FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: CHR/H/TERIZ 650 WG

Product name(s): Undito 650 WG, Jotamun 650 WG, Metodus 650 WG

Chemical active substance(s):

Terbuthylazine, 400 g/kg
Isoxaflutole, 100 g/kg
Mesotrione, 150 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

Core Assessment- renewal of authorisation
(Poland)

Applicant: Innvigo Sp. Z o.o.

Submission date: October 2019; November 2021; December 2021

MS Finalisation date: December 2021; June 2023

Version history

When	What
October 2019	New data for isoxaflutole based on the renewal of active substance. New data marked in yellow
November 2021	Draft asessment by zRMS
November 2021	New data of calculation for isoxaflutole metabolite. New data marked in green.
December 2021	New data assessed by zRMS based on new calculation of predicted environmental concentration in groundwater.
December 2021	Draft asessment by zRMS
June 2023	Final Registration Report

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8 Fate and behaviour in the environment (KCP 9)

zRMS comments:

Report dRR was prepared by Applicant. All comments and conclusions of the zRMS are presented in grey. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information is struck through and shaded for transparency. New data for isoxaflutole based on the renewal of active substance are marked in yellow.
This document review only new data for isoxflutole, based on the renewal. No new study were performed.
For the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009, the guidance is given in the Document SANCO/2010/13170 for products containing two or more active substances. Assessments for the safe use of CHR/H/TERIZ 650 WG have been made using new endpoints agreed in the EU review of Isoxaflutole (EFSA Journal 2016;14(3):4416).

December 2021
It should be indicated that applicant in meantime changed the GAP Table by limitation of the application rate from 1 kg product/ha to only 0/8 kg product/ha (80 g isoxaflutole/ha).

In consequence, only data on the renewed active substance trifloxystrobin will be evaluated for Post AR review and data on the partner (non-reviewed) fluopyram should be submitted only for the areas of assessments where combined risk assessments are required.

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	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: ~~e.g. g safener/ synergist per ha~~	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Maize (ZEAMX)	F	Mono and dicotsweeds	Spray, medium sprayer	Spring BBCH 00, max. 3 days after sowing	a)1 b)1	n/a	a) 0.8 – 1.0 kg/ha b) 0.8 – 1.0 kg/ha	a) 0.52 kg a.s./ha (T 0.32 + I 0.08 + M 0.12) - 0.65 kg a.s./ha (T 0.4 + I 0.1 + M 0.15 b) 0.52 kg a.s./ha (T 0.32 + I 0.08 + M 0.12) - 0.65 kg a.s./ha (T 0.4 + I 0.1 + M 0.15	200-250	n/a		
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														

Minor uses according to Article 51 (zonal uses)														
Minor uses according to Article 51 (interzonal uses)														

Table 8.1-2a: Critical use pattern of the formulated product after limitation of the application rate from 1 kg product/ha to only 0/8 kg product/ha (80 g isoxaflutole/ha).

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Maize (ZEAMX)	F	Mono and dicotsweeds	Spray, medium sprayer	Spring BBCH 00, max. 3 days after sowing	a)1 b)1	n/a	a) 0.8 kg/ha b) 0.8 kg/ha	a) 0.52 kg a.s./ha (T 0.32 + I 0.08 + M 0.12) b) 0.52 kg a.s./ha (T 0.32 + I 0.08 + M 0.12)	200-250	n/a	**Application rate is 0.8 kg/ha prod-uct due the reduction of isoxaflutole to 80 g /ha and aplication in every third year - for content of RPA 202248 in ground water below trigeer value 0.1 µg/L.**	R- risk mitigation measures required **"aplication in every third year"**
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														

Minor uses according to Article 51 (zonal uses)														
Minor uses according to Article 51 (interzonal uses)														

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 8.1-3: Assessed (critical) uses during approval of Terbuthylazine concerning the Section Environmental Fate (Terbuthylazine SAN-CO/11337/2011 rev 2 - 17 June 2011)

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

	France (N) Germany (N) The Neth-erlands (N)	Maize	F	Annual and perennial broad leaved weeds	Tractor - mounted sprayer	Preemergence Early post emergence (12-16)	1	N/A	1.5 – 1.69 L/ha	740 – 844 g a.s/ha	200 - 500	Not applicable	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Table 8.1-3: Assessed (critical) uses during approval of Isoxaflutole concerning the Section Environmental Fate (EFSA Journal 2016;14(3):4416)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
	CEU	Maize	F	Broad-leaved weeds and grasses	Broadcast spraying	Pre-em to the 3 leaf stage BBCH 0-13	1	N/A	0.42 L/ha	100 g as/ha	150-400	Not appli-cable	
	SEU	Maize	F	Broad-leaved weeds and grasses	Broadcast spraying	Pre-em to the 3 leaf stage BBCH 0-13	1	N/A	0.42 L/ha	100 g as/ha	150-400	Not appli-cable	
	CEU	Sweet corn	F	Broad-leaved weeds and grasses	Broadcast spraying	Pre-emergence stage BBCH 00-09	1	N/A	0.42 L/ha	100 g as/ha	150-400	Not appli-cable	
	SEU	Sweet corn	F	Broad-leaved weeds and grasses	Broadcast spraying	Pre-emergence stage BBCH 00-09	1	N/A	0.42 L/ha	100 g as/ha	150-400	Not appli-cable	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Table 8.1-4: Assessed (critical) uses during approval of Mesotrione concerning the Section Environmental Fate (EFSA Journal 2016;14(3):4419)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
	CEU	EU N&S	F	annual broadleaved weeds and some annual grasses such as Echi-nochloa crus-galli	Foliar spray applica-tion using a hydraulic vehicle-mounted spray equipment	BBCH 12-18	1	N/A	1.2 – 1.5 L/ha	120 g as/ha – 150 g as/ha	200-400	Not applicable	

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

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

8.2 Metabolites considered in the assessment

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

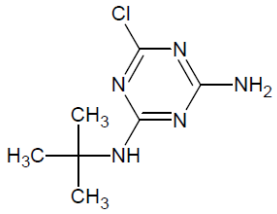
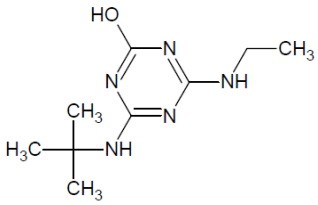
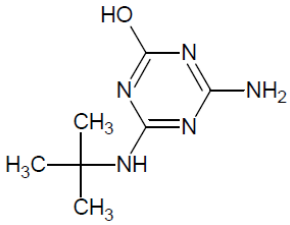
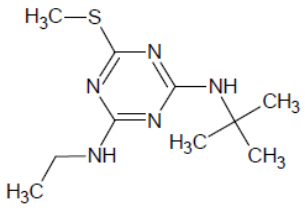
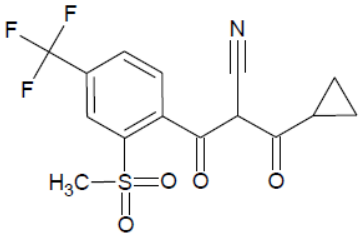
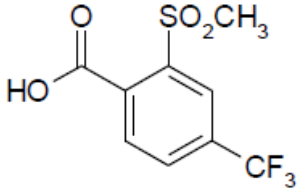
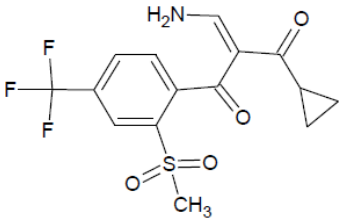
Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
MT1 desethyl-terbuthylazine (GS 26379)	201.7		Soil (lab): max 25.1% AR Maximum occurrence observed in sediment/ water studies: 7.3 %	PECgw: leaching potential to groundwater PECsoil PECsw/sed: if not covered by EU assessment
MT13 Hydroxy-terbuthylazine Or 2-hydroxy ter-buthylazine GS 23158	211.3		Soil (Lab): max 34.5 % AR Maximum occurrence observed in sediment/ water studies: 20.0 %	PECsoil PECgw: leaching potential to groundwater
MT14 desethyl-hydroxyterbuthylazine or desethyl-2-hydroxy terbuthylazine GS 28620	183.2		Soil (Lab): mx 1.7% AR Maximum occurrence observed in sediment/ water studies: N/A (soil metabolite only)	PECsoil PECgw: leaching potential to groundwater PEC sw
MT26	241.4		Maximum occurrence observed in sediment/ water studies: 7.4 %	PECsw

Table 8.2-2: Metabolites of Isoxaflutole potentially relevant for exposure assessment

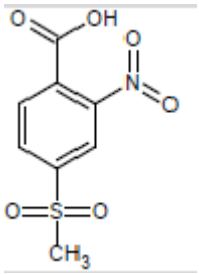
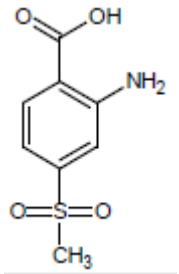
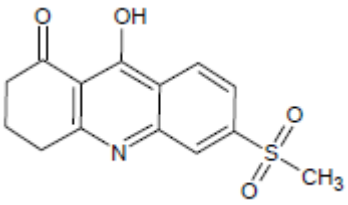
Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
RPA 202248	359.32		Soil (lab): max 96.4 % AR Maximum occurrence observed in sediment/ water studies: 70.3 %	PECsoil PECgw: leaching potential to groundwater PEC sw
RPA 203328	268.22		Soil (Lab): max 90 % AR Maximum occurrence observed in sediment/ water studies: 10.8 %	PECsoil PECgw: leaching potential to groundwater PECsw

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
RPA 205834	361.34		Soil (Lab): mx 2.3 % AR Maximum occurrence observed in sediment/ water studies: 26.4%	PEC sw

zRMS comments:

The metabolites of Isoxaflutole are in line EFSA Journal 2016;14(3):4416.

Table 8.2-3: Metabolites of Mesotrione potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
MNBA	245		Soil (lab): max 57.2 % AR Maximum occurrence observed in sediment/ water studies: 7.9 %	PECsoil PECgw: leaching potential to groundwater PEC sw
AMBA	215		Soil (Lab): max 9.7 % AR Maximum occurrence observed in sediment/ water studies: 24.6 %	PECsoil PEC_{gw}: leaching potential to groundwater PECsw
SYN546974	291		Soil (Lab): mx 1E-10 % AR Maximum occurrence observed in sediment/ water studies: 33%	PEC sw

8.3 Rate of degradation in soil (KCP 9.1.1)

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

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

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

- **Terbuthylazine** - EFSA Journal 2011; 9(1):1969
- **Isoxaflutole** - - EFSA Journal 2016;14(3):4416
- **Mesotrione** - EFSA Journal 2016;14(3):4419

8.3.1.1 Terbuthylazine and its metabolites

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

Terbuthylazine	Aerobic conditions							
Soil name and classification	% OM	pH (KCl or $CaCl_2$)	temp. °C / soil moisture for study (% w/w)	Soil moisture at pF 2 (% w/w)	$DT_{50, actual}$ (d)	$DT_{50, ref}$ 20 °C pF2 (d)	Min chi^2 error (%)	Method of calc.
Gartenacker Sandy Loam	3.79	7.25	20 °C / 26.73 %	48.92	78.7	51.6	1.7	SFO
Pappelacker Loamy Sand	1.9	7.6	20 °C / 15.8 %	29.3	93.1	60.4	2.9	SFO
Weide Sandy Loam	2.24	7.5	20 °C / 18.96 %	36.6	65.0	41.0	2.5	SFO
Speyer 2.2 Loamy Sand	3.91	6.1	20 °C / 19.2 %	12.1	167	167	2.1	SFO
Borstel Loamy Sand	2.59	5.8	20 °C / 10.88 %	14[b]	143	120	1.0	SFO
Lorsch Sandy Clay Loam	3.1	5.3	20 °C / 19.92 %	22[b]	110	103	1.4	SFO
Gartenacker Silt Loam 1.57 kg/ha	3.59	7.32	20 °C / 29.17 %	48.61	77.0	53.9	4.4	SFO
Gartenacker Silt Loam 0.15 kg/ha	3.59	7.32	20 °C / 29.17 %	48.61	59.7	41.8	4.9	SFO
Collombey Sand	2.29	7.7	20 °C / 16.8 %	25.31	80.0	60.0	5.9	SFO
Les Evouettes Silt Loam	2.41	6.1	20 °C / 22.12 %	40.21	58.4	38.2	7.7	SFO
Speyer 2.2 Loamy Sand	4.4	6.0	20 °C / 16.16 %	21.21	122	101	2.2	SFO
Speyer 2.3 Sandy Loam	1.28	6.6	20 °C / 12.56 %	18.61	112	85.2	2.4	SFO
Les Evouettes Loam	6.4	6.8	20 °C / 35.85 %	47.8	69.7	57.0	4.3	SFO
Speyer 2.2 Loamy Sand	3.95	6.18	20 °C / 17.72 %	14[b]	136	138	5.6	SFO
Sisseln Sandy Loam	2.71	7.16	20 °C / 20.96 %	19[b]	83.7	83.7	4.1	SFO
Collombey Loamy Sand	2.02	7.45	20 °C / 16.12 %	14[b]	73.6	73.6	4.2	SFO
Diegten Clay Loam	2.74	6.9	20 °C / 20.76 %	28[b]	117	94.9	1.9	SFO
Geometric mean[a]					**91.1**	**72.0**	-	-
Median					**88.4**	**75.1**	-	-

(a) Geometric mean for replicate soil values calculated first (excluding the two Les Evouettes soils that were considered to be substantially 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-terbuthylazine	Aerobic conditions (where metabolite applied as starting material)							
Soil name and classification	% OM	pH (KCl or $CaCl_2$)	temp. °C / soil moisture for study (% w/w)	Soil moisture at pF 2 (% w/w)	$DT_{50,\ actual}$ (d)	$DT_{50,\ ref}$ 20 °C pF2 (d)	Min chi^2 error (%)	Method of calc.
Borstel – Loamy Sand	2.63	5.79	20 °C / 10.9 %	14[a]	83.9	70.3	1.9	SFO
Gartenacker* - Loam	3.20	7.28	20 °C / 26.7 %	25[a]	61.8	61.8	3.1	SFO
Lorsch – Sandy Clay Loam	3.16	5.25	20 °C / 19.9 %	22[a]	40.7	38.0	3.3	SFO
Speyer 2.3 – Sandy Loam	2.1	6.4	20 °C / 15.6 %	19[a]	61.8	53.8	6.7	SFO
Speyer 2.1 – Sand	1.07	5.9	20 °C / 12.4 %	12[a]	45.2	45.2	4.9	SFO
Speyer 2.2 – Loamy Sand	4.00	5.6	20 °C / 19.2 %	14[a]	50.7	50.7	4.1	SFO
Westmaas – Silt Loam	2.41	7.4	20 °C / 15.6 %	26[a]	93.8	65.6	6.0	SFO
Geometric mean					**60.0**	**54.0**	-	-
Median					**61.8**	**53.8**	-	-

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

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

Hydroxy-terbuthylazine	Aerobic conditions (where metabolite formed from parent terbuthylazine during the study)					
Soil type	% OM	pH (KCl or $CaCl_2$)	Visual inspection	Form. frac. (ffm	Min chi^2 error (%)	Method of calc.
Gartenacker Sandy Loam	3.79	7.25	Acceptable	0.080	12.1	SFO using a fixed DT_{50} of 325 d
Pappelacker Loamy Sand	1.9	7.6	Acceptable	0.065	28.0	SFO using a fixed DT_{50} of 325 d
Weide Sandy Loam	2.24	7.5	Acceptable	0.059	28.6	SFO using a fixed DT_{50} of 325 d
Speyer 2.2 Loamy Sand	3.91	6.1	Acceptable	0.313	26.4	SFO using a fixed DT_{50} of 325 d
Borstel Loamy Sand	2.59	5.8	Very good	0.219	3.0	SFO using a fixed DT_{50} of 325 d
Lorsch Sandy Clay Loam	3.1	5.3	Very good	0.379	7.0	SFO using a fixed DT_{50} of 325 d
Gartenacker Silt Loam 2.6 kg/ha	3.59	7.32	Acceptable	0.064	18.1	SFO using a fixed DT_{50} of 325 d
Gartenacker Silt Loam 0.25 kg/ha	3.59	7.32	Acceptable	0.073	21.8	SFO using a fixed DT_{50} of 325 d
Collombey Sand	2.29	7.7	Acceptable	0.301	18.2	SFO using a fixed DT_{50} of 325 d
Les Evouettes Silt Loam	2.41	6.1	Good	0.381	9.6	SFO using a fixed DT_{50} of 325 d
Speyer 2.2 Loamy Sand	4.4	6.0	Good	0.379	12.0	SFO using a fixed DT_{50} of 325 d
Speyer 2.3 Sandy Loam	1.28	6.6	Acceptable	0.250	27.1	SFO using a fixed DT_{50} of 325 d
Speyer 2.2 Loamy Sand	3.95	6.18	Reasonable	0.515	23.1	SFO using a fixed DT_{50} of 325 d
Sisseln Sandy Loam	2.71	7.16	Acceptable	0.149	15.0	SFO using a fixed DT_{50} of 325 d
Collombey Loamy Sand	2.02	7.45	Good	0.112	15.4	SFO using a fixed DT_{50} of 325 d
Diegten Clay Loam	2.74	6.9	Very good	0.203	3.8	SFO using a fixed DT_{50} of 325 d
Arithmetic mean[a]				**0.217**	-	-
Median[a]				**0.207**	-	-

[a]FOCUS default moisture content based on soil texture
[b]the geomean was calculated assuming a default DT50 of 1000 d for Cranfield 115 and Cranfield 164 soils (the results for the Cranfield 115 and Cranfield 164 soils were excluded from the geometric mean calculated by the Applicants on the basis of unacceptable parameter significance based on results of the t-test (Applicants geomean DT50, actual = 325 d
[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	Aerobic conditions (where metabolite applied as starting material)							
Soil type	% OM	pH (KCl)	temp. °C / soil moisture for study (% w/w)	Soil moisture at pF 2 (% w/w)	$DT_{50, actual}$ (d)	$DT_{50, ref}$ 20 °C pF2 (d)	Min chi^2 error (%)[b]	Method of calc.
Borstel – Loamy Sand	2.6	5.8	20 °C / 10.88 %	14[a]	135	113	7.7	SFO
Gartenacker – Loam	2.8	7.6	20 °C / 25.08 %	25[a]	50.1	50.1	5.3	SFO
Lorsch – sandy clay loam	3.1	5.3	20 °C / 19.92 %	22[a]	377	351	5.1	SFO
Vetroz – Silt Loam	3.1	7.7	20 °C / 23.56 %	26[a]	69.7	65.1	4.0	SFO
Geometric mean					**115**	**107**	-	-

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

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

8.3.1.2 Isoxaflutole and its metabolites

Table 8.3-11: Summary of aerobic degradation rates for Isoxaflutole - laboratory studies

Isoxaflutole			Dark aerobic conditions					
Soil type	O.C. (%)	pH[a)]	t. °C /% MWHC	DT_{50} /DT_{90} (d) #	St. (χ^2)	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation §
95/02 (Ferreira et al., 1996) Loam	1.9	4.8	20 °C / 60%	3.9/18.6 DFOP	8.2	4	9.3	SFO
95/04 (Burr, 1996) Sandy-Loam	2.2	5.3	20 °C / 60.28%	2.4/8.1 SFO	3.8	2.4	3.8	SFO
95/05 (Ferreira et al., 1996) Clay Loam	2.5	8.2	20°C/77.79 %	0.28/0.94 SFO	3.4	0.2	3.4	SFO
95/06 (Ferreira et al., 1996) Loamy Sand	1.1	7.4	20°C/38.82 %	0.57/1.9 SFO	4.9	0.4	4.9	SFO
95/02 10°C (Ferreira and Jones, 1996)	1.9	4.8	10°C/59.91 %	5.9-35.8 DFOP			10.4	SFO
Geometric mean (if not pH dependent)						**0.9**		
pH dependence					yes	However geomean agreed for use in assessment as degradation rate is always fast.		

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
non-normalised for trigger evaluation
§ for modelling purposes

Table 8.3-12: Summary of aerobic degradation rates for RPA 202248 laboratory studies

RPA 202248			Dark aerobic conditions Isoxaflutole dosed from which the f.f. was derived was 1						
Soil type	O.C. (%)	pH[a)]	t. °C /% MWHC	DT_{50}/ DT_{90} (d) #	f. f. k_f / k_{dp}	St. (χ^2)	DT_{50} (d) 20 °C pF2/10kPa [b)]	St. (χ^2)	Method of calculation §
Hoefchen am Hohenseh (Heinemann, 2012) Silty Loam	1.6	6.5	20 °C / 51.8%	14 /47 SFO*	-	5.1	14.2	5.1	SFO
95/02 (Ferreira et al., 1996) Loam	1.9	4.8	20 °C / 60%	43.4/144 DFOP+SFO	1	11.3	44.9	11.3	SFO+SFO
95/04 (Burr, 1996) Sandy-Loam	2.2	5.3	20 °C / 60.28%	10.4/34.4 SFO+SFO	1	14.7	10.4	14.7	SFO+SFO
95/05 (Ferreira et al., 1996) Clay Loam	2.5	8.2	20°C/77.79 %	41.7/139 SFO+SFO	1	5.6	27.8	5.6	SFO+SFO
95/06 (Ferreira et al., 1996) Loamy Sand	1.1	7.4	20°C/38.82 %	29.4/97.6 SFO+SFO	1	13.5	21	13.5	SFO+SFO
95/02 10°C (Ferreira and Jones, 1996) Loam	1.9	4.8	10°C/59.91 %	44.8/149 DFOP+SFO	1	14.7		17	SFO+SFO
Geometric mean (if not pH dependent)							**20.8**		
Arithmetic mean					1				
pH dependence,						no			

(a): Measured in water
(b): Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
non-normalised for trigger evaluation
§ for modelling purposes
* RPA 202248-dosed study

Table 8.3-13: Summary of aerobic degradation rates for RPA 203328 laboratory studies

RPA 203328			Dark aerobic conditions Isoxaflutole dosed						
Soil type	O.C. (%)	pH[a)]	t. °C /% MWHC	DT_{50}/ DT_{90} (d) #	f. f. k_f / k_{dp}	St. (χ^2)	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation §
95/02 (Ferreira et al., 1996) Loam	1.9	4.8	20 °C / 60%	204/678 DFOP+SFO+SFO	1	3.2	210	3.8	SFO+SFO+SFO
95/04 (Burr, 1996) Sandy-Loam	2.2	5.3	20 °C / 60.28%	>1000/ >1000 SFO+SFO+SFO	0.868	4.8	1000	4.8	SFO+SFO+SFO
95/05 (Ferreira et al., 1996) Clay Loam	2.5	8.2	20°C/77.79%	3.5/11.6 SFO+SFO+SFO	1	16.9	2.3	16.9	SFO+SFO+SFO
95/06 (Ferreira et al., 1996) Loamy Sand	1.1	7.4	20°C/38.82%	>1000/ >1000 SFO+SFO+SFO	0.966	19.4	1000	19.4	SFO+SFO+SFO
95/02 10°C (Ferreira and Jones, 1996) Loam	1.9	4.8	10°C/59.91%	112/379 DFOP+SFO+SFO	1			4.8	SFO+SFO+SFO
Geometric mean (if not pH dependent)							148.2		
Arithmetic mean					0.96				
pH dependence						No			

(a): Measured in water
(b): Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
non-normalised for trigger evaluation
§ for modelling purposes

zRMS comments:

The aerobic degradation rates for Isoxaflutole and its metabolites studies are in line EFSA Journal 2016;14(3):4416.

8.3.1.3 Mesotrione and its metabolites

Table 8.3-14: Summary of aerobic degradation rates for Mesotrione - laboratory studies

Parent	Dark aerobic conditions - Modelling Endpoints					
Soil type	pH*) water	t. °C/% MWHC	DT_{50} /DT_{90} (days)	DT_{50} (d) 20 °C pF2/ 10 kPa**)	St. (χ^2)	Method of calculation
sandy loam (ERTC)	6.4	20°C /19[a]	11.6/ 38.5	8.2	18	SFO
loam (Toulouse)	7.7	20°C /25[a]	4.3/ 14.3	4.0	16.4	SFO
clay loam (Pickett Piece)	7.1	20°C /28[a]	5.3/ 17.7	5.3	6.5	SFO
clay loam (721)	5.6	25°C /28[a]	20.2 /(67.1)	32.3	4.1	SFO
silty clay loam (722)	5.7	25°C /30[a]	10.3/ (34.2)	16.5	3.9	SFO
silt loam (723)	5.4	25°C /26[a]	17.6/ (58.5)	28.2	3.4	SFO
loamy sand (724)	4.8	25°C /14[a]	23.8/ (78.9)	31.1	4.3	SFO
loam (725)	5.8	25°C /25[a]	6.1/ 20.3	9.5	7.6	SFO
clay loam (727)	5.1	25°C /28[a]	20.8/ (69.2)	32.4	6.4	SFO
sandy loam (728)	5.9	25°C /25[a]	7.2/ 24	9.7	5.6	SFO
silt loam (729)	5.6	25°C /26[b]	12.7/ (42.2)	20.3	1.6	SFO
clay loam (730)	5.3	25°C /28[a]	17.1/ (56.9)	26.9	8.9	SFO
silty clay loam (731)	6.1	25°C /30[a]	14.1/ (46.9)	22.6	1.0	SFO
silty clay loam (732)	5.0	25°C /30[a]	14.0/ (46.4)	22.4	5.3	SFO
silty clay loam (741)	5.7	25°C /30[a]	28.7/ (95.3)	44.3	4.5	SFO
silty clay loam (742)	7.2	25°C /34.4[a]	9.7/ (32.1)	15.5	5.5	SFO
silt loam Richmond (Vispetto & Tovshteyn, 1997)	6.2	25°C /32.04[b]	13.2/ 44.0	14.68 (Average DT_{50}/ref of	3.1	SFO
silt loam	6.2	25°C /32.04[b]	11.8/ 39.3	15.5 & 13.9	4.9	SFO

Table 8.3-15: Summary of aerobic degradation rates for MNBA - laboratory studies

MNBA	Dark aerobic conditions - Modelling Endpoints					
Soil type	pH*) water	t. °C /% MWHC	DT_{50} /DT_{90} (days)	DT_{50} (d) 20 °C pF2/ 10kPa**)	St. (χ^2)	Method of calculation
silty clay loam (722)	5.7	25°C /30[a]	0.6/1.89	1.0	10	SFO
loam (725)	5.8	25°C /25[a]	0.5/1.5	0.8	10.8	SFO
sandy loam (728)	5.9	25°C /25[a]	5.1/16.97	6.9	3.1	Decline from peak
silt loam (729)	5.6	25°C /26[b]	1.66/5.52	2.7	3.88	SFO
clay loam (730)	5.3	25°C /28[a]	2.81/9.35	4.4	14.17	SFO
silty clay loam (731)	6.1	25°C /30[a]	15.7/52.3	25.2	1.6	SFO
sandy loam (ERTC)	6.4	20°C /19[a]	6.2/20.7	4.4	21.89	Decline from peak
loam (Toulouse)	7.7	20°C /25[a]	5/16.65	4.6	13.08	Decline from peak
silt loam Richmond (Subba-Rao, 1996)	6.2	25°C /32.04[b]	1.1/3.67	1.3	11.2	SFO
silt loam Richmond (Miller, 1997)	6.1	20°C /32.04[b]	6.3/21.03	5.1	20.13	Decline from peak
Geometric mean (if not pH dependent)				3.4		
pH dependence				No		

*) Measured in [medium to be stated, usually calcium chloride solution or water]
**) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[a] FOCUS default; [b]measured pF2

Table 8.3-16: Summary of aerobic degradation rates for AMBA - laboratory studies

AMBA	Dark aerobic conditions - Modelling Endpoints					
Soil type	pH*) water	t. °C/% MWHC	DT_{50}/DT_{90} (d)	DT_{50} (d) 20 °C pF2/ 10kPa**)	St. (χ^2)	Method of calculation
Wisborough	4.9	20°C /	7.8	3.7	5.52	DFOP DT90/3.32
Wisconsin	6.4	20°C /	33/109	23.5	7.98	DFOP K2
East Anglia	7.9	20°C /	58.7/195	47.4	3.66	DFOP K2
Spinks	6.7	20°C /	10.2/34	9.7	6.94	FOMC
Richmond	6.2	25°C /	13.6/45.2	16.0	14.8	SFO
Richmond	*6.1*	*20°C/*	*>1000*	*>1000*	*26.6*	*SFO*
Geometric mean (if not pH dependent)				14.5		
pH dependence				No		

*) Measured in [medium to be stated, usually calcium chloride solution or water]
**) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[a] FOCUS default; [b] measured pF2 italics - outlier

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

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

- **Terbuthylazine** - EFSA Journal 2011; 9(1):1969
- **Isoxaflutole** - EFSA Journal 2016;14(3):4416
- **Mesotrione** - EFSA Journal 2016;14(3):4419

8.3.2.1 Terbuthylazine and its metabolites

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

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

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

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

8.3.2.2 Isoxaflutole and its metabolites

Table 8.3-19: Summary of anaerobic degradation rate for Isoxaflutole - laboratory studies

Isoxaflutole	**Dark anaerobic conditions**						
Soil type	O.M. (%)	pH[a)]	t. °C /% MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C[b)]	St. (χ^2)	Method of calculation
Water (Burr et al., 1995)	-	7	21±1°C/ -	0.083/n.c.	n.c.	n.c.	Experimental evidence
Sediment (Burr et al., 1995)	16.78	6.25	21±1°C/ -	Not detected	n.c.	n.c.	n.c.
Sediment/water anaerobic aquatic system (Burr et al., 1995)	-	-	21±1°C/ -	0.083/n.c.	n.c.	n.c.	Experimental evidence
Geometric mean (if not pH dependent)				0.083/n.c.	n.c.	n.c.	Experimental evidence

(a): Measured in unknown medium
(b): Normalised using a Q10 of 2.58

Table 8.3-20: Summary of anaerobic degradation rate for RPA 202248 - laboratory studies

RPA 202248	Dark anaerobic conditions Metabolite dosed or the precursor from which the f.f. was not derived.							
Soil type	O.M. (%)	pH[a)]	t. °C /% MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20°C[b)]	St. (r^2)	Method of calculation
Water (Burr et al., 1995)	-	7	21±1°C/ -	316/n.c.	n.c.	n.c.	0.42	Pseudo first order kinetics
Sediment (Burr et al., 1995)	16.78	6.25	21±1°C/ -	n.c.	n.c.	n.c.	n.c.	n.c.
Sediment/water anaerobic aquatic system (Burr et al., 1995)	-	-	21±1°C/ -	n.c.	n.c.	n.c.	n.c.	n.c.
Geometric mean (if not pH dependent)				316/n.c.	n.c.	n.c.	n.c.	Pseudo first order kinetics
Arithmetic mean				316/n.c.	n.c.	n.c.	n.c.	Pseudo first order kinetics

(a): Measured in unknown medium
(b): Normalised using a Q10 of 2.58

Table 8.3-21: Summary of anaerobic degradation rate for RPA 203328 - laboratory studies

RPA 203328	Dark anaerobic conditions Metabolite dosed or the precursor from which the f.f. was not derived.							
Soil type	O.M. (%)	pH[a)]	t. °C /% MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20°C[b)]	St. (r^2)	Method of calculation
Water (Burr et al., 1995)	-	7	21±1°C/ -	48/n.c.	n.c.	n.c.	0.77	Pseudo first order kinetics
Sediment (Burr et al., 1995)	16.78	6.25	21±1°C/ -	235/n.c.	n.c.	n.c.	0.88	Pseudo first order kinetics
Sediment/water anaerobic aquatic system (Burr et al., 1995)	-	-	21±1°C/ -	131/n.c.	n.c.	n.c.	0.88	Pseudo first order kinetics
Geometric mean (if not pH dependent)				n.c.	n.c.	n.c.	n.c.	n.c.
Arithmetic mean				n.c.	n.c.	n.c.	n.c.	n.c.

(a): Measured in unknown medium
(b): Normalised using a Q10 of 2.58

zRMS comments:

The anaerobic degradation rates for Isoxaflutole and its metabolites studies are in line EFSA Journal 2016;14(3):4416.

Mesotrione and its metabolites

Table 8.3-22: Summary of anaerobic degradation route for Mesotrione and metabolites- laboratory studies

Mineralization after 100 days	up to 16.1% after 30 d, [14C- Cyclohexane]-label (n= 1) <0.5% after 59 d, [14C- Phenyl]-label (n= 1)
Non-extractable residues after 100 days	up to 23.4% after 30 d, [14C- Cyclohexane]-label (n= 1) up to 17% after 59 d, [14C- Phenyl]-label (n= 1)
Metabolites that may require further consideration for	[14C- Cyclohexane]-label

risk assessment – name and/or code, % of applied (range and maximum)	None identified [14C- Phenyl]-label AMBA 40.7% at 30 days declining to 21.9% at 59 days. (n=1) MNBA not detected Sterile conditions: 0%AR CO2 after 121 d, 12%AR unextracted, <0.1% MNBA or AMBA (n=1) [14C-Phenyl]-label Sterile conditions: ≤1% CO2 after 180 d, 14.2-28% unextracted over 180 days, no metabolites reported, (n= 1) [14C- Cyclohexane]-label

Table 8.3-23: Summary of anaerobic degradation rate for Mesotrione - laboratory studies

Parent Soil type	Dark anaerobic conditions pH[a)]	t. °C /% MWHC	DT_{50} / DT_{90} (days)	DT_{50} (d) 20 °C[b)]	St. (χ^2)	Method of calculation
Wisconsin silt loam cyclohexane-label	6.2	25°C/	4 days / 14 days		r^2= 0.98	first order (linear least squares fit of natural log of concentration vs. Sampling interval).
Wisconsin silt loam phenyl-label	6.2	25°C/	4 days / 12 days		r^2= 0.97	first order (linear least squares fit of natural log of concentration vs. Sampling interval).
Geometric mean (if not pH dependent)						

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) Normalised using a Q10 of 2.58

8.4 Field studies (KCP 9.1.1.2)

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

-**Terbuthylazine** - EFSA Journal 2011; 9(1):1969
- **Isoxaflutole - EFSA Journal 2016;14(3):4416**
-**Mesotrione -** EFSA Journal 2016;14(3):4419

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

8.4.1.1 Terbuthylazine and its metabolites

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

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

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

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

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

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

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

8.4.1.2 Isoxaflutole and its metabolites

There were no field studies for the active substance Isoxaflutole evaluated during EU review.

Table 8.4-4: Summary of aerobic degradation rates for RPA 202248 - field studies

RPA 202248	Aerobic conditions Metabolite dosed									
Soil type	Location	O.C. (%)	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm[b)].	f. f. k_f / k_{dp}	Method of calculation
Wipperfuerth, Loam	Germany	0.1-3	4.6-5.7	0-100	14 DFOP	81 DFOP	15	24.1	-	FOMC (DT_{90}/3.32) parent alone
Great Chishill, Clay-Clay Loam	UK	0.5-2.2	7.2	0-100	40 DFOP	177 DFOP	15	33.2	-	SFO
Chilly, Silt Loam	France	0.3-1.4	7.0-7.2	0-100	21 SFO	69 SFO	15	16.8	-	SFO
Burscheid, Silt Loam-Loam	Germany	0.1-1.3	6.2-6.4	0-100	29 SFO	97 SFO	15	5.7	-	HS-K2 after lag phase; parent alone
Albaro, Silty Clay Loam-Loam-Silt Loam	Italy	0.3-1.2	7.7-7.8	0-100	28 SFO	92 SFO	12	17.5	-	SFO
Vilobi d'Onyar, Sandy Loam-Sandy Clay Loam	Spain	0.2-0.7	5.6-5.8	0-100	8.2 DFOP	37 DFOP	11	11.7	-	SFO
Geometric mean (if not pH dependent)								**15.8**		
Arithmetic mean									-	
pH dependence						No				

(a): Measured in $CaCl_2$
(b): Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 values are DegT50matrix

Table 8.4-5: Summary of aerobic degradation rates for RPA 203328 - field studies

RPA 203328	Aerobic conditions RPA 202248 dosed from which the f.f. was derived was 0.96									
Soil type	Location	O.C. (%)	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm[b)].	f. f. k_f / k_{dp}	Method of calculation
Wipperfuerth, Loam	Germany	0.1-3	4.6-5.7	0-100	-	-	17.5	32.5	1	SFO + SFO
Great Chishill, Clay-Clay Loam	UK	0.5-2.2	7.2	0-100	-	-	22.2	12.6	0.771	SFO + SFO
Chilly, Silt Loam	France	0.3-1.4	7.0-7.2	0-100	-	-	22.8	13	1	SFO + SFO
Burscheid, Silt Loam-Loam	Germany	0.1-1.3	6.2-6.4	0-100	-	-	9.4	2.7	1	HS + SFO
Albaro, Silty Clay Loam-Loam-Silt Loam	Italy	0.3-1.2	7.7-7.8	0-100	-	-	9.2	4.3	1	SFO + SFO
Vilobi d'Onyar, Sandy Loam-Sandy Clay Loam	Spain	0.2-0.7	5.6-5.8	0-100	-	-	19.3	48.9	1	SFO + SFO
Geometric mean (if not pH dependent)								**12**		
Arithmetic mean									0.96	
pH dependence						No				

(a): Measured in $CaCl_2$
(b): Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7 values are $DegT_{50}$matrix

zRMS comments:

The field degradation rates for Isoxaflutole and its metabolites studies are in line EFSA Journal 2016;14(3):4416.

8.4.1.3 Mesotrione and its metabolites

Table 8.4-6: Summary of aerobic degradation rates for mesotrione - field studies (no new studies were evaluated during Annex I renewal)

From original DAR, not relied on for renewal

Parent	Aerobic conditions							
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH[a] [j)]	Depth (cm)	DT_{50} (days) actual	DT_{90} (days) actual	St. (χ^2)	DT_{50} (days) Norm[b].	Method of calculation
clay loam (bare soil)	France	6.0	0-10	7	73	-	-	sqrt 1st order - linear regression
clay loam (bare soil)	Italy	6.1	0-10	5	59	-	-	sqrt 1st order - linear regression
sandy loam (bare soil)	Italy	8.0	0-10	4	39	-	-	sqrt 1st order - linear regression
sandy loam (bare soil)	Germany	6.2	0-10	7	78	-	-	sqrt 1st order - linear regression
loam (bare soil)	Germany	5.8	0-10	/	/	-	-	sqrt 1st order - linear regression
loam (bare soil)	Germany	7.0	0-10	3	36	-	-	sqrt 1st order - linear regression
sandy clay loam (bare soil)	Germany	6.9	0-10	3	38	-	-	sqrt 1st order - linear regression
Geometric mean (if not pH dependent)							-	
pH dependence				Not reported				

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

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

- **Terbuthylazine** - EFSA Journal 2011; 9(1)
- **Isoxaflutole** - EFSA Journal 2016;14(3):4416
- **Mesotrione** - EFSA Journal 2016;14(3):4419

8.4.2.1 Terbuthylazine – soil accumulation testing

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

8.4.2.2 Isoxaflutole – soil accumulation testing

According to the EFSA Journal 2016;14(3):4416 the soil accumulation is not relevant (Plateau concentration of 0.000 mg/kg reached after 0 years, based on calculation).

8.4.2.3 Mesotrione – soil accumulation testing

The soil accumulation was not triggered (Plateau concentration ist he same as initial PEC soil).

8.5 Mobility in soil (KCP 9.1.2)

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

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

- **Terbuthylazine** - EFSA Journal 2011; 9(1):1969
- **Isoxaflutole** - EFSA Journal 2016;14(3):4416
- **Mesotrione** - EFSA Journal 2016;14(3):4419

8.5.1 Terbuthylazine and its metabolites

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

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

NR = not recorded

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

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

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

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

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

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

Desethyl-hydroxy-terbuthylazine (MT14) ‡							
Soil Type	OC %	Soil pH ($CaCl_2$)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Borstel Loamy Sand	1.3	5.0	1.8	136	1.44	111	0.93
Lorsch Sandy Clay Loam	1.8	5.3	3.8	211	3.39	188	0.97
Gartenacker Loam/Silt Loam	2.0	7.1	1.2	59	1.10	55	0.98
Vetroz Silt Loam	4.7	7.2	2.8	60	2.67	57	0.98
Wisborough- Silty Clay Loam	3.44	5.02	4.40	375	3.36	98	0.8892
18 Acres - Sandy Clay Loam	1.95	5.27	4.79	242	3.34	171	0.9166
Kochi - Loam	1.17	5.65	8.26	213	2.98	254	0.8991
Bosket - Loam*	0.58	5.68	3.97	158	5.83	1010	0.9572
Ushiku - Sandy Clay Loam	1.98	5.99	6.98	1208	2.83	143	0.8674
Tsukuba - Loam	3.87	6.49	5.23	152	5.07	131	0.8881
Pappelacker - Sandy Loam	2.76	7.06	0.78	28	0.61	22	0.9220
Champaign - Silty Clay	2.52	7.34	4.62	236	2.50	99	0.8787
Median (all data, n=12)					**2.91**	**121**	**0.92**
pH dependence (yes or no)					No		

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

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

8.5.2 Isoxaflutole and its metabolites

Table 8.5-12: Summary of soil adsorption/desorption for Isoxaflutole

Isoxaflutole							
Soil Type	O.C. (%)	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Sand, US (93/24)	0.5	7.2	n.c.	n.c.	0.24	48	1.03
Sandy loam, UK (93/7)	0.9	5.6	n.c.	n.c.	0.84	93	0.87
Clay loam, UK (93/30)	2.4	6.9	n.c.	n.c.	1.68	70	0.91
Silty clay, UK (93/32)	7.5	4.8	n.c.	n.c.	8.15	109	0.94
Geometric mean (if not pH dependent)*							
Arithmetic mean (if not pH dependent)					2.73	79.8	0.94
pH dependence, no							

a) Measured in CaCl2
* Only relevant after implementation of the published EFSA guidance.

Table 8.5-13: Summary of soil adsorption/desorption for RPA 202248

RPA 202248							
Soil Type	O.C. (%)	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
andy loam, US (93/22)	1.3	5.5	n.c.	n.c.	0.35	27	0.86
Loam, UK (95/02)	1.9	4.3	n.c.	n.c.	1.87	99	0.91
Sandy loam, UK (95/04)	2.2	4.7	n.c.	n.c.	1.65	75	0.91
Clay, US (96/12)	1.2	6.2 [b)]	n.c.	n.c.	0.27	22	0.75
Sand, US (96/13)	0.4	6.8 [b)]	n.c.	n.c.	0.13	35	0.87
Loamy Sand, US (96/14)	0.3	6.4 [b)]	n.c.	n.c.	0.21	62	0.91
Silty Loam, US (96/15)	0.5	6.5 [b)]	n.c.	n.c.	0.19	41	0.86
Sandy loam Wurmwiese	2.0	5.1	n.c.	n.c.	0.62	30.8	0.90
Silt loam Hoefchen	2.9	6.3	n.c.	n.c.	0.37	12.8	0.86
Loamy sand, UK (95/06)	1.1	6.7	n.c.	n.c.	0.12	11	0.87
Silt loam Springfield NE	1.7	6.6	n.c.	n.c.	0.20	11.6	0.92
Loam Dollendorf II	4.4	7.3	n.c.	n.c.	0.53	12.1	0.86
Sandy loam Guadalupe CA	0.7	6.7	n.c.	n.c.	0.10	14.5	0.92
Geometric mean *							
Arithmetic mean of soils pH($CaCl_2$) >6.5 as there was pH dependence						12.3	0.89
pH dependence,			Yes				

a) Measured in CaCl2
b) Measured in water
* Only relevant after implementation of the published EFSA guidance.

Table 8.5-14: Summary of soil adsorption/desorption for RPA 203348

RPA 203328							
Soil Type	O.C. (%)	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
sandy loam - Little Shelford	1.5	7.6	n.c.	n.c.	c)	c)	c)
clay loam - Shelley Field	1.9	7.3	n.c.	n.c.	0.03	1.49	0.57
sandy clay - Lockington	3.3	5.9	n.c.	n.c.	c)	c)	c)
sandy loam - Manningtree	1.0	6.3	n.c.	n.c.	0.01	0.88	0.85
silt loam - Goch	1.6	5.6	n.c.	n.c.	0.02	1.14	0.53
Value selected by peer review						0	
pH dependence,			No				

a) Measured in $CaCl_2$
b) Measured in water
c) Adsorption too low to reliably measure

zRMS comments:

The soil adsorption/desorption studies for Isoxaflutole and its metabolites are in line EFSA Journal 2016;14(3):4416.

8.5.3 Mesotrione and its metabolites

Table 8.5-13: Summary of soil adsorption/desorption for Mesotrione

Parent Soil Type	OC%	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Wisborough Green silty clay loam	2.63	5.1			4.46	171	0.902
Wisconsin silt loam	1.58	6.2			0.74	47	0.921
Toulouse clay	1.79	6.5			1.25	70	0.915
Garonne loam	1.03	7.8			0.15	14	0.971
Visalia sandy loam	0.53	8.2			0.13	25	0.959
Wisconsin silt loam	1.28	6.1			0.61	48	0.947
ERTC sandy loam	0.58	6.4			0.33	57	0.950
Pickett Piece clay loam	3.31	7.1			0.97	29	0.932
Garonne loam	0.87	7.7			0.16	18	0.954
Champaign (1:2 ratio) silty clay loam	3.0	4.4			6.16	354	0.94
Geometric mean (if not pH dependent)							
Arithmetic mean (if not pH dependent)							**0.94**
Median							
Worst case						**14**	
pH dependence	Yes, sorption decreases as pH increases. Kfoc y= 8583.4e^{-0785x} (log) r^2 0.8977						

a) Measured in [medium to be stated, usually calcium chloride solution or water]

Table 8.5-14: Summary of soil adsorption/desorption for MNBA

MNBA Soil Type	OC%	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Wisborough Green silty clay loam	2.63	5.1			0.16	6.1	0.32
Wisconsin silt loam	1.58	6.2			0.05	3.2	0.61
Worst case						3.2	0.9[b]
Geometric mean (if not pH dependent)						-	
Arithmetic mean (if not pH dependent)							-
pH dependence	No						

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) FOCUS default

Table 8.5-15: Summary of soil adsorption/desorption for AMBA

AMBA Soil Type	OC%	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Wisborough Green silty clay loam	2.63	5.1			3.2	122	0.83
Wisconsin silt loam	1.58	6.2			0.71	44.9	0.85
Toulouse clay	1.79	6.5			0.91	51.0	0.85
Garonne loam	1.03	7.8			0.18	18.1	0.82
Visalia sandy loam	0.53	8.2			0.12	23.9	0.90
Arithmetic mean (if not pH dependent)						pH dependent (51.9)	0.85
Worst case						18.1	
pH dependence	Yes, sorption decreases as pH increases. Kfoc $y = 1865e^{-0.563x}$ (log) r^2 0.9062						

a) Measured in [medium to be stated, usually calcium chloride solution or water]

Table 8.5-16: Summary of soil adsorption/desorption for SYN 546974

SYN 546974 Soil Type	OC%	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Gartenacker Loam	1.8	7.2			30.63	1702	0.82
18 Acres Sandy Clay Loam	2.2	5.7			220.07	10003	0.96
Marysville Clay Loam	1.6	7.6			432.49	27031	0.96
Sarpy Silt loam	1.7	6.5			376.10	22124	0.88
Seven Springs Loamy sand	0.6	5.2			19.56	3260	0.84
Arithmetic mean (if not pH dependent)						13000	0.89
Worst case							
pH dependence	No						

8.5.4 Column leaching (KCP 9.1.2.1)

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

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

- **Terbuthylazine** - EFSA Journal 2011; 9(1):1969
- **Isoxaflutole - EFSA Journal 2016;14(3):4416**
- **Mesotrione** - EFSA Journal 2016;14(3):4419

8.5.4.2 Terbuthylazine

Column leaching	Eluation (mm): 200 mm Time period (d): 2 d

	Leachate: < 0.01 - 0.04 % total residues/radioactivity in leachate 82.45 - 90.14 % active substance and 0.46 - 1.49 % extractable metabolites in soil. 45.48 – 87.37 % total residues/radioactivity retained in top 2 cm

8.5.4.3 Isoxaflutole

Column leaching	Elution (mm): 360 mm Time period (d): 9 d
	Leachate: 89.4% total residues/radioactivity in leachate (worst-case of 5 soils) 0% active substance, 100% RPA 202248 >1.98 % total residues/radioactivity retained in top 6 cm (worst-case of 5 soils)

zRMS comments:

The column leaching study for Isoxaflutole is in line EFSA Journal 2016;14(3):4416.

8.5.4.4 Mesotrione

According to the EFSA EFSA Journal 2016;14(3):4419 mobility in soil column leaching is not required.

8.5.5 Lysimeter studies (KCP 9.1.2.2)

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

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

- **Terbuthylazine** - EFSA Journal 2011; 9(1):1969
- **Isoxaflutole** - EFSA Journal 2016;14(3):4416
- **Mesotrione** - SANCO/1416/2001 –Final - 14 April 2003

8.5.5.1 Terbuthylazine and metabolites.

Lysimeter/ field leaching studies ‡ (SYN) **Summary of metabolite codes:-** MT1 = GS26379 MT13 = GS23158 MT14 = GS28620 MT19 = GS17792 MT20 = GS28273 MT22 = G28279 LM1 = MT24 = G35713 LM2 = MT28 = CSAA036479 LM3 = SM9 = CSCD692760 LM4 = CSAA404949 LM5 = MT23 = SM12 = GS16984 LM6 = SM6 = CSCD648241	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 ‡ (SYN)	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 metabo-lites in the leachate were determined based on analysis during the original study coupled with additional information from further more recent accurate mass structural elucidation work. Parent and desethyl terbuthylazine were identified in the

	original study. Two further metabolites were plausibly assigned to LM3 and LM6 based on the additional mass spectral elucidation work. 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 □g/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 ‡ (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 ter-buthylazine, hydroxy terbuthyalzine 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 ‡ (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 terbuthyalzine was only analysed for in 1999-2000 and 2000-2001. Desethylhydroxy terbuthylazine was only analysed for in 1997-1998, 1999-2000 and 2000-2001.
	Location: 10 sites in 5 regions (Emilia Romagna, Friuli Venezia – Giulia, Lombardia, Piemonte, Veneto) innNorthern Italy Study type (e.g.lysimeter, field): field leaching study Soil properties: texture class – 5 sandy loams, 3 loams , 1 sandy clay and 1 clay loam; pH = 4.9 7.7; OC= 0.9 – 3.6%; MWHC = not reported Groundwater depth: 0.12 to 7.1m below ground surface

	Dates of application : 2005 to 2007 Crop : maize Irrigation: sprinkler, basin , border or no irrigation Interception estimated: 0 % (applications made shortly after seeding maize) Number and rate of applications: between 2005 and 2007, 7 sites had 3 annual applications of 856 g terbuthylazine/ha. The remaining 3 sites had either 2 or 1 annual application. Duration: bi-monthly sampling for 3 years (17 sampling events) Average annual rainfall (mm): Reported to be below the overall average for the period 2000-2007 but supplemented by irrigation at 9 out of 10 sites. Frequency of detections, detection >0.1µg/l and maximum conc. (excluding basin irrigated sites, n=8): Terbuthylazine: 62 detections out of 395 samples; 3% (~13 samples) >0.1µg/l; maximum concentration = 3.20µg/l. Desethyl terbuthylazine: 125 detections out of 395 samples; 5% (~21 samples) >0.1µg/l; maximum concentration = 3.18µg/l. Desethyl hydroxyterbuthylazine: 57 detections out of 144 samples; 29% (~42 samples) >0.1µg/l; maximum concentration = 2.65µg/l. 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) Note that as high concentrations were also found in the upstream monitoring wells, parts of residues found in downstream monitoring wells are likely to derive from previous usage following several years of commercial application in the upstream areas.

8.5.5.2 Isoxaflutole and metabolites.

Studies not required for isoxaflutole.

8.5.5.3 Mesotrione and metabolites.

Studies not required for mesotrione.

8.5.6 Field leaching studies (KCP 9.1.2.3)

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

Lysimeter/ field leaching studies ‡ (SYN) **Summary of metabolite codes:-** MT1 = GS26379 MT13 = GS23158 MT14 = GS28620 MT19 = GS17792 MT20 = GS28273 MT22 = G28279 LM1 = MT24 = G35713 LM2 = MT28 = CSAA036479 LM3 = SM9 = CSCD692760 LM4 = CSAA404949 LM5 = MT23 = SM12 = GS16984 LM6 = SM6 = CSCD648241	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 ‡ (SYN)	Location: Itingen, Switzerland Study type (e.g.lysimeter, field): lysimeter Soil properties (0 – 30 cm): Neustadt Sand, pH = 6.1, OC= 1.05, MWHC = 34.5 % Dates of application : May 1992 Crop : maize followed by two rotations of winter wheat Interception estimated: 25 % (based on standard crop interception values and growth stage of maize at time of application) Number of applications: 1 application to maize in first year only Duration: Application rate: 891 g/ha Average annual rainfall (mm): 1090 mm Average annual leachate volume (mm): 413.2 mm % radioactivity in leachate (maximum/year): 2.34 % AR Structural assignments for the parent and metabolites in the leachate were determined based on analysis during the original study coupled with additional information from further more recent accurate mass structural elucidation work. Parent and desethyl terbuthylazine were identified in the original study. Two further metabolites were plausibly assigned to LM3 and LM6 based on the additional mass spectral elucidation work. 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 ter-buthylazine (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 □g/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 ‡ (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 ter-buthylazine, hydroxy terbuthyalzine 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 ‡ (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 appli-

	cable % 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 terbuthyalzine was only analysed for in 1999-2000 and 2000-2001. Desethylhydroxy terbuthylazine was only analysed for in 1997-1998, 1999-2000 and 2000-2001.
	Location: 10 sites in 5 regions (Emilia Romagna, Friuli Venezia – Giulia, Lombardia, Piemonte, Veneto) innNorthern Italy Study type (e.g.lysimeter, field): field leaching study Soil properties: texture class – 5 sandy loams, 3 loams , 1 sandy clay and 1 clay loam; pH = 4.9 7.7; OC= 0.9 – 3.6%; MWHC = not reported Groundwater depth: 0.12 to 7.1m below ground surface Dates of application : 2005 to 2007 Crop : maize Irrigation: sprinkler, basin , border or no irrigation Interception estimated: 0 % (applications made shortly after seeding maize) Number and rate of applications: between 2005 and 2007, 7 sites had 3 annual applications of 856 g terbuthylazine/ha. The remaining 3 sites had either 2 or

	1 annual application. Duration: bi-monthly sampling for 3 years (17 sampling events) Average annual rainfall (mm): Reported to be below the overall average for the period 2000-2007 but supplemented by irrigation at 9 out of 10 sites. Frequency of detections, detection >0.1µg/l and maximum conc. (excluding basin irrigated sites, n=8): Terbuthylazine: 62 detections out of 395 samples; 3% (~13 samples) >0.1µg/l; maximum concentration = 3.20µg/l. Desethyl terbuthylazine: 125 detections out of 395 samples; 5% (~21 samples) >0.1µg/l; maximum concentration = 3.18µg/l. Desethyl hydroxyterbuthylazine: 57 detections out of 144 samples; 29% (~42 samples) >0.1µg/l; maximum concentration = 2.65µg/l. 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) Note that as high concentrations were also found in the upstream monitoring wells, parts of residues found in downstream monitoring wells are likely to derive from previous usage following several years of commercial application in the upstream areas.

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

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

- **Terbuthylazine** - EFSA Journal 2011; 9(1):1969
- **Isoxaflutole** - EFSA Journal 2016;14(3):4416
- **Mesotrione** - EFSA Journal 2016;14(3):4419

8.6.1 Terbuthylazine and its metabolites

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

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

NC = not calculated

Table 8.6-2: Summary of observed metabolites

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

Water/sediment system		(Y) EFSA Journal 2011; 9(1):1969

8.6.2 Isoxaflutole and its metabolites

Table 8.6-3: Summary of degradation in water/sediment of Isoxaflutole

Isoxaflutole	**Distribution** (Manningtree system: max 84.4% of AR by day zero in water, zero% in sediment at any time point; River Roding system; max 82.6% of AR by day zero in water, zero% in sediment at any point)									
Water / sediment system	pH water phase	pH sed [a]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Sandy - Manningtree	6.1 (KCl)	-	20	0.57 d (1.9 d)	5.9	0.57 d (1.9 d)	5.9	1000 d	-	SFO
Loamy - River Roding	7.5 (KCl)	-	20	0.23 d (0.78 d)	10.8	0.23 d (0.78 d)	10.8	1000 d	-	SFO
Geometric mean at 20°C [b]				0.36 d		0.36 d				

[a] Not measured
[b] Normalised using a Q10 of 2.58

Table 8.6-4: Summary of degradation in water/sediment of RPA 202248

RPA 202248	**Distribution** (Manningtree system maximum: max 52.1% by day 2 in water, max 38.9% by day 62 in sediment; River Roding system: max 63.9% by day 100 in water, max of 22.9% by day 100 in sediment). **kinetic formation fraction (k_f/k_{dp}): 0.72 from isoxaflutole (arithmetic mean whole system)**									
Water / sediment system	pH water phase	pH sed [a]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Sandy - Manningtree	6.1 (KCl)	-	20	334 d (>1000 d)	7.4	53.9 d (179 d)	11.7	1000 d	-	SFO
Loamy - River Roding	7.5 (KCl)	-	20	168 d (559 d)	8.6	71.8 d (239 d)	9.9	1000 d	-	SFO
Geometric mean at 20°C [b]				237		62.2 d				

[a] Not measured
[b] Normalised using a Q10 of 2.58

Table 8.6-5: Summary of degradation in water/sediment of RPA 202248

RPA 205834	**Distribution** (Manningtree system: max of 15.2% by day 2 in water, max of 13.6% by day 14 in sediment; River Roding system: max of 20.4% by day 7 in water, max of 8.0% by day 30 in sediment). **kinetic formation fraction (k_f/k_{dp}): 0.24 from isoxaflutole (arithmetic mean whole system)**									
Water / sediment system	pH water phase	pH sed [a]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Sandy - Manningtree	6.1 (KCl)	-	20	81.4 d (270 d)	16.4	33.9 d [b]	15.6	1000 d	-	SFO DFOP [b]
Loamy - River Roding	7.5 (KCl)	-	20	71.5 d (237 d)	23.6	23.6 d (78.4 d)	11.4	1000 d	-	SFO
Geometric mean at 20°C[b]				76.2 d		28.3 d				

[a] Not measured
b) water calulated from the DFOP slow-phase k2 of 0.02043

zRMS comments:

The degradation sudies in water/sediment of Isoxaflutole and its metabolites are in line EFSA Journal 2016;14(3):4416.

8.6.3 Mesotrione and its metabolites

Table 8.6-6: Summary of degradation in water/sediment of Mesotrione

Parent	**Distribution (max in water 98.7% after 0 d. Max. sed 4.3% after 1d)**									
Water / sediment system (radiolabel)	**pH water phase**	**pH sed [a]**	**t. °C**	**DT_{50} /DT_{90} whole sys.[c]**	**St. (χ^2)**	**DT_{50} /DT_{90} water**	**St. (χ^2)**	**DT_{50} /DT_{90} sed**	**St. (χ^2)**	**Method of calculation**
Basing (Phenyl)	7.86		20	2.6	6.8	2.5	6.2	n/a	n/a	SFO
Basing (Cyclohexane)			20	4.2	13.3	4.2	13.3	n/a	n/a	SFO
Virginia (Phenyl)	7.40		20	5.5	12.3	5.3	13.5	n/a	n/a	SFO
Virginia (Cyclohexane)			20	7.2	14.4	7.0	13.4	n/a	n/a	SFO
Calwich (Phenyl)	8.4/7.8 (aerobic/anaerobic)	7.6	20	6.6	4.5	6.7	3.4	n/a	n/a	SFO
Swiss (Phenyl)	7.4/7.5 (aerobic/anaerobic)	6.1	20	11.1	3.5	11.0	3.3	n/a	n/a	SFO
Geometric mean at 20°C[b]				5.6		5.5		n/a		

[a] Measured in [medium to be stated, usually calcium chloride solution or water]
[b] Normalised using a Q10 of 2.58

Table 8.6-7: Summary of degradation in water/sediment of MNBA

Metabolite **MNBA**	Distribution (max in water 7.4%* after 3 days. Max. sed <1%*). Max in total system 7.4% after 3 days. *Detected in Cary., 1999. Not detected in Graham R, 2013 kinetic formation fraction (k_f/k_{dp}): Not available									
Water / sediment system	**pH water phase**	**pH sed** [a]	**t.° C**	**DT_{50} /DT_{90} whole sys.**	**St. (χ^2)**	**DT_{50} /DT_{90} water**	**St. (χ^2)**	**DT_{50} /DT_{90} sed**	**St. (χ^2)**	**Method of calculation**
n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Geometric mean at 20°C[b]**				n/a		n/a		n/a		n/a

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) Normalised using a Q10 of 2.58
** 1000 day default value used in risk assessment

Table 8.6-8: Summary of degradation in water/sediment AMBA

Metabolite **AMBA**	Distribution (max in water 15.8% after 46 d. Max. sed 8.8 % after 46 d). Max in total system 24.6% after 46 days, kinetic formation fraction (kf/kdp): Not available									
Water / sediment system	**pH water phase**	**pH sed** [a]	**t. oC**	**DT50 /DT90 whole sys.**	**St. (χ^2)**	**DT50 /DT90 water**	**St. (χ^2)**	**DT50 /DT90 sed**	**St. (χ^2)**	**Method of calculation**
n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Geometric mean at 20°C[b]*				n/a		n/a		n/a		n/a

* 1000 days default value used in risk assessment

Table 8.6-9: Summary of degradation in water/sediment SYN 546974

Metabolite **SYN546974**	Distribution (max in water 9.4% after 29 d. Max. sed 25.6% after 102 d). Max in total system 33% after 29 days. kinetic formation fraction (k_f/k_{dp}): Not available									
Water / sediment system	**pH water phase**	**pH sed** [a]	**t. °C**	**DT_{50} /DT_{90} whole sys.**	**St. (χ^2)**	**DT_{50} /DT_{90} water**	**St. (χ^2)**	**DT_{50} /DT_{90} sed**	**St. (χ^2)**	**Method of calculation**
n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Geometric mean at 20°C[b]				n/a		n/a		n/a		n/a

* 1000d default value used in risk assessment

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

8.7.1 Justification for new endpoints

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

- **Terbuthylazine - EFSA Journal 2011; 9(1):1969).**
- **Isoxaflutole - EFSA Journal 2016;14(3):4416**
- **Mesotrione -** EFSA Journal 2016;14(3):4419

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

Refernce: L.Lupicki (2016) : PEC soil calculations in ESCAPE 2 model.

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

Use No.	1
Crop	Maize
Application rate (g as/ha)	Terbuthylazine: 400 g a.s/ha Isoxaflutole: 100 g a.s/ha Mesotrione: 150 g a.s/ha
Number of applications/interval	1/-
Crop interception (%)	0%
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm – no tillage

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

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU end-point y/n/ Reference
Terbuthylazine	229.7	-	DT50: 46.6 d Kinetics: SFO Field or Lab: representative worst case un-normalised values from field studies.	EFSA Journal 2011; 9(1):1969
Desethyl-terbuthylazine (MT1)	201.7	32.9%	DT50:223d Kinetics: SFO Field or Lab: representative worst case un-normalised values from field studies	EFSA Journal 2011; 9(1):1969
Hydroxy-terbuthylazine	211.3	34.5%	DT50:453 d Kinetics: SFO using a fixed DT50 Field or Lab: representative worst case un-normalised values from field studies	EFSA Journal 2011; 9(1):1969
Isoxaflutole	359	-	DT50: 3.9d Kinetics: DFOP Field or Lab: representative worst case from	EFSA Journal 2016;14(3):4416

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU end-point y/n/ Reference
			laboratory studies (field studies were invalidated).	
RPA 202248	359.32	100%	DT50:53.4 d Kinetics: DFOP Field or Lab: As a conservative approach, a pseudo-SFO DT50 of 53.4 days has been derived (DFOP DT90/3.32) for the PECsoil calculations.	EFSA Journal 2016;14(3):4416
RPA 203328	268.22	Application rate assumed: 60.428 g a.s./ha (assumed Met 203328 is formed at a maximum of 90.02% of the applied dose).	maximum initial PECsoil calculated, therefore no DT50 needed	EFSA Journal 2016;14(3):4416
Mesotrione	339.3	-	DT50 (d): 43.4 d Kinetics: DFOP Field or Lab: representative worst case from laboratory studies before normalisation.	EFSA Journal 2016;14(3):4419
MNBA	245	57.2%	DT50 (d): 25.2 d Kinetics: SFO Field or Lab: representative worst case from laboratory studies	EFSA Journal 2016;14(3):4419
AMBA	215	9.7%	DT50:1000d Kinetics: SFO Field or Lab: representative worst case from laboratory studies	EFSA Journal 2016;14(3):4419

8.7.2.1 Terbuthylazine and its metabolites

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

PEC_{soil} (mg/kg)	Maize	
	Single application	Multiple applications

		Actual	TWA	Actual	TWA
Initial		0.5333	-	-	-
Short term	24h	0.5255	0.5294	-	-
	2d	0.5177	0.5255	-	-
	4d	0.5025	0.5178	-	-
Long term	7d	0.4806	0.5065	-	-
	14d	0.4331	0.4815	-	-
	21d	0.3902	0.4581	-	-
	28d	0.3517	0.4362	-	-
	50d	0.2535	0.3762	-	-
	100d	0.1205	0.2775	-	-
Plateau concentration (5 cm) after year 10		0.0023	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.5357	-		

PEC_{soil} of metabolites

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

PEC_{soil} (mg/kg)		Maize			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.1020	-		-
Short term	24h	0.1020	0.1020		
	2d	0.1020	0.1020		
	4d	0.1020	0.1020		
Long term	7d	0.1019	0.1020		
	14d	0.1016	0.1020		
	21d	0.1011	0.1020		
	28d	0.1005	0.1019		
	50d	0.0976	0.1016		
	100d	0.0885	0.1001		
Plateau concentration (5 cm) after year 10		0.0644	-		-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.1665			

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

PEC_{soil} (mg/kg)	Maize			
	Single application		Multiple applications	
	Actual	TWA	Actual	TWA
Initial	0.1208	-	-	-

Short term	24h	0.1208	0.1208	-	-
	2d	0.1207	0.1208	-	-
	4d	0.1207	0.1208	-	-
Long term	7d	0.1207	0.1207	-	-
	14d	0.1204	0.1207	-	-
	21d	0.1200	0.1207	-	-
	28d	0.1194	0.1206	-	-
	50d	0.1169	0.1203	-	-
	100d	0.1087	0.1191	-	-
Plateau concentration (5 cm) after year 10		0.1165	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.2373	-	-	-

8.7.2.2 Isoxaflutole and its metabolites

Table 8.7-6: PEC_{soil} for Isoxaflutole on maize

PEC_{soil} (mg/kg)		Maize			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.1333	-	-	-
Short term	24h	0.1116	0.1225	-	-
	2d	0.0934	0.1125	-	-
	4d	0.0655	0.0957	-	-
Long term	7d	0.0384	0.0765	-	-
	14d	0.0111	0.0493	-	-
	21d	0.0032	0.0350	-	-
	28d	0.0009	0.0267	-	-
	50d	<0.0001	0.0150	-	-
	100d	<0.0001	0.0075	-	-
Plateau concentration (5 cm) after year 10		<0.0001	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.1333			

PEC_{soil} of metabolites

Table 8.7-7: PEC_{soil} for RPA 202248 on maize

PEC_{soil} (mg/kg)	Maize	
	Single application	Multiple applications

		Actual	TWA	Actual	TWA
Initial		0.1092	-	-	-
Short term	24h	0.1091	0.1092	-	-
	2d	0.1087	0.1092	-	-
	4d	0.1076	0.1090	-	-
Long term	7d	0.1050	0.1087	-	-
	14d	0.0974	0.1072	-	-
	21d	0.0894	0.1051	-	-
	28d	0.0817	0.1025	-	-
	50d	0.0615	0.0931	-	-
	100d	0.0321	0.0733	-	-
Plateau concentration (5 cm) after year 10		0.0010	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.1103			

Table 8.7-8: PEC_{soil} for RPA 203328 on maize

PEC_{soil} (mg/kg) Application rate assumed: 68.113 g a.s./ha (assumed Met 203328 is formed at a maximum of 90.02% of the applied dose)		Maize			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0908		-	-
Short term	24h	0.0908	0.0908	-	-
	2d	0.0907	0.0908	-	-
	4d	0.0906	0.0907	-	-
Long term	7d	0.0904	0.0906	-	-
	14d	0.0899	0.0904	-	-
	21d	0.0895	0.0902	-	-
	28d	0.0891	0.0899	-	-
	50d	0.0877	0.0893	-	-
	100d	0.0847	0.0877	-	-
Plateau concentration (5 cm) after year 10		Not relevant for this metabolite		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		Not relevant for this metabolite			

zRMS comments:

The calculations of PEC_s for active substance **isoxaflutole** (1x100g/ha) and **its metabolites** submitted by the Applicant for the proposed use in maize has been accepted. Calculations were performed according FOCUS EU guidance. Calculations were performed for proposed use in GAP. The interception according to FOCUS is 0% (maize, growth stage BBCH 00). Agreed endpoints in line EFSA Journal 2016;14(3):4416 were used as input parameters.

December 2021:
It should be indicated that applicant in meantime changed the GAP Table by limitation of the application rate from 1 kg product/ha to only 0/8 kg product/ha (80 g isoxaflutole/ha).

Althought he applicant did not provide PECs calculation for lower rate PECs calculations performed for 100g isoxaflutole/ha was accepted as worse case by zRMS.

8.7.2.3 Mesotrione and its metabolites

Table 8.7-9: PEC_{soil} for Mesotrione on maize

PEC_{soil} (mg/kg)		Maize			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.2000		-	-
Short term	24h	0.1968	0.1984	-	-
	2d	0.1937	0.1968	-	-
	4d	0.1876	0.1937	-	-
Long term	7d	0.1788	0.1892	-	-
	14d	0.1599	0.1792	-	-
	21d	0.1430	0.1699	-	-
	28d	0.1279	0.1613	-	-
	50d	0.0900	0.1378	-	-
	100d	0.0405	0.0999	-	-
Plateau concentration (5 cm) after year 10		0.0006	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.2006	-		

PEC_{soil} of metabolites

Table 8.7-10: PEC_{soil} for MNBA on maize

PEC_{soil} (mg/kg)		Maize			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0229	-	-	-
Short term	24h	0.0229	0.0229	-	-
	2d	0.0229	0.0229	-	-
	4d	0.0228	0.0229	-	-
Long term	7d	0.0227	0.0229	-	-
	14d	0.0221	0.0228	-	-
	21d	0.0213	0.0227	-	-
	28d	0.0203	0.0226	-	-

	50d	0.0166	0.0219	-	-
	100d	0.0091	0.0195	-	-
Plateau concentration (5 cm) after year 10		Not relevant for this metabolite		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)					

Table 8.7-11: PEC_{soil} for AMBA on maize

PEC_{soil} (mg/kg)		Maize			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0110	-	-	-
Short term	24h	0.0110	0.0110	-	-
	2d	0.0110	0.0110	-	-
	4d	0.0110	0.0110	-	-
Long term	7d	0.0110	0.0110	-	-
	14d	0.0110	0.0110	-	-
	21d	0.0110	0.0110	-	-
	28d	0.0110	0.0110	-	-
	50d	0.0109	0.0110	-	-
	100d	0.0106	0.0109	-	-
Plateau concentration (5 cm) after year 10		Not relevant for this metabolite		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		Not relevant for this metabolite			

8.7.2.4 PEC_{soil} of formulation CHR/H/TERIZ

Table 8.7-5: PEC_{soil} for CHR/H/TERIZ on maize

Active substance/ preparation	Application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa}21 d (mg/kg)	Tillage depth (cm)	$PEC_{soil,plateau}$ (mg/kg)	PEC_{accu} = PEC_{act} + $PEC_{soil,plateau}$ (mg/kg)
CHR/H/TERIZ	1000	1.3333	1.3237	5cm	4.6315	5.9649

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

8.8.1 Justification for new endpoints

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

- **Terbuthylazine** - EFSA Journal 2011; 9(1):1969
- **Isoxaflutole** - EFSA Journal 2016;14(3):4416
- **Mesotrione** - EFSA Journal 2016;14(3):4419

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

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

Use No.	1
Crop	Maize
Application rate (g as/ha)	Terbuthylazine: 400 g a.s/ha Isoxaflutole: 100 g a.s/ha Mesotrione: 150 g a.s/ha
Number of applications/interval (d)	1/-
Relative application date	3 days after sowing
Crop interception (%)	0%
Frequency of application	annual,
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3

Table 8.8-2: Application dates used for groundwater risk assessment in FOCUS PELMO 5.5.3 and PEARL 4.4.4

Crop	Scenario	Application dates (absolute)
Maize	Châteaudun	20th April
	Hamburg	20th April
	Kremsmünster	20th April
	Okehampton	20th April
	Piacenza	20th April
	Porto	20th April
	Sevilla	20th April
	Thiva	20th April

8.8.2.1 Terbuthylazine and its metabolites

Table 8.8-3a: Input parameters related to active substance Terbuthylazine and metabolite(s) for PEC_{gw} calculations

Compound	Terbuthylazine	Desethyl-terbuthylazine (GS26379, MT1)	2-Hydroxy-terbuthylazine (GS23158, MT13)	Desethyl-hydroxy-terbuthylazine (GS28620, MT14)	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	229.7	201.7	211.3	183.2	EFSA Journal 2011; 9(1):1969
Water solubility (g/mol):	8.5	327.1	7.19	18	EFSA Journal 2011; 9(1):1969
Saturated vapour pressure (Pa):	0	0	0	0	EFSA Journal 2011; 9(1):1969
DT_{50} in soil (d)	19.4 d (normalised median of field studies)	26.9 (geomean of field studies).	453	107	EFSA Journal 2011; 9(1):1969
Transformation rate	**0.01608** to MT1 **0.0073959**to MT13 **0.01074367** to CO2	**0.007215** to MT14 **0.018553**to CO2	0.00153to CO2	0.006478to CO2	EFSA Journal 2011; 9(1):1969
K_{foc} (mL/g)/K_{fom}	worst case assessment using lowest Kfoc value of 151 L/kg Kfom=87.6	Kfoc=78 L/kg Kom=45.2 L/kg	Kfoc=187.1 L/kg Kom=108 L/kg	Kfoc=111 L/kg Kom=64.4 L/kg	EFSA Journal 2011; 9(1):1969
1/n	0.93 (worst case)	0.895	0.91	0.92	EFSA Journal 2011; 9(1):1969
Plant uptake factor	0.5	0.5	0	0	EFSA Journal 2011; 9(1):1969
Formation fraction		0.45 from A.S	0.207 from A.S	0.28 from MT1	EFSA Journal 2011; 9(1):1969

* Delete row in case of no pH dependency

Table 8.8-4: PEC_{gw} for Terbuthylazine and metabolites on maize (with FOCUS PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		Terbuthylazine	MT1	MT13	MT14
maize	Châteaudun	0.000	0.008	7.216	0.716
	Hamburg	0.001	0.093	8.026	1.312
	Kremsmünster	0.001	0.069	6.571	1.013
	Okehampton	0.002	0.105	6.437	1.188
	Piacenza	0.002	0.092	5.614	0.928
	Porto	0.000	0.024	3.861	0.574
	Sevilla	0.000	0.000	2.276	0.044
	Thiva	0.000	0.003	8.635	0.513

Table 8.8-5: PECgw for Terbuthylazine and metabolites on maize (with FOCUS PEARL 4.4.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		Terbuthylazine	MT1	MT13	MT14
maize	Châteaudun	0.001096	0.134481	10.643035	1.891077
	Hamburg	0.017491	0.585884	14.950592	3.454771
	Kremsmünster	0.014860	0.361594	10.584839	2.444283
	Okehampton	0.019920	0.534528	9.501658	2.433190
	Piacenza	0.002785	0.130733	10.936496	0.130733
	Porto	0.000531	0.062991	5.276715	0.936995
	Sevilla	0.000001	0.001553	0.293709	0.293709
	Thiva	0.000027	0.010503	14.653369	1.260256

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

a) a) Full sample details not provided. 27103 sample data from Germany for the occurrence of terbuthylazine in groundwater. 328 detections of terbuthylazine were observed with 41 > (0.15% of the total analyses) displaying residues in excess of 0.1 µg/L. The Applicant states that none of these exceedences were due to the correct GAP for approved uses being applied.

b) Full sample details not provided. Groundwater samples from more than 1000 intakes from 15 municipalities in counties around Denmark in 1990 – 2001 were analysed for residues of plant protection products and their degradation products. The mean depth to the top of the groundwater sample was 24 - 25 m with a mean intake length of 3.5 m. In addition to the groundwater survey, the report also contained information on the analyses of water samples taken from a group of "other borings" which are not used to extract groundwater for drinking purposes. 1016 intakes were analysed for terbuthylazine (the number of analyses was 4086). There were 17 (1.7 %) intakes with detections of terbuthylazine,

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

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

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

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

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

e) In 1997, a monitoring study was carried out in four maize cultivated areas in the plain of the river Po in Italy to evaluate the degree of contamination of the groundwater table. No residues of terbuthylazine were detected above 0.1µg/l in the 1997 study. A follow-up study was conducted in 2006 in the same areas identified in the previous monitoring study. The majority of superficial wells sampled were over 20 m deep, with deep wells often greater than 50m. In these follow-up studies 8 out of approximately 100 wells were found to contain residues of terbuthylazine or its metabolites desethyl-terbuthylazine and hydroxy-terbuthylazine above 0.1 µg/l. However the average age of the wells was over 30 years and characterised by degraded materials, rust, holes or cracks etc and as a whole, the 90th percentile terbuthylazine and metabolite residues were all <0.05 µg/l on the basis of this monitoring.

f) A retrospective monitoring study was conducted in four regions of Portugal from 1999 to 2007. As a retrospective study, only limited details on the history of pesticide use in the upstream areas was available. However throughout the eight year duration of the study, 773 water samples were taken and analysed for terbuthylazine and desethyl-terbuthylazine from 68 different sampling sites, generating a total of 1546 data points. Sampling sites covered a relatively wide variety of sales history, cropping density, depth to groundwater and nitrate concentration (this last parameter used as general indicator for the vulnerability of an aquifer to agricultural practices). Although terbuthylazine has not been in widespread use in two of the monitored regions, it has been extensively used in vineyards in the Oeste and the Douro valley at a rate of 490 g/ha (1400 g/ha in row). Neither terbuthylazine nor desethyl-terbuthylazine residues exceeded 0.05 µg/l at the 90th percentile of the population. Overall the RMS considered that the additional data from the Portuguese monitoring programs did provide useful information. However it should be noted that the monitoring is only of partial relevance in the regions where prior use of terbuthylazine is known to be extensive, and also taking into account that the use covers applications to vineyards rather than the extensive use on maize as investigated in the German and Italian studies. Taking these caveats into account, the RMS considers that the data should be viewed as providing supporting information alongside the monitoring data from other regions, as well as taking into account the results of the standard first tier FOCUS groundwater exposure assessments.

g) Retrospective monitoring studies were conducted in 3 regions of Spain covering use of terbuthylazine on olive crops in Andalucia (2000 to 2003), use on maize and citrus crops in South Eastern Spain (2000 to 2001) and use on maize and vineyards in Northern Spain (2000- 2001). As retrospective studies, only limited details on the history of pesticide use in the upstream areas was available. In addition in many cases, the relatively large distance between the discharge point and the upland aquifer made it difficult to relate monitored residues back to a specific product use pattern. However throughout each study sampling sites were selected using local knowledge of cropping density, regional product sales data, hydrogeological information and informationpertaining to the integrity of the respective sampling sites. In three regions the 90th percentile concentration was less than 0.1 µg/l for both terbuthylazine and metabolite desethyl-terbuthyalzine (the only metabolite monitored for). However it should be noted that methods of analysis were unvalidated and the LOQ was only reported to be 0.1µg/l in the studies conducted in South Eastern Spain. In Andalucia, following extensive use of terbuthylazine on olive crops, the 90th percentile concentration of terbuthylazine was 0.14 µg/l. However the majority of detections in this region came from springs discharging groundwater into lagoons, troughs or drainage canals that were not protected from direct contamination. Overall the RMS considered that the additional data from the Spanish monitoring programs did provide limited useful information. However it should be noted that the monitoring is only of partial relevance in the regions where prior use of terbuthylazine is known to be extensive, and also taking into account that the monitoring covers areas where terbuthylazine may be applied to olive crops, citrus and vineyards in addition to use on maize in two of the three regions investigated. In addition, the sampling of groundwater from springs discharging to surface water bodies meant that the influence of direct contamination (rather than conventional leaching) could not be excluded. Taking these caveats into account, the RMS considers that the data should be viewed as providing limited supporting information only alongside the monitoring data from other regions, as well as taking into account the results of the standard first tier FOCUS groundwater exposure assessments.

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

8.8.2.2 Isoxaflutole and its metabolites

Table 8.8 6: Input parameters related to active substance Isoxaflutole and metabolite(s) for PECgw calculations

Compound	Isoxaflutole	RPA202248	RPA203328	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	359.32	359.32	268.22	EFSA Journal 2016;14(3):4416
Water solubility (g/mol):	6.2	6.2 from parent	6.2 from parent	EFSA Journal 2016;14(3):4416
Saturated vapour pressure (Pa):	3.22 x 10-7 Pa at 20°C	Vapour pressure: 3.22 x 10-7 Pa at 20°C	Vapour pressure: 3.22 x 10-7 Pa at 20°C	EFSA Journal 2016;14(3):4416
DT_{50} in soil (d)	0.9 d lab (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).	DT50field 15.8 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58).	DT50field 12d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58).	EFSA Journal 2016;14(3):4416
Transformation rate	0.770164 to RPA202248	0.04387 to RPA203328	0.057762 to CO2	EFSA Journal 2016;14(3):4416
K_{foc} (mL/g)/K_{fom}	KOC: 79.8 mL/g, arithmetic mean	RPA202248 , arithmetic mean 12.3 (*Koc arithmetic mean of pH>6.5),	KOC, arithmetic mean: 0	EFSA Journal 2016;14(3):4416
1/n	0.935	0.89	1	EFSA Journal 2016;14(3):4416
Plant uptake factor	0	0	0	EFSA Journal 2016;14(3):4416
Formation fraction	-	ff isoxaflutole to RPA202248=1	ff RPA202248 to RPA203328= 1	EFSA Journal 2016;14(3):4416

PEC_{gw} for Isoxaflutole and metabolites on maize (with FOCUS PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Isoxaflutole	RPA 202248	RPA 203328
maize	Châteaudun	0.000	0.169	0.176
	Hamburg	0.000	0.389	0.383
	Kremsmünster	0.000	0.486	0.406
	Okehampton	0.000	**0.691**	0.636
	Piacenza	0.000	0.207	**0.921**
	Porto	0.000	0.044	0.181
	Sevilla	0.000	0.005	0.023
	Thiva	0.000	0.040	0.083

Table 8.8-8: PEC_{gw} for Isoxaflutole and metabolites on maize (with FOCUS PEARL 4.4.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Isoxaflutole	RPA 202248	RPA 203328
maize	Châteaudun	0.000000	0.326010	1.175407
	Hamburg	0.000000	**1.154090**	**3.867183**
	Kremsmünster	0.000000	0.683356	1.543770
	Okehampton	0.000000	0.688668	1.706206
	Piacenza	0.000000	0.187448	0.579869
	Porto	0.000000	0.055729	0.269952
	Sevilla	0.000000	0.011470	0.073625
	Thiva	0.000000	0.092189	0.352074

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

According to EFSA Journal 2016;14(3):4416 metabolite RPA 202248 have a pesticidal activity and has not to exceed the trigger value 0.1 µg/L. Therefore, new calculation in Tier 2 for 80 g isoxaflutole/ha with PUF 0.5 in every third year for metabolites are presented below to minimalize content of RPA 202248 in water to be below trigeer value 0.1 µg/L

Table 8.8-7b:PEC_{gw} for Isoxaflutole and metabolites on maize (with FOCUS PELMO 5.5.3) (TIER 2) – 80g/ha isoxaflutole in every third year

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Isoxaflutole	RPA 202248	RPA 203328
maize	Châteaudun	0.000	0.019	0.080
	Hamburg	0.000	0.052	0.236
	Kremsmünster	0.000	0.071	0.239
	Okehampton	0.000	0.122	0.277
	Piacenza	0.000	0.033	0.086
	Porto	0.000	0.005	0.025
	Sevilla	0.000	0.000	0.002
	Thiva	0.000	0.002	0.009

Table 8.8-8b: PEC_{gw} for Isoxaflutole and metabolites on maize (with FOCUS PEARL 4.4.4) (TIER 2) – 80g/ha isoxaflutole in every third year

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Isoxaflutole	RPA 202248	RPA 203328
maize	Châteaudun	0.000000	0.039082	0.1582
	Hamburg	0.000000	0.098935	0.4223

	Kremsmünster	0.000000	0.079814	0.2966
	Okehampton	0.000000	0.1163	0.2957
	Piacenza	0.000000	0.04086	0.1148
	Porto	0.000000	0.0062	0.0299
	Sevilla	0.000000	0.00009	0.0011
	Thiva	0.000000	0.00042	0.0197

Metabolit RPA 202248 exceed trigger value 0.1 only in scenario – Okehampton, which is not relevant scenario in Poland. Metabolit RPA 203328 exceed trigger value 0.1 in 5 scenrios in PEARL and 4 scenario is PELMO. Assessment of relevance of ground water metabolites is performed and presented in section b10 of dRR.

zRMS comments:

The calculations of PEC_{gw} for active substance **isoxaflutole** (1x100g/ha) and **its metabolites** submitted by the Applicant for the proposed use in maize has been accepted. Calculations were performed according FOCUS EU guidance. Calculations were performed for proposed use in GAP. The interception according to FOCUS is 0% (maize, growth stage BBCH 00). Agreed endpoints in line EFSA Journal 2016;14(3):4416 were used as input parameters.
The PEC_{gw} for isoxaflutole are < 0.1 µg/L. However, its metabolite exceed trigger value 0.1 µg L^{-1}in 2 scenarios. Assessment of relevance of ground water metabolite is performed and presented in section B 10 of dRR.

December 2021:
zRMS was accepted new calculation for metabolite isoxaflutole of RPA 202248 80 g isoxaflutole/ha with PUF 0.5 in every third year for metabolites are presented below to minimalize content of RPA 202248 in water to be below trigeer value 0.1 µg/L. However, only the minimum application rate of 80 g of product /ha has to be accepted.
Risk mitigation measure: product Metodus can be used once every three years.

8.8.2.3 Mesotrione and its metabolites

Table 8.8 9: Input parameters related to active substance Mesotrione and metabolite(s) for PECgw calculations

Compound	Mesotrione	MNBA	AMBA	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	339.32	245	215	EFSA Journal 2016;14(3):4419
Water solubility (g/mol):	160	160	160	EFSA Journal 2016;14(3):4419
Saturated vapour pressure (Pa):	0	0	0	EFSA Journal 2016;14(3):4419
DT_{50} in soil (d)	4 d (shortest normalised laboratory DT50) acid value for **pH 5.1** (10th percentile maize crop area) - **DT50 =**	DT50:3.4 days (SFO, normalised, geometric mean DT50lab)	DT50: 14.5 days (SFO normalised, geometric mean DT50lab)	EFSA Journal 2016;14(3):4419

Compound	Mesotrione	MNBA	AMBA	Value in accordance with EU endpoint y/n/ Reference*
	27.88 d (linear), alkali value for **pH 7.9** (90th percentile maize crop area) **- DT50 = 5.4 d** (linear), intermediate **pH 6.5 14.2 d (linear)**			
Transformation rate	pH 5.1 linear 0.0249 pH 6.5 linear 0.0488 pH 7.9 linear 0.128361 shortest DT50 0.173 A.S to MNBA	0.0510 to AMBA, 0.1529 to CO2	0.0478 to CO2	EFSA Journal 2016;14(3):4419
K_{foc} (mL/g)/K_{fom}	acid value for **pH 5.1** (10th percentile maize crop area) **- Kfoc 156.6 l/kg (log)** (iii) alkali value for **pH 7.9** (90th percentile maize crop area) - **17.39 l/kg** (log), Kfom 10.12 l/kg, median (iv) intermediate pH 6.5 - **52.2 l/kg** (log) (i) **worst case Koc 14 l/kg** for that soil	worst case (of n = 2): Kfoc 3.2 l/kg, Kfom 1.86 l/kg	-worst case Koc 18.1 l/kg with 1/n 0.82 for that soil - acid value for pH 5.1 (10th percentile maize crop area) - Kfoc 105.61 l/kg (log), arithmetic mean 1/n = 0.85 - alkali value for pH 7.9 (90th percentile maize crop area) - Kfoc 21.8 L/kg (log), arithmetic mean 1/n = 0.85 - intermediate pH 6.5 – 48.02 l/kg (log)	EFSA Journal 2016;14(3):4419
1/n	worst case 1/n 0.97 acid value for pH 5.1 1/n = 0.94 alkali value for pH 7.9 1/n = 0.94	0.9	0.82	EFSA Journal 2016;14(3):4419
Plant uptake factor	0	0	0	EFSA Journal 2016;14(3):4419
Formation fraction	-	Formation fraction: 1.0 from parent	Formation fraction: 0.25 from MNBA	EFSA Journal 2016;14(3):4419

Table 8.8-10: PEC_{gw} for mesotrione and metabolites on maize (with FOCUS PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Mesotrione DT50-4 d Koc=14 g/L	**MNBA**	**AMBA Koc=18.1 g/l**
maize	Châteaudun	0.000	0.000	0.003
	Hamburg	0.000	0.001	0.014

	Kremsmünster	0.001	0.003	0.048
	Okehampton	0.003	0.017	0.096
	Piacenza	0.000	0.002	0.013
	Porto	0.000	0.000	0.003
	Sevilla	0.000	0.000	0.000
	Thiva	0.000	0.000	0.000
Crop	**Scenario**	**80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)**		
		Mesotrione DT50-27.88 (pH5.1) Koc=156.6g/L	**MNBA**	**AMBA Koc=105.61 g/l(pH5.1)**
maize	Châteaudun	0.001	0.008	0.001
	Hamburg	0.009	0.160	0.020
	Kremsmünster	0.005	0.039	0.005
	Okehampton	0.010	0.097	0.010
	Piacenza	0.012	0.035	0.006
	Porto	0.003	0.038	0.001
	Sevilla	0.000	0.003	0.000
	Thiva	0.000	0.005	0.000
Crop	**Scenario**	**80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)**		
		Mesotrione DT50-5.4 (pH7.9) Koc=17.39g/L	**MNBA**	**AMBA Koc=21.8 g/l(pH7.9)**
maize	Châteaudun	0.000	0.000	0.006
	Hamburg	0.001	0.002	0.024
	Kremsmünster	0.003	0.006	0.056
	Okehampton	0.008	0.023	**0.107**
	Piacenza	0.001	0.002	**0.017**
	Porto	0.000	0.000	0.003
	Sevilla	0.000	0.000	0.000
	Thiva	0.000	0.000	0.001
Crop	**Scenario**	**80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)**		
		Mesotrione DT50-14.2 (pH6.5) Koc=52.2g/L	**MNBA**	**AMBA Koc=48.02 g/l(pH7)**
maize	Châteaudun	0.004	0.008	0.001
	Hamburg	0.023	0.065	0.016
	Kremsmünster	0.022	0.030	0.008
	Okehampton	0.053	0.067	0.016

	Piacenza	0.018	0.015	0.006
	Porto	0.003	0.006	0.000
	Sevilla	0.000	0.001	0.000
	Thiva	0.001	0.002	0.000

Table 8.8-11: PEC_{gw} for Mesotrione and metabolites on maize (with FOCUS PEARL 4.4.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Mesotrione DT50-4 d Koc=14 g/L	**MNBA**	**AMBA Koc=18.1 g/l (worst case Koc)**
maize	Châteaudun	0.000082	0.000419	0.038766
	Hamburg	0.001254	0.007666	**0.118335**
	Kremsmünster	0.000711	0.003235	**0.161013**
	Okehampton	0.001806	0.007662	0.007662
	Piacenza	0.000118	0.000717	0.023550
	Porto	0.000004	0.000020	0.003635
	Sevilla	0.000000	0.000000	0.000264
	Thiva	0.000000	0.000002	0.004661
Crop	**Scenario**	**80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)**		
		Mesotrione DT50-27.88 (pH5.1) Koc=156.6g/L	**MNBA**	**AMBA Koc=105.61 g/l(pH5.1)**
maize	Châteaudun	0.010010	0.018853	0.002984
	Hamburg	0.081076	0.200007	0.055838
	Kremsmünster	0.049192	0.048195	0.019936
	Okehampton	0.069334	0.089391	0.023174
	Piacenza	0.017126	0.020619	0.006998
	Porto	0.006001	0.024094	0.001118
	Sevilla	0.000076	0.004061	0.000208
	Thiva	0.000872	0.002968	0.000182
Crop	**Scenario**	**80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)**		
		Mesotrione DT50-5.4 (pH7.9) Koc=17.39g/L	**MNBA**	**AMBA Koc=21.8 g/l(pH7.9)**
maize	Châteaudun	0.000543	0.001060	0.031609
	Hamburg	0.005456	0.016547	0.109005
	Kremsmünster	0.004477	0.006232	0.135655
	Okehampton	0.005964	0.011722	0.156681

	Piacenza	0.000431	0.001212	0.020597
	Porto	0.000022	0.000085	0.002806
	Sevilla	0.000000	0.000001	0.000146
	Thiva	0.000009	0.000016	0.003046
Crop	**Scenario**	**80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)**		
		Mesotrione DT50-14.2 (pH6.5) Koc=52.2g/L	**MNBA**	**AMBA Koc=48.02 g/l(pH7)**
maize	Châteaudun	0.000004	0.000172	0.001012
	Hamburg	0.000066	0.005984	0.015041
	Kremsmünster	0.000078	0.001644	0.020296
	Okehampton	0.000192	0.003163	0.024983
	Piacenza	0.000003	0.000268	0.003901
	Porto	0.000000	0.000008	0.000042
	Sevilla	0.000000	0.000000	0.000000
	Thiva	0.000000	0.000001	0.000005

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

8.9.1 Justification for new endpoints

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

- **Terbuthylazine** - EFSA Journal 2011; 9(1):1969
- **Isoxaflutole** - EFSA Journal 2016;14(3):4416
- **Mesotrione** - EFSA Journal 2016;14(3):4419

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

Table 8.9-1: Input parameters related to application for $PEC_{SW/SED}$ calculations

Plant protection product	CHR/H/TERIZ
Use No.	1
Crop	Maize
Application rate (kg as/ha)	Terbuthylazine: 400 g a.s/ha Isoxaflutole: 100 g a.s//ha Mesotrione:150 g a.s/ha
Number of applications/interval (d)	1/-
Application method	Boom sprayer

Models used for calculation	STEP 1-2, FOCUS SWASH STEP 3, SWAN STEP 4

8.9.2.1 Terbuthylazine and its metabolites

Table 8.9-2: Input parameters related to active substance Terbuthylazine and metabolite(s) for $PEC_{sw/sed}$ calculations Focus Models

Compound	Terbuthylazine	Desethyl-terbuthylazine	Hydroxy-terbuthylazine	Desethyl hydroxyl-terbuthylazine	Terbutryn (MT26)	Value in accordance to EU end-point y/n/ Reference
Molecular weight (g/mol)	229.7	201.7	211.3	183.2	241.4	EFSA Journal 2011; 9(1):1969
Saturated vapour pressure (Pa)	0	0	0	0	0	EFSA Journal 2011; 9(1):1969
Diffusion coefficient in water (m^2/d)	4.3×10^{-5}	not required for Step 1+2/	not required for Step 1+2	not required for Step 1+2	4.3×10^{-5}	default
Diffusion coefficient in air (m^2/d)	0.43	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	0.43	default
Water solubility (mg/L)	8.5	327.1	7.19	18	8.5	EFSA Journal 2011; 9(1):1969
K_{foc} (mL/g)	151	78	187.1	121	518	EFSA Journal 2011; 9(1):1969
Plant Uptake	0.5	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	0	default
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/	not required for Step 1+2/	not required for Step 1+2/	0.05 (MACRO) 0.50 (PRZM)	default
$DT_{50,soil}$ (d)	20 d (median of field data; SFO) [updated DT50 of 20.0 d assuming a Q10 of 2.58 should be used]	26.9 (geometric mean of field data; SFO)	453 days (geometric mean of lab data; SFO)	107d (geometric mean of lab data used as a conservative input parameter; SFO)	0.1 d	EFSA Journal 2011; 9(1):1969
$DT_{50,water}$ (d)	1000d	1000 d	1000 d	1000 d	1000 d	EFSA Journal 2011; 9(1):1969
$DT_{50,sed}$ (d)	69.9 d	1000 d	1000 d	1000 d	190 d	
$DT_{50,whole\ system}$ (d)	69.9 d	1000 d	1000d	1000 d	190 d	
Maximum occurrence observed (% molar basis with respect to the parent)		Maximum occurrence observed in soil: 54 % Maximum	Maximum occurrence observed in soil: 34.5 % Maximum	Maximum occurrence observed in soil: 28 % Maximum	Maximum occurrence observed in soil: 0.001 %	EFSA Journal 2011; 9(1):1969

Compound	Terbuthylazine	Desethyl-terbuthylazine	Hydroxy-terbuthylazine	Desethyl hydroxyl-terbuthylazine	Terbutryn (MT26)	Value in accordance to EU end-point y/n/ Reference
		occurrence observed in sediment/ water studies: 7.3 %	occurrence observed in sediment/ water studies: 20.0 %	occurrence observed in sediment/ water studies: N/A (soil metabolite only)	Maximum occurrence observed in sediment/ water studies: 7.4 %	

Table 8.9-3: FOCUS Step 1,2 and 3 PECsw and PECsed for active substance Terbuthylazine following single of product to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	114.6665	runoff/drainage	110.2258	167.5916
Step 2		22.5483	runoff/drainage	22.2357	33.4375
Northern Europe	March-May				
Step 3					
D3	ditch	2.097	drainage	0.3326	0.5452
D4	pond	0.1279	drainage	0.1272	0.4082
D4	stream	1.800	drainage	0.1046	0.1206
D5	pond	0.1253	drainage	0.1212	0.3214
D5	stream	1.805	drainage	0.02636	0.1135
D6	ditch	2.104	drainage	0.5388	0.7078
R1	pond	0.1866	runoff	0.1808	0.4035
R1	stream	5.826	runoff	0.3589	1.138

Values above RAC for Terbuthylazine are in red. RAC for terbuthylazine is indicated by algae EC50=12µg/L (RAC is equal 1.2)

FOCUS Step 4

Table 8.9-4: Global maximum PEC_{sw} values for Terbuthylazine, following single application(s) of CHR/H/TERIZ to maize according to the central EU zone GAP according to surface water Step 4 (relevant scenarios for GAP are D3,D4 and R1)

PEC_{sw} (µg/L)	Scenario

Nozzle reduction	Vegetative strip (m)	None	10*	~~10m VFSmod~~
	No spray buffer (m)	1	10*	~~10m VFSmod~~
None	D3 ditch	2.097	0.3644	~~0.3644~~
None	D4 pond	0.1279	0.1216	~~0.1216~~
None	D4 stream	1.800	0.4043	~~0.4043~~
None	D5 pond	0.1253	0.09497	~~0.09497~~
None	D5 stream	1.805	0.4136	~~0.4136~~
None	D6 ditch	2.104	0.3660	~~0.3660~~
None	R1 pond	0.1866	0.09135	~~0.05438~~
None	R1 stream	5.555	2.356	~~0.3237~~

***10 m buffer zone inputs in SWAN 4.01**
Reduction run-off mode:
Fractional reduction in run-off volume: 0.6
Fractional reduction in run-off flux: 0.6
Fractional reduction in erosion mass: 0.85
Fractional reduction in erosion flux: 0.85
Spray drift buffer with: 10m

Metabolite(s) of Terbuthylazine

Table 8.9-5: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Desethyl-terbuthylazine following single application(s) to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	65.2686	runoff/drainage	65.0900	50.6614
Step 2		11.8999	runoff/drainage	11.8647	9.2345
Northern Europe	March-May				

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

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	54.1762	runoff/drainage	53.9198	101.0408
Step 2		10.7289	runoff/drainage	10.6673	19.9879
Northern Europe	March-May				

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

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	25.9371	runoff/drainage	25.8743	28.7901
Step 2		5.0547	runoff/drainage	5.0425	5.6107
Northern Europe	March-May				

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

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	6.4201	runoff/drainage	6.2318	32.5320
Step 2		1.2627	runoff/drainage	1.2311	6.3792
Northern Europe	March-May				
Step 3					
D3	ditch	0.000046	drainage	0.000015	0.001932
D4	pond	0.000309	drainage	0.000308	0.01121
D4	stream	0.000047	drainage	0.000016	0.001322
D5	pond	0.000747	drainage	0.000747	0.01782
D5	stream	0.000073	drainage	0.000073	0.001834
D6	ditch	0.000108	drainage	0.000045	0.003808
R1	pond	0.000614	runoff	0.000613	0.01627
R1	stream	0.000446	runoff	0.000028	0.003561

Monitoring studies for Terbuthylazine in Surface water were presented EFSA Journal 2011; 9(1):1969:

a) Two sites in Germany susceptible to run-off and adjacent to streams in typical maize growing areas were selected. Upstream and downstream points of streams were monitored for terbuthylazine and desethylterbuthylazine (MT1) from May to August in 1999 and 2000 following terbuthylazine application to maize in adjacent field. Samples were taken every hour and combined into weekly samples. Samples also taken after heavy rainfall events. Neither analyte detected at 'Ramholz' site at concentrations > 0.05 µg/L (LOQ). Max weekly concentrations at the 'Kemading' site were 0.28 and 0.08 µg/L for terbuthylazine and desethylterbuthylazine (MT1) respectively. Max concentrations in event samples were 0.87 µg/L and 0.20 µg/L. Concentrations similar at upstream and downstream sample sites indicate residues arose from applications in upstream catchment.

b) Two sites in Germany adjacent to brooks were selected each with 10 m vegetated filter strip. Formulations were applied to maize between growth stages BBCH 13 and 16 in 1999 and 2000, and brook surface water samples at the upstream and downstream field edges were taken from one week before application (early May) until early September. Streams were sampled hourly and combined into weekly samples. Samples were also taken after heavy rainfall events. At the 'Adenstadt' site neither terbuthylazine nor desethylterbuthylazine (MT1) were observed at concentrations > LOQ (0.05 µg/L). Only once, in the first week following application was terbuthylazine detected at the 'Süplingen' site at a max concentration of 0.07 µg/L in a weekly sample. Desethyl-terbuthylazine (MT1) was not detected above the LOQ.

8.9.2.2 Isoxaflutole and its metabolites

Table 8.9-9: Input parameters related to active substance Isoxaflutole and metabolite(s) for $PEC_{sw/sed}$ calculations Focus Models

Compound	Isoxaflutole	RPA 202248	RPA 205834	RPA 203328	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	359.32	359.32	361.34	268.22	EFSA Journal 2016;14(3):4416
Saturated vapour pressure (Pa)	3.22×10-7 Pa at 25 °C	0	0	0	EFSA Journal 2016;14(3):4416
Water solubility (mg/L)	6.2	22660	6.2	6.2	EFSA Journal 2016;14(3):4416
K_{foc} (mL/g)	79.8	12.3	0	0	EFSA Journal 2016;14(3):4416
$DT_{50,soil}$ (d)	0.9 days (geomean field DT50)	15.8	1000d	12 d	EFSA Journal 2016;14(3):4416
$DT_{50,water}$ (d)	0.36 d	237 d	76.2 d	1000 d	EFSA Journal 2016;14(3):4416
$DT_{50,sed}$ (d)	0.36 d	237 d	76.2 d	1000 d	
$DT_{50,whole\ system}$ (d)	0.36 d	237 d	76.2 d	1000 d	
Maximum occurrence observed (% molar basis with respect to the parent)	-	Maximum occurrence observed Total Water and Sediment: 70.3% Water: 63.9% Soil: 100%	Maximum occurrence observed Total Water and Sediment: 26.4% Soil: 2.3%	Maximum occurrence observed Total Water and Sediment: 10.8% Soil: 62%	EFSA Journal 2016;14(3):4416

Table 8.9-10: FOCUS Step 1,2 and 3 PECsw and PECsed for active substance isoxaflutole following single of product to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	31.0474	runoff/drainage	2.8751	24.0419
Step 2		0.9197	runoff/drainage	0.1329	0.2211
Northern Europe	March-May				
Step 3					
D3	ditch	0.5244	drainage	0.03938	0.06152
D4	pond	0.02117	drainage	0.003444	0.003933
D4	stream	0.4493	drainage	0.005496	0.02099
D5	pond	0.02116	drainage	0.002772	0.003383
D5	stream	0.4477	drainage	0.002662	0.01142
D6	ditch	0.5259	drainage	0.03736	0.05693
R1	pond	0.02116	runoff	0.003859	0.004184
R1	stream	0.3625	runoff	0.01498	0.02888

Table 8.9-11: Global maximum PECsw µg/l values for isoxaflutole, following single application(s) of CHR/H/TERIZ to maize according to the central EU zone GAP according to surface water Step 4 (relevant scenarios for this authorisation is D3,D4, R1)

PEC_{sw} (µg/L)	Scenario			
Nozzle reduction	Vegetative strip (m)	None	10	20
	No spray buffer (m)	1	10	20
None	D3 ditch	0.5244	0.09112	0.04737
None	D4 pond	0.02117	0.01358	0.009085
None	D4 stream	0.4493	0.1002	0.05220
None	D5 pond	0.02116	0.01358	0.009083
None	D5 stream	0.4477	0.09983	0.05202
None	D6 ditch	0.5259	0.09139	0.04751
None	R1 pond	0.02116	0.01357	0.009082
None	R1 stream	0.3625	0.08082	0.04212

Metabolite(s) of isoxaflutole

Table 8.9-12: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for RPA 202248 following single application(s) to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	56.4972	runoff/drainage	55.9133	6.9276
Step 2		6.3473	runoff/drainage	6.2797	0.7780
Northern Europe	March-May				
Step 3					
D3	ditch	0.1756	drainage	0.05485	0.07280
D4	pond	0.07457	drainage	0.07441	0.1124
D4	stream	0.06562	drainage	0.04137	0.04191
D5	pond	0.03193	drainage	0.03167	0.04382
D5	stream	0.05288	drainage	0.01369	0.01323
D6	ditch	0.2255	drainage	0.06474	0.03979
R1	pond	0.02004	runoff	0.01969	0.01940
R1	stream	1.476	runoff	0.09067	0.1261

Table 8.9-13: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for RPA 205834 following single application(s) to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	9.8646	runoff/drainage	9.5571	0.0000
Step 2		0.4705	runoff/drainage	0.4558	0.0000
Northern Europe	March-May				

Table 8.9-14: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for RPA 203328 following single application(s) to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	18.1884	runoff/drainage	18.1443	0.0000
Step 2		2.5475	runoff/drainage	2.5413	0.0000
Northern Europe	March-May				

zRMS comments:

The calculations of PEC_{sw} for active substance **isoxaflutole** (1x100g/ha) and **its metabolites** submitted by the Applicant for the proposed use in maize has been accepted. Calculations were performed according FOCUS EU guidance and by models Step1 & 2 and 3 & 4. Calculations were performed for proposed use in GAP. Agreed endpoints in line EFSA Journal 2016;14(3):4416 were used as input parameters. The mitigations measure was considered: 10m and 20m buffer zone (drift and vegetative) . The mitigation measures based on FOCUS Landscape and Mitigation are considered acceptable for further STEP 4 refinement.

December 2021:
It should be indicated that applicant in meantime changed the GAP Table by limitation of the application rate from 1 kg product/ha to only 0/8 kg product/ha (80 g isoxaflutole/ha).

Althought he applicant did not provide PECsw/sed calculation for lower rate calculations performed for 100g isoxaflutole/ha was accepted as worse case by zRMS.

8.9.2.3 Mesotrione and its metabolites

Table 8.9-15: Input parameters related to active substance Mesotrione and metabolite(s) for $PEC_{sw/sed}$ calculations Focus Models Step 1-2 and Step 3 and STEP 4.

Compound	Mesotrione	MNBA	AMBA	SYN 546974	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	339	245	215	291	EFSA Journal 2016;14(3):4419
Saturated vapour pressure (Pa)	1.0E-10 Pa at 20°C	0	0	0	EFSA Journal 2016;14(3):4419
Water solubility (mg/L)	160	160	160	160	EFSA Journal 2016;14(3):4419
K_{foc} (mL/g)	156.7 (log fit, pH 5.1 value) 17.4 (log fit, pH 7.9 value)	3.2	18.0 (linear fit, pH 7.9 value) worst case	27031	EFSA Journal 2016;14(3):4419
$DT_{50,soil}$ (d)	27.88 (linear fit, pH 5.1 value) 5.4 d (linear fit, pH 7.9 value)	3.6 d	14.5 d	0.1 d	EFSA Journal 2016;14(3):4419
$DT_{50,water}$ (d)	5.5 d	1000 d	1000 d	1000 d	EFSA Journal 2016;14(3):4419
$DT_{50,sed}$ (d)	5.6d	1000 d	1000 d	1000 d	
$DT_{50,whole\ system}$ (d)	5.6 d	1000 d	1000 d	1000 d	
Maximum occurrence observed (% molar basis with respect to the parent)		Total Water and Sediment: 7.9 Soil: 57.2	Total Water and Sediment: 24.6 Soil: 9.7	Total Water and Sediment: 33.0 Soil: 1.0E-10*	EFSA Journal 2016;14(3):4419

Table 8.9-16: FOCUS Step 1,2 and 3 PECsw and PECsed for active substance Mesotrione following singleof product to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Input values for pH 5.1					
Step 1	---	42.7383	runoff/drainage	28.4522	64.8092
Step 2		8.2207	runoff/drainage	5.4485	12.5013
Northern Europe	March-May				
Input values for pH 7.9					
Step 1	-	50.2458	runoff/drainage	33.5990	8.5027
Step 2	-	6.7242	runoff/drainage	4.4702	1.1226
Step 3 for pH 5.1					
D3	ditch	0.7865	drainage	0.1174	0.1980
D4	pond	0.08332	drainage	0.08265	0.1561
D4	stream	0.6771	drainage	0.1039	0.1251
D5	pond	0.04569	drainage	0.04373	0.08568
D5	stream	0.6845	drainage	0.03457	0.08271
D6	ditch	0.7893	drainage	0.1786	0.2475
R1	pond	0.05675	runoff	0.04620	0.07359
R1	stream	2.223	runoff	0.1369	0.4398
Step 3 for pH 7.9					
D3	ditch	0.7866	drainage	0.1179	0.08049
D4	pond	0.03178	drainage	0.02496	0.009895
D4	stream	0.6742	drainage	0.008685	0.02198
D5	pond	0.03175	drainage	0.02440	0.009717
D5	stream	0.6718	drainage	0.004106	0.01382
D6	ditch	0.7893	drainage	0.1803	0.09957
R1	pond	0.03174	runoff	0.02583	0.01363
R1	stream	1.761	runoff	0.1086	0.1526

Table 8.9-17: Global maximum PECsw µg/l values for mesotrione, following single application(s) of CHR/H/TERIZ to maize according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 Mesotrione pH 5.1		
Nozzle reduction	Vegetative strip (m)	None	10	20

	No spray buffer (m)	1	10	20
None	D3 ditch	0.7865	0.1368	0.07106
None	D4 pond	0.08332	0.08331	0.08331
None	D4 stream	0.6771	0.1537	0.1354
None	D5 pond	0.04569	0.04568	0.04568
None	D5 stream	0.6845	0.1629	0.09071
None	D6 ditch	0.7893	0.1378	0.07181
None	R1 pond	0.05675	0.02486	0.01357
None	R1 stream	2.223	0.9430	0.4810
PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Mesotrione pH 7.9**		
Nozzle reduction	Vegetative strip (m)	None	10	20
	No spray buffer (m)	1	10	20
None	D3 ditch	0.7866	0.1369	0.07108
None	D4 pond	0.03178	0.02040	0.01361
None	D4 stream	0.6742	0.1507	0.07827
None	D5 pond	0.03175	0.02037	0.01358
None	D5 stream	0.6718	0.1501	0.07789
None	D6 ditch	0.7893	0.1376	0.07165
None	R1 pond	0.03174	0.02036	0.01357
None	R1 stream	1.761	0.7469	0.3811

Metabolite(s) of Mesotrione

Table 8.9-18: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for MNBA following single application(s) to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	23.5032	runoff/drainage	23.4459	0.7516
Step 2		2.3242	runoff/drainage	2.3184	0.0743
Northern Europe	March-May				

Table 8.9-19: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AMBA following single application(s) to maize for the worst case parameters.

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	10.8371	runoff/drainage	10.8062	1.9484
Step 2		1.6192	runoff/drainage	1.6138	0.2910
Northern Europe	March-May				

Table 8.9-20: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for SYN 546974 following single application(s) to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.7732	runoff/drainage	0.4191	106.1382
Step 2		0.3908	runoff/drainage	0.0889	15.2041
Northern Europe	March-May				

zRMS comments:

The calculations of PEC_{sw} for active substance **mesotrione** and **its metabolites** submitted by the Applicant were early assessed in dRR B8 02.2019 r. The calculations are acceptable.

PEC_{sw} of CHR/H/TERIZ assuming application 1000 g {TERIZ}/ha on maize in Drift calculator into surface water from SWASH ver 5.3

Intended use	maize
Formulation	CHR/H/TERIZ
Application rate (g[prod]/ha)	1 X 1000
Entry into surface water via spraydrift (Drift alculator from SWASH)	
Buffer zone (m)	**PECsw [µg prod/L**
1	5.3119
5	1.7415
10	0.9236

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

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	**Terbuthylazine**
Direct photolysis in air	Not studied - no data requested
Quantum yield of direct phototransformation	Not studied - no data requested
Photochemical oxidative degradation in air	DT50 of 13.55 hours derived by the Atkinson model. OH (12 h) concentration assumed = 1.5 x 106 cm-3.
Volatilisation	from plant surfaces (BBA guideline): ≤ 10.2 % after 24 hours from soil surfaces (BBA guideline): ≤ 13.8 % after 24 hours
Metabolites	None

Compound	**Mesotrione EFSA Journal 2016;14(3):4419**
Direct photolysis in air	Not studied - no data requested
Photochemical oxidative degradation in air	DT50 of 17.635 hours (1.5 days) derived by the Atkinson model (AOP version 1.8). OH (12h) concentration assumed = 1.5 x 106 OH/cm3
Volatilisation	from plant surfaces (BBA guideline): <10% after 24 hours from soil surfaces (BBA guideline): <10% after 24 hours
Metabolites	None

Compound	**Isoxaflutole EFSA Journal 2016;14(3):4416**
Direct photolysis in air	Not studied - no data requested due to low volatility
Photochemical oxidative degradation in air	Isoxaflutole: DT50 of 1.83 days derived by the computer program AOPWIN (version 1.91) and the methodology derived by Atkinson. OH (12h) concentration assumed = 1.5x106 molecule cm-3. RPA 202248 DT50: 0.62 – 1.42 days derived by the computer program AOPWIN (version 1.91) and the methodology derived by Atkinson. OH (12h) concentration assumed = 1.5×106 molecule cm-3.
Volatilisation	from plant surfaces (BBA guideline): <1% after 24 hours from soil surfaces (BBA guideline): negligible after 24 hours
Metabolites	None

ZRMS comments:

Accepted.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.3	L.Lupicki	2016	CHR/H/TERIZ 650 WG Predicted environmental concentration of terbuthylazine, isoxaflutole, mesotrione and their metabolites in soil, ground water and surface water. PUH Chemirol Sp. z o.o. Study code: TERIZ-B8 Non GLP Unpublished	N	Chemirol
KCP 9.2.4	L.Lupicki	2016	CHR/H/TERIZ 650 WG Predicted environmental concentration of terbuthylazine, isoxaflutole, mesotrione and their metabolites in soil, ground water and surface water. PUH Chemirol Sp. z o.o. Study code: TERIZ-B8 Non GLP Unpublished	N	Chemirol
KCP 9.2.5	L.Lupicki	2016	CHR/H/TERIZ 650 WG Predicted environmental concentration of terbuthylazine, isoxaflutole, mesotrione and their metabolites in soil, ground water and surface water. PUH Chemirol Sp. z o.o. Study code: TERIZ-B8 Non GLP Unpublished	N	Chemirol
KCP 9.3.1	L.Lupicki	2016	CHR/H/TERIZ 650 WG Predicted environmental concentration of terbuthylazine, isoxaflutole, mesotrione and their metabolites in soil, ground water and surface water. PUH Chemirol Sp. z o.o.	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Study code: TERIZ-B8 Non GLP Unpublished		
KCP 9.1.3/02	L.Lupicki	2019	CHR/H/TERIZ 650 WG Predicted environmental concentration of isoxaflutole and their metabolites in soil, ground water and surface water after renewal of active substance isoxaflutole. Study code: TERIZ-B8 Non GLP Unpublished	N	Chemirol
KCP 9.2.4/02	L.Lupicki	2019	CHR/H/TERIZ 650 WG Predicted environmental concentration of isoxaflutole and their metabolites in soil, ground water and surface water after renewal of active substance isoxaflutole PUH Chemirol Sp. z o.o. Study code: TERIZ-B8 Non GLP Unpublished	N	Chemirol
KCP 9.2.5/02	L.Lupicki	2019	CHR/H/TERIZ 650 WG Predicted environmental concentration of isoxaflutole and their metabolites in soil, ground water and surface water after renewal of active substance isoxaflutole. PUH Chemirol Sp. z o.o. Study code: TERIZ-B8 Non GLP Unpublished	N	Chemirol

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/01	Schaffer A. Nicollier G.	1997a	Degradation of ^{14}C-labelled GS13529 in Gartenacker loam soil under aerobic conditions at 10 and 20 C and under anaerobic/sterile conditions at 20 C. Syngenta Crop Protection AG. Study No. 96AS01. GLP: Yes Published: No Report No. GS135239/1475.	N	Syngenta
KCP 9.1.1/02	Schaffer A. Nicollier G.	1997a	Degradation of ^{14}C-labelled GS13529 in Gartenacker loam soil under aerobic conditions at 10 and 20 C and under anaerobic/sterile conditions at 20 C. Syngenta Crop Protection AG. Study No. 96AS05. GLP: Yes Published: No Report No. GS135239/1475.	N	Syngenta

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCP 9.1.1/03	Morgenroth, U	2000a	Degradation of [triazine-U-14C]-labelled GS 13529 in two soils under aerobic conditions at 20°C Novartis Crop Protection AG, Basel, Switzerland, Report No 99MO06 GLP Not Published Syngenta File N° GS13529/1673	N	Syngenta
KCP 9.1.1/04	Glaenzel, A.	1998	Rate of degradation of GS 13529 in one soil under various conditions Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 97RP02 GLP Not Published Syngenta File N° GS13529/1582	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/05	Galicia H., Morgenroth, U.	1993	Degradation of 14C-Terbuthylazin Technical (GS 13529): in Four Soils Incubated under Aerobic Conditions Novartis Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, Report No 243224 GLP Not Published Syngenta File N° GS13529/1219	N	Syngenta
KCP 9.1.1/06	Purghart, V.	2000	Terbuthylazine (GS 13529): soil photolysis Novartis Crop Protection AG, Basel, Switzerland Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland, Report No 1047.102.720 GLP Not Published Syngenta File N° GS13529/1706	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/07	Abildt, U.	1991	Aerobic degradation of GS 13529 in soil under various test-conditions Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 38-90 GLP Not Published Syngenta File N° GS13529/0855	N	Syngenta
KCP 9.1.1/08	Reischmann, F.	2000a	Rate of degradation of Triazine-U-14C) labelled GS 26379 in three soils under aerobic laboratory conditions at 20° C Novartis Crop Protection AG, Basel, Switzerland, Report No 99RF04 GLP Not Published Syngenta File N° GS26379/0008	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/09	Glaenzel, A.	2000a	Rate of degradation of 14C-triazine labelled GS 23158 in three soils under laboratory conditions at 20°C Novartis Crop Protection AG, Basel, Switzerland, Report No 99AG05 GLP Not Published Syngenta File N° GS23158/0006	N	Syngenta
KCP 9.1.1/10	Phaff,R.	2000a	Degradation of 14C-triazine labelled GS 28620 in four soils under aerobic conditions at 20°C Novartis Crop Protection AG, Basel, Switzerland, Report No 99RP05 GLP Not Published Syngenta File N° GS28620/0008	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/11	Nicollier,G.	1997	Field dissipation of GS 13529 after bareground application of [triazine-(U)-14C] labelled material Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No CMR 08/97 GLP Not Published Syngenta File N° GS13529/1485	N	Syngenta
KCP 9.1.1/12	Offizorz, P., Resseler, H.	1990a	Dissipation rate determination of terbuthylazine Novartis Crop Protection AG, Basel, Switzerland RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany, Report No 170425 Not GLP Not Published Syngenta File N° GS13529/0924	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/13	Offizorz, P., Resseler, H.	1990b	Field soil, Dissipation rate determination of terbuthylazine Novartis Crop Protection AG, Basel, Switzerland RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany, Report No 170414 Not GLP Not Published Syngenta File N° GS13529/0926	N	Syngenta
KCP 9.1.1/14	Offizorz, P., Resseler, H.	1991a	Field soil dissipation rate determination of terbuthylazine (Exp.-No. 51-90B) Novartis Crop Protection AG, Basel, Switzerland RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany, Report No 223740 GLP Not Published Syngenta File N° GS13529/0925	N	Syngenta
KCP 9.1.1/15	Offizorz, P., Resseler, H.	1991b	Field soil dissipation rate determination of terbuthylazine (Exp.-No. 25-90B) Novartis Crop Protection AG, Basel, Switzerland RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany, Report No 223727 GLP Not Published Syngenta File N° GS13529/0927	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/16	Offizorz, P., Resseler, H.	1991c	Field soil dissipation rate determination of terbuthylazine (Exp.-No. 24-90B) Novartis Crop Protection AG, Basel, Switzerland RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany, Report No 223716 GLP Not Published Syngenta File N° GS13529/0928	N	Syngenta
KCP 9.1.1/17	Offizorz, P., Resseler, H.	1991d	Field soil dissipation rate determination of terbuthylazine (Exp.-No. 50-90B) Novartis Crop Protection AG, Basel, Switzerland RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany, Report No 223738 GLP Not Published Syngenta File N° GS13529/0929	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/18	Evans, P.	2004a	Terbuthylazine (GS13529) and S-Metolachlor (CGA77102): Dissipation Study with Terbuthylazine (GS13529) and S-Metolachlor (CGA77102) in or on Cultivated Soil in France (South) Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, Report No RJ3521B GLP Not Published Syngenta File N° CGA77102/0806	N	Syngenta
KCP 9.1.1/19	Evans, P.	2004b	Terbuthylazine (GS13529) and S-Metolachlor (CGA77102) : Dissipation Study with Terbuthylazine and S-Metolachlor (CGA77102) in or on Cultivated Soil in Italy Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, Report No RJ3522B GLP Not Published Syngenta File N° CGA77102/0807	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/20	Edwards,P., Evans, P.	2004	Terbuthylazine: Residue Stability Study for Terbuthylazine (GS13529) and its Metabolites (GS26379, GS23158 and GS28620) in Soil under Freezer Storage Conditions - Interim Report Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, Report No RJ3492B GLP Not Published	N	Syngenta
KCP 9.1.1/21	Mamouni A., Morgenroth U.	1995	METABOLISM AND DEGRADATION OF 14C-TERBUTHYLAZINE IN FOUR SOILS INCUBATED UNDER AEROBIC CONDITIONS RCC AG., Itingen, Switzerland Oxon Italia S.P.A, Pero, Italy Report-no. 324505 GLP: yes published: no	N	Oxon
KCP 9.1.1/22	Wonders J.,van Noorloos.B.	2003	ANAEROBIC SOIL METABOLISM OF TERBUTHYLAZINE Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 356906 GLP: yes published: no	N	Oxon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/23	Willems H., Wonders J.	2001	PHOTODEGRADATION OF TERBUTHYLAZINE ON SOIL SURFACES Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 308148 GLP: yes published: no	N	Oxon
KCP 9.1.1/24	Willems H.	1998a	DETERMINATION OF THE METABOLISM AND DEGRADATION RATE OF DESETHYLTERBUTHYLAZINE IN SOIL Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 197786 GLP: yes published: no	N	Oxon
KCP 9.1.1/25	Willems H.	1998b	DETERMINATION OF THE DEGRADATION RATE OF DESETHYLTERBUTHYLAZINE IN THREE SOILS Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 197775 GLP: yes published: no	N	Oxon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/26	Slangen P.J.	2001a	DETERMINATION OF THE DEGRADATION RATE OF 2-HYDROXYTERBUTHYLAZINE IN THREE SOILS Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 308251 GLP: yes published: no	N	Oxon
KCP 9.1.1/26	Glanzel A.	2000	RATE OF DEGRADATION OF 14C-TRIAZINE LABELLED GS 23158 IN THREE SOILS UNDER LABORATORY CONDITIONS AT 20°C. Novartis Crop Protection AG, Basel, Switzerland. Unpublished report No. 99AG05. Study dates: 11 October 1999 – 15 March 2000 Syngenta File N° GS 23158/0006	N	Oxon
KCP 9.1.1/27	Roberts N.L.	1999	CLICK 50 SC: SOIL DISSIPATION WITH TERBUTHYLAZINE IN FRANCE Huntingdon Life Sciences Ltd., Cambridgeshire, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 162/983485 GLP: yes published: no	N	Oxon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/28	Roberts N.L.	2000	CLICK 50 SC: SOIL DISSIPATION WITH TERBUTHYLAZINE IN ITALY Huntingdon Life Sciences Ltd., Cambridgeshire, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 162/984733 GLP: yes published: no	N	Oxon
KCP 9.1.1/29	Blaschke U.G.	1998	CLICK 50 SC: SOIL DISSIPATION WITH TERBUTHYLAZINE IN GERMANY Huntingdon Life Sciences Ltd., Suffolk, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 188/983486 GLP: yes published: no	N	Oxon
KCP 9.1.1/30	Todd M.	1999	2 HYDROXY TERBUTHYLAZINE: VALIDATION AND DETERMINATION OF RESIDUES IN SOIL SAMPLES GENERATED FROM FIELD DISSIPATION TRIALS HELD IN NORTHERN EUROPE Huntingdon Life Sciences Ltd., Suffolk, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 227/993260 GLP: yes published: no	N	Oxon

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Battelle UK Ltd., Ongar, United Kingdom, NC/08/006A Not GLP, not published		
KCP 9.1.1/35	Hardy I	2008b	Terbuthylazine - Kinetic Modelling Analysis of Data from Aerobic Soil Degradation Studies With the Metabolite MT1 (GS26379) in Order to Derive DT50 Values and Formation Fractions for Use as Modelling Endpoints Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Battelle UK Ltd., Ongar, United Kingdom, NC/08/006B Not GLP, not published	N	Syn/Oxn
KCP 9.1.1/36	Hardy I	*2008c*	Terbuthylazine - Kinetic Modelling Analysis of Data from Aerobic Soil Degradation Studies With the Metabolite MT13 (GS23158) in Order to Derive DT50 Values for Use as Modelling Endpoints Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia S.p.a., Pero, Italy. Battelle UK Ltd., Ongar, United Kingdom, *NC/08/006C* *Not GLP, not published*	N	Syn/Oxn
KCP 9.1.1/37	Hardy I	2008d	Terbuthylazine - Kinetic Modelling Analysis of Data from Aerobic Soil Degradation Studies With the Metabolite MT14 (GS28620) in Order to Derive DT50 Values for Use as Modelling Endpoints Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Battelle UK Ltd., Ongar, United Kingdom, NC/08/006D Not GLP, not published	N	Syn/Oxn
KCP	Hardy I	2008e	Terbuthylazine - Kinetic Modelling Analysis of Data from	N	Syn/Oxn

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
9.1.1/38			Field Soil Dissipation Studies in Order to Derive Normalised DT50 Values and Formation Fractions for Use as Modelling Endpoints Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Battelle UK Ltd., Ongar, United Kingdom, NC/08/006E Not GLP, not published		
KCP 9.1.1/39	Lucini L	2007	Characterisation of soils tested in field dissipation studies with Click 50 SC Oxon Italia S.p.a., Pero, Italy , OXO - TBA - AII -0701010202 GLP, not published	N	Oxon
KCP 9.1.1/40	Trevisan M	2009	Terbuthylazine - Multi-site Study for the Monitoring of Terbuthylazine and its Metabolites in Soil Syngenta CP S.p.A, Milano, Italy; Oxon Italia S.p.a., Pero, Italy. CERZOO, Piacenza, Italy, CZ/07/020/UCSC/TBASOI/RF, T008420-07 GLP, not published	N	Syn/Oxn
KCP 9.1.1/41	Hardy, I. A. J.	2001	Isoxaflutole: Kinetic modelling analysis of a European terrestrial field soil dissipation study Battelle AgriFood Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C015653, Edition Number: M-200916-01-1 EPA MRID No.: 45658806 Date: 2001-12-04 GLP/GEP: no, unpublished	N	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/42	Gatzweiler, E. W.	1996	RPA 201772: terrestrial field soil dissipation study Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: C034014, Report includes Trial Nos.: AR53-94 Edition Number: M-234225-01-1 Date: 1996-02-14 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.1/43	Heinemann, O.	2012	[Cyclopropyl-1-14C]RPA 202248:: Aerobic degradation/metabolism in one European soil Bayer CropScience, Report No.: MEF-11/486, Edition Number: M-427583-01-1 Date: 2012-03-12 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.1/45	Burr C. M.; Jones, M. K.; Newby, S. E.	1995	RPA201772 Anaerobic Aquatic Metabolism Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom BCS, Report No.: R016760, Edition Number: M-192288-01-1 Date: 1995-01-30 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.1/46	Ferreira, E. M.	1994	RPA201772 - Soil photolysis Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom BCS, Report No.: R000311, Edition Number: M-158351-01-1 Date: 1994-02-04 GLP/GEP: yes, unpublished	N	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/47	Hardy, I. A. J.	2001	Isoxaflutole: Kinetic modelling analysis of a European terrestrial field soil dissipation study Battelle AgriFood Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C015653, Edition Number: M-200916-01-1 EPA MRID No.: 45658806 Date: 2001-12-04 GLP/GEP: no, unpublished	N	Bayer CropScience
KCP 9.1.1/48	Gatzweiler, E. W.	1996	RPA 201772: terrestrial field soil dissipation study Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: C034014, Report includes Trial Nos.: AR53-94 Edition Number: M-234225-01-1 Date: 1996-02-14 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.1/49	Ferreira, E. M.; Jones, M. K.; Newby, S. E.	1994	RPA201772: Aerobic soil metabolism Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom BCS, Report No.: R000347, Edition Number: M-158435-01-1 Date: 1994-10-13 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.1/50	Burr, C. M.	1995	Herbicides: RPA 201772 Route of degradation (aerobic metabolism) in one soil (interim report) Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom	N	Bayer CropScience

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
			Bayer CropScience, Report No.: C022444, Edition Number: M-213110-01-1 Date: 1995-12-18 GLP/GEP: yes, unpublished		
KCP 9.1.1/51	Burr, C. M.	1996	Herbicides: Isoxaflutole Route of Degradation (Aerobic Metabolism) in one Soil Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: B003826, Edition Number: M-240821-01-1 EPA MRID No.: 45658804 Date: 1996-08-12 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.1/52	Ferreira, E. M.; Bullus, C. M.; Jones, M. K.; Simmonds, M. B.	1996	RPA 201772: Rate of Degradation under Aerobic Conditions in Three Soil Types Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: B003827, Edition Number: M-240822-01-1 EPA MRID No.: 45658805 Date: 1996-01-10 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.1/53	Ferreira, E. M.	1996	RPA 201772: Rate of degradation under aerobic conditions in one soil at 10 degrees C Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C022445, Edition Number: M-213113-01-1 Date: 1996-01-24	N	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP/GEP: yes, unpublished		
KCP 9.1.1/54	Hardy, I. A. J.	2013	Isoxaflutole: Kinetic modelling evaluation of aerobic soil degradation study data to derive trigger endpoints Battelle UK Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: VC/13/007C, Edition Number: M-464601-01-1 Date: 2013-07-17 GLP/GEP: no, unpublished	N	Bayer CropScience
KCP 9.1.1/55	Hardy, I. A. J.	2013	Isoxaflutole: Kinetic modelling evaluation of aerobic soil degradation study data to derive modelling endpoints Battelle UK Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: VC/13/007B, Edition Number: M-464596-01-1 Date: 2013-07-17 GLP/GEP: no, unpublished	N	Bayer CropScience
KCP 9.1.1/56	Ferreira, E. M.; Jones, M. K.; Newby, S. E.	1994	RPA201772: Aerobic soil metabolism Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom BCS, Report No.: R000347, Edition Number: M-158435-01-1 Date: 1994-10-13 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.1/57	Burr, C. M.	1995	Herbicides: RPA 201772 Route of degradation (aerobic metabolism) in one soil (interim report) Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C022444, Edition Number: M-213110-01-1	N	Bayer CropScience

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
			Date: 1995-12-18 GLP/GEP: yes, unpublished		
KCP 9.1.1/58	Burr, C. M.	1996	Herbicides: Isoxaflutole Route of Degradation (Aerobic Metabolism) in one Soil Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: B003826, Edition Number: M-240821-01-1 EPA MRID No.: 45658804 Date: 1996-08-12 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.1/59	Ferreira, E. M.; Bullus, C. M.; Jones, M. K.; Simmonds, M. B.	1996	RPA 201772: Rate of Degradation under Aerobic Conditions in Three Soil Types Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: B003827, Edition Number: M-240822-01-1 EPA MRID No.: 45658805 Date: 1996-01-10 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.1/60	Ferreira, E. M.	1996	RPA 201772: Rate of degradation under aerobic conditions in one soil at 10 degrees C Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C022445, Edition Number: M-213113-01-1 Date: 1996-01-24 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.1/61	Heinemann, O.	2012	[Cyclopropyl-1-14C]RPA 202248:: Aerobic degradation/metabolism in one European soil	N	Bayer CropScience

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
			Bayer CropScience, Report No.: MEF-11/486, Edition Number: M-427583-01-1 Date: 2012-03-12 GLP/GEP: yes, unpublished		
KCP 9.1.1/62	Hardy, I. A. J.	2013	Isoxaflutole: Kinetic modelling evaluation of aerobic soil degradation study data to derive trigger endpoints Battelle UK Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: VC/13/007C, Edition Number: M-464601-01-1 Date: 2013-07-17 GLP/GEP: no, unpublished	N	Bayer CropScience
KCP 9.1.1/63	Hardy, I. A. J.	2013	Isoxaflutole: Kinetic modelling evaluation of aerobic soil degradation study data to derive modelling endpoints Battelle UK Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: VC/13/007B, Edition Number: M-464596-01-1 Date: 2013-07-17 GLP/GEP: no, unpublished	N	Bayer CropScience
KCP 9.1.1/64	Gatzweiler, E. W.	1996	RPA 201772: terrestrial field soil dissipation study Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: C034014, Report includes Trial Nos.: AR53-94 Edition Number: M-234225-01-1 Date: 1996-02-14 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP	Gatzweiler, E.	1996	RPA 201772: terrestrial field soil dissipation study on four Europe-	N	Bayer CropScience

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
9.1.1/65	W.		an soils Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: R000410, Report includes Trial Nos.: P94/009 Edition Number: M-158573-01-1 GLP/GEP: no, unpublished		
KCP 9.1.1/66	Heinemann, O.	2012	Determination of the residues of AE 0540092 in/on soil after spraying of AE 0540092 WP 20 in the field in Germany, United Kindom, France (North), Italy and Spain Bayer CropScience, Report No.: 10-2702, Report includes Trial Nos.: 10-2702-01 10-2702-02 10-2702-03 10-2702-04 10-2702-05 10-2702-06 Edition Number: M-428564-01-1 Date: 2012-03-19 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.1/67	Hardy, I. A. J.	2013	Kinetic modelling analysis of AE 0540092 and AE B197555 from a field soil residue study conducted in Europe (Normalisation to 20degree and pF2) Battelle UK Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: VC/13/007A, Edition Number: M-464592-01-1 Date: 2013-07-17 GLP/GEP: no, unpublished	N	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/68	IAJ Hardy and ND Jastrzebski,	2015	Kinetic modelling analysis of AE 0540092 and AE B197555 from a field soil residue study conducted in Europe (Normalisation to 20°C and pF2) Battelle UK Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: VC/15/013A, Edition Number: M-53318701-1 Date: 2015-09-10 GLP/GEP: no, unpublished	N	Bayer CropScience
KCP 9.1.1/69	Hardy, I. A. J.	2013	Isoxaflutole: Kinetic modelling endpoint summary Battelle UK Ltd., Chelmsford, United Kingdom Bayer CropScience, Report No.: VC/13/007J, Edition Number: M-464899-01-1 Date: 2013-09-18 GLP/GEP: no, unpublished	N	Bayer CropScience
KCP 9.1.1/70	IAJ Hardy and ND Jastrzebski	2015	Isoxaflutole: Kinetic modelling endpoint summary Battelle UK Ltd., Chelmsford, United Kingdom Bayer CropScience, Report No.: VC/15/013B, Edition Number: M-533191-01-1 Date: 2015-09-10 GLP/GEP: no, unpublished	N	Bayer CropScience
KCP 9.1.1/71	Fish L.	2013	GIS study of the proportion of acid and alkaline soils under maize crop in Europe Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, RAJ1012B Not GLP, not published Syngenta File No ZA1296_10160	N	Syngenta
KCP	Hand L.	2013	Mesotrione - Assessment of the significance of unidentified	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
9.1.1/72			components from harsh extraction of soil residues in 14Ccyclohexanedione labelled mesotrione soil metabolism studies Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, Not GLP, not published Syngenta File No ZA1296_10185		
KCP 9.1.1/73	Graham R., Gilbert J.	2013	Mesotrione - Kinetic Modelling Analysis of Data from Aerobic Soil Degradation Studies to Derive Modelling and Persistence Endpoint DT50 Values Syngenta Battelle UK Ltd., Ongar, United Kingdom, NC/11/059C Not GLP, not published Syngenta File No ZA1296_10135	N	Syngenta
KCP 9.1.1/74	Bramley YM, Pinheiro S I, Verity A A	2002	Mesotrione Comparison of Adsorption Properties of Mesotrione and Its copper Salt in Four Soils Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel Switzerland, RJ3289B GLP, not published Syngenta File No ZA1296/0831	N	Syngenta
KCP 9.1.1/75	Hurst L.	2013	SYN546974 - Adsorption and Desorption Properties of Phenyl-U-14C-SYN546974, a Metabolite of Mesotrione Syngenta Smithers Viscient (ESG) Ltd, Harrogate, UK, 8252095 GLP, not published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/76	Marth, J.L.	1997	[14C]AMBA, a Metabolite of ZA 1296: Rate of Degradation in Soil Under Aerobic Laboratory Conditions. Zeneca Agrochemicals Report No: RR97-032 In DAR (1999) GLP, not published	N	Syngenta
KCP 9.1.1/77	Miller, M.M.	1997	[Phenyl-U-14C]ZA 1296: Route and Rate of Degradation in Wisconsin Silt Loam Soil Under Aerobic Laboratory Conditions. Zeneca Agrochemicals Report No: RR97-033B In DAR (1999) GLP, not published	N	Syngenta
KCP 9.1.1/78	Miller, M.M., Wilson, W.R.	1997	[phenyl-U-14C]ZA 1296. Rate of Degradation in Three Soils Under Aerobic Laboratory Condition. Zeneca Agrochemicals Report No: RR96-099B GLP, not published	N	Syngenta
KCP 9.1.1/79	Subba-Rao, R.V.	1996	[Phenyl 14C-ZA 1296. Aerobic soil metabolism study. Zeneca Agrochemicals Report No: RR95-082B GLP, not published	N	Syngenta
KCP 9.1.1/80	Tarr, J.B.	1997	[phenyl-U-14C]ZA 1296. Metabolism in Thirteen Soils Under Aerobic Conditions.	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Zeneca Agrochemicals Report No: RR93-092B GLP, not published		
KCP 9.1.1/81	Vispetto, A.R., Tovshtey n, M.	1996	[cyclohexane-2-14C]ZA 1296. Anaerobic Aquatic Soil Metabolism. Zeneca Agrochemicals Report No: RR95-048B GLP, not published	N	Syngenta
KCP 9.1.1/82	Vispetto, A.R., Tovshtey n, M.	1997	Addendum to: [Cyclohexane-2-14C]ZA 1296. Aerobic soil metabolism study. Zeneca Agrochemicals Report No: RR95-047B ADD GLP, not published	N	Syngenta
KCP 9.1.1/83	Lay, M.M	2000	[Phenyl-U-14C] AMBA : Rate of Degradation in Soil under Aerobic Laboratory Conditions Zeneca Ag products Western Research Center Report No RR 99-096B GLP, not published	N	Syngenta
KCP 9.1.1/84	Graham, D.G. et al	1997a	Field Soil Dissipation Study Carried Out in France During 1995-1996. Zeneca Agrochemicals Report No: RR97-026B GLP, not published	N	Syngenta
KCP 9.1.1/85	Graham, D.G. et al	1997b	Field Dissipation Study Carried Out in Italy During 1995-1996. Zeneca Agrochemicals Report No: RR97-025B	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP, not published		
KCP 9.1.1/86	Graham, D.G. et al	1997c	Field Dissipation Study Carried Out in Germany During 1995-1996. Zeneca Agrochemicals Report No: RR97-051B GLP, not published	N	Syngenta
KCP 9.1.1/87	Graham, D.G. et al	1998a	Field Dissipation Study Carried Out in Germany During 1996-1997. Zeneca Agrochemicals Report No: RR97-067B GLP, not published	N	Syngenta
KCP 9.1.1/88	Graham, D.G. et al	1998b	Field Dissipation Study Carried Out in Italy During 1996-1997. Zeneca Agrochemicals Report No: RR97-070B GLP, not published	N	Syngenta
KCP 9.1.1/89	Wiebe, L.A., Yeh, S. M.	1999	ZA 1296: Stability of ZA 1296 and the metabolites MNBA and AMBA in Frozen Soil (WRC-98-158). (WINO 12775). Zeneca Agrochemicals Report No: RR98-065B	N	Syngenta
KCP 9.1.2/01	Phaff,R.	2000b	Adsorption / Desorption of GS 13529 in various soils Novartis Crop Protection AG, Basel, Switzerland, Report No 99RP04 GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2/02	Mueller J.	1991a	Determining the adsorption and desorption of terbuthylazine. Novartis Crop Protection AG. Fraunhofer Institute for Environmental Chemistry and Ecotoxicology. Report No CIB-004/7-13. GLP: Yes Published: No	N	Syngenta
KCP 9.1.2/03	Reischamnn F.	2000b	Adsorption / desorption of Triazine-U-14C-labelled GS 26379 in soil lorsch Novartis Crop Protection AG, Basel, Switzerland, Report No 00RF04 GLP Not Published	N	Syngenta
KCP 9.1.2/04	McLaughlin, S., Galicia,H.	1996a	GS 26379: Determination of adsorption and desorption in three soils Novartis Crop Protection AG, Basel, Switzerland Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland, Report No 95-058-1008 GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2/05	Mueller,J.	1991b	Determination of adsorption/desorption of desethyl-terbuthylazine. Fraunhifer-Institut fur Umweltchemie und Okotoxicologie. Report No. CIB-05/7-13. GLP: Yes Published: No	N	Syngenta
KCP 9.1.2/06	Adam, D.	2000a	Adsorption / desorption of GS 23158 in Borstel soil Novartis Crop Protection AG, Basel, Switzerland, Report No 99DA11 GLP Not Published	N	Syngenta
KCP 9.1.2/07	Mclaughlin,S., Galicia,H.	1996b	GS 23158: Determination of adsorption and desorption in three soils Novartis Crop Protection AG, Basel, Switzerland Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland, Report No 95-059-1008 GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2/08	Morgenroth,U.	2000b	Adsoption / Desorption of Triazine-U-14C labelled GS 28620 in various soils Novartis Crop Protection AG, Basel, Switzerland, Report No 00MO01 GLP Not Published	N	Syngenta
KCP 9.1.2/09	Morgenroth,U.	1995	ADSORPTION/DESORPTION OF 14C-TERBUTHYLAZINE ON FOUR SOILS RCC AG., Itingen, Switzerland Oxon Italia S.P.A, Pero, Italy Report-no. 385582 GLP: yes published: no	N	Oxon
KCP 9.1.2/10	Willems H.	1997	ADSORPTION/DESORPTION OF DESETHYLTERBUTHYLAZINE ON SOIL Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 197797 GLP: yes published: no	N	Oxon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2/11	Slangen P.J.	2001b.	ADSORPTION/DESORPTION OF 2-HYDROXYTERBUTHYLAZINE ON SOIL Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 308238 GLP: yes published: no	N	Oxon
KCP 9.1.2/12	McLaughlin S, Lentz N	2008	14C-GS28620 (Desethyl-hydroxy-terbuthylazine). Adsorption of 14C-GS28620 (Desethyl-hydroxy-terbuthylazine) on Multiple Soils. Syngenta - Jealott's Hill, Bracknell, United Kingdom; ; Oxon Italia S.p.a., Pero, Italy. Springborn Laboratories Inc., Wareham, USA, 1781.6712, T001654-08 GLP, not published	N	OXON/SYN
KCP 9.1.2/13	Ulbrich R.	1998	Adsorption / desorption of GS 14260 in various soils Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 97UL03 GLP, not published	N	OXON/SYN
KCP 9.1.2/14	Simmonds M, Burgess M	2009	Terbuthylazine - Estimation of Adsorption Coefficient (Koc) on Soil of CSCD648241, a Soil Metabolite, by HPLC (OECD 121) Syngenta - Jealott's Hill, Bracknell, United Kingdom; ; Oxon Italia S.p.a., Pero, Italy. Battelle UK Ltd., Ongar, United Kingdom, NC/09/009, T000357-09 GLP, not published	N	OXON/SYN

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

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

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

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

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

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

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Syngenta; Oxon Italia S.p.a., Pero, Italy. Syngenta - Jealott's Hill, Bracknell, United Kingdom, REP_GLP 10372116, 08AS064 GLP, not published		
KCP 9.1.2/39	Saeed M	2009b	Confirmation of identity and estimate the quantity of 14C-labelled Leachate components in Leachate water sample extract J7357/03/01 Syngenta; Oxon Italia S.p.a., Pero, Italy. Syngenta - Jealott's Hill, Bracknell, United Kingdom, REP_GLP 10387599, 09AS006 GLP, not published	N	Oxon/Syngenta
KCP 9.1.2/40	Hand L.	2009	Review of the Separation and Identification of Terbuthylazine Metabolites Detected in Lysimeter Leachate Samples Syngenta; Oxon Italia S.p.a., Pero, Italy. Syngenta - Jealott's Hill, Bracknell, United Kingdom, T000412-09/3Not GLP, not published	N	Oxon/Syngenta
KCP 9.1.2/41	Sapiets A	2009	Field leaching study to investigate the movement of terbuthylazine and its metabolites to shallow groundwater in Northern Italy Syngenta; Oxon Italia S.p.a., Pero, Italy. Syngenta - Jealott's Hill, Bracknell, United Kingdom, T000412-09/3 Not GLP, not published	N	Oxon/Syngenta
KCP 9.1.2/42	Baravelli P L	2009	Terbuthylazine - Determination of Residues of Terbuthylazine Metabolites GS26379, CSCD648241 and GS16984 in Groundwater Samples Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia S.p.a., Pero, Italy. AgriParadigma S.r.l. Ravenna, Italy, AGRI 039/08 GLP, T000450-08 GLP, not published	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2/43	Adam D.	2013	SYN545666/LM6(Terbuthylazine Metabolite) – Adsorption/Desorption Properties in Three Soils Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Innovative Environmental Services (IES) Ltd., Switzerland. 115 09 013 GLP, not published	N	Oxon/Syngenta
KCP 9.1.2/44	Adam D.	2013a	GS16984/LM5(Terbuthylazine Metabolite) – Adsorption/Desorption Properties in Three Soils Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Innovative Environmental Services (IES) Ltd., Switzerland. 115 08 013 GLP, not published	N	Oxon/Syngenta
KCP 9.1.2/45	Volkel W.	2013	GS40436/LM4(Terbuthylazine Metabolite) – Adsorption/Desorption Properties in Three Soils Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Innovative Environmental Services (IES) Ltd., Switzerland. 115 07 013 GLP, not published	N	Oxon/Syngenta
KCP 9.1.2/46	Volkel W.	2013a	SYN546009/LM3(Terbuthylazine Metabolite) – Adsorption/Desorption Properties in Three Soils Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Innovative Environmental Services (IES) Ltd., Switzerland. 115 06 013 GLP, not published	N	Oxon/Syngenta
KCP 9.1.2/47	Volkel W.	2013b	CGA46571/LM2(Terbuthylazine Metabolite) – Adsorption/Desorption Properties in Three Soils	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Innovative Environmental Services (IES) Ltd., Switzerland. 115 05 013 GLP, not published		
KCP 9.1.2/48	Adam D.	2013b	G35713/LM1(Terbuthylazine Metabolite) – Adsorption/Desorption Properties in Three Soils Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Innovative Environmental Services (IES) Ltd., Switzerland. 115 04 013 GLP, not published	N	Oxon/Syngenta
KCP 9.1.2/49	Luciani G. and Belosi	2012	Determination of Residues of CGA46571 (LM2), SYN546009 (LM3), GS40436 (LM4), GS16984 (LM5) and SYN545666 (LM6) in Groundwater samples collected from a Multisite Field Leaching Programme Syngenta – Via Gallarate Nr.139, 20151 Milan, Italy; Oxon Italia, S.p.a, Pero, Italy AgriParadigma S.r.l. Via Faentina, 224 Ravenna-Italy AGRI 026/10 GLP, not published	N	Oxon/Syngenta
KCP 9.1.2/50	Zietz E.	2013	Determination of Storage Stability of the Terbuthylazine Metabolites CGA46571 (LM2) and GS40436 (LM4) in Groundwater Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy SGS Institut Fresenius GmbH Im Maisel 14 D-65232 Taunusstein Germany IF-11/01811957 GLP, not published	N	Oxon/Syngenta
KCP	Zietz E.	2011	Residues method for the determination of Metabolites CGA46571	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
9.1.2/51			(LM2), SYN546009 (LM3), GS40436 (LM4), GS16984 (LM5) and SYN545666 (LM6) in water Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS Institut Fresenius GmbH Im Maisel 14 D-65232 Taunusstein Germany GRM015.07A GLP, not published		
KCP 9.1.2/51	Zietz E.	2012a	Validation of an Analytical Method (Draft GRM015.07A) for the Determination of CGA46571 (LM2), SYN546009 (LM3), GS40436 (LM4), GS16984 (LM5) and SYN545666 (LM6) in water Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy SGS Institut Fresenius GmbH Im Maisel 14 D-65232 Taunusstein Germany IF-10/01707329 GLP, not published	N	Oxon/Syngenta
KCP 9.1.2/52	Zietz E.	2012b	Terbuthylazine – Storage Stability Investigation of the Terbuthylazine Metabolites SYN546009 (LM3), GS16984 (LM5 and SYN545666 (LM6) in Water by RE-Analysis of Selected Groundwater Samples Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy SGS Institut Fresenius GmbH Im Maisel 14 D-65232 Taunusstein Germany IF-09/01345520 GLP, not published	N	Oxon/Syngenta
KCP 9.1.2/53	Lowden, P.; Cooper, I.; Simmonds, M.; Burr, C. M.;	1993	[^{14}C]-RPA 201722: Adsorption/desorption to and from four soils and an aquatic sediment - Addendum report Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience,	N	Bayer CropScience

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
	Newby, S. E.		Report No.: M-065963-03-1, Edition Number: M-065963-03-1 Date: 1993-11-25 GLP/GEP: yes, unpublished		
KCP 9.1.2/54	Burr C. M.; Newby, S. E.	1993	RPA 201772: Adsorption / desorption to and from four soils and an aquatic sediment Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: R000307, Edition Number: M-158343-01-1 Date: 1993-11-25 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.2/55	Burr, C. M.	1996	(^{14}C)-RPA202248: Adsorption / desorption to and from four soils and an aquatic sediment Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Report No.: R016762, Edition Number: M-192293-01-1 Date: 1996-07-17 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.2/56	Lowden, P.; Cooper, I.; Simmonds, M.; Burr, C. M.	1995	[^{14}C]-RPA 202248: Adsorption/desorption to and from four soils - Addendum report Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom BCS, Report No.: CX/03/070A, Edition Number: M-066355-03-1 Date: 1995-11-20 **...Amended: 2004-04-08** GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.2/57	Burr, C. M.	1995	RPA202248: Adsorption / desorption to and from four soils Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom	N	Bayer CropScience

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
			Report No.: R016761, Edition Number: M-192291-01-1 Date: 1995-11-20 GLP/GEP: yes, unpublished		
KCP 9.1.2/58	Burr, C. M.	1996	(^{14}C)-RPA202248: Adsorption / desorption to and from four soils and an aquatic sediment Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Report No.: R016762, Edition Number: M-192293-01-1 Date: 1996-07-17 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.2/59	Burr, C. M.; Burrs, C. M.	1996	RPA 203328: Adsorption/desorption to and from four soils Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C025651, Edition Number: M-209743-02-1 Date: 1996-01-02 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.2/60	Burr, C. M.	1996	[^{14}C]-RPA203328: Adsorption / desorption to and from four soils and a sediment Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: R000447, Report includes Trial Nos.: 11487 Edition Number: M-158651-01-1 Date: 1996-07-30 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.2/61	Lowden, P.; Cooper, I.; Simmonds, M.;	1996	[^{14}C]-RPA 202248: Adsorption/desorption to and from four soils and an aquatic sediment Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom	N	Bayer CropScience

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
	Burr, C. M.		Bayer CropScience, Report No.: 11486, Edition Number: M-066483-01-1 Date: 1996-07-17 GLP/GEP: yes, unpublished		
KCP 9.1.2/62	Burr, C. M.	1996	RPA 203328: Adsorption/desorption to and from four soils Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Report No.: C026341, Edition Number: M-211226-01-1 Date: 1996-01-02 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.2/63	Hein, H.; Moendel, M.	2012	[cyclopropyl-1-^{14}C] AE 0540092: Adsorption/desorption in five different soils RLP AgroScience GmbH, Neustadt a. d. Weinstraße, Germany Bayer CropScience, Report No.: AS200, Edition Number: M-429399-01-1 Date: 2012-03-14 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.2/64	Mills, E. A. M.; Simmonds, M. B.	2004	(^{14}C)-RPA 203328: Adsorption / desorption in five soils Battelle AgriFood Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C040534, Edition Number: M-229091-01-1 EPA MRID No.: 46801704 Date: 2004-04-06 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.2/65	Hardy, I. A. J.	2001	Isoxaflutole: Leaching risk assessment for isoxaflutole and two metabolites using the European FOCUS groundwater scenarios (AE B197278, AE 0540092, AE B197555)	N	Bayer CropScience

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
			Battelle AgriFood Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: MO-04-004596, Edition Number: M-066960-01-1 Date: 2001-09-14 GLP/GEP: no, unpublished		
KCP 9.1.2/66	Newby, S. E.; Godward, P. J.; Jones, M. K.	1995	RPA 201772: Aged leaching study in four soils and a sediment Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: R000361, Edition Number: M-158471-01-1 Date: 1995-01-10 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.2/67	Carley, S.E.	1996	[phenyl-U-14C]ZA 1296 Anaerobic Aquatic Soil Metabolism. Zeneca Agrochemicals Report No: RR96-033B In DAR (1999)	N	Syngenta
KCP 9.1.2/68	Diaz, D.G.	1995	[14C]ZA 1296. Adsorption and Desorption Properties in Soil. Zeneca Agrochemicals Report No: RR95-070B In DAR (1999)	N	Syngenta
KCP 9.1.2/69	Diaz, D.G.	1996a	[14C]MNBA. Adsorption and Desorption Properties in Soil of a ZA 1296 Metabolite. Zeneca Agrochemicals Report No: RR96-008B In DAR (1999)	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.2/70	Diaz, D.G.	1996b	[14C]AMBA. Adsorption and Desorption Properties in Soil of a ZA 1296 Metabolite. Zeneca Agrochemicals Report No: RR96-009B In DAR (1999)	N	Syngenta
KCP 9.1.2/71	Marth, J.L.	1997	[14C]AMBA, a Metabolite of ZA 1296: Rate of Degradation in Soil Under Aerobic Laboratory Conditions. Zeneca Agrochemicals Report No: RR97-032 In DAR (1999)	N	Syngenta
KCP 9.2/01	Doyle R	1991	Hydrolysis of 14C-Terbuthylazine Novartis Crop Protection AG, Basel, Switzerland IIT Research Institute, Newington, United States, Report No IITRI-VTC-9004 GLP Not Published	N	Syngenta
KCP 9.2/02	Adam D.	2000b	Hydrolysis of [triazine-U-14C]-labelled GS 26379 under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland, Report No 00DA01 GLP Not Published	N	Syngenta

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 9.2/03	Van der Gaauw A.	2002	14C-Triazine Ring labelled GS23158: Hydrolysis at three different pH values Syngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, Report No 815668 GLP Not Published	N	Syngenta
KCP 9.2/04	Zetzsch, C., Palm, W.	1993	GS 13529 UV-Absorption sprectra of Terbuthylazin - estimation of aqueous photolysis maximum rate constant and minimum half-life in sunlight Novartis Crop Protection AG, Basel, Switzerland ITA Frauenhofer-Inst., Hannover, Germany, Report No PC91-3 GLP Not Published	N	Syngenta
KCP 9.2/05	Mamouni, A.	2002	Aqueous Photolysis of 14C-Triazine Ring Labelled GS 13529 under Laboratory Conditions Syngenta Crop Protection AG, Basel, Switzerland, Report No 820642 GLP Not Published	N	Syngenta

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 9.2/06	Glaenzel	2000b	Aqueous photolysis of 14C-triazine labelled GS 26379 under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland, Report No 99AG06 GLP Not Published	N	Syngenta
KCP 9.2/07	Bader,U.	1990	GS 13529, Report on the test for ready biodegradability in the Modified Sturm Test Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 901360 GLP Not Published	N	Syngenta
KCP 9.2/08	Mamouni, A,	1998	14C-Terbuthylazine: degradation and metabolism in aquatic systems Novartis Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, Report No 608207 GLP Not Published	N	Syngenta

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 9.2/09	Reischmann, F.	1995	volatilization of GS 13529 from water (calculation) Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 95RF14 GLP Not Published	N	Syngenta
KCP 9.2/10	Reischmann, F.	1992	Volatilization of GS 13529 from soil surface under controlled laboratory conditions Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 17/92 GLP Not Published	N	Syngenta
KCP 9.2/11	Sandmeier, P.	1992	GS 13529 Volatility from plant and soil surfaces Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 92PSA06 GLP Not Published	N	Syngenta

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 9.2/12	Sandmeier, P.	1993	Volatilization of GS 13529 from Plant and Soil after Postemergent Spray Application of 14C-labelled Material on Maize under Indoor Conditions Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 93PSA17 GLP Not Published	N	Syngenta
KCP 9.2/13	Stamm, E.	1997	Atmospheric oxidation of terbuthylazine GS 13529 by hydroxyl radicals; rate estimation Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 95A97007SM GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/14	Reese-Staehler,G.	2000	Monitoring of GS13529 (Terbuthylazine) in Surface Water in the Area of Fields Endangered by Run off. Sites: Adenstedt (Lower Saxony) and Süplingen (Sachsen Anhalt) Novartis Agro GmbH, Frankfurt, Germany Biologische Bundesanstalt für Land- und Forstwirtschaft, Braunschweig, Germany, Report No OC9902 GLP: Yes Published: No	N	Syngenta
KCP 9.2/15	Schmidt, B., Zietz,E.	2000	Monitoring site-related evaluation of terbuthylazine findings in Groundwater. Novartis Agro GmbH, Frankfurt, Germany Institut Fresenius Taunusstein, Germany. Report No. 100-1522-1738 Not GLP Not published	N	Syngenta
KCP 9.2/16	Anon	2002	Groundwater Survey 2002. Part 5: Pesticides and Degradation Products Pages 57-74 Syngenta Crop Protection AG, Basel, Switzerland Not GLP Published	N	Syngenta

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 9.2/17	Kjaer,J.	2003	The Danish Pesticide Leaching Assessment Programme. Monitoring Results May 1999 - June 2002. Third Report Geological Survey of Denmark and Greenland, the Danish Institute of Agricultural Science and the National Environmental Research Institute http://pesticidvarsling.dk/monitor_uk/2002_uk/index.html Not GLP Published	N	Published reference
KCP 9.2/18	Kjaer,J.	2003	The Danish Pesticide Leaching Assessment Programme. Monitoring Results May 1999 - June 2002. Third Report Geological Survey of Denmark and Greenland, the Danish Institute of Agricultural Science and the National Environmental Research Institute http://pesticidvarsling.dk/monitor_uk/2002_uk/index.html Not GLP Published	N	Published reference

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 9.2/19	Hennecke D.	2004a	AQUATIC PHOTODEGRADATION AND QUANTUM YIELD OF DESETHYL-TERBUTHYLAZINE Fraunhofer Institut, 57392 Schmallenberg-Grafschaft, Germany Oxon Italia S.P.A, Pero, Italy Report-no. GAB-006/7-05 GLP: yes published: no	N	Oxon
KCP 9.2/20	Hennecke D.	2004b	AQUATIC PHOTODEGRADATION AND QUANTUM YIELD OF 2-HYDROXY-TERBUTHYLAZINE Fraunhofer Institut, 57392 Schmallenberg-Grafschaft, Germany Oxon Italia S.P.A, Pero, Italy Report-no. GAB-007/7-05 GLP: yes published: no	N	Oxon
KCP 9.2/21	Desmares-Koopmans M.J.E	2001	DETERMINATION OF 'READY' BIODEGRADABILITY: CARBON DIOXIDE (CO2) EVOLUTION TEST (MODIFIED STURM TEST) WITH TERBUTHYLAZINE TECHNICAL Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 308115 GLP: yes published: no	N	Oxon

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 9.2/22	Mamouni A.	1995	[14C]-TERBUTHYLAZINE DEGRADATION AND METABOLISM IN WATER/SEDIMENT SYSTEMS RCC AG., Itingen, Switzerland Oxon Italia S.P.A, Pero, Italy Report-no. 385593 GLP: yes published: no	N	Oxon
KCP 9.2/23	Burgener	1995	INVESTIGATION OF THE VOLATILIZATION OF [14C]-TERBUTHYLAZINE FROM SOIL AND DWARF RUNNER BEAN RCC, Itingen, Switzerland Oxon Italia S.P.A, Pero, Italy Report-no. 385604 GLP: yes published: no	N	Oxon
KCP 9.2/24	Hardy I	2012	Terbuthylazine-Overview of FOCUS Kinetic Modelling of Laboratory and Field Soil Studies and selection of Modelling Endpoints Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia S.p.a., Pero, Italy. Battelle UK Ltd, Fyfield Buisness and Research Park, Ongar Essex, UK NC/11/058D Not published	N	Oxon/Syngenta
KCP 9.2/25	Hardy I	2012a	Terbuthylazine-Overview of FOCUS Kinetic Modelling of Laboratory and Field Soil Studies and selection of Modelling Endpoints Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia S.p.a., Pero, Italy. Battelle UK Ltd, Fyfield Buisness and Research Park, Ongar Essex, UK NC/11/058D	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Not published		
KCP 9.2/26	Hardy I	2012b	Terbuthylazine- Kinetic Modelling Analysis of Data from Aerobic Soil Degradation Studies in order to derive DT50 values and Formation Fractions for use as Modelling Endpoints Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia S.p.a., Pero, Italy. Battelle UK Ltd, Fyfield Buisness and Research Park, Ongar Essex, UK NC/11/058C Not published	N	Oxon/Syngenta
KCP 9.2/27	Hardy I	2012c	Terbuthylazine- Kinetic Modelling Analysis of Data from Field Dissipation Studies in order to derive Normalisation DT50 values and Formation Fractions for use as Modelling Endpoints (Q10 2.58) Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia S.p.a., Pero, Italy. Battelle UK Ltd, Fyfield Buisness and Research Park, Ongar Essex, UK NC/11/058A Not published	N	Oxon/Syngenta
KCP 9.2/28	Zietz E	2009	Terbuthylazine - Storage Stability Investigation of the Terbuthylazine Metabolites CSCD648241, CSAA404791 and CSCD692760 in Water by Re Analysis of Selected Groundwater Samples Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia S.p.a., Pero, Italy. SGS Institut Fresenius GmbH, Geneva, Switzerland, IF-09/01345520, T000403-09 GLP, not published	N	Oxon/Syngenta

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 9.2/29	Phaff R.	2000	Degradation and metabolism of 14C-triazine ring-labelled GS 14260 in two aerobic aquatic systems under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 97RP07 GLP, not published	N	Oxon/Syngenta
KCP 9.2/30	Adam D.	2010	SYN545666/LM6(Terbuthylazine Metabolite) - Rate of Degradation under aerobic laboratory conditions in three soils at 20°C Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Innovative Environmental Services (IES) Ltd., Switzerland. 115 10 023 GLP, not published	N	Oxon/Syngenta
KCP 9.2/31	Adam D.	2010a	GS16984/LM5(Terbuthylazine Metabolite) - Rate of Degradation under aerobic laboratory conditions in three soils at 20°C Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Innovative Environmental Services (IES) Ltd., Switzerland. 115 09 023 GLP, not published	N	Oxon/Syngenta
KCP 9.2/32	Rosenwald J.	2010	SYN546009/LM3(Terbuthylazine Metabolite) - Rate of Degradation under aerobic laboratory conditions in three soils at 20°C Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Innovative Environmental Services (IES) Ltd., Switzerland. 115 07 023 GLP, not published	N	Oxon/Syngenta
KCP 9.2/33	Volkel W.	2011	CS40436/LM4(Terbuthylazine Metabolite) - Rate of Degradation under aerobic laboratory conditions in three soils at 20°C Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Innovative Environmental Services (IES) Ltd., Switzerland. 115 08 023 GLP, not published		
KCP 9.2/34	Rosenwald J.	2010a	CGA46571/LM2(Terbuthylazine Metabolite) - Rate of Degradation under aerobic laboratory conditions in three soils at 20°C Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Innovative Environmental Services (IES) Ltd., Switzerland. 115 06 023 GLP, not published	N	Oxon/Syngenta
KCP 9.2/35	Rosenwald J.	2011	G35713/LM1(Terbuthylazine Metabolite) - Rate of Degradation under aerobic laboratory conditions in three soils at 20°C Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.a, Pero, Italy Innovative Environmental Services (IES) Ltd., Switzerland. 115 05 023 GLP, not published	N	Oxon/Syngenta
KCP 9.2/36	Schmidt B.	2003	Description of selected groundwater monitoring wells and the local hydrogeological situation in Schleswig-Holstein, Germany Syngenta Agro GmbH, Maintal, Germany Institut Fresenius, Taunusstein, Germany, 1688503 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/37	Schmidt B.	2003a	Description of selected groundwater monitoring wells and the local hydrogeological situation in Mecklenburg-West Pomerania, Germany Syngenta Agro GmbH, Maintal, Germany Institut Fresenius, Taunusstein, Germany, 1688504 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/38	Schmidt B. Klaas P.	2004	Description of Groundwater Monitoring Wells and the Local Hydrogeological Conditions in the Southern	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Upper Rhine Valley (Ortenau und Breisgau), Germany [translated version] Syngenta Crop Protection AG, Basel, Switzerland Institut Fresenius, Taunusstein, Germany, 1488606 Not GLP, not published		
KCP 9.2/39	Schmidt B.	2005	Description of Groundwater Monitoring Wells and the Local Hydrogeological Conditions in the Rottal, Germany [translated version] Syngenta Crop Protection AG, Basel, Switzerland Institut Fresenius, Taunusstein, Germany, 1488602 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/40	Schmidt B., Klaas P.	2005	Description of Groundwater Monitoring Wells and the Local Hydrogeological Conditions in the Hessian Ried, Germany [translated version] Syngenta Crop Protection AG, Basel, Switzerland Institut Fresenius, Taunusstein, Germany, 1488604 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/41	Schneider M., Klaas P.	2005a	Description of selected groundwater monitoring wells and the local hydrogeological situation in the region Muensterland/ Emsland, Germany Syngenta Crop Protection AG, Basel, Switzerland Institut Fresenius, Taunusstein, Germany, 1488607 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/42	Resseler H	2009a	Terbuthylazine: Results of farmer interviews on the use of terbuthylazine (GS13529) in the vicinity of groundwater monitoring wells in Germany in 2004 - 2006 including characterisation of the monitoring regions Syngenta Agro GmbH, Maintal, Germany , HR 02 2009 Not GLP, not published	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/43	Glaenzel A.	2005	Determination of Terbuthylazine (GS 13529), GS 26379, GS 28260 and GS 23158 in Water Samples from Ground Water Monitoring in Schleswig-Holstein and Bavaria in Germany Syngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, 856134 GLP, not published	N	Oxon/Syngenta
KCP 9.2/44	Schmidt B	2009	Terbuthylazine: Analysis of terbuthylazine (GS13529) and its metabolites CSCD648241 (LM6), GS16984 (LM5), GS26379, GS23158 and GS28620 in groundwater samples from wells with documented uses of terbuthylazine on upstream fields in Germany Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia S.p.a., Pero, Italy. SGS Institut Fresenius GmbH, Geneva, Switzerland , IF-08/01230035 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/45	Zietz E	2009a	Terbuthylazine: Analysis of CSCD692760 (LM3) in groundwater samples from wells with documented uses of terbuthylazine on upstream fields in Germany Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia S.p.a., Pero, Italy. SGS Institut Fresenius GmbH, Geneva, Switzerland, IF-09/01393295, T0001794-09 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/46	Maroni M, Bersani M	1997	Weed Control in Maize Areas of the Po Plain Impact Assessment for Triazines in the Groundwater Table Novartis SpA Italy Syngenta - Jealott's Hill, Bracknell, United Kingdom International Centre for Pesticide Safety, Busto Garolfo, Milano, Italy GLP, not published	N	Oxon/Syngenta

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 9.2/47	Auteri	2007	Assessment of the Contamination of Groundwater Table by Terbuthylazine, Hydroxyterbuthylazine and Desethylterbuthylazine in the Po Plain Novartis SpA Italy Syngenta - Jealott's Hill, Bracknell, United Kingdom International Centre for Pesticide Safety, Busto Garolfo, Milano, Italy. T019446-04 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/48	Seville A	2009	Water Monitoring Study in the Ribatejo, Beira Litoral, Oeste and Douro Regions of Portugal, 1999-2007 Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom T004961-02-REG Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/49	Various	2000	Groundwater Monitoring Portugal, Hydrogeological Assessment Report: Ribatejo Syngenta Crop Protection AG, Basel, Switzerland Universidade de Lisboa, Lisboa, Portugal, Ribatejo, Portugal Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/50	Various	2000a	Groundwater Monitoring Portugal, Hydrogeological Assessment Report: Oeste and Douro, Portugal Syngenta Crop Protection AG, Basel, Switzerland Universidade de Lisboa, Lisboa, Portugal, Oesta and Douro Portugal Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/51	Various	2000b	Groundwater Monitoring Portugal, Hydrogeological Assessment Report: Biera Litoral, Portugal Syngenta Crop Protection AG, Basel, Switzerland Hidrogeo, Consultores de Hidrogeologia e Ambiente Lda., Lisboa, Portugal, Biera Litoral Portugal	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Not GLP, not published		
KCP 9.2/52	Various	2003	Annex 1, Monitoring Network, Hydrogeological Assessment Report: Biera Litoral, Portugal Syngenta Crop Protection AG, Basel, Switzerland Hidrogeo, Consultores de Hidrogeologia e Ambiente Lda., Lisboa, Portugal, Annex 1 Biera Litoral Portugal Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/53	Seville A	2009a	Terbuthylazine (GS13529) - Retrospective Groundwater Monitoring in Southern Spain 2000 to 2003 Syngenta - Jealott's Hill, Bracknell, United Kingdom , T004964-02-REG, T004964-02 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/54	Pulido A	2000	Groundwater Monitoring South Spain ? Hydrological Assessment Syngenta - Jealott's Hill, Bracknell, United Kingdom Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/55	Cornejo J	2002	Ground and Surface Water Monitoring in Major Olive Regions in Andalucia Syngenta - Jealott's Hill, Bracknell, United Kingdom Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/56	Cornejo J	2004	Ground and Surface Water Monitoring in Major Olive Regions in Andalucia Syngenta - Jealott's Hill, Bracknell, United Kingdom Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/57	Seville A	2009b	Terbuthylazine (GS13529) - Retrospective Groundwater Monitoring in South Eastern Regions of Spain 2000 to 2001 Syngenta - Jealott's Hill, Bracknell, United Kingdom , T005761-04-REG, T005761-04 Not GLP, not published	N	Oxon/Syngenta
KCP	Ruiz A, de	2001	Monitoring Surface Water and Groundwater in Eastern Spain Sam-	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
9.2/58	Barreda Diego G		pling and Analytical Results Syngenta - Jealott's Hill, Bracknell, United Kingdom Diego Gomez de Barreda Castillo; (2001); I.V.I.A-L.A., Moncada, Valencia, Spain Not GLP, not published		
KCP 9.2/59	Robinson N, Wallace D	2009	Terbuthylazine (GS13529) - Retrospective Groundwater Monitoring in Northern Spain, 2000 to 2004 Syngenta - Jealott's Hill, Bracknell, United Kingdom , T004962-02-REG, T004962-02 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/60	Candela L	2000	Regional Hydrological and Hydrogeological Studies Aimed at Monitoring Pesticide Residues **Final Report** 2000 Syngenta - Jealott's Hill, Bracknell, United Kingdom Department of Geotechnical and Geoscience, Technical University of Catalonia-UPC, Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/61	Candela L	2000a	Regional Hydrological and Hydrogeological Studies Aimed at Monitoring Pesticide Residues **Appendices** Syngenta - Jealott's Hill, Bracknell, United Kingdom Department of Geotechnical and Geoscience, Technical University of Catalonia-UPC, Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/62	Candela L	2003	Regional Hydrological and Hydrogeological Studies Aimed at Monitoring Pesticide Residues Addendum 2003 Syngenta - Jealott's Hill, Bracknell, United Kingdom Department of Geotechnical and Geoscience, Technical University of Catalonia-UPC, Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/63	Barcelo D, Lacorte S	2001	Water Monitoring Study in Northern Spain Syngenta - Jealott's Hill, Bracknell, United Kingdom	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Department of Environmental Chemistry, IIQAB-CSIC, Jordi Girona 18-26, 08034 Barcelona, Spain, Not GLP, not published		
KCP 9.2/64	Schmidt B	2009a	Terbuthylazine - Retrospective Groundwater Monitoring in the Fricktal Region (Switzerland) Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS Institut Fresenius GmbH, Geneva, Switzerland, T008940-08-REG2, T008940-08 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/65	Schmidt B	2009b	Terbuthylazine - Retrospective Groundwater Monitoring in the Region Stein-Sisseln-Kaisten (Switzerland) Final Study Report Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS Institut Fresenius GmbH, Geneva, Switzerland, T008940-08-REG1, T008940-08 Not GLP, not published	N	Oxon/Syngenta
KCP 9.2/66	Schmidt B	2006	Clarification of Monitoring Point related Findings of Terbuthylazine in the Groundwater in Germany. Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS Institut Fresenius GmbH, Taunusstein, Germany. Final Study Report No. IF-06/00639090. GLP, not published	N	Oxon/Syngenta
KCP 9.2/67	Schmidt B	2009c	Clarification of Monitoring Point related Findings of Terbuthylazine / Desethyl terbuthylazine in the Groundwater in Germany 2005-2008. Syngenta Agro GmbH, Maintal, Germany SGS Institut Fresenius GmbH, Taunusstein, Germany. Final Study Report No. IF-08/01287363. Syngenta Ltd, Bracknell, UK GLP, not published	N	Oxon/Syngenta
KCP	Zietz E.	2007	Monitoring of GS 13529 (terbuthylazine) in surface water adjacent	N	Oxon/Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
9.2/68			to fields susceptible to run-off Syngenta Agro GmbH, Maintal, Germany SGS Institut Fresenius GmbH, Taunusstein, Germany. Final Study Report No. IF-99/07972-00 GLP, not published		
KCP 9.2/69	Bischoff G	2006	MONITORING OF GS 13529 (TERBUTHYLAZINE) IN SURFACE WATER ADJACENT TO FIELDS PRONE TO RUNOFF Sites Adenstedt (Lower Saxony) and Suplingen (Saxony-Anhalt) Syngenta Agro GmbH, Maintal, Germany Federal Biological Research Centre for Agriculture and Forestry, Berlin, Germany, OC9902 GLP, not published	N	Oxon/Syngenta
KCP 9.2/70	Corgier, M. M.; Robin, J. M.; Plewa, A. P.	1994	Hydrolysis 14C-RPA201772 Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: R002384, Report includes Trial Nos.: 93-180 Edition Number: M-162558-01-1 Date: 1994-05-02 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2/71	Corgier, M. M.; Plewa, A. P.	1995	Photodegradation in water 14C-RPA201772 (isoxaflutole) Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: R002507, Report includes Trial Nos.: 94-11 Edition Number: M-162794-01-1 Date: 1995-01-13 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2/72	Roohi, A.; Caine, J.	2002	Photolysis in distilled water RPA202248 Battelle AgriFood Ltd., Ongar, Essex, United Kingdom	N	Bayer CropScience

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
			Report No.: C027919, Report includes Trial Nos.: 36662 CX/02/066 Edition Number: M-214288-01-1 Date: 2002-12-11 GLP/GEP: yes, unpublished		
KCP 9.2/73	Desmares-Koopmans, M. J. E.	1996	Determination of ready biodegrability: Carbon dioxide (CO_2) evolution test (modified Sturm test) with isoxaflutole Notox B.V., 's-Hertogenbosch, Netherlands Bayer CropScience, Report No.: C026345, Edition Number: M-211235-01-1 Date: 1996-01-23 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2/74	Desmares-Koopmans, M. J. E.	1996	Determination of 'ready' biodegradability carbon dioxyde (CO_2) - Evolution test (modified sturm test) with RPA201772 Notox B.V., 's-Hertogenbosch, Netherlands Bayer CropScience, Report No.: R002745, Report includes Trial Nos.: 58077 96-22 Edition Number: M-163261-01-1 Date: 1996-01-23 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2/75	Walther, D.	2013	[^{14}C] Isoxaflutole: Aerobic mineralization in surface water Harlan Laboratories Ltd., Itingen, Switzerland Bayer CropScience, Report No.: D62847, Edition Number: M-459354-02-1	N	Bayer CropScience

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
			Date: 2013-06-26 **...Amended: 2013-07-02** GLP/GEP: yes, unpublished		
KCP 9.2/76	Ayliffe, J. M.; Newby, S. E.	1995	RPA 201772: Degradation and retention in two water / sediment systems Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: R000377, Edition Number: M-158508-01-1 Date: 1995-05-04 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2/77	Hardy, I. A. J.	2013	Isoxaflutole: Kinetic modelling evaluation of water sediment degradation study data to derive total system DT_{50} values Battelle UK Ltd., Ongar, United Kingdom Bayer CropScience, Report No.: VC/13/008A, Edition Number: M-464901-01-1 Date: 2013-07-17 GLP/GEP: no, unpublished	N	Bayer CropScience
KCP 9.2/78	Hardy, I. A. J.	2013	Isoxaflutole: Kinetic modelling evaluation of water sediment degradation study data to derive water phase DT_{50} values Battelle UK Ltd., Ongar, United Kingdom Bayer CropScience, Report No.: VC/13/008B, Edition Number: M-464903-01-1 Date: 2013-07-17 GLP/GEP: no, unpublished	N	Bayer CropScience
KCP 9.2/79	Ayliffe, J. M.; Newby, S. E.	1995	RPA 201772: Degradation and retention in two water / sediment systems Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom	N	Bayer CropScience

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
			Bayer CropScience, Report No.: R000377, Edition Number: M-158508-01-1 Date: 1995-05-04 GLP/GEP: yes, unpublished		
KCP 9.2/80	Lowden, P.; Cooper, I.; Simmonds, M.; Burr, C. M.	1996	[^{14}C]-RPA 202248: Adsorption/desorption to and from four soils and an aquatic sediment Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: 11486, Edition Number: M-066483-01-1 Date: 1996-07-17 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2/81	Burr, C. M.	1996	[^{14}C]-RPA203328: Adsorption / desorption to and from four soils and a sediment Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: R000447, Report includes Trial Nos.: 11487 Edition Number: M-158651-01-1 Date: 1996-07-30 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2/82	Oliver R., Edwards P.	2005	Mesotrione (ZA1296): [U-14C]-Phenyl Labelled Sterile Natural Water Photolysis Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, RJ3634B 04JH012 GLP, not published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2/83	Graham R., Yeomans P.	2013	Mesotrione - Aerobic Mineralisation of 14C-Phenyl Labelled ZA1296 in Surface Water Syngenta Smithers Viscient (ESG) Ltd, Harrogate, UK, 8252099 GLP, not published	N	Syngenta
KCP 9.2/84	Graham R., Gilbert J.	2013a	Mesotrione - Aerobic and Anaerobic Aquatic Sediment Metabolism of [Phenyl-14C]-Mesotrione Syngenta Smithers Viscient (ESG) Ltd, Harrogate, UK, Covance Laboratories Limited, Harrogate, UK, 8236956 GLP, not published	N	Syngenta
KCP 9.2/85	Hardy I.	2013a	Mesotrione - Kinetic Modelling Analysis of Data from Water Sediment Studies to Derive Modelling and Persistence Endpoint DT50 Values Syngenta Battelle UK Ltd., Ongar, United Kingdom, NC/11/059A Not GLP, not published	N	Syngenta
KCP 9.3/01	Maestracci, M. P.	1996	Isoxaflutole - Estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: C022447, Report includes Trial Nos.: 95-116	N	Bayer CropScience

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
			Edition Number: M-213115-01-1 Date: 1996-01-08 GLP/GEP: yes, unpublished		
KCP 9.3/02	Kubiak, R.	1997	Investigation of the volatilization of 14C-isoxaflutole formulated corresponding to EXP31130A from plant and soil surfaces under laboratory conditions SLFA Neustadt, Neustadt, Germany Bayer CropScience, Report No.: R014793, Report includes Trial Nos.: 97-18 97-19 Edition Number: M-189768-01-1 Date: 1997-02-26 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.3/03	Buntain, I. G.	2003	Isoxaflutole: Estimation of degradation by photo-oxidation in air Model calculation according to Atkinson Battelle AgriFood Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C038406, Report includes Trial Nos.: CX/03/081 Edition Number: M-224922-01-1 Date: 2003-12-03 GLP/GEP: no, unpublished	N	Bayer CropScience
KCP 9.3/04	Buntain, I. G.	2003	RPA202248: Estimation of degradation by photo-oxidation in air Model calculation according to Atkinson Battelle AgriFood Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C038405, Report includes Trial Nos.: CX/03/080 Edition Number: M-224920-01-1	N	Bayer CropScience

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
			Date: 2003-12-03 GLP/GEP: no, unpublished		

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

No new studies provided.