FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: CHR/H/ETO 500 SC

Product name(s): BITT 500 SC, BETRON 500 SC, ETONAL 500 SC

Chemical active substance(s):

Ethofumesate, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: June 2021

MS Finalisation date: 14/01/2022

Version history

When	What
06/2021	Dossier sent for evaluation to Merit Mark (PL)
11/2021	zRMS finalised evaluation
01/2022	Final version prepared by zRMS after Commenting period

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Evaluator comments:
The text highlighted in grey was provided by the evaluator.

8 Fate and behaviour in the environment (KCP 9)

In the following document, data for active substance ethofumesate was described during its renewal process in 2016. Were reference to active substance data in the current risk assessment has been made, it was based on the data presented by Bayer.
In June 14th, 2018r Kemiron Koncentrat 500SC product has been renewed in Poland thus according to the art. 59 reg. 1107/2009, data protection for mentioned data expired 30 months from date of first renewal of authorisation of product containing that active substance (in this case December, 14th 2020).
Considering analogous arguments (art. 59 reg 1107/2009) – data protection of studies presented by UPL for renewal of product Bettix Combi 500 SC (renewal of authorisation granted in Poland 14.02.2019 r.) expires August 14th, 2021.
Taking into account that some data was presented by others Notyfiers, Applicant would like to emphasise that unprotected Bayer's endpoints and input parameters accepted during renewal of active substance, should be treated as an equivalent matching data in cases where any of endpoints might be protected.

8.1 Critical GAP and overall conclusions

GAP, date: 2020-07-27

PPP product name:		Formulation type:	SC [a, b]
product code:	CHR/H/ETO		
Active substance 1:	ethofumesate	Conc. of as 1:	500 g/l [c]
Active substance 2:	-	Conc. of as 2:	- [c]
Active substance 3:	-	Conc. of as 3:	-
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	Innvigo Sp. z o.o.	Professional use:	☒
Zone(s):	Central [d]	Non professional use:	☐

Verified by MS: ~~No~~ yes

Field of use: herbicide

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
Use-No. [e]	**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: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:**	ZRMs 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		e.g. g safener/synergist per ha [f]	Grounwater

Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL,CZ	Sugar beet *Beta vulgaris* subsp. *vulgaris* var. *altissima* (BEAVA)	F	Dicotylenous weeds	Spray, medium sprayer	Spring BBCH 11-18	a) 2 b) 2	5	a) 1.0 l/ha b) 2.0 l/ha	a) 0.5 kg a.s./ha b) 1.0 kg a.s./ha	200 - 300			
~~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)~~														
2	PL, CZ	Sugar beet *Beta vulgaris* subsp. *vulgaris* var. *altissima* (BEAVA)	F	Dicotylenous weeds	Spray, medium sprayer	Spring BBCH 11-18	a) 3 b) 3	5	a) 0,6 l/ha b) 1,8 l/ha	a) 0,3 kg a.s/ha b) 0,9 kg a.s/ha	200 - 300			
3														
Minor uses according to Article 51 (zonal uses)														
4														
5														
Minor uses according to Article 51 (interzonal uses)														
6														
7														

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

(d) Select relevant

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

(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

* 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

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

The application every third was taken into consideration in PECgw assessment.

Table 8.1-1: Assessed (critical) uses during approval of Ethofumesate concerning the Section Environmental Fate (Ethofumesate EFSA Journal 2016;14(1):4374)

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) (a)	F, Fn, Fpn G, Gn, Gpn or I (b)	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) (c)	**Application**				**Application rate**			PHI (days) (l)	Remarks: e.g. g safener/ synergist per ha (m)
					Method / Kind (f-h)	Timing / Growth stage of crop & season (j)	Max. number a) per use b) per crop/ season (k)	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		
	North and South EU	Sugar beet, Fodder beet, red beet	F	Annual dicot weeds and annual grasses	Overall spray	Postemergence BBCH16 to BBCH18	1-3	5	a) 0.4 b) 2.0	a) 0.2 b) 1.0	100-400	*	The maximum amount of active substance must not exceed 1.0 kg/ha every 3 years.
	Northern, central, southern EU	Sugar beet, fodder beet	F	Annual weeds	Overall spray	Preemergence	1	-	-	1	300-400	-	PHI covered by the vegetation period, max. 1 kg a.s./ha every three years
	Northern, central, southern EU	Sugar beet, fodder beet	F	Annual weeds	Overall spray	Postemergence until BBCH 18	6**	5	-	0.16**	200-300	-	PHI covered by the vegetation period, max. 1 kg a.s./ha every three years

* PHI is covered by the normal vegetation period between last application and harvest

**Splitting application with a maximum total rate of 1 kg a.s./ha per season. The maximum application rate per treatment is 0.33 kg a.s./ha. The critical GAP therefore is 3 applications of 0.33 kg a.s./ha. More applications (max.6) at a lower application rate are possible, but they do not represent the critical GAP.

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds

(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide

(f) All abbreviations used must be explained

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

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).

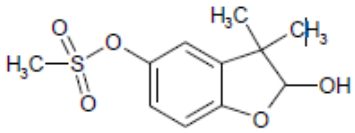
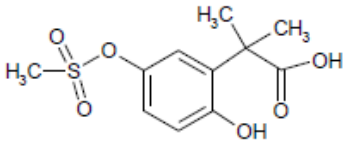
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) Indicate the minimum and maximum number of applications possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha

(m) PHI – minimum pre-harvest interval

8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
NC 8493 ethofumesate-2-hydroxy	258.3		Total Water and Sediment: - Soil: 24.2% molar basis with respect to the parent	PECsoil, PECgw, PECsw
NC 20645	274.3		Total Water and Sediment: 18.8 molar basis with respect to the parent Soil: 1.82% molar basis with respect to the parent	PECgw, PECsw, PECsed

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 :

- **Ethofumesate** - EFSA Journal 2016;14(1):4374

8.3.1.1 Ethofumesate and its metabolites

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

Parent	Dark aerobic conditions						
Soil type	**X^{20}**	**pH ($CaCl_2$)**	**t. °C / % MWHC**	**DT_{50} /DT_{90} (d)**	**DT_{50} (d) 20 °C pF2/10kPa** [b]	**St. (χ^2)**	**Method of calculation**
Sandy Loam Abington		7.0	25°C / 75% of WHC at 33kPa	137 / 454	208	5.8	SFO
Loam/Silt Loam Terling		5.8	25°C / 75% of WHC at 33kPa	68.7 / 228	80.5	3.0	SFO
Sandy Loam AX		6.1	20.7°C / 55%	28.5 / 94.7	30.4	5.1	SFO
Silt Loam HF		6.5	20.7°C / 55%	19.4 / 64.4	20.5	3.3	SFO
Sandy Loam WW		5.4	20.7°C / 55%	19.7 / 65.6	21.1	5.3	SFO
Clay Loam DD		7.2	20.7°C / 55%	19.1 /63.6	20.4	2.0	SFO
Sand Lufa 2.2		5.8	20°C / 40% MWHC	69.9 / 232	69.9	15.4	SFO
Silt Loam Fislis		6.82	20°C / pF 2.5	16.0 / 53.0	14.1	2.2	SFO
Loam Horn		7.23	20°C / pF 2.5	9.4 / 31.2	8.5	6.2	SFO
Clay Montesqiuieu		7.37	20°C / pF 2.5	20.4 / 67.8	17.9	4.8	SFO
Sandy Loam Sevelen		7.51	20°C / pF 2.5	11.7 / 38.7	9.3	3.4	SFO
Loam Mussbach		7.21	20°C / 50%	17.72 / 58.86	15.2	6.0	SFO
Sandy loam Lufa 5.2		7.3	20°C / 50%	15.36 / 51.01	14.5	6.9	SFO
Loamy sand Lufa 2.2		5.5	20°C / 50%	12.78 / 42.47	12.8	7.9	SFO
Clay loam UK1		6.80	20°C / 50%	25.52 / 84.79	25.5	6.5	SFO
Sandy loam UK2		6.83	20°C / 50%	23.29 / 77.37	23.3	3.5	SFO
Loam North France		7.41	20°C / 50%	13.63 / 45.28	11.4	9.6	SFO
Silt loam Austria		7.14	20°C / 50%	12.53 / 41.61	12.5	4.5	SFO
Silt loam Spain		7.38	20°C / 50%	17.27 / 57.36	15.5	4.1	SFO
Geometric mean (if not pH dependent)					21.6		
pH dependence					No		

[a] Measured in $CaCl_2$
[b] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Table 8.3-2: Summary of aerobic degradation rates for NC8493 - laboratory studies

NC8493	Dark aerobic conditions Metabolite dosed.							
Soil type	**X[7]**	**pH[a)]**	**t. °C / % MWHC**	**DT_{50}/DT_{90} (d)**	**f. f. k_f / k_{dp}**	**DT_{50} (d) 20 °C pF2/10kPa[b)]**	**St. (χ^2)**	**Method of calculation**
Silt loam	Fislis	6.82	20°C / pF 2.5	0.05/0.18	-	0.04	27.2	SFO
Loam	Horn	7.23	20°C / pF 2.5	0.07/0.24	-	0.06	10.5	SFO
Sandy loam	Sevelen	7.51	20°C / pF 2.5	0.05/0.17	-	0.04	21.1	SFO
Sandy loam	AX	5.5	20°C / 55%	0.02/0.07	-	0.02	5.1	SFO
Silt loam	HH	6.1	20°C / 55%	0.02/0.07	-	0.02	1.4	SFO
Clay loam	DD	7.2	20°C / 55%	0.01/0.03	-	0.01	1.4	SFO
Sandy loam	WW	5.0	20°C / 55%	0.02/0.06 k1 = 76.44 k2 = 12.59 g = 0.5346	-	0.06 [c)]	2.2	DFOP
Geometric mean (if not pH dependent)						0.03		
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
[c)] Calculated from slow-phase degradation constant

Table 8.3-3: Summary of aerobic degradation rates for NC20645 - laboratory studies

NC20645	Dark aerobic conditions Metabolite dosed.							
Soil type	**X[7]**	**pH[a)]**	**t. °C / % MWHC**	**DT_{50}/ DT_{90} (d)**	**f. f. k_f / k_{dp}**	**DT_{50} (d) 20 °C pF2/10kPa[b)]**	**St. (χ^2)**	**Method of calculation**
Sandy loam	AX	5.9	20°C / 55%	0.11 / 0.40	-	0.11	7.1	SFO
Silt loam	HH	6.1	20°C / 55%	0.08 / 0.25	-	0.08	3.0	SFO
Clay loam	DD	7	20°C / 55%	0.15 / 0.52	-	0.15	5.3	SFO
Sandy loam	WW	5.2	20°C / 55%	0.05/0.30 k1 = 5.1835 k2 = 126.72 g = 0.28569	-	0.17[c)]	0.0001	DFOP
Geometric mean (if not pH dependent)						0.12		
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
[c)] Calculated from slow-phase degradation constant

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 :

- **Ethofumesate** - EFSA Journal 2016;14(1):4374

8.3.2.1 Ethofumesate and its metabolites

Table 8.3-4: Summary of anaerobic degradation route for Ethofumesate - laboratory studies

Mineralization after 100 days	4.7% after 90 d, [14C-Phenyl-UL]-label (n= 1)
Non-extractable residues after 100 days	25% after 90 d, [14C-Phenyl-UL]-label (n= 1)
Metabolites that may require further consideration for risk assessment – name and/or code, % of applied (range and maximum)	None

Table 8.3-5: Summary of anaerobic degradation rate for Ethofumesate - laboratory studies

Parent	Dark anaerobic conditions						
Soil type	**X^{21}**	**pH[a)]**	**t. °C / % MWHC**	**DT_{50} / DT_{90} (d)**	**DT_{50} (d) 20 °C[b)]**	**St. (χ^2)**	**Method of calculation**
Sandy loam		7.6	25°C / 75% of WHC at 33 kPa	1000	1000	-	SFO
Geometric mean (if not pH dependent)					1000		

[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 :

- **Ethofumesate** - EFSA Journal 2016;14(1):4374

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

8.4.1.1 Ethofumesate and its metabolites

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

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	**Location (country or USA state).**		**pH[a)]**	**Depth (cm)**	**DT_{50} (d) actual**	**DT_{90}(d) actual**	**St. (χ^2)**	**DT_{50} (d) Norm[b)]**	**Method of calculation**
MainzA Loamy silt	Germany	bare soil	7.5	0-30	116	384	13.3	69.5	SFO
MainzB Loamy silt	Germany	bare soil	7.5	0-30	114	379	11.3	47.4	SFO
Mainz A/B Loamy silt	Germany	bare soil	7.5	0-30	-	-	-	57.4 [d)]	SFO
SpeyerA Silty sand	Germany	bare soil	6.7	0-30	21 α = 0.004 β = 0.05	333	12.5	47.2 [c)]	FOMC DFOP
SpeyerB Silty sand	Germany	bare soil	6.7	0-30	13.6 k1 = 0.09528 k2 = 0.00772 g = 0.6392	166	3.9	46.5 [c)]	DFOP
Isleham Loamy sand bare	UK	bare soil	7.5	0-30	59	196	12.3	25.7	SFO
Willingham Sandy clay loam bare	UK	bare soil	7.5	0-30	44	147	22	18.0	SFO
Fresno Sandy loam	California	cropped with alfalfa and sugar beet	6.5	0-90	89	295	20.7		SFO
Northwood Clay loam	North Dakota	cropped with alfalfa and sugar beet	7.3	0-90	1000	-	-	-	SFO
Weeze sand	Germany	bare soil	5.8	0-30	157	522	15.0	75.7	SFO
Nierswalde Sandy loam	Germany	bare soil	3.5	0-30	1000	-	-	-	SFO
NZ11007/1 Clay loam	UK	bare soil	7.13	0-30	21.6	72	16	15.2	SFO
NZ11007/2 Silty clay loam	Germany	bare soil	7.57	0-30	10.2	74	4.1	13.5	SFO

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	**Location (country or USA state).**		**pH[a)]**	**Depth (cm)**	**DT_{50} (d) actual**	**DT_{90} (d) actual**	**St. (χ^2)**	**DT_{50} (d) Norm[b)]**	**Method of calculation**
NZ11007/3 Silty clay loam	France	bare soil	7.72	0-30	35.9 k1 = 0.03878 k2 = 0.003795 g = 0.5968	367	6.1	110 [c)]	DFOP
NZ11007/4 Loam	Spain	bare soil	7.7	0-30	12.3 k1 = 0.1805 k2 = 0.00662 g = 0.0518	237	12.0	60 [c)]	DFOP
Geometric mean (if not pH dependent)								37.8	
pH dependence					No				

[a)] Solute in which the pH was measured not reported
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix
[c)] Modelling endpoint derived from slow-phase degradation constant
[d)] geomean of the paired trials Mainz A and Mainz B to be used for exposure assessment

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 :

- **Ethofumesate** - EFSA Journal 2016;14(1):4374

8.4.2.1 Ethofumesate – soil accumulation testing

Table 8.4.2-2: Summary of soil accumulation testing for Ethofumesate

Soil accumulation and plateau concentration	Plateau concentration of 0.003 mg/kg reached after 50 years (based on calculation)

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

- **Ethofumesate** - EFSA Journal 2016;14(1):4374

8.5.1 Ethofumesate and its metabolites

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

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
Mueller Podsol	1.5	6.1			3.7	247	0.96
Mueller Parabraunerde	1.1	7.6			1.1	100	0.91
Mueller light sand	1.5	6.7			3.0	200	0.94
Bruhl Sandy loam	1.16	6.0			1.13	97	0.84
Cameron Sand	1.12	4.6			0. 7	63	0.92
Cameron Acidic sandy loam	1.45	5.7			0.7	48	0.92
Cameron Alkaline Sandy loam	1.66	7.3			0.8	48	0.93
Icklingham, Sand	0.35	6.8			0.73	209	0.87
Abington, sandy loam	1.9	7.4			2.3	121	0.93
Terling, silt clay loam	3.2	6.6			5.3	166	0.89
Shelford clay	4.9	6.6			6.2	127	0.82
UPL loamy sand	1.41	7.3			2.6	187	0.93
Geometric mean (if not pH dependent)					1.74	118	
Arithmetic mean (if not pH dependent)							0.905
pH dependence Measured in $CaCl_2$			No				

Table 8.5-2: Summary of soil adsorption/desorption for metabolite NC8493

NC8493

Soil Type	OC %	Soil pH	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc}[a)] (mL/g)	1/n
-	-	-	-	20.82	-		1
pH dependence, [a)] Compound is unstable, K_{Foc} calculated with EPI WIN			No				

Table 8.5-3: Summary of soil adsorption/desorption for metabolite NC20645

NC20645

Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Silt loam HH	2.9	6.3			0.12	4.3	0.93
Loam DD	4.4	7.3			0.16	3.7	0.91
Sandy loam CA	0.7	6.7			0.03	4.3	0.87
Silt loam NE	1.7	6.6			0.17	10.0	0.99
Geometric mean (if not pH dependent)					0.10	5.1	
Arithmetic mean (if not pH dependent)							0.93
pH dependence, Measured in $CaCl_2$			No				

8.5.2 Column leaching (KCP 9.1.2.1)

Studies on column leaching with the formulation were not performed. Appropriate data can't be extrapolated because of lack of reliable column leaching studies with a not aged design.

8.5.3 Lysimeter studies (KCP 9.1.2.2)

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

- Ethofumesate - EFSA Journal 2016;14(1):4374

8.5.3.1 Ethofumesate and metabolites.

Lysimeter/ field leaching studies	Location: Bedfordshire, UK Study type (e.g. lysimeter, field): 3 lysimeters Soil properties: sand 83-96%, silt 1–7%, clay 3–8%, pH =6.1–6.5, OC = 1.02-0.02%, MWHC = n.d. Dates of application : April 1992 Crop : sugar beet /Interception estimated: 0% Number of applications: 1 year, 1 application per year Duration. 2 years Application rate: 1.25 k g/ha/year Average annual rainfall and irrigation (mm): 571 mm Average annual leachate volume (mm): Lysimeter 4: 356 mm Lysimeter 9: 323 mm Lysimeter 10: 347 mm % radioactivity in leachate (maximum/year): 1.65% AR (Lysimeter 10, 2nd year) Individual annual maximum concentrations (e.g. 1st, 2nd, 3rd yr): Ethofumesate: < 0.1 µg/L in all leachate samples NC8493: < 0.1 µg/L in all leachate samples NC9607: < 0.1 µg/L in all leachate samples NC20645: < 0.1 µg/L in all leachate samples NC 17900: < 0.1 µg/L in all leachate samples “Peak A”: Lysimeter 9: 0.41 (1st yr), 0.5 (2nd yr) µg parent equivalents /L Lysimeter 4, 10: not measured “Peak A” identified as NC8493-glycoside and NC20645-glycoside; FOCUS groundwater exposure assessment carried out for the respective aglycon: NC8493-aglycon and NC20645-aglycon < 0.1 µg/L in 9/9 FOCUS scenarios Unidentified radioactivity Annual max: Lysimeter 4: <0.1 µg/L parent equivalents (1st and 2nd yr) Lysimeter 9: 0.13 µg/L parent equivalents (1st vr) Lysimeter 10: <0.1 µg/L parent equivalents (1st and 2nd yr) Indivdual max: Lysimeter 4: 0.12µg/L parent equivalents (1st yr) Lysimeter 9: 0.16 µg/L parent equivalents (1st vr) Lysimeter 10: 0.11 µg/L parent equivalents (2nd yr) Amount of radioactivity in the soils at the end of the study = 50.3% AR; 6.49% AR as parent, 43.81% AR as NER
	Location: Itingen, Switzerland Study type (e.g. lysimeter, field): 2 lysimeters

	Soil properties: sand 88–99.7%, silt 0.3–7.3%, clay 0.3–5.6%, pH = 5.9–7.3 , OC = 1.05%–0.01% , MWHC = 27.5% Dates of application : Lysimeter 19: May 1993 Lysimeter 20: May 1993, May 1994 Crop : sugar beet/Interception estimated:20% Number of applications: Lysimeter 19: 1 application 1st yr Lysimeter 20: 2 years, 1 application per year Duration: 3 yr Application rate: 1500 g/ha/year Average annual rainfall (mm): 1093 mm Average annual leachate volume (mm): Lysimeter 19: 407 mm Lysimeter 20: 428 mm % radioactivity in leachate (maximum/year): Lysimeter 19: 0.27% AR Lysimeter 20: 0.53% AR Ethofumesate: < 0.1 µg/L in all leachate samples NC 20645: <0.1 µg/L in all leachate samples Individual annual maximum concentrations (e.g. 1st, 2nd, 3rd yr): Unidentified radioactivity, >4 components, 4.23 µg/L parent equivalents (Lysimeter 20, 3rd yr) Amount of radioactivity in the soils at the end of the study = 30.6% AR; 4% AR as parent
	Location: Essex, UK Study type (e.g. lysimeter, field): 2lysimeters Soil properties: : sand 85.9–96.4%, silt 0.9–7.3%, clay 2.7–6.9%, pH = 6.1–6.5 , OC= 1.3–0.2%, MWHC n.d. Dates of application : May-June 2001 Crop : sugar beet /Interception estimated: 20% Number of applications: 1 years, 3 applications per year Duration: 2 yr Application rate: 333 g/ha/year (1000 g/ha/yr total) Average annual rainfall (mm): 837 mm Average annual leachate volume (mm): Lysimeter A:166 mm Lysimeter B: 215 mm % radioactivity in leachate (maximum/year): Lysimeter A: 0.40% AR Lysimeter B: 0.53% AR Ethofumesate: <0.1 µg/L in all samples NC9607: <0.1 µg/L in all samples Individual annual maximum concentrations: Unidentified radioactivity Lysimeter A: 1.83 µg/L parent equivalents (2nd year). Lysimeter B: 2.53 µg/L parent equivalents (2nd year). Individual annual average): Unidentified radioactivity Lysimeter A:1.43 µg/L parent equivalents (2nd yr) Lysimeter B: 1.77 µg/L parent equivalents.(2nd yr)

	Amount of radioactivity in the soils at the end of the study = 37.5% AR; 36% AR as NERv
	Location: Neustadt, Germany Study type (e.g. lysimeter, field): lysimeter Soil properties: sand 80.88–99.07%, silt 0.22–12.65%, clay 0.71–6.47%, pH = 5.60–4.95 , OC= 1.77 – <0.01%, MWHC = 23.89–30.94, pH = , OC= , MWHC = Dates of application : Crop : sugar beet /Interception estimated: 20% Number of applications: 1 1yr Duration: 2 yr Application rate: 1 x 200 and 2 x 400 g/ha/year (1000g/ha/yr total) Average annual rainfall and irrigation (mm): 979 mm Average annual leachate volume (mm): Lysimeter 1: 515 mm Lysimeter 2: 532 mm % radioactivity in leachate (maximum/year): 0.79% AR Ethofumesate: <0.1 µg/L in all samples NC9607: <0.1 µg/L in all samples Lysimeter I Individual annual average concentrations (e.g. 1st, 2nd, 3rd yr): Unidentified radioactivity, >14 components, µg/L parent equivalents. Lysimeter II Individual annual average concentrations (e.g. 1st, 2nd, 3rd yr): Unidentified radioactivity, >14 components, 0.427 µg/L parent equivalents. Amount of radioactivity in the soils at the end of the study = 37% AR; 5.5% AR as parent

8.5.4 Field leaching studies (KCP 9.1.2.3)

Field leaching study was performed for ethofumesate and evaluated during EU review, according to the EFSA Journal 2016;14(1):4374.

Lysimeter/ field leaching studies	Location: Bedfordshire, UK Study type (e.g. lysimeter, field): 3 lysimeters Soil properties: sand 83-96%, silt 1–7%, clay 3–8%, pH =6.1–6.5, OC = 1.02-0.02%, MWHC = n.d. Dates of application : April 1992 Crop : sugar beet /Interception estimated: 0% Number of applications: 1 year, 1 application per year Duration. 2 years Application rate: 1.25 k g/ha/year Average annual rainfall and irrigation (mm): 571 mm Average annual leachate volume (mm): Lysimeter 4: 356 mm Lysimeter 9: 323 mm Lysimeter 10: 347 mm

	% radioactivity in leachate (maximum/year): 1.65% AR (Lysimeter 10, 2nd year) Individual annual maximum concentrations (e.g. 1st, 2nd, 3rd yr): Ethofumesate: < 0.1 µg/L in all leachate samples NC8493: < 0.1 µg/L in all leachate samples NC9607: < 0.1 µg/L in all leachate samples NC20645: < 0.1 µg/L in all leachate samples NC 17900: < 0.1 µg/L in all leachate samples "Peak A": Lysimeter 9: 0.41 (1st yr), 0.5 (2nd yr) □g parent equivalents /L Lysimeter 4, 10: not measured "Peak A" identified as NC8493-glycoside and NC20645-glycoside; FOCUS groundwater exposure assessment carried out for the respective aglycon: NC8493-aglycon and NC20645-aglycon < 0.1 µg/L in 9/9 FOCUS scenarios Unidentified radioactivity Annual max: Lysimeter 4: <0.1 µg/L parent equivalents (1st and 2nd yr) Lysimeter 9: 0.13 µg/L parent equivalents (1st vr) Lysimeter 10: <0.1 µg/L parent equivalents (1st and 2nd yr) Indivdual max: Lysimeter 4: 0.12µg/L parent equivalents (1st yr) Lysimeter 9: 0.16 µg/L parent equivalents (1st vr) Lysimeter 10: 0.11 µg/L parent equivalents (2nd yr) Amount of radioactivity in the soils at the end of the study = 50.3% AR; 6.49% AR as parent, 43.81% AR as NER
	Location: Itingen, Switzerland Study type (e.g. lysimeter, field): 2 lysimeters Soil properties: sand 88–99.7%, silt 0.3–7.3%, clay 0.3–5.6%, pH = 5.9–7.3 , OC = 1.05%–0.01% , MWHC = 27.5% Dates of application : Lysimeter 19: May 1993 Lysimeter 20: May 1993, May 1994 Crop : sugar beet/Interception estimated:20% Number of applications: Lysimeter 19: 1 application 1st yr Lysimeter 20: 2 years, 1 application per year Duration: 3 yr Application rate: 1500 g/ha/year Average annual rainfall (mm): 1093 mm Average annual leachate volume (mm): Lysimeter 19: 407 mm Lysimeter 20: 428 mm % radioactivity in leachate (maximum/year): Lysimeter 19: 0.27% AR Lysimeter 20: 0.53% AR Ethofumesate: < 0.1 µg/L in all leachate samples NC 20645: <0.1 µg/L in all leachate samples Individual annual maximum concentrations (e.g.

	1st, 2nd, 3rd yr): Unidentified radioactivity, >4 components, 4.23 µg/L parent equivalents (Lysimeter 20, 3rd yr) Amount of radioactivity in the soils at the end of the study = 30.6% AR; 4% AR as parent
	Location: Essex, UK Study type (e.g. lysimeter, field): 2lysimeters Soil properties: : sand 85.9–96.4%, silt 0.9–7.3%, clay 2.7–6.9%, pH = 6.1–6.5 , OC= 1.3–0.2%, MWHC n.d. Dates of application : May-June 2001 Crop : sugar beet /Interception estimated: 20% Number of applications: 1 years, 3 applications per year Duration: 2 yr Application rate: 333 g/ha/year (1000 g/ha/yr total) Average annual rainfall (mm): 837 mm Average annual leachate volume (mm): Lysimeter A:166 mm Lysimeter B: 215 mm % radioactivity in leachate (maximum/year): Lysimeter A: 0.40% AR Lysimeter B: 0.53% AR Ethofumesate: <0.1 µg/L in all samples NC9607: <0.1 µg/L in all samples Individual annual maximum concentrations: Unidentified radioactivity Lysimeter A: 1.83 µg/L parent equivalents (2nd year). Lysimeter B: 2.53 µg/L parent equivalents (2nd year). Individual annual average): Unidentified radioactivity Lysimeter A:1.43 µg/L parent equivalents (2nd yr) Lysimeter B: 1.77 µg/L parent equivalents.(2nd yr) Amount of radioactivity in the soils at the end of the study = 37.5% AR; 36% AR as NERv
	Location: Neustadt, Germany Study type (e.g. lysimeter, field): lysimeter Soil properties: sand 80.88–99.07%, silt 0.22–12.65%, clay 0.71–6.47%, pH = 5.60–4.95 , OC= 1.77 – <0.01%, MWHC = 23.89–30.94, pH = , OC= , MWHC = Dates of application : Crop : sugar beet /Interception estimated: 20% Number of applications: 1 1yr Duration: 2 yr Application rate: 1 x 200 and 2 x 400 g/ha/year (1000g/ha/yr total) Average annual rainfall and irrigation (mm): 979 mm Average annual leachate volume (mm): Lysimeter 1: 515 mm Lysimeter 2: 532 mm % radioactivity in leachate (maximum/year): 0.79% AR Ethofumesate: <0.1 µg/L in all samples

	NC9607: <0.1 µg/L in all samples Lysimeter I Individual annual average concentrations (e.g. 1st, 2nd, 3rd yr): Unidentified radioactivity, >14 components, µg/L parent equivalents. Lysimeter II Individual annual average concentrations (e.g. 1st, 2nd, 3rd yr): Unidentified radioactivity, >14 components, 0.427 µg/L parent equivalents. Amount of radioactivity in the soils at the end of the study = 37% AR; 5.5% AR as parent

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 :

- **Ethofumesate** - EFSA Journal 2016;14(1):4374

8.6.1 Ethofumesate and its metabolites

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

Parent	Distribution Max. 72.2%AR in Sediment after 104 d									
Water / sediment system	pH water phase	pH sed [a]	t. °C	$DegT_{50}$ /DT_{90} whole sys.	St. (χ^2)	$DissT_{50}$ /DT_{90} water	St. (χ^2)	$DissT_{50}$ /DT_{90} sed	St. (χ^2)	Method of calculation
Rückhaltebecken	8.1	7.2[1]	20	250 / 830	1.4	52 / 457 [c]	2.4	1000	-	SFO
Waldwinkel	7.7	7.1[1]	20	294 / 976	2.3	7.8 / 101 [c]	2.2	1000	-	SFO
Anglersee	8.6	6.8[2]	20	89 / 296	4.2	43 / 187 [c]	2.3	96 / 320	3.2	SFO
Hönniger Weiher	7.2	6.3[2]	20	141 / 469	3.4	9.9 / 130 [c]	4.4	1000	-	SFO
Rhine River	7.9	6.9[2]	20	103 / 342	1.1	13.3 / 94 [c]	10.1	1000	-	SFO
Anwiler Teich	7.9	6.9[2]	20	164 / 543	2.0	23 / 155 [c]	2.5	1000	-	SFO
Pond	7.9	7.8[2]	20	217 / 722	5.0	37 / 343 [c]	5.7	258 / 857	6.6	SFO
Creek	8.2	7.5[2]	20	209 / 693	3.6	141 / 804 [c]	2.4	273 / 907	1.7	SFO
Geometric mean at 20°C[b]				170 / 564		-		536 / 840		

[a] Measured in water (1) or CaCl2 (2)
[b] Normalised using a Q10 of 2.58

Table 8.6-2: Summary of degradation in water/sediment of metabolite NC20645

Metabolite NC20645	Distribution Max in whole system: 18.8 % after 125 days Kinetic formation fraction (k_f/k_{dp}): Anglersee……0.385 (from parent; whole system) Pond……0.443 (from parent; whole system)	Evaluated on EU level: EFSA Journal 2016;14(1):4374

Water / sediment system	pH	pH	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
Anglersee	8.6	6.8	20	19 / 62	18.1	1000 [c]	-	36 / 118	3.2	SFO
Hönniger Weiher	7.2	6.3	20	1000 [d]	-	1000 [d]	-	1000 [d]	-	SFO
Pond	7.9	7.8	20	99 / 329	32.4	1000 [d]	-	1000 [c]	-	SFO
Creek	8.2	7.5	20	1000 [c]	-	81 / 269	11.7	- [e]	-	SFO
Geometric mean at 20°C [b]				208 / -		533 / -		330 / -		

[a] Measured in $CaCl_2$
[b] Normalised using a Q10 of 2.58
[c] No reliable DT50 could be calculated
[d] Maximum not reached at study end, no reliable DT50 could be calculated
[e] Not detected

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

Evaluator's Comments:

Calculations of PEC_S for active substance and its metabolite were accepted.

The PECs for formulation, not submitted by the Applicant, was assessed by evaluator.

The relevant endpoints used for PECs assessment were agreed at the EU level.

The risk envelope approach was used for PECs assessment. The multiple application was taken into consideration (2 x 500 g a.s./ha). This application rate covers the application of 3 x 300 g a.s./ha with the same interception of 20%.

Ethofumesate. The PECs values presented in Table 8.7-3 were corrected according to to submitted PECs assessment (ESCAPE model) presented in report.

Metabolite NC8493. The PECs accum is not relevant as DT_{50} = 0.07 d.

Formulation. The application of 1.0 L prod./ha was considered.

The maximum PEC_S values for active substance and its metabolites for multiple application are presented in following table:

Compound	Sugar beet
	PECs ini mg/kg soil
Ethofumesate 2 x 500 g a.s./ha	1.055 1.318*
NC8493	0.001
Formulation 1 x 1.0 L/ha	1.208

PECs accum

These values will be used in further risk assessment.

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:

- **Ethofumesate** - EFSA Journal 2016;14(1):4374

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

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

Use No.	1
Crop	Sugar beet
Application rate (g as/ha)	500 g as./ha
Number of applications/interval	2 / 5
Crop interception (%)	20 %
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm

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

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Ethofumesate	286.3	-	157 days	EFSA Journal 2016;14(1):4374
NC8493	258.3	24.2%	0.07 days	EFSA Journal 2016;14(1):4374

8.7.2.1 Ethofumesate and its metabolites

Table 8.7-3: PEC_{soil} for Ethofumesate on sugar beets

PEC_{soil} (mg/kg)		Sugar beets			
		~~Single~~ Multiple application		~~Multiple applications~~	
		Actual	TWA	~~Actual~~	~~TWA~~
Initial		1.0550	NA	~~1.3181~~	~~NA~~
Short term	24h	1.0504	1.0527	~~1.3135~~	~~1.3158~~
	2d	1.0457	1.0504	~~1.3088~~	~~1.3135~~
	4d	1.0366	1.0458	~~1.2996~~	~~1.3089~~
Long term	7d	1.0229	1.0389	~~1.2860~~	~~1.3020~~
	14d	0.9918	1.0231	~~1.2549~~	~~1.2862~~
	21d	0.9616	1.0076	~~1.2247~~	~~1.2707~~
	28d	0.9323	0.9924	~~1.1954~~	~~1.2555~~
	50d	0.8460	0.9467	~~1.1091~~	~~1.2098~~
	100d	0.6785	0.8540	~~0.9415~~	~~1.1171~~
Plateau concentration (5 cm) after year 10		0.2631	NA	~~0.2631~~	~~NA~~

$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)	1.3181	NA	~~1.5812~~	~~NA~~

PEC_{soil} of metabolites

Table 8.7-4: PEC_{soil} for NC8493 on sugar beets

PEC_{soil} (mg/kg)		Sugar beets			
		~~Single~~ Multiple application		~~Multiple applications~~	
		Actual	TWA	~~Actual~~	~~TWA~~
Initial		0.0010	NA	~~0.0013~~	~~NA~~
Short term	24h	0.0010	0.0010	~~0.0013~~	~~0.0013~~
	2d	0.0010	0.0010	~~0.0013~~	~~0.0013~~
	4d	0.0010	0.0010	~~0.0013~~	~~0.0013~~
Long term	7d	0.0010	0.0010	~~0.0012~~	~~0.0013~~
	14d	0.0010	0.0010	~~0.0012~~	~~0.0012~~
	21d	0.0009	0.0010	~~0.0012~~	~~0.0012~~
	28d	0.0009	0.0010	~~0.0011~~	~~0.0012~~
	50d	0.0008	0.0009	~~0.0011~~	~~0.0012~~
	100d	0.0007	0.0008	~~0.0009~~	~~0.0011~~
Plateau concentration (5 cm) after year 10		0.0003	NA	~~0.0003~~	~~NA~~
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0013	NA	~~0.0016~~	~~NA~~

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

Evaluator's Comments:	The submitted PECgw assessment was accepted. Calculations of PEC_{GW} for active substance and its relevant metabolite were provided in with PUF = 0.0. The application every third year was taken into consideration. The recommended FOCUS models were used: FOCUS PELMO, FOCUS PEARL and FOCUS MACRO. All used endpoints were agreed at the EU level. **The maximum PEC_{GW} values for active substance and metabolites is below the trigger value of 0.1 µg/L if formulation is applied every third year.**

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:

- **Ethofumesate -** EFSA Journal 2016;14(1):4374

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	Sugar beet
Application rate (g as/ha)	500 g as/ha
Number of applications/interval (d)	2/5
Relative application date	+5 (emergence) / -177 (harvest)
Crop interception (%)	20 %
Frequency of application	Every three years
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3

8.8.2.1 Ethofumesate and its metabolites

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

Compound	Ethofumesate	NC8493	NC20645	Value in accordance with EU endpoint y/n
Molecular mass (g/mol)	286.3	258.3	274.3	EFSA Journal 2016;14(1):4374
Solubility in water (mg/L) at 20°C	50 at pH 7 and 25°C	2019 at pH 7 and 25°C (Calculated with EPI Suite)	16170 at pH 7 and 25°C (Calculated with EPI Suite)	EFSA Journal 2016;14(1):4374
Saturated vapour pressure (Pa)	6.5×10^{-4} Pa at 25°C	3.73×10^{-6} Pa at 25°C	7.4×10^{-7} Pa at 25°C	EFSA Journal 2016;14(1):4374
DT_{50} in soil (d) (geometric mean, normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7)	26.2 d	0.03 d (0.1 d used for modelling)	0.12 d	EFSA Journal 2016;14(1):4374
K_{foc} (mL/g) (geometric mean)	118 mL/g	2.082 mL/g,	5.1 mL/g	EFSA Journal 2016;14(1):4374
K_{fom} (mL/g)	68 mL/g	1.208 mL/g	3.0 mL/g	Calculated from K_{foc} (K_{fom}= K_{foc}/1.724) (NC8493), EFSA Journal 2016;14(1):4374
1/n (arithmetic mean)	0.905	1	0.93	EFSA Journal 2016;14(1):4374
Plant uptake factor	0.5 (0 used for modelling)	0	0	EFSA Journal 2016;14(1):4374

Formation fraction	-	-	1	EFSA Journal 2016;14(1):4374

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

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.040011	<0.0001 <0.001	0.0007
	Hamburg	0.01618	<0.0001	<0.0001
	Jokioinen	0.001068	<0.0001	0.0007
	Kremsmünster	0.010372	<0.0001	0.0002
	Okehampton	0.018098	<0.0001	0.0002
	Piacenza	0.020410	<0.0001	0.0001
	Porto	0.002276	<0.0001	<0.0001
	Sevilla	0.000722	<0.0001	<0.0001
	Thiva	0.000553	<0.0001	<0.0001

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

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.005	<0.001	<0.001
	Hamburg	0.008	<0.001	<0.001
	Jokioinen	0.001	<0.001	0.003
	Kremsmünster	0.009	<0.001	<0.001
	Okehampton	0.021	<0.001	<0.001
	Piacenza	0.027	<0.001	<0.001
	Porto	0.011	<0.001	0.001
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001

Assessment of relevance of ground water metabolites is performed and presented in section B10 of dRR.

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

Evaluator's Comments:	The submitted PECsw and PECsed calculations were accepted. The recommended FOCUS models were used: FOCUS Step 1 & 2 and Step 3. All used endpoints for active substances and their metabolites were agreed at the EU level.

D3, D4 and R1 and R3 scenarios relevant for Central Zone were taken into consideration.
The interzonal uses (Use No. 2) is covered by field application.

The risk envelope was used in PECsw assessment.
In proposed application of 2 x 500 g a.s./ha and 3 x 300 g a.s./ha, the effective application rate with interception consideration of 20% is higher for the former one (800 g a.s./ha) and it was used for PECsw assessment.

The max PECsw for CZ and Poland are presented in the table below.

Crop	Application rate g a.s./ha	Member State	Max PECsw (µg/L)	Max PECsed (µg/kg)
Sugar beet	2 x 500	Central Zone	12.78 R3 stream	3.544 R3 stream
		Poland	4.828 R1 stream	2.151 D4 pond

No mitigation measure was proposed.

The drift exposure was assessed using the Drift Calculator in SWASH model:

Crop	Application rate g a.s./ha	No spray buffer (m)	Max PEC_{sw} (µg/L)
Sugar beet	1132 g [prod]/ha equivalent to 500 g a.s/ha	1	6.013
		5	1.971

The relevant mitigation measure will be recommended in ecotoxicological section.

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:

- **Ethofumesate** - EFSA Journal 2016;14(1):4374

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/ETO
Use No.	1
Crop	Sugar beet
Application rate (kg as/ha)	0.5
Number of applications/interval (d)	2/5
Application method	sprayer

Models used for calculation	FOCUS SWASH v3.1, FOCUS PRZM v3.3.1, FOCUS MACRO v5.5.3, FOCUS TOXWA v3.3.1

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

Crop	Scenario	Application window used in modelling
Sugar beets	D3	1 May – 5 June
	D4	9 May – 13 June
	R1	21 April – 26 May
	R3	26 March – 30 April

8.9.2.1 Ethofumesate and its metabolites

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

Compound	Ethofumesate	NC8493	NC20645	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	286.3	258.3	274.3	EFSA Journal 2016;14(1):4374
Saturated vapour pressure (Pa)	6.5 x 10^{-4} Pa at 25°C	3.73 x 10^{-6} Pa at 25°C	7.4 x 10^{-7} Pa at 25°C	EFSA Journal 2016;14(1):4374
Diffusion coefficient in water (m^2/d)	4.3 x 10^{-5}	not required for Step 1+2/	not required for Step 1+2	default
Diffusion coefficient in air (m^2/d)	0.43	not required for Step 1+2	not required for Step 1+2	default
Water solubility (mg/L)	50 at pH 7 and 25°C	2019 at pH 7 and 25°C	16170 at pH 7 and 25°C	EFSA Journal 2016;14(1):4374
K_{foc} (mL/g)	118	2.082	5.1	EFSA Journal 2016;14(1):4374
Plant Uptake	0.5	not required for Step 1+2	not required for Step 1+2	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/	default
$DT_{50,soil}$ (d)	26.2	0.03	0.12	EFSA Journal 2016;14(1):4374
$DT_{50,water}$ (d)	170	1000	208	EFSA Journal 2016;14(1):4374
$DT_{50,sed}$ (d)	170 (step 1,2), 1000 (step 3)	1000	208	
$DT_{50,whole\ system}$ (d)	170	1000	208	

Compound	Ethofumesate	NC8493	NC20645	Value in accordance to EU endpoint y/n/ Reference
Maximum occurrence observed (% molar basis with respect to the parent)	-	Maximum occurrence observed in soil: 24.2 %	Maximum occurrence observed (% molar basis with respect to the parent): - Total Water and Sediment: 18.8 % Soil: 1.82 %	EFSA Journal 2016;14(1):4374

Table 8.9-4: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for ethofumesate following multiple application(s) of CHR/H/ETO 500 SC to sugar beets

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	297.22	drainage/run off	283.68	347.82
Step 2	---	46.05	drainage/run off	43.83	53.74
Northern Europe	March-May	46.05	drainage/run off	43.83	53.74
Step 3					
D3	Ditch	2.278	drainage	0.2627	0.7617
D4	Pond	0.5293	drainage	0.5189	2.151
D4	stream	1.949	drainage	0.2934	0.7919
R1	pond	0.3601	runoff and erosion	0.3315	0.8107
R1	stream	4.828	runoff and erosion	0.1937	1.101
R3	stream	12.78	runoff and erosion	0.6382	3.544

* single applications should be marked.
** twa-time as required by ecotox

According to EFSA Journal 2016;14(1):4374, for ethofumesate Regulatory Acceptable Concentration RAC=15.6 µg a.s./L and it is set by *Danio rerio* study on the basis of NOEC=0.156 mg a.s./L (nominal).

Metabolite(s) of ethofumesate

Table 8.9-6: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for NC8493 following multiple application(s) to sugar beets

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	72.58	drainage/run off	72.05	1.51
Step 2	---	<0.01	drainage/run off	<0.01	<0.01
Northern Europe	March-May	<0.01	drainage/run off	<0.01	<0.01

* single applications should be marked.
** twa-time as required by ecotox

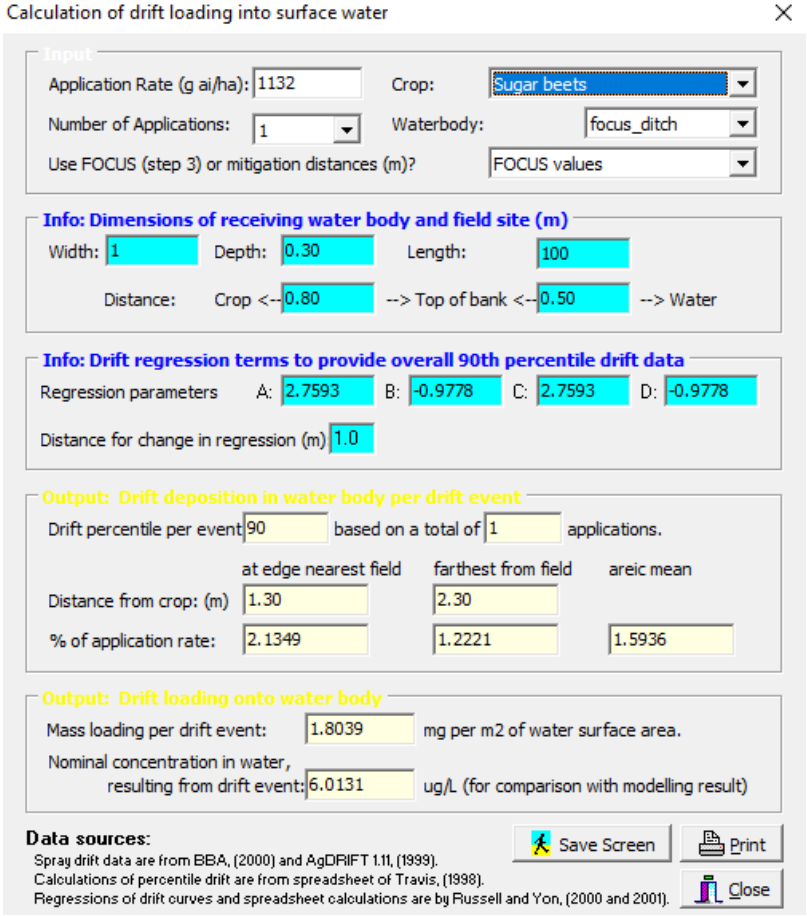
Table 8.9-7: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for NC20645 following multiple application(s) to sugar beets

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	76.76	drainage/run off	74.14	3.91
Step 2	---	<0.01	drainage/run off	<0.01	<0.01
Northern Europe	March-May	<0.01	drainage/run off	<0.01	<0.01

* single applications should be marked.
** twa-time as required by ecotox

$PEC_{sw/sed}$ of CHR/H/ETO 500 SC

Method of calculation	Drift calculator in SWASH tool calculating instantaneous PECsw at a single drift event 1 m from the field
Application rate sugar beets	1 x 1132 g [prod]/ha equivalent to 1 x 500 g a.s/ha
Resulting PECsw sugar beets	6.0131 µg[prod]/L



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

Table 8.10-1 Summary of atmospheric degradation and behaviour

Direct photolysis in air	Not studied - no data requested
Photochemical oxidative degradation in air	DT_{50} of 4.1 hours derived by the Atkinson model (version not specified). OH (24 h) concentration assumed = 5×10^5
Volatilisation	No volatilisation expected
Metabolites	None

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

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	Waring, A.R.	1992	[14C]-ETHOFUMESATE: AEROBIC METABOLISM IN TWO SOILS AT TWO MOISTURE CONTENTS Hazleton UK; Bayer CropScience, Report No.: A83385, Report includes Trial Nos.: 194/58 89B Edition Number: M-155653-01-1 Date: 1992-07-22 GLP/GEP: yes, unpublished	N	Bayer CropScienceforce
KCP	Waring, A. R.;	1992	ANAEROBIC SOIL METABOLISM (14C)-Ethofumesate	N	Task

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
9.1.1/02			Report/Doc. number: A83390 / W 135 / M-155658-01-1 Guideline(s): None GLP: yes Status: Previous evaluation in DAR for original approval / baseline dossier.		Force Ethofumesate
KCP 9.1.1/03	Menke, U.; Telscher, M.	2008	[Phenyl-UL-14C]ethofumesate (AE B049913): Time - dependent sorption in soils Bayer CropScience, Report No.: MEF-08/514, Edition Number: M-313317-01-1 Date: 2008-12-16 GLP/GEP: yes, unpublished	N	Task Force Ethofumesate
KCP 9.1.1/04	Traub, M.	2011	AE C508493 (ethofumesate-2-hydroxy): Aerobic degradation in four European soils Eurofins Agroscience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S11-00957, Edition Number: M-431094-01-1	N	Task Force Ethofumesate
KCP 9.1.1/05	Traub, M.	2012	Ethofumesate-carboxylic acid (as potassium salt: AE C639175): Aerobic degradation in four European soils Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S11-03264, Edition Number: M-432551-01-1 Date: 2012-05-22 GLP/GEP: yes, unpublished	N	Task Force Ethofumesate
KCP	Aldag, R.	1992	TESTS ON THE DEGRADATION OF	N	Bayer

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
9.1.1/09			ETHOFUMESATE IN THE TOPSOIL UNDER FIELD CON DITIONS AT FOUR DIFFERENT LOCATIONS. Kemira Agro Oy, Helsinki, FIN; Bayer CropScience, Report No.: A87554, Edition Number: M-161457-01-1 Date: 1992-11-10 GLP/GEP: no, unpublished		CropScience
KCP 9.1.1/8	Snowdon, P. J.	1991	DECLINE OF ETHOFUMESATE RESIDUES IN SOIL FOLLOWING APPLICATION WITH A 50 SC FORMULATION IN THE UK 1990/91 Schering AG, Berlin, Germany Bayer CropScience, Report No.: A83357, Report includes Trial Nos.: 041/04/056 Edition Number: M-155626-01-1 Date: 1991-10-25 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.1/9	Moede, J.	1992	DISSIPATION OF ETHOFUMESATE IN SOIL FOLLOWING TREATMENT OF AN EC CO-FORMULATION WITH PHENMEDIPHAM AND DESMEDIPHAM IN THE FEDERAL REPUBLIC OF GERMANY 1990 Schering AG, Berlin, Germany Bayer CropScience, Report No.: A83378, Report includes Trial Nos.:	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
			PF-R 91 076 Edition Number: M-155646-01-1 Date: 1992-01-13		
KCP 9.1.1/10	Castro, L. E.	1991	DISSIPATION OF ETHOFUMESATE IN SOIL FOLLOWING USE OF NORTRON EC IN SUGAR BEET CULTIVATION USA 1989 Nor-Am Chemical Company, Pikeville, NC, USA Bayer CropScience, Report No.: A83366, Edition Number: M-155634-02-1 EPA MRID No.: 41997205 Date: 1991-03-05 ...Amended: 1991-08-23 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.2/01	Muellert, J.	1990	Determination of adorption/desorption for ethofumesate Fraunhofer Institut fuer Umweltchemie und Oekotoxikologie, Schmallenberg, Germany Feinchemie Schebda , Report No.: OFC00004873, Edition Number: M-352102-01-1 Date: 1990-08-27 GLP/GEP: yes, unpublished	N	Adama (former Feinchemie Schwebda)
KCP 9.1.2/02	Allen, R.	1988	[14C]-ETHOFUMESATE: ADSORPTION/DESORPTION IN SOIL Hazleton UK; Bayer CropScience, Report No.: A83336,	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 includes Trial Nos.: 194/18 64b Edition Number: M-155605-01-1 Date: 1988-01-14 GLP/GEP: yes, unpublished		
KCP 9.1.2/03	Allen, R.; MacKenzie, E.; Hibbert, L.; Lander, G.	1995	ETHOFUMESATE SC 50% W/V CR 19035/1 and CR 18654/1 LEACHING IN SOIL LYSIMETERS MAINTAINED UNDER OUTDOOR CONDITIONS Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: A89221, Report includes Trial Nos.: ENVIR/97B Edition Number: M-164392-01-1 Date: 1995-03-31 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.2/04	Burgener, A.	1997	Report amendment to 14C-ethofumesate: Mobility and Degradation in soil in outdoor lysimeters RCC Umweltchemie AG, Itingen, Switzerland Bayer CropScience, Report No.: A91247, Report includes Trial Nos.: ENVIR/113B Edition Number: M-167946-02-1 Date: 1997-07-25 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 9.1.2/09	Mackie, J. A.; Hall, B. E.	1992	AGED SOIL LEACHING OF [14C]-ETHOFUMESATE Inveresk Research Int. Ltd., Tranent, Scotland Bayer CropScience, Report No.: A83391, Report includes Trial Nos.: 95B Edition Number: M-155659-01-1 Date: 1992-08-04 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1.2/10	Stupp, H. P.; Junge, T.	2013	[Phenyl-UL-14C]ethofumesate: Investigation of metabolites previously detected in lysimeter leachates by an outdoor experiment with three EU soils Bayer CropScience, Report No.: EnSa-13-0234, Edition Number: M-461417-01-1 Date: 2013-08-01 GLP/GEP: yes, unpublished	N	Task Force Ethofumesate
KCP 9.2.2/01	Blech, S.	1996	Ethofumesate - Fate and behaviour in water/sediment A&M, Labor fuer Analytik und Metabolismusforschung Service GmbH, Bergheim, Germany Feinchemie Schebda , Report No.: OFC00004877, Edition Number: M-352106-01-1 Date: 1996-07-31 GLP/GEP: yes, unpublished	N	Adama (former Feinchemie Schwebda)
KCP	Schmitt, W.	2008	Kinetic evaluation of the degradation of	N	Task

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
9.2.2/02			ethofumesate in an aerobic water/sediment system Bayer CropScience, Report No.: MEF-08/247, Edition Number: M-301623-01-1 Date: 2008-05-13 GLP/GEP: no, unpublished		Force
KCP 9.2.2/03	Kellner, G.	1995	DEGRADATION AND METABOLISM OF 14C ETHOFUMESATE IN AQUATIC SYSTEMS RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany Bayer CropScience, Report No.: A87625, Edition Number: M-161568-01-1 Date: 1995-05-18 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2.2/05	Howarth, R.; Tremain, S. P.; Bartlett, A. J.	1991	TECHNICAL ETHOFUMESATE: DETERMINATION OF PHYSICOCHEMICAL PROPERTIES Safepharm Lab. Ltd., Derby, United Kingdom Bayer CropScience, Report No.: A87526, Report includes Trial Nos.: 245/25 Edition Number: M-161417-01-1 Date: 1991-01-07 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2.2/06	Keirs, D. C.	2000	Aqueous photolysis (14C)-ethofumesate Inveresk Research Int. Ltd., Tranent,	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
			Scotland Bayer CropScience, Report No.: C009667, Edition Number: M-199018-01-1 EPA MRID No.: 46157901 Date: 2000-09-13 GLP/GEP: yes, unpublished		
KCP 9.2.2/07	Weuthen, M.; Stupp, H. P.	2013	[Phenyl-UL-14C]Ethofumesate: Phototransformation in water Bayer CropScience, Report No.: EnSa-12-0228, Edition Number: M-453458-01-1 Date: 2013-04-19 GLP/GEP: yes, unpublished	N	Task Force Ethofumesate
KCP 9.2.2/08	Hellpointner, E.	2013	Ethofumesate: Assessment of the environmental half-life of the direct photodegradation in water Bayer CropScience, Report No.: EnSa-13-0355, Edition Number: M-461408-01-1 Date: 2013-08-06 GLP/GEP: yes, unpublished	N	Task Force Ethofumesate
KCP 9.2.2/10	Bogers, M.	1993	READY BIODEGRADABILITY: 28 DAYS CLOSED BOTTLE TEST WITH ETHOFUMESATE RCC Notox B.V., s'Hertogenbosch, Netherlands Bayer CropScience, Report No.: A87607, Edition Number: M-161538-01-1 Date: 1993-03-31	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 9.2.2/11	Wuethrich, V.	1993	DETERMINATION OF BIOCHEMICAL AND CHEMICAL OXYGEN DEMAND OF ETHOFUMESATE DISPERSED IN WATER RCC Umweltchemie AG, Itingen, Switzerland Bayer CropScience, Report No.: A87608, Edition Number: M-161539-01-1 Date: 1993-04-28 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2.2/12	Douglas, M. T.; Sewell, I. G.	1989	ASSESSMENT OF READY BIODEGRADABILITY OF ETHOFUMESATE Huntingdon Research Centre Ltd., Huntingdon, United Kingdom Bayer CropScience, Report No.: A83351, Report includes Trial Nos.: 80B Edition Number: M-155620-01-1 Date: 1989-10-17 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2.2/14	Fahrbach, M.	2012	[14C]Ethofumesate: Aerobic mineralization in surface water Harlan Laboratories Ltd., Itingen, Switzerland Bayer CropScience, Report No.: D25330, Edition Number: M-439697-01-1	N	Task Force Ethofumesate

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: 2012-07-31 GLP/GEP: yes, unpublished		
KCP 9.2.2/15	Kellner, G.	1995	DEGRADATION AND METABOLISM OF 14C ETHOFUMESATE IN AQUATIC SYSTEMS RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany Bayer CropScience, Report No.: A87625, Edition Number: M-161568-01-1 Date: 1995-05-18 GLP/GEP: yes, unpublished	N	Bayer CropScience

Appendix 2 Detailed evaluation of the new Annex II studies

Not required