	>76%	SFO	
Loamy sand-Bare soil	Lorsch Helming, Germany	1.4	5.25	2.13	7.08	0.256	22.1	>68%	SFO	
Clay loam – Bare soil	Grisolles, Southern	1.62	7.3	51	169	0.767	15.6	>99%	SFO	

	France									
Silt loam – Bare soil	Molinella, Italy	1.31	7.6	208	693	0.513	6.6	>77%	SFO	
Silt loam – Bare soil	St Firmin, France (North) (1.0)	1.6	8.4	15.5	51.6	0.829	18.1	>99%	SFO	
Silt loam – Bare soil	St Firmin, France (North) (1.5)	1.6	8.4	19	63.2	0.445	3.1	>96%	SFO	
Silt loam – Bare soil	Charny, France (North) (1.0)	1.0	5.9	47.3	157	0.306	5.8	>97%	SFO	
Silt loam – Bare soil	Charny, France (North) (1.5)	1.0	5.9	69.9	231	0.258	11.4	>97%	SFO	
Soft clayey sand – Bare soil	Hilgermissen, Germany	1.5	5.9	23.4	77.8	0.695	8	>99%	SFO	
Arithmetic mean[a,b]				**-**	**-**	**0.444**	-	-		
Geometric mean[a,c]				**26.8**	**89.2**	**-**	-	-		
Median[a,c]				**27.2**	**90.4**	**-**				

[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 2.58 using a time step normalisation 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

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Accumulation studies shown no evidence of accumulation 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)

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

8.5.1 Laboratory studies (KCP 9.1.2.1)

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

Terbuthylazine						
Soil Type	**OC %**	**Soil pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2 Loamy Sand-OXON	2.29	6.0	5.34	233	0.98	Yes, EFSA Journal
Les Evouettes Sandy Loam–OXON	1.20	5.9	2.95	246	0.90	

Sisseln Sandy Loam – OXON	1.57	7.1	2.37	151	0.93	2017; 15(6):4868
Vetroz Silt Loam - OXON	4.1	7.3	8.18	200	0.90	
Pappelacker Loamy Sand–SYN	1.1	7.6	2.10	191	0.92	
Lorsch Sandy Clay Loam–SYN	1.8	5.3	5.86	318	0.94	
Gartenacker Loam – SYN	2.0	7.1	3.74	187	0.88	
Vetroz Silt Loam - SYN	4.7	7.2	10.49	223	0.97	
Borstel Loamy Sand – SYN*	1.48	6.1	4.93	333	0.91	
Arithmetic mean			**5.1**	**231**	**0.93**	
pH dependence (yes or no)			Possible weak negative correlation between sorption and soil pH (r^2 = 0.5456)			

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

Desethyl-terbuthylazine (MT1)						
Soil Type	**OC %**	**Soil pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Collombey Loamy Sand - SYN	0.80	7.3	0.594	74.0	0.85	Yes, EFSA Journal 2017; 15(6):4868
Les Evouettes Silt Loam – SYN	2.40	7.2	1.43	59.0	0.86	
Vetroz Silt Loam - SYN	4.70	7.2	3.29	70.0	0.91	
Speyer 2.1 Sand – OXON	0.6	5.9	0.43	67.2	0.95	
Speyer 2.2 Loamy Sand – OXON	2.3	5.6	1.9	81.7	0.91	
Beek Silt Loam – OXON	0.6	6.6	0.28	43.8	0.94	
Marknesse Silt Loam - OXON	1.3	7.5	1.24	96.9	0.92	
Lorsch Sandy Clay Loam - SYN	1.84	5.25	1.56	85.0	0.94	
Borstel Loamy Sand – SYN	1.48	6.1	1.80	122	0.77	
Arithmetic mean			**1.39**[a]	**77.7** [a]	**0.89**	
pH dependence (yes or no)			no			

[a] arithmetic mean based on all data

Table 8.5-3: Summary of soil adsorption/desorption for hydroxy-terbuthylazine (MT13)

Hydroxy-terbuthylazine (MT13)						
Soil Type	**OC %**	**Soil pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Cranfield 115 Clay Loam – OXON	1.7	7.9	3.51	208.6	0.82	Yes, EFSA Journal 2017; 15(6):4868
Cranfield 164 Silt Loam – OXON	3.0	7.1	5.94	196.9	0.8	
Cranfield 243 Sandy Loam - OXON	1.1	5.4	2.14	193.1	0.85	
Borstel Sandy Loam - SYN	1.3	5.0	3.64	279.7	0.87	

Collombey Loamy Sand - SYN	0.80	7.3	1.19	149	0.91	
Les Evouettes Silt Loam - SYN	2.40	7.2	2.49	104	0.79	
Vetroz Silt Loam - SYN	4.70	7.2	8.36	178	1.31	
Arithmetic mean			**3.90**	**187**	**0.91**	
pH dependence (yes or no)			no			

Table 8.5-4: Summary of soil adsorption/desorption for desethyl-hydroxy-terbuthylazine (MT14)

Desethyl-terbuthylazine (MT14)								
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**
Borstel Loamy Sand	1.3	5.0	1.8	136	1.44	111	0.93	Yes, EFSA Journal 2017; 15(6):4868
Lorsch Sandy Clay Loam	1.8	5.3	3.8	211	3.39	188	0.97	
Gartenacker Loam/Silt Loan	2.0	7.1	1.2	59	1.10	55	0.98	
Vetroz Silt Loam	4.7	7.2	2.8	60	2.67	57	0.98	
Wisborough - Silty Clay Loa	3.44	5.02	4.40	375	3.36	98	0.8892	
18 Acres - Sandy Clay Loan	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 - Loama	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**	
Median (n=11)					**-**	**111***	**-**	
pH dependence (yes or no)					no			

*median values excluding results from the Bosket loam soil

Table 8.5-5: Summary of soil adsorption/desorption for LM1

LM1							
Soil Type	**OC %**	**Soil pH**	**Koc (mL/g)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Gartenacker Silt Loam	2.95	7.1	30	0.51	30.2	1.03	Yes, EFSA Journal 2017; 15(6):4868
18 Acres Clay Loam	4.34	7.2	34	0.82	32.7	0.98	
Vetroz Loam	4.09	7.6	35	0.87	36.6	1.05	

Arithmetic mean				**0.73**	**33.2**	**1.02**	
pH dependence (yes or no)			No evidence from narrow pH range studied				

Table 8.5-6: Summary of soil adsorption/desorption for LM2

LM2							
Soil Type	**OC %**	**Soil pH**	**Koc (mL/g)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Gartenacker Silt Loam	2.95	7.1	8.7	0.16	9	1.07	Yes, EFSA Journal 2017; 15(6):4868
18 Acres Clay Loam	4.74	6.1	13.7	0.35	13	0.93	
Vetroz Loam	4.09	7.6	6.1	0.15	6	1.1	
Arithmetic mean				**0.22**	**9.4**	**1.03**	
pH dependence (yes or no)				Yes - slight trend relating increasing Kfoc with decreasing pH. However, given the low sorptionthe mean was considered appropriate for modelling.			

Table 8.5-7: Summary of soil adsorption/desorption for LM3

LM3							
Soil Type	**OC %**	**Soil pH**	**Koc (mL/g)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Gartenacker Silt Loam	2.95	7.1	4.8	0.071	4.2	0.85	Yes, EFSA Journal 2017; 15(6):4868
18 Acres Clay Loam	4.74	6.1	3.7	0.091	3.3	0.9	
Vetroz Loam	4.09	7.6	4.1	0.087	3.7	0.87	
Arithmetic mean				**0.083**	**3.7**	**0.87**	
pH dependence (yes or no)				No evidence from narrow pH range studied			

Table 8.5-8: Summary of soil adsorption/desorption for LM4

LM4							
Soil Type	**OC %**	**Soil pH**	**Koc (mL/g)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Gartenacker Silt Loam	2.95	7.1	6	0.097	4.9	0.81	Yes, EFSA Journal 2017; 15(6):4868
18 Acres Clay Loam	4.74	6.1	17.2	0.463	15.4	0.91	
Vetroz Loam	4.09	7.6	4.5	0.096	3.8	0.84	
Arithmetic mean				**0.22**	**8.0**	**0.85**	
pH dependence (yes or no)			Yes - trend relating increasing Kfoc with decreasing pH. How-				

	ever, given the low sorptionthe mean was considered appropriate for modelling.

Table 8.5-9: Summary of soil adsorption/desorption for LM5

LM5							
Soil Type	**OC %**	**Soil pH**	**Koc (mL/g)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Gartenacker Silt Loam	2.95	7.1	24	0.32	19	0.87	Yes, EFSA Journal 2017; 15(6):4868
18 Acres Clay Loam	4.74	6.1	20	0.39	14	0.88	
Vetroz Loam	4.09	7.6	21	0.31	13	0.83	
Arithmetic mean				**0.34**	**15.3**	**0.86**	
pH dependence (yes or no)			No evidence from narrow pH range studied				

Table 8.5-10: Summary of soil adsorption/desorption for LM6

LM6							
Soil Type	**OC %**	**Soil pH**	**Koc (mL/g)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Gartenacker Silt Loam	2.95	7.1	16	0.23	13	0.92	Yes, EFSA Journal 2017; 15(6):4868
18 Acres Clay Loam	4.74	6.2	18	0.4	14	0.93	
Vetroz Loam	4.09	7.6	18	0.31	13	0.89	
Arithmetic mean				**0.38**	**13.3**	**0.91**	
pH dependence (yes or no)			No evidence from narrow pH range studied				

8.5.2 Column leaching (KCP 9.1.2.1)

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

Table 8.5-11: Summary of column leaching studies for terbuthylazine

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

8.5.3 Lysimeter studies (KCP 9.1.2.2)

Lysimeter studies for terbuthylazine and its metabolites were conducted. Summarized results of the lysimeter and field leaching studies from EFSA Journal 2017; 15(6):4868 are presented in table below.

Table 8.5-12: Summary of lysimeter / field leaching studies for terbuthylazine and metabolites

Lysimeter/ field leaching studies (SYN) Summary of metabolite codes: - MT1 = GS26379 MT13=GS23158MT14=GS28620 MT19=GS17792MT20=GS28273 MT22 = G28279 LM1 = MT24 = G35713 LM2=MT28=CSAA036479 LM3 = SM9 = CSCD692760 LM4 = CSAA404949 LM5 = MT23 = SM12 = GS16984 LM6 = SM6 = CSCD648241	Location: Schmallenberg/Grafschaft, Germany Study type (e.g.lysimeter, field): lysimeter (x2) Soil properties (0 – 30 cm): Borstel Sandy Loam, pH = 5.7, OC= 1.5 %, MWHC = not stated (FC = 20 – 34 % by volume) Dates of application: 28/05/1990 Crop: maize followed by the rotational crops winter wheat and winter barley. Number of applications: 1 application to maize in first year only Duration: 2 years, Application rate: 700 - 790 g/ha Average annual rainfall (mm): 863 mm Average annual leachate volume (mm): 418.3 mm % radioactivity in leachate (maximum/year): 1.45 – 1.48 % AR Annual average maximum concentrations (e.g. 1st or 2nd yr, Lysimeter 38 or 44) :< 0.02 µg/L terbuthylazine, < 0.02 µg/L desethyl-terbuthylazine, 0.03 µg/L hydroxy-terbuthylazine, 0.03 µg/L G 28273 (MT20), 0.05 µg/L GS 17792 (MT19), < 0.02 µg/L G 28279 (MT22), G 28260 (MT14), 1.96 µg/L Unidentified radioactivity Bi-annual average concentrations (e.g. 1st and 2nd yr, Lysimeter 38 and 44): < 0.02 µg/L terbuthylazine, < 0.02 µg/L desethyl-terbuthylazine, 0.02 µg/L hydroxy-terbuthylazine. 0.02 µg/L G 28273 (MT20), 0.03 µg/L GS 17792 (MT19), < 0.02 µg/L G 28279 (MT22), G 28260 (MT14), 1.21 µg/L Unidentified radioactivity. Amount of radioactivity in the soils at the end of the study = 65.6 – 75.2 % AR; consisting of: 5.9 – 6.4 % AR as terbuthylazine, 1.2 – 1.5 % AR as desethyl-terbuthylazine, 0.2 – 0.5 % AR as hydroxy-terbuthylazine, < LOD – 0.2 % AR as G 28279 (MT22), 0.1 – 0.2 % AR as GS 28260 (MT14)
Lysimeter/ field leaching studies ‡(OXON)	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 furthermore 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. Assignation 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 desethylterbuthylazine (2nd year); < 0.05 µg/L desethylterbuthylazine (mean of 1st and 2nd year), 0.12 µg/L LM1* (1st year); 0.33 µg/L LM1* (2nd year); 0.25 µg/L LM1* (mean of 1st and 2nd year), 0.17 µg/L LM2* (1st year); 0.17 µg/L LM2* (2nd year); 0.17 µg/L LM2* (mean of 1st and 2nd year), 0.43 µg/L LM3 (1st year); 1.09 µg/L LM3 (2nd year); 0.84 µg/L LM3 (mean of 1st and 2nd year), 0.36 µg/L LM5* (1st year); 0.70 µg/L LM5* (2nd year); 0.57 µg/L LM5* (mean of 1st and 2nd year), 0.07 µg/L MT14 and LM4* (1st year); 0.11 µg/L MT14 and LM4* (2nd year); 0.09 µg/L MT14 and LM4* (mean of 1st and 2nd year), 0.05 µg/L LM6 (1st year); 0.50 µg/L LM6 (2nd year); 0.33 µg/L LM6 (mean of 1st and 2nd year), 0.25 µg/L LM7* (1st year); 0.05 µg/L LM7* (2nd year); 0.12 µg/L LM7* (mean of 1st and 2nd year) *= structures tentatively assigned to peaks Additional unidentified radioactivity (sum of smaller peaks) 0.11 µg/L (1st year); 0.29µg/l (2nd year); 0.22µg/l (mean of 1st and 2nd year) Amount of radioactivity in the soils at the end of the study = 67.7 % AR; consisting of (0 – 18 cm depth only) 0.92 % AR as parent, 0.92 % AR as desethyl-terbuthylazine, 11.97 % AR as hydroxy-terbuthylazine, 1.52 % as desethyl-hydroxy-terbuthylazine, 6.29 % unidentified
Lysimeter/ field leaching studies ‡ (SYN)	Location: Itingen, Switzerland Study type (e.g.lysimeter, field): lysimeter (x2) Soil properties (0 – 30 cm): Neustadt Sand, pH = 6.1, OC= 1.05, MWHC = 34.5 % Dates of application: 18/05/93 Crop: maize, followed by two rotations of winter wheat Number of applications: 1 application to maize in first year only. Duration: 2 years Application rate: 905 g/ha/lysimeter 7; 929 g/ha/lysimeter 9 (application in first year only) Average annual rainfall (mm): 1090 mm Average annual leachate volume (mm): 485.6 mm

	% radioactivity in leachate (maximum/year): 1.60 - 1.70 % AR Annual average concentrations (e.g. 1st and 2nd yr, Lysimeter 7 and 9): not detected – terbuthylazine, desethyl terbuthylazine, hydroxy terbuthylazine; 0.04/0.06µg/l LM1 (lysimeter 7/9, 1st year); 0.12/0.15µg/l LM1 (lysimeter 7/9, 2nd year) 0.04/0.03µg/l LM2 (lysimeter 7/9, 1st year); 0.10/0.10µg/l LM2 (lysimeter 7/9, 2nd year) 0.26/0.31µg/l LM3 (lysimeter 7/9, 1st year); 0.85/0.83µg/l LM3 (lysimeter 7/9, 2nd year) 0.38/0.40µg/l LM4 (lysimeter 7/9, 1st year); 0.14/0.18µg/l LM4 (lysimeter 7/9, 2nd year) 0.10/0.08µg/l LM5 (lysimeter 7/9, 1st year); 0.71/0.62µg/l LM5 (lysimeter 7/9, 2nd year) 0.03/0.01µg/l LM6 (lysimeter 7/9, 1st year); 0.53/0.40µg/l LM6 (lysimeter 7/9, 2nd year), 0.08/0.08µg/l LM7 (lysimeter 7/9, 1st year); 0.06/0.03µg/l LM7 (lysimeter 7/9, 2nd year) Amount of radioactivity in the soils at the end of the study = 76.20 - 80.62 %AR; consisting of (0 – 38 cm depth only – max values) 6.4 % AR as terbuthylazine, 1.0 % AR as desethyl-terbuthylazine, 53.8 % AR as hydroxy-terbuthylazine, 30 - 52 % AR unextraced radioactivity
Lysimeter/ field leaching studies ‡(OXON)	Location: Itingen, Switzerland Study type (e.g.lysimeter, field): lysimeter (x2) Soil properties (0 – 30 cm): Neustadt Sand, pH= 6.1, OC= 1.05, MWHC = 34.5 % Dates of application: 18/05/93 Crop: maize, followed by two rotations of winter wheat Number of applications: 1 application to maize in first year only. Duration: 2 years Application rate: 905 g/ha/lysimeter 7; 929 g/ha/lysimeter 9 (application in first year only) Average annual rainfall (mm): 1090 mm Average annual leachate volume (mm): 485.6 mm % radioactivity in leachate (maximum/year): 1.60 - 1.70 % AR Annual average concentrations (e.g. 1st and 2nd yr, Lysimeter 7 and 9): not detected – terbuthylazine, desethyl terbuthylazine, hydroxy terbuthylazine, 0.04/0.06µg/l LM1 (lysimeter 7/9, 1st year); 0.12/0.15µg/l LM1 (lysimeter 7/9, 2nd year) 0.04/0.03µg/l LM2 (lysimeter 7/9, 1st year); 0.10/0.10µg/l LM2 (lysimeter 7/9, 2nd year) 0.26/0.31µg/l LM3 (lysimeter 7/9, 1st year); 0.85/0.83µg/l LM3 (lysimeter 7/9, 2nd year) 0.38/0.40µg/l LM4 (lysimeter 7/9, 1st year); 0.14/0.18µg/l LM4 (lysimeter 7/9, 2nd year) 0.10/0.08µg/l LM5 (lysimeter 7/9, 1st year); 0.71/0.62µg/l LM5 (lysimeter 7/9, 2nd year) 0.03/0.01µg/l LM6 (lysimeter 7/9, 1st year); 0.53/0.40µg/l LM6 (lysimeter 7/9, 2nd year), 0.08/0.08µg/l LM7 (lysimeter 7/9, 1st year); 0.06/0.03µg/l LM7 (lysimeter 7/9, 2nd year) Amount of radioactivity in the soils at the end of the study = 76.20 - 80.62 %AR; consisting of (0 – 38 cm depth only – max values): 6.4 % AR as terbuthylazine, 1.0 % AR as desethyl-terbuthylazine, 53.8 % AR as hydroxy-terbuthylazine, 30 - 52 % AR unextraced radioactivity
Lysimeter/ field leaching studies ‡ (OXON)	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, 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); All concentrations are in µg metabolite/l. Amount of radioactivity in the soils at the end of the study = not reported
Lysimeter/ field leaching studies ‡ (SYN)	Location: Lorsch, Hessen, Germany Study type (e.g.lysimeter, field): Field leaching study Soil properties (0 – 30 cm): sandy loam, pH = 5.2 – 6.3, OC= 2.3 – 2.6, MWHC = not reported Dates of application: 1990, 1992, 1994 – 1997, 1999 - 2000 Crop: maize in application years. Interception estimated: 25 % (based on standard crop interception values and growth stage of maize at time of application) Number of applications: 8 applications, maximum of 1 per year Duration: 11 years Application rate: 735 g/ha in 1990; 750 g/ha in all other application years Average annual rainfall (mm): 587 mm (NB. data from 1993, 1995 and 1998 not reported) Average annual leachate volume (mm): Not applicable % radioactivity in leachate (maximum/year): Not applicable. Frequency of detections, detections above >0.1µg/l and maximum conc.: Terbuthylazine: 1 detection out of 418 samples; 0% (~0 samples) >0.1µg/l; maximum concentration = 0.09µg/l. Desethyl terbuthylazine: 0 detections out of 419 samples; Desethyl hydroxyterbuthylazine: 17 detections out of 51 samples; 24% (~12 samples) >0.1µg/l; maximum concentration = 0.41µg/l. 2-hydroxy terbuthylazine: 10 detections out of 51 samples, 0%(0 samples) >0.1µg/l; maximum concentration = 0.08µg/l. Individual annual maximum concentrations (e.g. 1st, 2nd,

	3rd yr): < 0.05 µg/L terbuthylazine, < 0.05 µg/L desethyl-terbuthylazine, 0.06 µg/L 2-hydroxy-terbuthylazine, 0.25 µg/L desethylhydroxy-terbuthylazine, Individual annual average concentrations (e.g. 1st, 2nd, 3rd yr): < 0.05 µg/L terbuthylazine, < 0.05 µg/L desethyl-terbuthylazine, < 0.05 µg/L 2-hydroxy-terbuthylazine, < 0.05 - 0.12 µg/L desethylhydroxy- terbuthylazine Amount of radioactivity in the soils at the end of the study = not reported Note that 2-hydroxy terbuthylazine was only analysed for in 1999-2000 and 2000-2001. Desethylhydroxy terbuthylazine was only analysed for in 1997-1998, 1999-2000 and 2000-2001.
Lysimeter/ field leaching studies ‡ (SYN)	Location: 10 sites in 5 regions (Emilia Romagna, Friuli Venezia – Giulia, Lombardia, Piemonte, Veneto) in Northern Italy Study type (e.g.lysimeter, field): field leaching study Soil properties: texture class – 5 sandy loams, 3 loams, 1 sandy clay and 1 clay loam; pH = 4.9 7.7; OC= 0.9 – 3.6%; MWHC = not reported Groundwater depth: 0.12 to 7.1m below ground surface Dates of application: 2005 to 2007 Crop: maize Irrigation: sprinkler, basin, border or no irrigation Interception estimated: 0 % (applications made shortly after seeding maize) Number and rate of applications: between 2005 and 2007, 7 sites had 3 annual applications of 856 g terbuthylazine/ha. The remaining 3 sites had either 2 or 1 annual application. Duration: bi-monthly sampling for 3 years (17 sampling events) Average annual rainfall (mm): Reported to be below the overall average for the period 2000- 2007 but supplemented by irrigation at 9 out of 10 sites. Frequency of detections, detection >0.1µg/l and maximum conc. (excluding basin irrigated sites, n=8): Terbuthylazine: 62 detections out of 395 samples; 3% (~13 samples) >0.1µg/l; maximum concentration = 3.20µg/l. Desethyl terbuthylazine: 125 detections out of 395 samples; 5% (~21 samples) >0.1µg/l; maximum concentration = 3.18µg/l. Excluding results from the V2 site after April 2007 when contamination may have occurred, the peak monitored concentration was 1.984µg/l and actual concentrations >0.1µg/l were observed in 17 out of 384 samples (4.4 %). 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.

	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) Additional monitoring between 2009-2010 at 7 sites across 4 regions (Emilia Romagna, Lombardy, Veneto and Friuli-Venezia-Giulia) to measure residues of LM2, 3, 4, 5 and 6. LM2 maximum concentration = 0.26µg/l, LM3 maximum concentration = 0.29µg/l, LM4 maximum concentration = 0.50µg/l, LM5 maximum concentration = 0.50µg/l, LM6 maximum concentration = 1.4µg/l Annual average concentrations in downstream clusters: LM2 <0.05 - 0.11µg/l LM3 <0.05 - 0.14µg/l LM4 <0.05 - 0.13µg/l LM5 <0.05 - 0.27µg/l LM6 <0.05 - 0.53µg/l Note that as high concentrations were also found in the upstream monitoring wells (all substances), parts of residues found in downstream monitoring wells are likely to derive from previous usage following several years of commercial application in the upstream areas.

8.5.4 Field leaching studies (KCP 9.1.2.3)

Not relevant. No studies submitted.

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

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. The relevant endpoints are provided in EFSA Journal 2017; 15(6):4868.

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

Water/sediment system	pH water phase	pH sed.	t. °C	DT50-DT90 whole syst.(d)	χ^2 %	DT50-DT90 water (d)	χ^2 %	DT50-DT90 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 2017; 15(6):4868

Pond Orma-lingen silt loam - SYN	8.1	7.5	20	33 - 110	0.9994	6 - 47	0.9991	NC	-	SFO – whole system 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 - OX-ON	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	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

Not relevant. No new endpoints proposed.

8.7.2 Active substance and relevant metabolites

The predicted environmental concentrations in soil PECs of terbuthylazine and its metabolites were calculated using single formulas in FOCUS guidance – FOCUS (1997): Soil persistence models and EU registration. The final report of the work of the Soil Modelling Work group of FOCUS (Forum for the Co-ordination of pesticide fate models and their Use). Metabolites listed as being relevant for soil risk assessment are desethyl-terbuthylazine (max. 32.9 %) and hydroxy-terbuthylazine (max. 34.5 %). Input parameters related to application and active substance/metabolites data for PECs calculation are summarized below.

Table 8.7-1: Input parameters related to application for PECs calculations

Use No.	1, 2	
Crop	maize	maize
Application rate (g as/ha)	750	500
Number of applications/intervals	1/-	1/-
Crop interception (%)	0	0
Depth of soil layer (relevant for plateau concentration) (cm)	5 (no tillage)	5 (no tillage)
Soil density (g/cm3)	1.5	1.5
Models used for calculation	single formula in FOCUS guidance	single formula in FOCUS guidance

Table 8.7-2: Input parameter for active substance and relevant metabolites for PECsoil calculation

Compound	Molecular weight (g/mol)	Max. observed in soil (%)	DT_{50} (days)	Value in accordance to EU endpoint y/n/ Reference
terbuthylazine	229.7	-	46.6 (SFO, worst case unnormalized values from field studies)	Yes, EFSA Journal 2017; 15(6):4868
Desethyl-terbuthylazine MT1	201.7	32.9	30.9 (maximum value from field studies relevant for central EU, Pleidesheim-Germany)	
Hydroxy-terbuthylazine MT13	211.3	34.5	1000 (worst case default)	

The metabolite desethy-hydroxy-terbuthylazine (MT14) was also included in the DAR but it is considered to be a minor metabolite, present at only 1.9% AR. Therefore, PECs was not calculated.

Table 8.7-3: PECs of terbuthylazine in soil after application to maize

PEC_{soil} (mg/kg)		Maize - 500 g as/ha			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		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	-	-
	28d	0.440	0.545	-	-
	50d	0.317	0.470	-	-
	100d	0.151	0.347	-	-
Average plateau concentration		Not required - no evidence of accumulation during a field soil accu-mulation trial		-	-
PEC_{soil} (mg/kg)		**Maize - 750 g as/ha**			
		Single application		**Multiple applications**	
		Actual	**TWA**	**Actual**	**TWA**
Initial		1.000	-	-	-
Short term	24h	0.985	0.993	-	-
	2d	0.971	0.985	-	-
	4d	0.942	0.971	-	-
Long term	7d	0.901	0.950	-	-
	14d	0.812	0.903	-	-
	21d	0.732	0.859	-	-
	28d	0.659	0.818	-	-
	50d	0.475	0.705	-	-
	100d	0.226	0.520	-	-
Average plateau concentration		Not required - no evidence of accumulation during a field soil accu-mulation trial		-	-

PEC_{soil} of metabolites

Table 8.7-4: PECs of desethyl-trbuthylazine (M1) in soil after application to maize

PEC_{soil} (mg/kg)		**Maize - 500 g as/ha**			
		Single application		**Multiple applications**	
		Actual	**TWA**	**Actual**	**TWA**
Initial		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	-	-
	28d	0.103	0.143	-	-
	50d	0.063	0.116	-	-
	100d	0.020	0.077	-	-
Plateau concentration		Not required - no evidence of accumulation during a field soil accu-mulation trial		-	-
PEC$_{soil}$ (mg/kg)		**Maize - 750 g as/ha**			
		Single application		**Multiple applications**	
		Actual	**TWA**	**Actual**	**TWA**
Initial		0.2889	-	-	-
Short term	24h	0.2825	0.2857	-	-
	2d	0.2762	0.2825	-	-
	4d	0.2641	0.2763	-	-
Long term	7d	0.2469	0.2674	-	-
	14d	0.2110	0.2479	-	-
	21d	0.1804	0.2304	-	-
	28d	0.1542	0.2145	-	-
	50d	0.0941	0.1737	-	-
	100d	0.0307	0.1151	-	-
Plateau concentration		Not required - no evidence of accumulation during a field soil accu-mulation trial		-	-

Table 8.7-5: PECs of metabolite hydroxy- terbuthylazine (M13) after application maize

PEC$_{soil}$ (mg/kg)		**Maize - 500 g as/ha**			
		Single application		**Multiple applications**	
		Actual	**TWA**	**Actual**	**TWA**
Initial		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	-	-
	28d	0.208	0.210	-	-

	50d	0.204	0.208	-	-
	100d	0.197	0.204	-	-
Plateau concentration		Not required - no evidence of accumulation during a field soil accu-mulation trial		-	-
PEC$_{soil}$ (mg/kg)		**Maize - 750 g as/ha**			
		Single application		**Multiple applications**	
		Actual	**TWA**	**Actual**	**TWA**
Initial		0.3174	-	-	-
Short term	24h	0.3152	0.3163	-	-
	2d	0.3130	0.3152	-	-
	4d	0.3087	0.3130	-	-
Long term	7d	0.3023	0.3098	-	-
	14d	0.2880	0.3025	-	-
	21d	0.2744	0.2953	-	-
	28d	0.2614	0.2885	-	-
	50d	0.2244	0.2682	-	-
	100d	0.1587	0.2289	-	-
Plateau concentration		Not required - no evidence of accumulation during a field soil accu-mulation trial		-	-

8.7.2.1 PEC$_s$ of formulation

PECs for formulation was obtained from PECs for terbuthylazine taking into account content of active substance and density of the formulation H-01-2022. TWA PECs, $_{background}$ PECs and accumulation PECs are not relevant for formulation.

Table 8.7-6: PECs for formulation after application to maize

Active substance/ preparation	**Application rate (g/ha)**	**PECs,$_{act}$ (mg/kg)**	**PECs,$_{twa}$21 d (mg/kg)**	**Tillage depth (cm)**	**PECs,$_{background}$ (mg/kg)**	**PECs,$_{accu}$ = PECs,$_{act}$ + PECs,$_{background}$ (mg/kg)**
terbuthylazine	500	0.667	0.573	5cm	-	-
H-01-2022	1119	1.493	NR	NR	NR	NR
terbuthylazine	750	1.000	0.859	5cm	-	-
H-01-2022	1679	2.239	NR	NR	NR	NR

* based on the density of the H-01-2022, d=1.119 g/L

Comments zRMS:

The calculations were accepted.
The EU agreed endpoints (EFSA Journal 2011; 9(1):1969) and EFSA Journal 2017; 15(6):4868 were used for calculations. The interception values based on the FOCUS guidance (*Generic Guidance for Tier 1 FOCUS Ground Water Assessments (version: 2.2, May 2014*) was considered.
Calculations were performed with consideration of the critical use pattern proposed in GAP for 500g/ha end 750 g/ha.

Below PECs for application 750g/ha

Terbuthylazine
PECsoil initial = 1.000 mg/kg

Desethyl-terbuthylazine (MT1)
PECsoil initial = 0.193 mg/kg

Hydroxy-terbuthylazine
PECsoil initial = 0.3174 mg/kg

H-01-2022 formulation
PECsoil initial = 2.239 mg/kg

PEC values for terbuthylazine 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

Not relevant. No new endpoints proposed.

8.8.2 Active substance and relevant metabolites (KCP 9.2.4)

PECgw for active substance and its metabolites after application to maize were calculated with PEARL v5.5.5, PELMO v6.6.4 and MACRO v. 5.5.4 for FOCUS groundwater scenarios. Application timing for each crop/scenario was settled with AppDate 3.06. Input parameters related to application and active substance and metabolites data for PECgw calculation are summarized below.

Table 8.8-1: Input parameters related to application for PECgw calculations

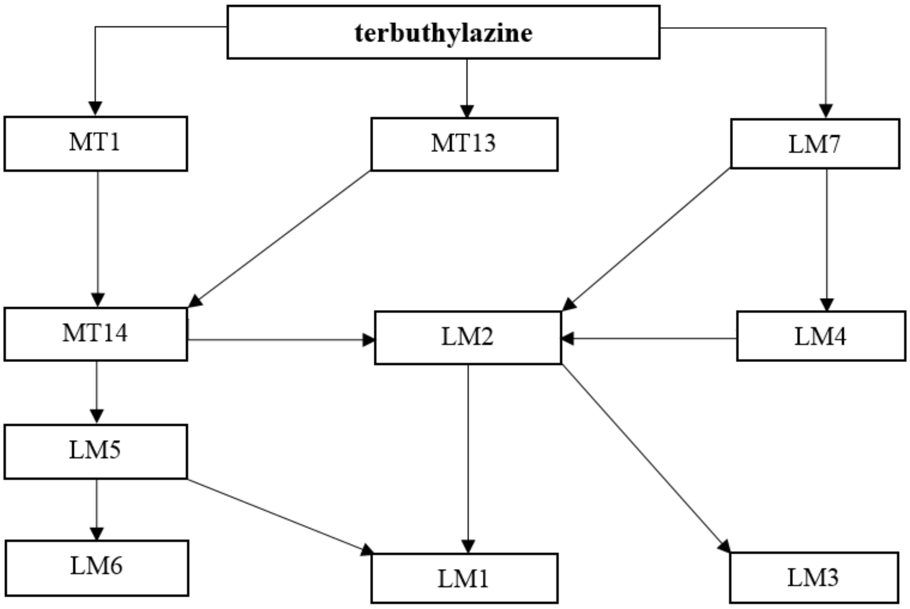
Use No.	1, 2	
Crop	maize	maize
Application rate (g/ha)	750	500
Number of applications/intervals	1/-	1/-
Crop interception (%)	0	0

Frequency of application	every 3rd year	every 3rd year
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, MACRO v5.5.4	

Table 8.8-2: Application dates used for groundwater risk assessment

Crop	Scenario	Application dates (relative)
maize BBCH 00 BBCH 12-16	Châteaudun	10 days before emergence & 10 days after emergence
	Hamburg	
	Kremsmünster	
	Okehampton	
	Piacenza	
	Porto	
	Sevilla	
	Thiva	

*for MACRO calculation, 110 and 129 respective Julian day were used (10 days before emergence and 10 days after emergence)



The calculation of the predicted environmental concentrations in groundwater (PECgw) of terbuthylazine and its major soil metabolites M1 desethyl-terbuthylazine, M13 hydroxy-terbuthylazine and M14 desethyl hydroxy-terbuthylazine have been assessed.

Moreover, seven leachate metabolites were found in a lysimeter study summarized in the Additional Report to the DAR, B.8 but only four of them are identified as major metabolites and coded LM3, LM4, LM5, LM6. LM4 was found at lower concentration than LM3, LM5 and LM6. According to the transformation scheme of terbuthylazine and metabolites, LM4 is a precursor to LM3 either directly or via metabolite LM2 thus PECgw values for LM3 is used as a surrogate for LM4. Two other metabolites LM1 and LM2 represent more minor fractions compared with other factions therefore they were characterized as minor metabolites and have not been subject for further assessment. Furthermore, the maximum annual average concentration of LM7 were below 0.1 µg/L in any study year and this metabolite can be excluded from further assessment.

Table 8.8-3: Input parameters related to active substance terbuthylazine and metabolites for PECgw calculations

Compound	Ter-buthylazine	MT1 desethyl-ter-buthylazine	MT13 hydroxy-ter-buthylazine	MT14 desethyl-hydroxy ter-buthylazine	LM1	LM2	LM3	LM4	LM5	LM6	Value in accordance to EUend-point y/n Reference
Molecular weight (g/mol)	229.7	201.7	211.3	183.2	128.1	213.2	198.2	241.2	184.2	198.2	Yes, EFSA Journal 2017; 15(6):4868
Water solu-bility (mg/L):	8.5 at 20°C	327.1 at 20°C	7.19 at 20°C	18 at 25°C	18 at 25°C	18 at 25°C	18 at 25°C	18 at 25°C	18 at 25°C	18 at 25°C	Yes, EFSA Journal 2017; 15(6):4868
Saturated vapour pres-sure (Pa):	0 at 20°C	0 at 20°C	0 at 20°C	0 at 20°C	0 at 20°C	0 at 20°C	0 at 20°C	0 at 20°C	0 at 20°C	0 at 20°C	Yes, EFSA Journal 2017; 15(6):4868
DT_{50} in soil (d)	20 (median, field studies, nor-malisation to pF2, 20°C with Q10 of 2.58, n=16)	26.8 (geometric mean, field studies, normalisation to pF2, 20°C with Q10 of 2.58, n=10)	453 (geometric mean, lab studies, normalisation to pF2, 20°C with Q10 of 2.58, n=6)	107 (geometric mean, lab studies, normalisation to pF2, 20°C with Q10 of 2.58, n=4)	0.4 (geometric mean, lab studies, normalisation to pF2, 20°C with Q10 of 2.58, n=3)	16.5 (geometric mean, lab studies, normalisation to pF2, 20°C with Q10 of 2.58, n=3)	12.2 (geometric mean, lab studies, normalisation to pF2, 20°C with Q10 of 2.58, n=3)	53.6 (geometric mean, lab studies, normalisation to pF2, 20°C with Q10 of 2.58, n=3)	47.0 (geometric mean, lab studies, normalisation to pF2, 20°C with Q10 of 2.58, n=3)	241 (geometric mean, lab studies, nor-malisation to pF2, 20°C with Q10 of 2.58, n=3)	Yes, EFSA Journal 2017; 15(6):4868
K_{foc} (mL/g)/K_{fom}	151 / 87.59 (worst case, lowest Kfoc value)	77.7 / 45.07 (arithmetic mean, n=9)	187 / 108.47 (arithmetic mean, n=7)	111 / 64.39 (median, n=11)	33.2 / 19.26 (arithmetic mean, n=3)	9.4 / 5.45 (arithmetic mean, n=3)	3.7 / 2.15 (arithmetic mean, n=3)	8.0 / 4.64 (arithmetic mean, n=3)	15.3 / 8.87 (arithmetic mean, n=3)	13.3 / 7.71 (arithmetic mean, n=3)	Yes, EFSA Journal 2017; 15(6):4868
1/n	0.93	0.89	0.91	0.92	1.02	1.03	0.87	0.85	0.86	0.91	Yes,

Compound	**Ter-buthylazine**	**MT1 desethyl-ter-buthylazine**	**MT13 hydroxy-ter-buthylazine**	**MT14 desethyl-hydroxy ter-buthylazine**	**LM1**	**LM2**	**LM3**	**LM4**	**LM5**	**LM6**	**Value in accordance to EUend-point y/n Reference**
	(arithmetic mean, n=9)	(arithmetic mean, n=9)	(arithmetic mean, n=7)	(arithmetic mean, n=12)	(arithmetic mean, n=3)	(arithmetic mean, n=3)	(arithmetic mean, n=3)	(arithmetic mean, n=3)	(arithmetic mean, n=3)	(arithmetic mean, n=3)	EFSA Journal 2017; 15(6):4868
Plant uptake factor	0	0	0	0	0	0	0	0	0	0	Yes, EFSA Journal 2017; 15(6):4868
Formation fraction	-	0.44 from parent	0.197 from parent	0.28 from M1	0.59 from LM5	1 from LM4	1 from LM2	0.08 from parent	0.47 from MT14	0.41 from LM5	Yes, EFSA Journal 2017; 15(6):4868
Conversion factor	-	0.386	0.181	0.223	0.329	0.928	0.863	0.084	0.377	0.354	for MACRO; molar mass (metabo-lite)/molar mass (parent) × formation fraction

Table 8.8-4: PECgw for terbuthylazine and metabolites on maize, application rate: 750 g as/ha (10 days before emergence; PELMO 6.6.4)

Scenario	Terbuthylazine µg/L	MT1 desethyl-terbuthylazine µg/L	MT13 hydroxy-terbuthylazine µg/L	MT14 desethyl-hydroxy ter-buthylazine µg/L	LM1 µg/L	LM2 µg/L	LM3 µg/L	LM4 µg/L	LM5 µg/L	LM6 µg/L
maize BBCH 00 (application rate 750 g as/ha) – application every 3rd year										
Châteaudun	0.000	0.000	**0.613**	0.059	0.000	**0.134**	**0.118**	**0.252**	0.036	**0.576**
Hamburg	0.000	0.000	**0.443**	0.048	0.000	**0.171**	**0.151**	**0.285**	0.040	**0.517**
Kremsmünster	0.000	0.000	**0.575**	0.094	0.000	**0.171**	**0.150**	**0.344**	0.054	**0.465**
Okehampton	0.000	0.002	**0.659**	**0.144**	0.000	**0.189**	**0.153**	**0.395**	0.093	**0.368**
Piacenza	0.001	0.078	**1.238**	**0.545**	0.001	**0.245**	**0.187**	**0.548**	**0.243**	**0.413**
Porto	0.000	0.001	**0.664**	**0.160**	0.001	**0.109**	0.084	**0.195**	**0.141**	**0.302**
Sevilla	0.000	0.000	**0.280**	0.008	0.000	0.052	0.042	0.070	0.012	**0.524**
Thiva	0.000	0.000	**1.536**	0.209	0.000	**0.241**	**0.210**	**0.483**	0.107	**1.034**

Table 8.8-5: PECgw for terbuthylazine and metabolites on maize, application rate: 500 g as/ha (10 days before emergence; PELMO 6.6.4)

Scenario	Terbuthylazine µg/L	MT1 desethyl-terbuthylazine µg/L	MT13 hydroxy-terbuthylazine µg/L	MT14 desethyl-hydroxy ter-buthylazine µg/L	LM1 µg/L	LM2 µg/L	LM3 µg/L	LM4 µg/L	LM5 µg/L	LM6 µg/L
maize BBCH 00 (application rate 500 g as/ha) – application every 3rd year										
Châteaudun	0.000	0.000	**0.374**	0.034	0.000	0.088	0.077	**0.159**	0.020	**0.378**
Hamburg	0.000	0.000	**0.267**	0.028	0.000	**0.113**	0.099	**0.178**	0.023	**0.339**
Kremsmünster	0.000	0.000	**0.353**	0.055	0.000	**0.111**	0.097	**0.218**	0.032	**0.305**
Okehampton	0.000	0.001	**0.411**	0.085	0.000	**0.125**	0.101	**0.253**	0.055	**0.243**
Piacenza	0.001	0.042	**0.778**	**0.340**	0.001	**0.164**	**0.124**	**0.358**	**0.152**	**0.274**
Porto	0.000	0.000	**0.417**	0.096	0.001	0.073	0.055	**0.125**	0.086	**0.201**
Sevilla	0.000	0.000	**0.163**	0.004	0.000	0.034	0.027	0.043	0.007	**0.343**
Thiva	0.000	0.000	**0.953**	**0.123**	0.000	**0.159**	**0.137**	**0.309**	**0.063**	**0.676**

Table 8.8-6: PECgw for terbuthylazine and metabolites on maize, application rate: 750 g as/ha (10 days after emergence; PELMO 6.6.4)

Scenario	Terbuthylazine µg/L	MT1 desethyl-terbuthylazine µg/L	MT13 hydroxy-terbuthylazine µg/L	MT14 desethyl-hydroxy ter-buthylazine µg/L	LM1 µg/L	LM2 µg/L	LM3 µg/L	LM4 µg/L	LM5 µg/L	LM6 µg/L
maize BBCH 12-16 (application rate 750 g as/ha) – application every 3rd year										
Châteaudun	0.000	0.000	**0.480**	0.042	0.000	**0.129**	**0.114**	**0.243**	0.025	0.512
Hamburg	0.000	0.000	**0.331**	0.039	0.000	**0.197**	**0.172**	**0.338**	0.031	0.452
Kremsmünster	0.000	0.000	**0.422**	0.062	0.000	**0.172**	**0.145**	**0.345**	0.036	0.416
Okehampton	0.000	0.001	**0.516**	0.099	0.000	**0.186**	**0.148**	**0.375**	0.062	0.343
Piacenza	0.001	0.070	**1.105**	**0.490**	0.001	**0.255**	**0.201**	**0.621**	**0.216**	0.392
Porto	0.000	0.001	**0.609**	**0.149**	0.001	**0.124**	0.095	**0.221**	**0.133**	0.289
Sevilla	0.000	0.000	**0.223**	0.007	0.000	0.044	0.035	0.054	0.011	0.478
Thiva	0.000	0.001	**1.378**	**0.191**	0.000	**0.277**	**0.239**	**0.563**	0.099	0.955

Table 8.8-7: PECgw for terbuthylazine and metabolites on maize, application rate: 500 g as/ha (10 days after emergence; PELMO 6.6.4)

Scenario	Terbuthylazine µg/L	MT1 desethyl-terbuthylazine µg/L	MT13 hydroxy-terbuthylazine µg/L	MT14 desethyl-hydroxy ter-buthylazine µg/L	LM1 µg/L	LM2 µg/L	LM3 µg/L	LM4 µg/L	LM5 µg/L	LM6 µg/L
maize BBCH 12-16 (application rate 500 g as/ha) – application every 3rd year										
Châteaudun	0.000	0.000	**0.289**	0.024	0.000	0.084	0.074	**0.153**	0.014	**0.333**
Hamburg	0.000	0.000	**0.200**	0.023	0.000	**0.130**	**0.113**	**0.212**	0.017	**0.295**
Kremsmünster	0.000	0.000	**0.258**	0.037	0.000	**0.113**	0.094	**0.218**	0.021	**0.273**
Okehampton	0.000	0.000	**0.318**	0.057	0.000	**0.123**	0.098	**0.238**	0.036	**0.226**
Piacenza	0.001	0.037	**0.692**	**0.299**	0.001	**0.170**	**0.133**	**0.405**	**0.134**	**0.260**
Porto	0.000	0.000	**0.383**	0.088	0.000	0.083	0.063	**0.142**	0.081	**0.193**
Sevilla	0.000	0.000	**0.130**	0.004	0.000	0.029	0.022	0.033	0.006	**0.311**
Thiva	0.000	0.000	**0.849**	**0.108**	0.000	**0.182**	**0.156**	**0.360**	0.059	**0.629**

Table 8.8-8: PECgw for terbuthylazine and metabolites on maize, application rate: 750 g as/ha (10 days before emergence; PEARL 5.5.5)

Scenario	**Terbuthylazine µg/L**	**MT1 desethyl-terbuthylazine µg/L**	**MT13 hydroxy-terbuthylazine µg/L**	**MT14 desethyl-hydroxy ter-buthylazine µg/L**	**LM1 µg/L**	**LM2 µg/L**	**LM3 µg/L**	**LM4 µg/L**	**LM5 µg/L**	**LM6 µg/L**
maize BBCH 00 (application rate 750 g as/ha) – application every 3rd year										
Châteaudun	0.000079	0.020838	**4.803076**	**0.712864**	0.003357	**0.869871**	**0.670652**	**2.007459**	**0.840856**	**1.443552**
Hamburg	0.001010	0.070159	**5.756388**	**0.982049**	0.004367	**1.302434**	**0.945830**	**2.963227**	**1.212409**	**1.297841**
Kremsmünster	0.000543	0.044732	**4.132021**	**0.715184**	0.003032	**0.858957**	**0.639997**	**2.021142**	**0.765668**	**1.131517**
Okehampton	0.001678	**0.118059**	**4.207604**	**0.994989**	0.003005	**0.750679**	**0.506428**	**1.960786**	**0.786506**	**0.601440**
Piacenza	0.000839	0.061970	**4.774301**	**0.736981**	0.002871	**0.609042**	**0.532135**	**1.377031**	**0.790388**	**1.476498**
Porto	0.000056	0.014132	**2.441093**	**0.423765**	0.002415	**0.374242**	**0.284739**	**0.809341**	**0.528018**	**0.551154**
Sevilla	0.000000	0.000124	**1.679687**	0.066343	0.001219	**0.289626**	**0.242064**	**0.504266**	**0.273450**	**2.023135**
Thiva	0.000004	0.003121	**7.139466**	**0.594952**	0.003415	**0.840482**	**0.725417**	**1.827474**	**0.884961**	**3.911373**

Table 8.8-9: PECgw for terbuthylazine and metabolites on maize, application rate: 500 g as/ha (10 days before emergence; PEARL 5.5.5)

Scenario	Terbuthylazine µg/L	MT1 desethyl-terbuthylazine µg/L	MT13 hydroxy-terbuthylazine µg/L	MT14 desethyl-hydroxy ter-buthylazine µg/L	LM1 µg/L	LM2 µg/L	LM3 µg/L	LM4 µg/L	LM5 µg/L	LM6 µg/L
maize BBCH 00 (application rate 500 g as/ha) – application every 3rd year										
Châteaudun	0.000037	0.010574	**3.064153**	**0.438458**	0.002177	**0.580834**	**0.444053**	**1.300527**	**0.533006**	**0.966562**
Hamburg	0.000573	0.037041	**3.706872**	**0.611567**	0.002807	**0.877351**	**0.627337**	**1.882986**	**0.775290**	**0.878966**
Kremsmünster	0.000291	0.023883	**2.636554**	**0.444189**	0.001971	**0.573165**	**0.425803**	**1.305858**	**0.487180**	**0.764164**
Okehampton	0.000872	0.064012	**2.719294**	**0.623345**	0.001979	**0.505261**	**0.338417**	**1.281690**	**0.509985**	**0.410714**
Piacenza	0.000444	0.033721	**3.014877**	**0.460666**	0.001824	**0.398661**	**0.351232**	**0.880928**	**0.498963**	**0.989558**
Porto	0.000027	0.007268	**1.585464**	**0.262103**	0.001617	**0.251504**	**0.188698**	**0.526681**	**0.339284**	**0.372632**
Sevilla	0.000000	0.000045	**1.018250**	0.038609	0.000758	**0.192557**	**0.158540**	**0.320718**	**0.164093**	**1.319935**
Thiva	0.000002	0.001477	**4.530008**	**0.355667**	0.002180	**0.552681**	**0.475367**	**1.171744**	**0.554823**	**2.585014**

Table 8.8-10: PECgw for terbuthylazine and metabolites on maize, application rate: 750 g as/ha (10 days after emergence; PEARL 5.5.5)

Scenario	Terbuthylazine µg/L	MT1 desethyl-terbuthylazine µg/L	MT13 hydroxy-terbuthylazine µg/L	MT14 desethyl-hydroxy ter-buthylazine µg/L	LM1 µg/L	LM2 µg/L	LM3 µg/L	LM4 µg/L	LM5 µg/L	LM6 µg/L
maize BBCH 12-16 (application rate 750 g as/ha) – application every 3rd year										
Châteaudun	0.000044	0.014209	**3.503290**	**0.512251**	0.002497	**0.668906**	**0.512745**	**1.518788**	**0.613953**	**1.084408**
Hamburg	0.000908	0.051941	**4.219805**	**0.716994**	0.003196	**1.011050**	**0.711260**	**2.260412**	**0.884346**	**0.983631**
Kremsmünster	0.000462	0.032431	**3.022445**	**0.520825**	0.002232	**0.661815**	**0.485047**	**1.538893**	**0.554998**	**0.849781**
Okehampton	0.001436	0.087511	**3.066727**	**0.712945**	0.002241	**0.582723**	**0.387006**	**1.498810**	**0.580962**	**0.455215**
Piacenza	0.000488	0.041949	**3.523421**	**0.539045**	0.002120	**0.483538**	**0.411236**	**1.074963**	**0.581293**	**1.109364**
Porto	0.000037	0.010231	**1.815446**	**0.311628**	0.001832	**0.305133**	**0.228517**	**0.637185**	**0.389014**	**0.415821**
Sevilla	0.000000	0.000060	**1.179760**	0.048276	0.000880	**0.235434**	**0.194871**	**0.400151**	**0.191041**	**1.502244**
Thiva	0.000004	0.002220	**5.210659**	**0.437448**	0.002546	**0.654429**	**0.560157**	**1.403083**	**0.652084**	**2.929205**

Table 8.8-11: PECgw for terbuthylazine and metabolites on maize, application rate: 500 g as/ha (10 days after emergence; PEARL 5.5.5)

Scenario	Terbuthylazine µg/L	MT1 desethyl-terbuthylazine µg/L	MT13 hydroxy-terbuthylazine µg/L	MT14 desethyl-hydroxy ter-buthylazine µg/L	LM1 µg/L	LM2 µg/L	LM3 µg/L	LM4 µg/L	LM5 µg/L	LM6 µg/L
maize BBCH 12-16 (application rate 500 g as/ha) – application every 3rd year										
Châteaudun	0.000021	0.007120	**2.232919**	**0.314072**	0.001610	**0.446670**	**0.339355**	**0.982313**	**0.386629**	**0.726061**
Hamburg	0.000516	0.027797	**2.701132**	**0.449111**	0.002050	**0.681063**	**0.471827**	**1.436324**	**0.564185**	**0.665761**
Kremsmünster	0.000231	0.017222	**1.939135**	**0.324415**	0.001446	**0.441551**	**0.321467**	**0.992247**	**0.351969**	**0.573595**
Okehampton	0.000737	0.047557	**1.977493**	**0.444804**	0.001480	**0.391861**	**0.258048**	**0.976026**	**0.377497**	**0.311644**
Piacenza	0.000257	0.022599	**2.223385**	**0.334423**	0.001344	**0.318956**	**0.270352**	**0.693850**	**0.365966**	**0.743628**
Porto	0.000017	0.005239	**1.172700**	**0.190897**	0.001224	**0.204092**	**0.151352**	**0.410484**	**0.249246**	**0.281169**
Sevilla	0.000000	0.000022	**0.713439**	0.027892	0.000547	**0.156464**	**0.127555**	**0.253864**	**0.114225**	**0.977271**
Thiva	0.000002	0.001042	**3.302261**	**0.260755**	0.001622	**0.429886**	**0.366616**	**0.897166**	**0.407723**	**1.934892**

Table 8.8-12: PECgw for terbuthylazine and metabolites on maize, application rate: 750 g as/ha (10 days before emergence; MACRO 5.5.4)

Scenario	Terbuthylazine µg/L	MT1 desethyl-terbuthylazine µg/L	MT13 hydroxy-terbuthylazine µg/L	MT14 desethyl-hydroxy ter-buthylazine µg/L	LM1 µg/L	LM2 µg/L	LM3 µg/L	LM4 µg/L	LM5 µg/L	LM6 µg/L
maize BBCH 00 (application rate 750 g as/ha) – application every 3rd year										
Châteaudun	0.001	0.002	0.007	**0.382**	0.000	**0.136**	0.000	**1.3**	**0.426**	**1.24**

Table 8.8-13: PECgw for terbuthylazine and metabolites on maize, application rate: 500 g as/ha (10 days before emergence; MACRO 5.5.4)

Scenario	Terbuthylazine µg/L	MT1 desethyl-terbuthylazine µg/L	MT13 hydroxy-terbuthylazine µg/L	MT14 desethyl-hydroxy ter-buthylazine µg/L	LM1 µg/L	LM2 µg/L	LM3 µg/L	LM4 µg/L	LM5 µg/L	LM6 µg/L
maize BBCH 00 (application rate 750 g as/ha) – application every 3rd year										
Châteaudun	0.000	0.001	0.004	**0.235**	0.000	0.091	0.000	**0.828**	**0.265**	**0.82**

Table 8.8-14: PECgw for terbuthylazine and metabolites on maize, application rate: 750 g as/ha (10 days after emergence; MACRO 5.5.4)

Scenario	Terbuthylazine µg/L	MT1 desethyl-terbuthylazine µg/L	MT13 hydroxy-terbuthylazine µg/L	MT14 desethyl-hydroxy ter-buthylazine µg/L	LM1 µg/L	LM2 µg/L	LM3 µg/L	LM4 µg/L	LM5 µg/L	LM6 µg/L
maize BBCH 12 (application rate 750 g as/ha) – application every 3rd year										
Châteaudun	0.000	0.001	0.003	**0.380**	0.000	**0.146**	0.000	**1.34**	**0.437**	**1.26**

Table 8.8-15: PECgw for terbuthylazine and metabolites on maize, application rate: 500 g as/ha (10 days after emergence; MACRO 5.5.4)

Scenario	Terbuthylazine µg/L	MT1 desethyl-terbuthylazine µg/L	MT13 hydroxy-terbuthylazine µg/L	MT14 desethyl-hydroxy ter-buthylazine µg/L	LM1 µg/L	LM2 µg/L	LM3 µg/L	LM4 µg/L	LM5 µg/L	LM6 µg/L
maize BBCH 12 (application rate 750 g as/ha) – application every 3rd year										
Châteaudun	0.000	0.000	0.001	**0.231**	0.000	0.097	0.033	**0.863**	**0.270**	**0.834**

In accordance with COMMISSION IMPLEMENTING REGULATION (EU) 2021/824 of 21 May 2021 amending Implementing Regulations (EU) No 540/2011 and (EU) No 820/2011 *as regards the conditions of approval of the active substance terbuthylazine,* use of terbuthylazine shall be limited to one application every three years on the same field at a maximum dose of 850 g terbuthylazine per hectare. Having regard to the above results for annual application are not considered.

Terbuthylazine and LM1

PECgw for the active substance and metabolite LM1 are below the trigger value of 0.1 µg/L. There is no unacceptable risk of groundwater contamination with those molecules.

MT1, MT13, MT14, LM2, LM3, LM4, LM5, LM6

PECgw are above the trigger value of 0.1 µg/L and in most cases above the trigger value of 0.75 µg/L. Further evaluation of metabolites relevance is necessary. Please refer to dRR Part B Section 10.

Comments RMS:

The calculations were accepted.
The calculations have been done according to FOCUS Groundwater guidelines. Models FOCUS-PEARL and FOCUS-PELMO and MACRO have been used.
All parameters have been taken according to List of Endpoints EFSA Journal 2011; 9(1):1969 or confirmatory data 10.2903/j.efsa.2019.5817.
The results of the simulations in both mentioned FOCUS groundwater models indicate that the overall maximum PECgw of metabolites were above 0.1 µg/L in most of the scenarios considered.
Updated peer review of the pesticide risk assessment for the active substance terbuthylazine in light of confirmatory (10.2903/j.efsa.2019.5817 includes an assessment in regard to metabolites.
In accordance with COMMISSION IMPLEMENTING REGULATION (EU) 2021/824 of 21 May 2021 amending Implementing Regulations (EU) No 540/2011 and (EU) No 820/2011 as regards the conditions of approval of the active substance terbuthylazine shall be limited to one application every three years on the same field at a maximum dose of 850 g terbuthylazine per hectare.
Having regard to the above regulation calculations submitted by applicant PECgw were performed for application of terbuthylazine for every 3rd year in this same field.
The PECgw for terbuthylazine, are below the trigger value 0,1 µg/L.
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.

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

8.9.1 Justification for new endpoints

Not relevant. No new endpoints proposed.

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

PECsw for terbuthylazine and its metabolites after application to maize were calculated with STEPS

1-2 in FOCUS v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXSWA v5.5.3, SWAN v5.0.1 Application timing for each crop/scenario was settled with AppDate 3.06. Input parameters related to application and active substance/metabolites data for PECsw/sed calculation are summarized below.

Table 8.9-1: Input parameters related to application for PECsw/sed calculations

Use No.	1, 2	
Crop	maize	maize
Application rate (g/ha)	750	500
Number of applications/intervals	1/-	1/-
Time of application:	March-May	March-May
Models used for calculation	Steps 1-2 in FOCUS 3.2, FOCUS SWASH 5.3, FOCUS PRZM 4.3.1, FOCUS MACRO 5.5.4, FOCUS TOXWA 5.5.3	

Table 8.9-2: FOCUS Step 3 and 4 scenario related input parameters for PECsw/sed calculations

Crop	Application window used in modelling (AppDate 3.06)		
Maize BBCH 00	**Scenario**	**first possible appl at BBCH 00**	**last possible appl at BBCH 00**
	D3	25-April (115)	25-May (145)
	D4	30-April (120)	30-May (150)
	D5	30-April (120)	30-May (150)
	D6	10-Apr (100)	10-May (130)
	R1	23-Apr (113)	13-May (143)
	R2	21-Apr (111)	21-May (141)
	R3	21-Apr (111)	21-May (141)
	R4	31- Mar (90)	30-Apr (120)
Maize BBCH 12-16	**Scenario**	**first possible appl at BBCH 12**	**last possible appl at BBCH 16**
	D3	12-May (132)	24-Jun (175)
	D4	18-May (138)	30-Jun (181)
	D5	15-May (135)	23-Jun (174)
	D6	25-April (115)	1-Jun (152)
	R1	10-May (130)	22-Jun (173)
	R2	9-May (129)	22-Jun (173)
	R3	8-May (128)	18-Jun (169)
	R4	15-Apr (105)	24-May (144)

Table 8.9-3: Input parameters related to active substance terbuthylazine for $PEC_{sw/sed}$ calculations

Compound	Terbuthylazine	MT1 desethyl-terbuthylazine	MT13 hydroxy-terbuthylazine	MT14 Desethyl hydroxy- terbuthylazine	MT26 terbutryn	Value in ac- accordance to EU endpoint y/n Reference
Molecular weight (g/mol)	229.7	201.7	211.3	183.2	241.4	Yes, EFSA Journal 2017; 15(6):4868
Water solubility (mg/L)	8.5 at 20°C	327.1 at 20°C	7.19 at 20°C	18 at 25°C	8.5 at 20°C	Yes / EFSA Journal 2011; 9(1):1969
Saturated vapour pressure (Pa):	0 at 20°C	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	Yes, EFSA Journal 2017; 15(6):4868
DT_{50} in soil (d)	20 (median, field studies, normalisation to pF2, 20°C with Q10 of 2.58, n=16)	26.8 (geometric mean, field studies, normalisation to pF2, 20°C with Q10 of 2.58, n=10)	453 (normalised, geometric mean, lab studies, normalisation to pF2, 20°C with Q10 of 2.58, n=6)	107 (geometric mean, lab studies, normalisation to pF2, 20°C with Q10 of 2.58, n=7)	0.1 (surrogate value for non-soil metabolite)	Yes, EFSA Journal 2017; 15(6):4868
K_{foc} (mL/g)/~~K_{fom}~~	151 / 87.59 (worst case, lowest Kfoc value)	77.7 / 45.07 (arithmetic mean, n=9)	187 / 108.47 (arithmetic mean, n=7)	111 / 64.39 (median, n=11)	518 /300.5 (arithmetic mean, n = 5)	Yes / EFSA Journal 2011; 9(1):1969
1/n	0.93 (arithmetic mean)	0.89 (arithmetic mean)	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	Yes, EFSA Journal 2017; 15(6):4868
$DT_{50,water}$ (d)	1000	1000	1000	1000	1000	Yes, EFSA Journal 2017; 15(6):4868
$DT_{50,sed}$ (d)	69.9	1000	1000	1000	190	Yes, EFSA Journal 2017; 15(6):4868
$DT_{50,system}$ (d)	69.9	1000	1000	1000	190	Yes, EFSA Journal 2017;

Compound	**Ter-buthylazine**	**MT1 desethyl-terbuthylazine**	**MT13 hydroxy-terbuthylazine**	**MT14 Desethyl hy-droxy- ter-buthylazine**	**MT26 terbutryn**	**Value in ac-accord-ance to EU endpoint y/n Reference**
						15(6):4868
Plant up-take factor	0	0	0	0	0	Yes, EFSA Journal 2017; 15(6):4868
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 7.3% Wa-ter/sediment: 45%	Soil: 34.5% Wa-ter/sediment: 20%	Soil: 28% Wa-ter/sediment: 0.001%	Soil: 0.001% Wa-ter/sediment: 7.4%	Yes, EFSA Journal 2017; 15(6):4868
		Formation fraction (soil): 0.44				Yes, EFSA Journal 2017; 15(6):4868

Table 8.9-4: FOCUS Step 1, 2 and 3 PECsw and PECsed for terbuthylazine following single application of H-01-2022, pre-emergence application

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	21d TWA PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
maize BBCH 00 (application rate 750 g as/ha)					
Step 1	NR	214.9996	193.0740	NR	319.7177
Step 2 NEU	NR	42.2782	41.0357	NR	62.6953
Step 3					
D3	ditch	3.935	0.2211	drainage	1.034
D4	pond	0.2505	0.2433	drainage	0.7808
D4	stream	3.377	0.1316	drainage	0.2334
D5	pond	0.2413	0.2244	drainage	0.6128
D5	stream	3.386	0.04470	drainage	0.2196
D6	ditch	3.949	0.2906	drainage	1.180
R1	pond	0.3481	0.3297	runoff and erosion	0.7438
R1	stream	10.85	0.3766	runoff and erosion	2.078
R2	stream	8.229	0.3230	runoff and erosion	1.790
R3	stream	3.846	0.09701	runoff and erosion	0.5801
R4	stream	26.38	1.245	runoff and erosion	6.932
maize BBCH 00 (application rate 500 g as/ha)					
Step 1	NR	143.3331	128.7160	NR	213.1452
Step 2 NEU	NR	28.1854	27.3571	NR	41.7969
Step 3					
D3	ditch	2.623	0.1474	drainage	0.6979
D4	pond	0.1661	0.1613	drainage	0.5238
D4	stream	2.250	0.08737	drainage	0.1564
D5	pond	0.1588	0.1475	drainage	0.4067
D5	stream	2.256	0.02854	drainage	0.1444
D6	ditch	2.631	0.1928	drainage	0.7938
R1	pond	0.2347	0.2230	runoff and erosion	0.5099
R1	stream	7.160	0.2523	runoff and erosion	1.386
R2	stream	5.391	0.2124	runoff and erosion	1.188
R3	stream	2.564	0.06750	runoff and erosion	0.3906
R4	stream	17.45	0.8267	runoff and erosion	4.647

Table 8.9-5: FOCUS Step 1, 2 and 3 PECsw and PECsed for terbuthylazine following single application of H-01-2022, post- emergence application

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	21d TWA PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
maize BBCH 12-16, application rate 750 g as/ha					
Step 1	NR	214.9996	193.0740	NR	319.7177
Step 2 NEU	NR	33.2200	32.1733	NR	49.1525
Step 3					
D3	ditch	3.936	0.2268	drainage	1.047
D4	pond	0.2602	0.2530	drainage	0.8268
D4	stream	3.379	0.1358	drainage	0.2505
D5	pond	0.2773	0.2600	drainage	0.7520
D5	stream	3.551	0.06655	drainage	0.3189
D6	ditch	3.948	0.2096	drainage	1.031
R1	pond	1.236	1.112	runoff and erosion	2.155
R1	stream	17.97	0.7390	runoff and erosion	5.378
R2	stream	9.993	0.3147	runoff and erosion	2.570
R3	stream	24.39	0.9646	runoff and erosion	5.092
R4	stream	25.81	1.171	runoff and erosion	6.795
maize BBCH 12-16, application rate 500 g as/ha					
Step 1	NR	143.3331	128.7160	NR	213.1452
Step 2 NEU	NR	22.1467	21.4489	NR	32.7683
Step 3					
D3	ditch	2.624	0.1512	drainage	0.7068
D4	pond	0.1724	0.1676	drainage	0.5539
D4	stream	2.252	0.09006	drainage	0.1676
D5	pond	0.1816	0.1701	drainage	0.5002
D5	stream	2.366	0.04233	drainage	0.2093
D6	ditch	2.631	0.1389	drainage	0.6928
R1	pond	0.8149	0.7331	runoff and erosion	1.441
R1	stream	11.84	0.4869	runoff and erosion	3.598
R2	stream	6.518	0.2056	runoff and erosion	1.700
R3	stream	16.07	0.6375	runoff and erosion	3.397
R4	stream	17.07	0.7781	runoff and erosion	4.553

Table 8.9-6: Global maximum Step 4PEC$_{sw}$ values for terbuthylazine, following application of H-01-2022, pre-emergence application 750 g as/ha

PEC$_{sw}$ (µg/L)	Scenario	STEP 4						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
None	D3 ditch	3.935	1.290	0.6839	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D4 pond	0.2505	0.2469	0.2387	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D4 stream	3.377	1.425	0.7589	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D5 pond	0.2413	0.2244	0.1845	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D5 stream	3.386	1.442	0.7779	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D6 ditch	3.949	1.303	0.6969	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1 pond	0.3481	0.3349	0.3040	-	0.1419	0.1020	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1 stream	10.85	10.85	10.85	-	1.145	0.6071	-

PEC_{sw} (µg/L)	Scenario	STEP 4						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R2 stream	8.229	8.229	8.229	-	1.522	0.8071	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R3 stream	3.846	1.736	1.736	-	1.619	0.8589	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R4 stream	26.38	26.38	26.38	-	1.144	0.6070	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-

Table 8.9-7: Global maximum Step 4PEC$_{sw}$ values for terbuthylazine, following application of H-01-2022, pre-emergence application 500 g as/ha

PEC_{sw} (µg/L)	Scenario	STEP 4						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
None	D3 ditch	2.623	0.8597	0.4558	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D4 pond	0.1661	0.1638	0.1583	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-

PEC$_{SW}$ (µg/L)	**Scenario**	**STEP 4**						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
90 %		-	-	-	-	-	-	-
None	D4 stream	2.250	0.9499	0.5055	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D5 pond	0.1588	0.1475	0.1209	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D5 stream	2.256	0.9605	0.5176	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D6 ditch	2.631	0.8674	0.4635	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1 pond	0.2347	0.2259	0.2053	-	0.09458	0.06800	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1 stream	7.160	7.160	7.160	-	0.7631	0.4046	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R2 stream	5.391	5.391	5.391	-	1.015	0.5378	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R3 stream	2.564	1.217	1.217	-	1.080	0.5724	-
50 %		-	-	-	-	-	-	-

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R4 stream	17.45	17.45	17.45	-	0.7630	0.4045	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-

Table 8.9-8: Global maximum Step 4PEC_{sw} values for terbuthylazine, following application of H-01-2022, post-emergence application 750 g as/ha

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
None	D3 ditch	3.936	1.290	0.6841	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D4 pond	0.2602	0.2567	0.2485	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D4 stream	3.379	1.428	0.7622	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D5 pond	0.2773	0.2603	0.2204	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-

PEC_{sw} (µg/L)	Scenario	STEP 4						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
None	D5 stream	3.551	1.515	0.8198	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D6 ditch	3.948	1.308	0.7039	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1 pond	1.236	1.221	1.185	-	0.1943	0.1020	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1 stream	17.97	17.97	17.97	-	1.268	0.6088	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R2 stream	9.993	9.993	9.993	-	1.535	0.8144	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R3 stream	24.39	24.39	24.39	-	1.611	0.8547	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R4 stream	25.81	25.81	25.81	-	1.144	0.6070	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-

Table 8.9-9: Global maximum Step 4PEC$_{sw}$ values for terbuthylazine, following application of H-01-2022, post-emergence application 500 g as/ha

PEC$_{sw}$ (µg/L)	**Scenario**	**STEP 4**						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
None	D3 ditch	2.624	0.8598	0.4559	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D4 pond	0.1724	0.1701	0.1646	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D4 stream	2.252	0.9520	0.5076	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D5 pond	0.1816	0.1703	0.1437	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D5 stream	2.366	1.009	0.5452	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D6 ditch	2.631	0.8713	0.4683	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1 pond	0.8149	0.8048	0.7810	-	0.1289	0.06800	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1 stream	11.84	11.84	11.84	-	0.8354	0.4057	-

PEC$_{sw}$ (µg/L)	**Scenario**	**STEP 4**						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R2 stream	6.518	6.518	6.518	-	1.024	0.5427	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R3 stream	16.07	16.07	16.07	-	1.074	0.5696	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R4 stream	17.07	17.07	17.07	-	0.7630	0.4045	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-

Metabolites of terbuthylazine

Table 8.9-10: FOCUS Step 1 and 2 PECsw and PECsed for metabolite MT1 following single application of H-01-2022, pre-emergence and post-emergence application

Scenario FOCUS	**Waterbody**	**Max PEC$_{sw}$ (µg/L)**	**21d TWA PEC$_{sw}$ (µg/L)**	**Dominant entry route**	**Max PEC$_{sed}$ (µg/kg)**
maize BBCH 00 (application rate 750 g as/ha)					
Step 1	NR	106.7594	105.7383	NR	82.6959
Step 2 NEU	NR	20.7462	20.5189	NR	16.0469
maize BBCH 00 (application rate 500 g as/ha)					
Step 1	NR	71.1730	70.4922	NR	55.1306
Step 2 NEU	NR	13.8308	13.6793	NR	10.6979

maize BBCH 12-16, application rate 750 g as/ha					
Step 1	NR	106.7594	105.7383	NR	82.6959
Step 2 NEU	NR	16.1953	16.0009	NR	12.5132
maize BBCH 12-16, application rate 500 g as/ha					
Step 1	NR	71.1730	70.4922	NR	55.1306
Step 2 NEU	NR	10.7969	10.6673	NR	8.3422

Table 8.9-11: FOCUS Step 1 and 2 PECsw and PECsed for metabolite MT13 following single application of H-01-2022, pre-emergence and post-emergence application

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	21d TWA PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
maize BBCH 00 (application rate 750 g as/ha)					
Step 1	NR	101.5911	100.6099	NR	189.3705
Step 2 NEU	NR	20.1189	19.9032	NR	37.4614
maize BBCH 00 (application rate 500 g as/ha)					
Step 1	NR	67.7274	67.0733	NR	126.2470
Step 2 NEU	NR	13.4126	13.2688	NR	24.9742
maize BBCH 12-16, application rate 750 g as/ha					
Step 1	NR	101.5911	100.6099	NR	189.3705
Step 2 NEU	NR	15.3604	15.1792	NR	28.5692
maize BBCH 12-16, application rate 500 g as/ha					
Step 1	NR	67.7274	67.0733	NR	126.2470
Step 2 NEU	NR	10.2403	10.1195	NR	19.0462

Table 8.9-12: FOCUS Step 1 and 2 PECsw and PECsed for metabolite MT14 following single application of H-01-2022, pre-emergence and post-emergence application

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	21d TWA PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
maize BBCH 00 (application rate 750 g as/ha)					
Step 1	NR	48.6336	48.2814	NR	53.9833
Step 2 NEU	NR	9.4779	9.4093	NR	10.5205
maize BBCH 00 (application rate 500 g as/ha)					

Step 1	NR	32.4224	32.1876	NR	35.9888
Step 2 NEU	NR	6.3186	6.2729	NR	7.0137
maize BBCH 12-16, application rate 750 g as/ha					
Step 1	NR	48.6336	48.2814	NR	53.9833
Step 2 NEU	NR	7.1855	7.1334	NR	7.9759
maize BBCH 12-16, application rate 500 g as/ha					
Step 1	NR	32.4224	32.1876	NR	35.9888
Step 2 NEU	NR	4.7903	4.7556	NR	5.3172

Table 8.9-13: FOCUS Step 1 and 2 PECsw and PECsed for metabolite MT26 following single application of H-01-2022, pre-emergence and post-emergence application

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	21d TWA PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
maize BBCH 00 (application rate 750 g as/ha)					
Step 1	NR	12.0378	11.3825	NR	60.9975
Step 2 NEU	NR	2.3677	2.2758	NR	11.9609
maize BBCH 00 (application rate 500 g as/ha)					
Step 1	NR	8.0252	7.5883	NR	40.6650
Step 2 NEU	NR	1.5784	1.5172	NR	7.9740
maize BBCH 12-16, application rate 750 g as/ha					
Step 1	NR	12.0378	11.3825	NR	60.9975
Step 2 NEU	NR	1.8671	1.7845	NR	9.3775
maize BBCH 12-16, application rate 500 g as/ha					
Step 1	NR	8.0252	7.5883	NR	40.6650
Step 2 NEU	NR	1.2447	1.1897	NR	6.2517

Maximum PECsw of terbutryn (MT26) are calculated by the following equation on PECsw of the parent substance terbuthylazine, taking into account the maximum occurrence of terbutryn in water/sediment studies (7.4 %) and molecular weights of the parent and metabolite.

Initial PECsw (terbutryn) = initial PECsw (terbuthylazine) × f_{MOL} × maximum occurrence (%)

where:

f_{MOL}(correction factor) = Molar mass of parent / Molar mass of metabolite = 1.051

Table 8.9-14: FOCUS Step 3 PECsw and PECsed for M26 following single application of H-01-2022, pre-emergence application

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	21d TWA PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
maize BBCH 00 (application rate 750 g as/ha)					
D3	ditch	0.306	-	drainage	-
D4	pond	0.019	-	drainage	-
D4	stream	0.263	-	drainage	-
D5	pond	0.019	-	drainage	-
D5	stream	0.263	-	drainage	-
D6	ditch	0.307	-	drainage	-
R1	pond	0.027	-	runoff and erosion	-
R1	stream	0.844	-	runoff and erosion	-
R2	stream	0.640	-	runoff and erosion	-
R3	stream	0.299	-	runoff and erosion	-
R4	stream	2.052	-	runoff and erosion	-
maize BBCH 00 (application rate 500 g as/ha)					
D3	ditch	0.204	-	drainage	-
D4	pond	0.013	-	drainage	-
D4	stream	0.175	-	drainage	-
D5	pond	0.012	-	drainage	-
D5	stream	0.175	-	drainage	-
D6	ditch	0.205	-	drainage	-
R1	pond	0.018	-	runoff and erosion	-
R1	stream	0.557	-	runoff and erosion	-
R2	stream	0.419	-	runoff and erosion	-
R3	stream	0.199	-	runoff and erosion	-
R4	stream	1.357	-	runoff and erosion	-

Table 8.9-15: FOCUS Step 3 PECsw and PECsed for MT26 following single application of H-01-2022, post- emergence application

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	21d TWA PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
maize BBCH 12-16, application rate 750 g as/ha					
D3	ditch	0.306	-	drainage	-

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	21d TWA PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
maize BBCH 12-16, application rate 750 g as/ha					
D4	pond	0.020	-	drainage	-
D4	stream	0.263	-	drainage	-
D5	pond	0.022	-	drainage	-
D5	stream	0.276	-	drainage	-
D6	ditch	0.307	-	drainage	-
R1	pond	0.096	-	runoff and erosion	-
R1	stream	1.398	-	runoff and erosion	-
R2	stream	0.777	-	runoff and erosion	-
R3	stream	1.897	-	runoff and erosion	-
R4	stream	2.007	-	runoff and erosion	-
maize BBCH 12-16, application rate 500 g as/ha					
D3	ditch	0.204	-	drainage	-
D4	pond	0.013	-	drainage	-
D4	stream	0.175	-	drainage	-
D5	pond	0.014	-	drainage	-
D5	stream	0.184	-	drainage	-
D6	ditch	0.205	-	drainage	-
R1	pond	0.063	-	runoff and erosion	-
R1	stream	0.921	-	runoff and erosion	-
R2	stream	0.507	-	runoff and erosion	-
R3	stream	1.250	-	runoff and erosion	-
R4	stream	1.328	-	runoff and erosion	-

Table 8.9-16: Global maximum Step 4 PEC_{sw} values for MT26, following application of H-01-2022, pre-emergence application 750 g as/ha

PEC_{sw} (µg/L)	Scenario	STEP 4						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
None	D3 ditch	0.306	0.1	0.053	-	-	-	-

PEC$_{sw}$ (µg/L)	**Scenario**	**STEP 4**						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D4 pond	0.019	0.019	0.019	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D4 stream	0.263	0.111	0.059	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D5 pond	0.019	0.017	0.014	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D5 stream	0.263	0.112	0.061	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D6 ditch	0.307	0.101	0.054	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1 pond	0.027	0.026	0.024	-	0.011	0.008	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1 stream	0.844	0.844	0.844	-	0.089	0.047	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
None	R2 stream	0.64	0.64	0.64	-	0.118	0.063	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R3 stream	0.299	0.135	0.135	-	0.126	0.067	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R4 stream	2.052	2.052	2.052	-	0.089	0.047	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-

Table 8.9-17: Global maximum Step 4 PEC_{sw} values for MT26, following application of H-01-2022, pre-emergence application 500 g as/ha

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
None	D3 ditch	0.204	0.067	0.035	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D4 pond	0.013	0.013	0.012	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D4 stream	0.175	0.074	0.039	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
90 %		-	-	-	-	-	-	-
None	D5 pond	0.012	0.011	0.009	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D5 stream	0.175	0.075	0.04	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D6 ditch	0.205	0.067	0.036	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1 pond	0.018	0.018	0.016	-	0.007	0.005	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1 stream	0.557	0.557	0.557	-	0.059	0.031	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R2 stream	0.419	0.419	0.419	-	0.079	0.042	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R3 stream	0.199	0.095	0.095	-	0.084	0.045	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R4 stream	1.357	1.357	1.357	-	0.059	0.031	-
50 %		-	-	-	-	-	-	-

PEC$_{sw}$ (µg/L)	Scenario	STEP 4						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-

Table 8.9-18: Global maximum Step 4 PEC$_{sw}$ values for MT26, following application of H-01-2022, post-emergence application 750 g as/ha

PEC$_{sw}$ (µg/L)	Scenario	STEP 4						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
None	D3 ditch	0.306	0.1	0.053	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D4 pond	0.02	0.02	0.019	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D4 stream	0.263	0.111	0.059	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D5 pond	0.022	0.02	0.017	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D5 stream	0.276	0.118	0.064	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D6 ditch	0.307	0.102	0.055	-	-	-	-

PEC$_{sw}$ (µg/L)	Scenario	STEP 4						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1 pond	0.096	0.095	0.092	-	0.015	0.008	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1 stream	1.398	1.398	1.398	-	0.099	0.047	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R2 stream	0.777	0.777	0.777	-	0.119	0.063	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R3 stream	1.897	1.897	1.897	-	0.125	0.066	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R4 stream	2.007	2.007	2.007	-	0.089	0.047	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-

Table 8.9-19: Global maximum Step 4 PEC$_{sw}$ values for MT26, following application of H-01-2022, post-emergence application 500 g as/ha

PEC$_{sw}$ (µg/L)	Scenario	STEP 4						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
None	D3 ditch	0.204	0.067	0.035	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D4 pond	0.013	0.013	0.013	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D4 stream	0.175	0.074	0.039	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D5 pond	0.014	0.013	0.011	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D5 stream	0.184	0.078	0.042	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	D6 ditch	0.205	0.068	0.036	-	-	-	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1 pond	0.063	0.063	0.061	-	0.01	0.005	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R1 stream	0.921	0.921	0.921	-	0.065	0.032	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**						
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	1/3	5	10	15	5	10	20
90 %		-	-	-	-	-	-	-
None	R2 stream	0.507	0.507	0.507	-	0.08	0.042	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R3 stream	1.25	1.25	1.25	-	0.084	0.044	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-
None	R4 stream	1.328	1.328	1.328	-	0.059	0.031	-
50 %		-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-

Comments ZRMS:

The calculations $PEC_{SW/SED}$ were accepted. The surface water modelling has been performed in accordance with the Generic guidance for FOCUS surface water Scenarios, Version: 1.4, date: May 2015 using FOCUS SWASH v5.3, FOCUS PRZMv4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXSWA v5.5.3, ECPA SWAN v5.0.1.
Input parameters for terbuthylazine and its metabolites have been taken from EFSA Journal 2017; 15(6):4868.

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.

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

The fate and behaviour in air of terbuthylazine were evaluated during the EU peer review. No additional studies have been performed.

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Not studied – no data requested
Quantum yield of direct phototransformation	Not studied – no data requested
Photochemical oxidative degradation in air	DT_{50} of 13.55 h derived by Atkinson model. OH (12h) concentration assumed = 1.5 x 10^6 cm^{-3}
Volatilisation	From plant surfaces: (BBA guideline): ≤ 10.2 % after 24 hours
	From soil: (BBA guideline): ≤ 13.8 % after 24 hours
Metabolites	None

The active substance terbuthylazine has a vapour pressure of 9.0 x 10-5 Pa m3/mol at 25 ºC and could be considered volatile. Volatilization of terbuthylazine from plant was ≤ 10.2 % after 24 hours and from soil ≤ 13.8 % after 24 hours. 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. Terbuthylazine does not need to be assessed for long range transport due to low DT_{50} in air.

Comments ZRMS:

Accepted. The PEC in air was not required.

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
KCP 9.2.4/01	Tabor E.	2024	H-01-2022 Calculation of predicted environmental concentrations of terbuthylazine and its metabolites in groundwater after application to maize using the FOCUS groundwater scenarios (PEARL v5.5.5, FOCUS PELMO v6.6.4 and MACRO v. 5.5.4) Company Report No: EST/1/2024 ESTICON Sp. z o.o. GLP: No Published: No	N	ProAgri International Sp. z o.o.
KCP 9.2.5/01	Tabor E.	2024	H-01-2022 Calculation of Predicted Environmental Concentrations of terbuthylazine and its metabolites in surface water after application to maize using the FOCUS scenarios (Steps 1, 2, 3 and 4) Company Report No: EST/2/2024 ESTICON Sp. z o.o. GLP: No Published: No	N	ProAgri International Sp. z o.o.

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

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

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

Not relevant.

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

Not relevant.