

# **FINAL REGISTRATION REPORT**

## **Part B**

### **Section 8**

#### **Environmental Fate**

Detailed summary of the risk assessment

Product code: **102000025743**

Product name(s): **Foramsulfuron + Thiencarbazone-methyl**  
Active substance(s): **OD 80 (50+30 g/L)**

#### **Central Zone**

**Zonal Rapporteur Member State: Poland**

**NATIONAL ASSESSMENT: Poland**  
**(Re-Authorisation)**

Applicant: **Bayer Crop Science Division**

Submission date: **31/08/2020**

MS Finalisation date : **06.2021; 12.2021**

## Version history

When	What
31/08/2020	Original Bayer CropScience document (Regulation 1107/2009 - Art. 43) Foramsulfuron
14/06/2021	Draft assessment of dRR performed by RMS to commenting
12/2021	Final version prepared by zRMS

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## **8                    Fate and behaviour in the environment (KCP 9)**

This national addendum contains FOCUS Step 4 PEC<sub>sw</sub> calculations considering VFSmod for foramsulfuron, AE F130619 and thiencazone-methyl.

## 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)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
22	POL	Sugar beet (BEAVA)	F	AETCY, ECHCG, VIOAR, STEME, LAMP, MATIN, CHEAL, GALAP, POLCO, POLAV, POLPE, BRSNN, VERPE, THLAR, POAAN, VERAR	spraying (broadcast, overall)	10-18	a) 1 b) 1	-	a) 1 b) 1	a) FSN 50 + TCM 30 b) FSN 50 + TCM 30	100-300	as per growth stage		
32	POL	Sugar beet (BEAVA)	F	AETCY, ECHCG, VIOAR, STEME, LAMP, MATIN, CHEAL, GALAP, POLCO, POLAV, POLPE, BRSNN, VERAR, THLAR, POAAN, VERPE	spraying (broadcast, overall)	10-18  B1: 10-12 B2: 12-18	a) B1: 1 B2: 1 b) 2	B1: - B2: - 10 d after B1	a) B1: 0.5 B2: 0.5 b) 1	a) FSN 25 + TCM 15 b) FSN 50 + TCM 30	100-300	as per growth stage		

\* 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

### Explanation for column 15 “Conclusion”

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

## **8.2 Metabolites considered in the assessment**

Please refer to the core dossier.

## **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.

Please refer to the core assessment.

### **8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)**

Please refer to the core assessment.

### **8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)**

Please refer to the core assessment.

## **8.4 Field studies (KCP 9.1.1.2)**

Please refer to the core assessment.

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

Please refer to the core assessment.

### **8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)**

Please refer to the core assessment.

## **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.

Please refer to the core assessment.

### **8.5.1 Column leaching (KCP 9.1.2.1)**

Please refer to the core assessment.

### **8.5.2 Lysimeter studies (KCP 9.1.2.2)**

Please refer to the core assessment.



### **8.5.3 Field leaching studies (KCP 9.1.2.3)**

Please refer to the core assessment.

### **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.

Please refer to the core assessment.

### **8.7 Predicted Environmental Concentrations in soil (PEC<sub>soil</sub>) (KCP 9.1.3)**

Please refer to the core assessment.

#### **8.7.1 Justification for new endpoints**

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

##### **8.7.2.1 PEC<sub>soil</sub> of FSN+TCM OD 80**

### **8.8 Predicted Environmental Concentrations in groundwater (PEC<sub>gw</sub>) (KCP 9.2.4)**

Please refer to the core assessment.

#### **8.8.1 Justification for new endpoints**

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

## 8.9 Predicted Environmental Concentrations in surface water (PEC<sub>sw</sub>) (KCP 9.2.5)

The effectiveness of vegetated filter strips for mitigating entries into surface water via runoff can be modelled using the PRZM-SWAN-VFSMOD models (SETAC MAGPIE working group, 2013)<sup>1</sup>. In addition to the FOCUS Step 4 calculations provided in the core dossier, FOCUS Step 4 calculations for R-scenarios considering VFSmod are therefore provided in this national addendum for foramsulfuron and its metabolite AE F130619 and for thien carbazon-methyl. **The calculations are based on the same substance and timing parameters previously used in the core dossier.**

### 8.9.1 Justification for new endpoints

Please refer to the core dossier

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

PEC<sub>sw</sub> reports provided by the applicant are listed in Appendix 3.3.

**Table 8.9-1: Input parameters related to application for PEC<sub>sw/SED</sub> calculations**

Plant protection product	FSN+TCM OD 80	FSN+TCM OD 80
Use No.	POL: <b>22</b>	POL: <b>32</b>
Crop	Sugar beet (arable crops)	Sugar beet (arable crops)
Application rate (kg as/ha)	Foramsulfuron: 50 g a.s./ha Thien carbazon-methyl: 30 g a.s./ha	Foramsulfuron: 25 g a.s./ha Thien carbazon-methyl: 15 g a.s./ha
Number of applications/interval (d)	1 / -	2 / 10
Application method	Spray application	Spray application
CAM (Chemical application method)	2 (application foliar linear)	2 (application foliar linear)
Soil depth (cm)	4 (default)	4 (default)
Models used for calculation	SWAN tool, version 5.0.1 FOCUS TOXSWA 4.4.3	SWAN tool, version 5.0.1 FOCUS TOXSWA 4.4.3

**Table 8.9-2: FOCUS Step 4 Scenario related input parameters for PEC<sub>sw/SED</sub> calculations for the application of FSN+TCM OD 80**

Crop	Scenario	Application window used in modelling
Sugarbeet 1 × 50 g a.s./ha 2 × 25 g a.s./ha	R1 Pond	17-Apr - 17-May
	R1 Stream	17-Apr - 17-May
	R3 Stream	21-Mar - 20-Apr

<sup>1</sup> SETAC, 2013: MAGPIE. Mitigating the Risks of Plant Protection Products in the Environment. Editors: Anne Alix, Colin Brown, Ettore Capri, Gerhard Goerlitz, Burkhard Golla, Katja Knauer, Volker Laabs, Neil Mackay, Alexandru Marchis, Elena Alonso Prados, Wolfgang Reinert, Martin Streloke, Véronique Poulsen. Proceedings of the two-part SETAC Workshop Mitigating the Risk of Plant Protection Products in the Environment. ISBN: 978-1-880611-99-9

### 8.9.2.1 Foramsulfuron and its metabolite AE F130619

The FOCUS Step 4 VFSmod calculations are based on the same substance input parameters as previously used for the FOCUS Steps 4 calculations in the core dossier.

#### FOCUS Step 4 considering VFSmod

**Sugar beets, 1 × 50 g a.s./ha**

**Table 8.9-3: Step 4 VFSmod results for foramsulfuron and its metabolite AE F130619, use sugar beets, 1 × 50 g a.s./ha**

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 foramsulfuron			STEP 4 AE F130619		
Nozzle reduction	Vegetated strip (m)	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m
	No spray buffer (m)	5 m	10 m	20 m	5 m	10 m	20 m
None	R1 Pond	0.0095	0.0068	0.0045	0.0002	0.0001	0.0001
50 %		0.0047	0.0034	0.0022	0.0001	0.0001	<0.0001
75 %		0.0024	0.0017	0.0011	0.0001	<0.0001	<0.0001
90 %		0.0011	0.0007	0.0004	0.0001	<0.0001	<0.0001
None	R1 Stream	0.0762	0.0404	0.0209	0.0015	<0.0001	<0.0001
50 %		0.0381	0.0202	0.0105	0.0015	<0.0001	<0.0001
75 %		0.0191	0.0101	0.0052	0.0015	<0.0001	<0.0001
90 %		0.0135	0.0040	0.0021	0.0015	<0.0001	<0.0001
None	R3 Stream	0.1478	0.0942	0.0294	0.0176	0.0113	0.0001
50 %		0.1478	0.0942	0.0147	0.0176	0.0113	<0.0001
75 %		0.1478	0.0942	0.0074	0.0176	0.0113	<0.0001
90 %		0.1478	0.0942	0.0029	0.0176	0.0113	<0.0001

**Sugar beets, 2 × 25 g a.s./ha**

**Table 8.9-4: Step 4 VFSmod results for foramsulfuron and its metabolite AE F130619, use sugar beets, 2 × 25 g a.s./ha**

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 foramsulfuron			STEP 4 AE F130619		
Nozzle reduction	Vegetated strip (m)	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m
	No spray buffer (m)	5 m	10 m	20 m	5 m	10 m	20 m
None	R1 Pond	0.0069	0.0048	0.0032	0.0002	0.0001	0.0001
50 %		0.0039	0.0024	0.0016	0.0002	0.0001	<0.0001
75 %		0.0026	0.0012	0.0008	0.0001	<0.0001	<0.0001
90 %		0.0017	0.0005	0.0003	0.0001	<0.0001	<0.0001
None	R1 Stream	0.0319	0.0166	0.0085	0.0028	<0.0001	<0.0001
50 %		0.0309	0.0083	0.0043	0.0028	<0.0001	<0.0001
75 %		0.0309	0.0041	0.0021	0.0028	<0.0001	<0.0001
90 %		0.0309	0.0017	0.0009	0.0028	<0.0001	<0.0001
None	R3 Stream	0.3451	0.2200	0.0120	0.0340	0.0218	<0.0001
50 %		0.3451	0.2200	0.0060	0.0340	0.0218	<0.0001
75 %		0.3451	0.2200	0.0030	0.0340	0.0218	<0.0001
90 %		0.3451	0.2200	0.0012	0.0340	0.0218	<0.0001

### 8.9.2.2 Thiencarbazone-methyl

The FOCUS Step 4 VFSmod calculations are based on the same substance input parameters as previously used for the FOCUS Steps 4 calculations in the core dossier.

#### FOCUS Step 4 considering VFSmod

Sugar beets, 1 × 30 g a.s./ha

**Table 8.9-5: Step 4 VFSmod results for thiencarbazone-methyl, use sugar beets I, 1 × 30 g a.s./ha**

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 thiencarbazone-methyl		
Nozzle reduction	Vegetated strip (m)	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m
	No spray buffer (m)	5 m	10 m	20 m
None	R1 Pond	0.0057	0.0041	0.0027
50 %		0.0028	0.0020	0.0013
75 %		0.0014	0.0010	0.0007
90 %		0.0006	0.0004	0.0003
None	R1 Stream	0.0458	0.0243	0.0127
50 %		0.0229	0.0122	0.0063
75 %		0.0114	0.0061	0.0032
90 %		0.0072	0.0024	0.0013
None	R3 Stream	0.0821	0.0519	0.0178
50 %		0.0821	0.0519	0.0089
75 %		0.0821	0.0519	0.0045
90 %		0.0821	0.0519	0.0018

**Sugar beets, 2 × 15 g a.s./ha**

**Table 8.9-6: Step 4 VFSmod results for thien carbazon-methyl, use sugar beets, 2 × 15 g a.s./ha**

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 thien carbazon-methyl		
Nozzle reduction	Vegetated strip (m)	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m
	No spray buffer (m)	5 m	10 m	20 m
None	R1 Pond	0.0040	0.0028	0.0019
50 %		0.0022	0.0014	0.0009
75 %		0.0015	0.0007	0.0005
90 %		0.0010	0.0003	0.0002
None	R1 Stream	0.0192	0.0100	0.0051
50 %		0.0168	0.0050	0.0026
75 %		0.0168	0.0027	0.0013
90 %		0.0168	0.0010	0.0005
None	R3 Stream	0.1907	0.1205	0.0072
50 %		0.1907	0.1205	0.0036
75 %		0.1907	0.1205	0.0018
90 %		0.1907	0.1205	0.0007

**8.9.2.3 PEC<sub>sw/sed</sub> of FSN+TCM OD 80**

Please refer to the core assessment.

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

Please refer to the core assessment.

**zRMS comments:**

In accordance with the Polish exposure arrangements, the calculations made with VFSmod are acceptable.  
 Therefore, zRMS accepted PEC<sub>sw/sed</sub>.

## 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 GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP 9.2.5 / 01	Chapple, A. C.; Srinivasan, P.	2019	Foramsulfuron (FSN) and metabolite: PECsw Step4 VFSSMOD EUR - Use in maize, cereals and sugar beet in Europe Report No.: EnSa-19-0507, Edition Number: M-684841-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.5 / 02	Zolfaghari, R.; Srinivasan, P.	2020	Thiencarbazone-methyl (TCM): PECsw Step4 VFSSMOD EUR - Use in maize, cereals and sugarbeets in Europe Report No.: EnSa-20-0171, Edition Number: M-684842-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer

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

Refer to Core section

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**List of data submitted by the applicant and not relied on**

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

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

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

## **Appendix 2 Detailed evaluation of the new Annex II studies**

**A 2.1 KCA 7.1 Fate and behaviour in soil**

**A 2.1.1 KCA 7.1.1 Route of degradation in soil**

**A 2.1.1.1 KCA 7.1.1.1 Aerobic degradation**

**A 2.1.1.2 KCA 7.1.1.2 Anaerobic degradation**

**A 2.1.1.3 KCA 7.1.1.3 Soil photolysis**

**A 2.1.2 KCA 7.1.2 Rate of degradation in soil**

**A 2.1.2.1 KCA 7.1.2.1 Laboratory studies**

**A 2.1.2.1.1 KCA 7.1.2.1.1 Aerobic degradation of the active substance**

**A 2.1.2.1.2 KCA 7.1.2.1.2 Aerobic degradation of metabolites, breakdown and reaction products**

**A 2.1.2.1.3 KCA 7.1.2.1.3 Anaerobic degradation of the active substance**

**A 2.1.2.1.4 KCA 7.1.2.1.4 Anaerobic degradation of metabolites, breakdown and reaction products**

**A 2.1.2.2 KCA 7.1.2.2 Field studies**

**A 2.1.2.2.1 KCA 7.1.2.2.1 Soil dissipation studies**

**A 2.1.2.2.2 KCA 7.1.2.2.2 Soil accumulation studies**

**A 2.1.3 KCA 7.1.3 Adsorption and desorption in soil**

**A 2.1.3.1 KCA 7.1.3.1 Adsorption and desorption**

<b>A 2.1.3.1.1</b>	<b>KCA 7.1.3.1.1 Adsorption and desorption of the active substance</b>
<b>A 2.1.3.1.2</b>	<b>KCA 7.1.3.1.2 Adsorption and desorption of metabolites, breakdown and reaction products</b>
<b>A 2.1.3.2</b>	<b>KCA 7.1.3.2 Aged sorption</b>
<b>A 2.1.4</b>	<b>KCA 7.1.4 Mobility in soil</b>
<b>A 2.1.4.1</b>	<b>KCA 7.1.4.1 Column leaching studies</b>
<b>A 2.1.4.1.1</b>	<b>KCA 7.1.4.1.1 Column leaching of the active substance</b>
<b>A 2.1.4.1.2</b>	<b>KCA 7.1.4.1.2 Column leaching of metabolites, breakdown and reaction products</b>
<b>A 2.1.4.2</b>	<b>KCA 7.1.4.2. Lysimeter studies</b>
<b>A 2.1.4.3</b>	<b>KCA 7.1.4.3 Field leaching studies</b>
<b>A 2.2</b>	<b>KCA 7.2 Fate and behaviour in water and sediment</b>
<b>A 2.2.1</b>	<b>KCA 7.2.1 Route and rate of degradation in aquatic systems (chemical and photochemical degradation)</b>
<b>A 2.2.1.1</b>	<b>KCA 7.2.1.1 Hydrolytic degradation</b>
<b>A 2.2.1.2</b>	<b>KCA 7.2.1.2 Direct photochemical degradation</b>
<b>A 2.2.1.3</b>	<b>KCA 7.2.1.3 Indirect photochemical degradation</b>
<b>A 2.2.2</b>	<b>KCA 7.2.2 Route and rate of biological degradation in aquatic systems</b>
<b>A 2.2.2.1</b>	<b>KCA 7.2.2.1 "Ready biodegradability"</b>
<b>A 2.2.2.2</b>	<b>KCA 7.2.2.2 Aerobic mineralisation in surface water</b>

<b>A 2.2.2.3</b>	<b>KCA 7.2.2.3 Water/sediment study</b>
<b>A 2.2.2.4</b>	<b>KCA 7.2.2.4 Irradiated water/sediment study</b>
<b>A 2.2.3</b>	<b>KCA 7.2.3 Degradation in the saturated zone</b>
<b>A 2.3</b>	<b>KCA 7.3 Fate and behaviour in air</b>
<b>A 2.3.1</b>	<b>KCA 7.3.1 Route and rate of degradation in air</b>
<b>A 2.3.2</b>	<b>KCA 7.3.2 Transport via air</b>
<b>A 2.3.3</b>	<b>KCA 7.3.3 Local and global effects</b>
<b>A 2.4</b>	<b>KCA 7.4 Definition of the residue</b>
<b>A 2.4.1</b>	<b>KCA 7.4.1 Definition of the residue for risk assessment</b>
<b>A 2.4.2</b>	<b>KCA 7.4.2 Definition of the residue for monitoring</b>
<b>A 2.5</b>	<b>KCA 7.5 Monitoring data</b>

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

**A 3.1 8.7 Predicted Environmental Concentrations in soil (PEC<sub>soil</sub>) (KCP 9.1.3)**

**A 3.2 8.8 Predicted Environmental Concentrations in groundwater (PEC<sub>gw</sub>) (KCP 9.2.4.1)**

**A 3.3 8.9 Predicted Environmental Concentrations in surface water (PEC<sub>sw</sub>) (KCP 9.2.5)**

#### **A 3.3.1 Foramsulfuron and metabolites relevant for risk assessment**

Comments of zRMS:	The study acceptable and used in evaluation.
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Reference:	<b>KCP 9.2.5/01</b>
Title:	Foramsulfuron (FSN) and metabolite: PEC <sub>sw</sub> Step4 VFSSMOD EUR - Use in maize, cereals and sugar beet in Europe
Report:	<a href="#">Chapple, A. C.; Srinivasan, P.; 2019; EnSa-19-0507; M-684841-01-1</a>
Authority registration No:	
Guideline(s):	not applicable
Deviations:	None
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

#### **A 3.3.2 Thien carbazon-methyl and metabolites relevant for assessment**

Comments of zRMS:	The study acceptable and used in evaluation.
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Reference:	<b>KCP 9.2.5/02</b>
Title:	Thien carbazon-methyl (TCM): PEC <sub>sw</sub> Step4 VFSSMOD EUR - Use in maize, cereals and sugarbeets in Europe
Report:	<a href="#">Zolfaghari, R.; Srinivasan, P.; 2020; EnSa-20-0171; M-684842-01-1</a>
Authority registration No:	
Guideline(s):	not applicable
Deviations:	None
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	