

Appendix to:

EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance oxasulfuron, EFSA Journal 2017;15(3):4722, doi:10.2903/j.efsa.2017.4722

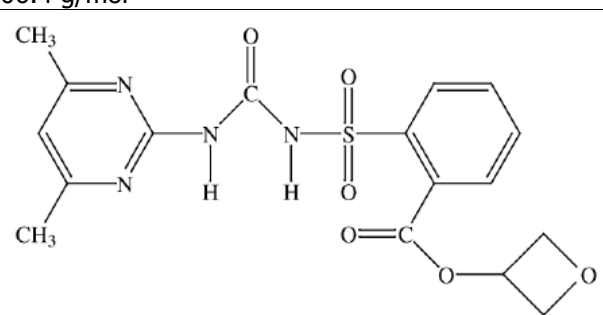
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## Appendix A – List of end points for the active substance and the representative formulation

### Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

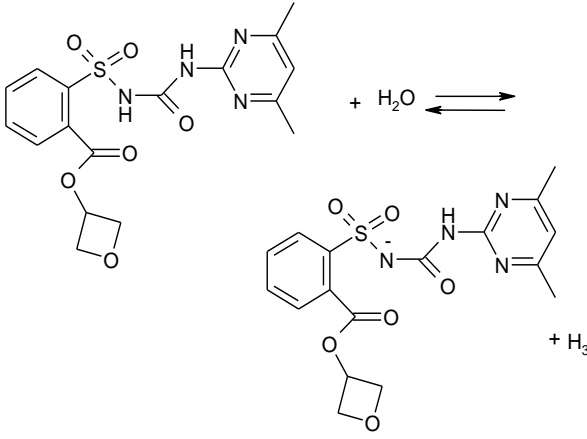
Active substance (ISO Common Name)	Oxasulfuron
Function ( <i>e.g.</i> fungicide)	Herbicide
Rapporteur Member State	Italy
Co-rapporteur Member State	Austria

### Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

Chemical name (IUPAC)	oxetan-3-yl 2-[(4,6-dimethylpyrimidin-2-yl)carbamoylsulfamoyl]benzoate
Chemical name (CA)	3-oxetan 2-[[[(4,6-dimethyl-2-pyrimidinyl)-amino]carbonyl]amino]sulfonyl]benzoate
CIPAC No	626
CAS No	144651-06-9
EC No (EINECS or ELINCS)	604-430-5
FAO Specification (including year of publication)	Not available
Minimum purity of the active substance as manufactured	985 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula	C <sub>17</sub> H <sub>18</sub> N <sub>4</sub> O <sub>6</sub> S
Molar mass	406.4 g/mol
Structural formula	

## Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

Melting point (state purity)	158°C with thermal decomposition (99.5%)
Boiling point (state purity)	Not measurable because of decomposition
Temperature of decomposition (state purity)	≥ 158°C (Purity: ≤99.5%)
Appearance (state purity)	White fine powder, odourless (Purity: 99.5%)
Vapour pressure (state temperature, state purity)	< 2·10 <sup>-6</sup> Pa at 25°C (Purity: 99.5%)
Henry's law constant (state temperature)	2.5·10 <sup>-3</sup> Pa m <sup>3</sup> mol <sup>-1</sup> (calculated, 25°C)
Solubility in water (state temperature, state purity and pH)	Solubility in water (25°C, Purity: 99.5%): pH 5.1: 52 mg/l (pure water) pH 5.0: 63 mg/l (buffer solution) pH 6.8: 1700 mg/l (buffer solution) pH 7.8: 19 g/l (buffer solution)
	Solubility in water (20°C, Purity: 98.2%): pH 5: 65.5 mg/l (double distilled water) pH 4: 69.9 mg/l (buffer solution) pH 7: 1.78 g/l (buffer solution) pH 9: 7.91 g/l (buffer solution)
Solubility in organic solvents (state temperature, state purity)	Solubility in organic solvents (25°C, Purity: 99.5%) hexane: 0.002 g/L toluene: 0.32 g/L dichloromethane: 69 g/L methanol: 1.5 g/L octanol: 0.099 g/L acetone: 9.3 g/L ethylacetate: 2.3 g/L
Surface tension (state concentration and temperature, state purity)	Data gap
Partition coefficient (state temperature, pH and purity)	log P <sub>ow</sub> at 25°C (Purity: 99.5%), uncorrected: 0.75 ± (0.008) at pH 5.0 -0.81 ± (0.006) at pH 7.0 -2.2 ± (0.016) at pH 8.9  log P <sub>ow</sub> at 25°C (Purity: 99.5%), corrected: 1.021± (0.004) at pH 5.0 1.079± (0.016) at pH 7.0 1.625± (0.016) at pH 8.9
Dissociation constant (state purity)	Dissociation constant (Purity: 99.5%): pK <sub>a,1</sub> = 5.10 (acidic) pK <sub>a,2</sub> = < 1 (basic)  The acidic dissociation constant describes the dissociation of the acidic proton of oxasulfuron in water according to the following equation

	<p>UV/VIS of purified oxasulfuron (99.5%) in methanol:</p> <table border="1"> <thead> <tr> <th><math>\lambda_{\max}</math> (nm)</th> <th><math>\epsilon</math> (L mol<sup>-1</sup> cm<sup>-1</sup>)</th> </tr> </thead> <tbody> <tr> <td>232.7</td> <td>23719</td> </tr> <tr> <td>271.2</td> <td>5951</td> </tr> </tbody> </table> <p><math>\epsilon</math> at 290 nm: not determined No absorption between 300 nm and 900 nm was observed.</p>	$\lambda_{\max}$ (nm)	$\epsilon$ (L mol <sup>-1</sup> cm <sup>-1</sup> )	232.7	23719	271.2	5951										
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<p>UV/VIS of non-purified oxasulfuron (98.2%) in aqueous methanol solution:</p> <table border="1"> <thead> <tr> <th><math>\lambda_{\max}</math> (nm)</th> <th><math>\epsilon</math> (L mol<sup>-1</sup> cm<sup>-1</sup>)</th> </tr> </thead> <tbody> <tr> <td>231</td> <td>25024</td> </tr> <tr> <td>271</td> <td>613</td> </tr> </tbody> </table> <p><math>\epsilon</math> at 290 nm: 1002 L·M<sup>-1</sup>·cm<sup>-1</sup></p>	$\lambda_{\max}$ (nm)	$\epsilon$ (L mol <sup>-1</sup> cm <sup>-1</sup> )	231	25024	271	613	<p><u>pH &lt; 2 (0.1 mol/L aqueous HCl)</u></p> <table border="1"> <thead> <tr> <th><math>\lambda_{\max}</math> (nm)</th> <th><math>\epsilon</math> (L mol<sup>-1</sup> cm<sup>-1</sup>)</th> </tr> </thead> <tbody> <tr> <td>232</td> <td>24661</td> </tr> <tr> <td>271</td> <td>5950</td> </tr> </tbody> </table> <p><u>pH &gt; 10 (0.1 mol/L aqueous NaOH)</u></p> <table border="1"> <thead> <tr> <th><math>\lambda_{\max}</math> (nm)</th> <th><math>\epsilon</math> (L mol<sup>-1</sup> cm<sup>-1</sup>)</th> </tr> </thead> <tbody> <tr> <td>242</td> <td>27563</td> </tr> </tbody> </table> <p>No absorption between 300 nm and 900 nm was observed.</p>	$\lambda_{\max}$ (nm)	$\epsilon$ (L mol <sup>-1</sup> cm <sup>-1</sup> )	232	24661	271	5950	$\lambda_{\max}$ (nm)	$\epsilon$ (L mol <sup>-1</sup> cm <sup>-1</sup> )	242	27563
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<p>Flammability (state purity)</p>	<p>Not highly flammable (Purity: 96.1%) auto-flammability: data gap</p>																
<p>Explosive properties (state purity)</p>	<p>Not explosive (Purity: 96.1%)</p>																
<p>Oxidising properties (state purity)</p>	<p>Not oxidizing (Purity: 96.1%)</p>																

**Summary of representative uses evaluated, for which all risk assessments needed to be completed (oxasulfuron)  
(Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)**

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Soya bean	S EU	Laguna 75 WG	F	Grass & Broad leaved weeds	WG	750 g/kg	spraying	between BBCH 10 and BBCH14 (from visible cotyledon to fourth trifoliate leaf unfolded)	1 (in full dose)	-	18.75 - 75	100 - 400	0.075	-	0.1 kg/ha (product dose rate)

(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. fluoroxypr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialdicarb-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

**Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (*name of active substance or the respective variant*)**  
**Regulation (EC) N° 1107/2009 Article 8.1(g)**

**Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses**

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
<b>MRL Application</b> (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															

(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)

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## Further information, Efficacy

### Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

Oxasulfuron is a herbicide and target weeds are *Abutilon theophrasti*, *Amaranthus retroflexus*, *Chenopodium album*, *Echinochloa crus-galli*, *Sorghum halepense* and *Polygonum spp.* between the cotyledons and the 4 leaves stage (BBCH 10-14) in soybean.

After application of oxasulfuron, growth of susceptible plant species ceases, followed by yellow or red discoloration. Death of those species affected occurs within one to three weeks. The visible symptoms of affected plants are like those of other sulfonylurea herbicides.

### Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

The repeated use of this product or with herbicides with the same mode of action may lead to selection of resistant weeds.

In order to prevent or slow down developing of resistant weed biotypes it is recommended to rotate with products having a different mode of action. The main emphasis should be on cultural options – rotation, cultivation and preventing weed spread.

### Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

Oxasulfuron and other sulfonylurea herbicides are given a classification B under Herbicide Resistance Action Committee (HRAC).

On 10<sup>th</sup> August 2015, 156 weed species were reported to have developed resistance to 'Group B' herbicides, among them 63 are reported for Europe.

The decision, if a resistance risk is acceptable, is following the EPPO (2003) guidelines, depends on whether the benefit of a compound is greater than a possible resistance risk.

Sulfonylurea herbicides are known to pose a higher resistance risk than other modes of action.

### Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

Activity against target organism

M3	M5(CGA 171895)	MT6	oxetan-3-ol(CGA 297691)	Saccharin (CGA 27913)
No information	No information	No information	Data gap	No

## Methods of Analysis

### Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	HPLC-UV (220 nm)
Impurities in technical a.s. (analytical technique)	Karl Fischer titration
Plant protection product (analytical technique)	HPLC-UV (235 nm)

### Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

#### Residue definitions for monitoring purposes

Food of plant origin	Oxasulfuron
Food of animal origin	None proposed
Soil	Oxasulfuron
Sediment	Oxasulfuron
Water surface	Oxasulfuron M3, MT6
drinking/ground	Oxasulfuron
Air	Oxasulfuron
Body fluids and tissues	Oxasulfuron

#### Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	<u>Substrates:</u> soya beans <u>Analysis:</u> LC-MS/MS <u>Determined analyte:</u> oxasulfuron <u>LOQ=</u> 0,01 mg/kg Method fully validated  data gap: ILV
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No method required.
Soil (analytical technique and LOQ)	Data gap
Water (analytical technique and LOQ)	Data gap
Air (analytical technique and LOQ)	Data gap
Body fluids and tissues (analytical technique and LOQ)	Data gap

### Classification and labelling with regard to physical and chemical data (Regulation (EU) No. 283/2013, Annex Part A, point 10)

Substance	oxasulfuron (ISO) oxetan-3-yl 2-[(4,6-dimethylpyrimidin-2-yl)- carbamoylsulfamoyl]benzoate
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Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]<sup>1</sup>:

No current harmonised classification with regard to physical and chemical data.

Peer review proposal <sup>2</sup> for harmonised classification according to Regulation (EC) No 1272/2008:

None

## Impact on Human and Animal Health

### Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability

Rapidly and highly absorbed: >80% within 48 hours, based on urine excretion

Toxicokinetics

C<sub>max</sub>: 20 ppm at a dose of 5 mg/kg bw and 200 ppm at 100 mg/kg bw

T<sub>max</sub>: 1h (rat)

T<sub>1/2</sub>: 6-8h (female), 11-14 h (male) in rat (blood)

Distribution

Widely distributed; highest levels in plasma, liver, kidneys and red blood cells

Potential for bioaccumulation

No evidence for accumulation

Rate and extent of excretion

Rapid (app. 84.4 to 97.2 % within 48 h), mainly via urine and faeces

Metabolism in animals

Up to 86% excreted as parent compound (CGA 277476). Metabolism included cleavage of the sulfonyl urea bridge, hydroxylation of the pyrimidinyl-methyl group, hydrolysis of the oxetanyl ester, and opening of the oxetane ring

*In vitro* metabolism

Data gap

Toxicologically relevant compounds (animals and plants)

Oxasulfuron (CGA 277476)

Toxicologically relevant compounds (environment)

oxetan-3-ol

### Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

Rat LD<sub>50</sub> oral

> 5000 mg/kg bw

Rat LD<sub>50</sub> dermal

> 2000 mg/kg bw

Rat LC<sub>50</sub> inhalation

> 5082 mg/m<sup>3</sup> (4h, nose-only exposure)

Skin irritation

Non-irritant

Eye irritation

Non-irritant

Skin sensitisation

Not- Sensitising (Buehler test, and Maximization)

<sup>1</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

<sup>2</sup> It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.



	test)
Phototoxicity	not phototoxic, unlikely to be photoreactive

### Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

Target organ / critical effect	<p><b>Rat:</b> liver (hepatocyte hypertrophy), spleen (hyperplasia of lymphatic follicles ) urinary system (inflammation of urinary bladder, pelvis dilatation in the kidney)and testis (inflammation of epididymis)</p> <p><b>Dog:</b> peripheral nerves (degeneration), muscles (weakness), brain (vacuolation), testes (decreased spermatogenic activity, accumulation of atypical cells in the lumen of the seminiferous tubules and oligospermia in the epididymides)</p> <p><b>Mouse:</b> effect on the liver (increased serum 5' nucleotidase) and red blood cells</p>
Relevant oral NOAEL	<p>Rat: 15.3 mg/kg bw per day (90-day)</p> <p>Dog: 1.3 mg/kg bw per day (90-day and 1-yr)</p> <p>Mouse: 672 mg/kg bw per day</p>
Relevant dermal NOAEL	Rat: >1000 mg/kg bw per day (28-day)
Relevant inhalation NOAEL	No data - not required

### Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

<i>In vitro</i> studies	<p><u>Bacterial gene mutation assay:</u> non mutagenic with and without metabolic activation in <i>S. typhimurium</i> and <i>E. Coli</i></p> <p><u>Mammalian gene mutation assay:</u> non mutagenic</p> <p><u>Mammalian cytogenetic assay:</u> Equivocal</p> <p><u>Unscheduled DNA repair assay:</u> no induction of unscheduled DNA repair</p>
<i>In vivo</i> studies	<p><u>Micronucleus test:</u> not clastogenic or aneugenic</p>
Photomutagenicity	No data - not required
Potential for genotoxicity	Oxasulfuron is unlikely to be genotoxic

### Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)	<b>Mice:</b> peripheral nerves (axonal degeneration), liver (hypertrophy). <b>Rats:</b> peripheral nerves (axonal degeneration), kidney (nephritis), liver (bile duct hyperplasia/ fibrosis), spleen (lymphatic depletion, pigmentation), testes (degeneration), muscles (neurogenic atrophy).	
Relevant long-term NOAEL	Mouse: 1.5 mg/kg bw per day (18-month) Rat: 8.3 mg/kg bw per day (2-year)	
Carcinogenicity (target organ, tumour type)	<b>Mice:</b> no carcinogenic potential <b>Rats:</b> Schwannomas at MTD in males were considered related to specific toxicity to the nervous system and not carcinogenic effect relevant to humans.	STOT RE 2, H373

### Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

#### Reproduction toxicity

Reproduction target / critical effect	Parental: decreased body weight gain, effects in testis Offspring: decreased body weight gain Reproductive: reduced number of pregnancies, increased number of post-implantation losses	Repr. cat 2 H361f
Relevant parental NOAEL	14.75 mg/kg bw per day	
Relevant reproductive NOAEL	340.5 mg/kg bw per day	
Relevant offspring NOAEL	340.5 mg/kg bw per day	

#### Developmental toxicity

Developmental target / critical effect	Maternal: decreased body weight gain and food consumption (rats) Developmental: increased skeletal variations (rats)	
Relevant maternal NOAEL	Rat: 300 mg/kg bw per day Rabbit: 1000 mg/kg bw per day	
Relevant developmental NOAEL	Rat: 300 mg/kg bw per day Rabbit: 1000 mg/kg bw per day	

### Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity	NOAEL 10 mg/kg bw, based on decreased rectal body temperature in females	
Repeated neurotoxicity	Peripheral neurotoxicity was observed in rats, mice and dogs in standard short- and long-term studies. It was	STOT RE 2; H373

	characterised by axonal degeneration of peripheral (motor) nerves leading to neurogenic atrophy of skeletal muscle observed in several species at different dose level and by brain vacuolization observed at 10.7 mg/kg in dog.	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	Not required	

### Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance	<i>Not required</i>	
Endocrine disrupting properties	Not conclusive (data gap)	
Studies performed on metabolites or impurities <b>oxetan-3-ol</b>	Acute oral LD <sub>50</sub> > 2000 mg/kg bw(rat) Acute dermal LD <sub>50</sub> > 4000 mg/kg bw(rat) Acute inhalation LC <sub>50</sub> >4.6 mg/L (nose only) Skin irritation Not irritating Eye irritation Not irritating Skin sensitisation Not a sensitiser (M&K)	
	28-day dog oral	NOAEL = 20 mg/kg bw per day based on minimal hepatocyte hypertrophy
	90-day dog oral	NOAEL = 50 mg/kg bw per day based on changes in erythropoietic system, liver and testes
<b>by-product</b>	Genotoxicity	Negative in bacterial reverse gene mutation assay and cytogenic test in chinese hamster ovaries
	Genotoxicity	Positive in gene mutation assay with <i>E. coli</i> without metabolic activation. No mutagenic activity observed with <i>S. typhimurium</i> .

### Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

No adverse health effects were found in routine medical surveillance of manufacturing plant personnel. No cases of poisoning have been reported.
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### Summary<sup>3</sup> (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

#### oxasulfuron

	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	0.013	1-year dog 90-day dog	100
Acute Reference Dose (ARfD)	Not allocated		
Acceptable Operator Exposure Level (AOEL)	0.013	dog, 90-day	100

Acute Acceptable Operator Exposure Level (AAOEL)

Not allocated

**oxetan-3-ol**

Acceptable Daily Intake (ADI)

0.05

16-week dog study

1000

**saccharin (and OH saccharin)**

Acceptable Daily Intake (ADI)

3.8

SCF (EC, 1997)

**Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)**

Representative formulation (Laguna 75 WG)

Human/rat *in vitro* studies and rat *in vivo* (triple pack) with the formulation Dynam 75 WG: not representative

Default values: 25% for the concentrate and 75% for the dilution

**Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)**

Operators

Use: Soybean, tractor mounted equipment, application rate 75 g as/ha

Exposure estimates (model): % of AOEL

UK POEM

Without PPE  
3000%

Gloves M/L and appl: 462%

German model

Without PPE: 336%

Gloves M/L/Appl and coverall appl  
20%

EFSA guidance

Without PPE  
254%

Gloves and work-wear M/L/Appl  
2.36%

Workers

EFSA guidance:

61% of the AOEL without PPE

Bystanders and residents

EFSA guidance:

Bystander: 2%-20% (adult), 3%-25% (child)

Resident: 2%-25% (adult), 4%-41% (child)

(considering distances of 10m and 1m)

## Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance :

oxasulfuron (ISO)  
oxetan-3-yl 2-[(4,6-dimethylpyrimidin-2-yl)-  
carbamoylsulfamoyl]benzoate

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]<sup>4</sup>:

STOT RE 2 - H373  
May cause damage to organs through prolonged or repeated exposure

Peer review proposal<sup>5</sup> for harmonised classification according to Regulation (EC) No 1272/2008:

Repr. Cat 2 - H361f  
Suspected of damaging fertility

## Residues in or on treated products food and feed

### Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

Primary crops (Plant groups covered) <b>OECD Guideline 501</b>	Crop groups	Crop(s)	Application(s)	DAT (days)
	Fruit crops			
	Root crops			
	Leafy crops			
	Cereals/grass crops			
	Pulses/Oilseeds	Soyabea n	Field application: <u>pre-emergence</u> , 1x 87 -111 g a.s./ha; <u>post-emergence</u> , 1x 89-90 g a.s./ha	Field application <u>pre-emergence</u> , 35, 42, 72 (1 <sup>st</sup> , 2 <sup>nd</sup> , 3 <sup>rd</sup> thinning) and 134 (maturity) <u>post-emergence</u> , 0, 7, 37 (1 <sup>st</sup> , 2 <sup>nd</sup> , 3 <sup>rd</sup> thinning), 99 (maturity)
			Greenhouse application: <u>pre-emergence</u> , 1x 381-326 g a.s./ha <u>post-emergence</u> , 1x 88-92 g a.s./ha	Greenhouse application: <u>pre-emergence</u> , 19-23, 27-31 (1 <sup>st</sup> , 2 <sup>nd</sup> thinning), 100-132 (maturity) <u>post-emergence</u> , 7 (2 <sup>nd</sup> thinning) and 76-112 (maturity)

<sup>4</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

<sup>5</sup> It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

			Greenhouse application ( <sup>14</sup> C oxetanyl label): <u>pre-emergence</u> , 1x 270 g a.s./ha <u>post-emergence</u> , 1x 97 g a.s./ha	
	Miscellaneous			
	In the greenhouse metabolism studies only glucose and glutamine conjugates of the HO-pyrimidine amine (CGA-340355) were found at levels >10% TRR in soya beans equivalent to max. 0.012 mg/kg. In the field metabolism studies the predominant metabolites in soya bean foliage were glycerol ester of Oxasulfuron (CGA-310785), saccharin (CGA-27913) and sulfamoylbenzoic acid (CGA-177288). The highest residue was equivalent to 0.021 mg/kg. Only saccharin (CGA-27913) occurred at a level >10% TRR in mature beans but the actual concentration was very low (0.002 mg/kg).			
<b>Rotational crops</b> (metabolic pattern) <b>OECD Guideline 502</b>	<b>Crop groups</b>	<b>Crop(s)</b>	<b>PBI (days)</b>	<b>Comments</b>
	Root/tuber crops	Turnip	35,120,383	Metabolism studies conducted with a bare soil application at 188 g/ha with <sup>14</sup> C-phenyl and 168 g/ha with <sup>14</sup> C-pyrimidinyl oxasulfuron.
	Leafy crops	Mustard	35, 120, 383	
	Cereal (small grain)	Wheat	35, 120, 383	
	Pulses and oilseed	-	-	
Rotational crop and primary crop metabolism similar?	Open Data gap: Since CGA 27913 and C 1801 were shown to be low to high persistent in soil (DT <sub>90</sub> of 28.8-788 and 10.8-1560 days, respectively), the potential for residues of these compounds to be present in the rotational crops needs to be investigated. Furthermore and pending upon the outcome of the requested DT <sub>50</sub> /DT <sub>90</sub> values on the metabolites CGA 171895 (M5), M3, CGA 179710, CGA 297691 and MT6 (data gaps in section 4), further rotational crops studies addressing the nature and magnitude of residues in regards to these compounds might be needed.			
<b>Processed commodities</b> (standard hydrolysis study) <b>OECD Guideline 507</b>	<b>Conditions</b>			
	20 min, 90°C, pH 4			
	60 min, 100°C, pH 5			
	20 min, 120°C, pH 6			
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Hydrolysis studies not triggered as oxasulfuron residues in soya beans <0.01 mg/kg (LOQ).			
Plant residue definition for monitoring (RD-Mo) <b>OECD Guidance, series on pesticides No 31</b>	Oxasulfuron			
Plant residue definition for risk assessment (RD-RA)	Oxasulfuron			
Conversion factor (monitoring to risk assessment)	None			

### Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

<b>OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish)</b>	<b>Animal</b>	<b>Dose</b> (mg/kg bw/d)	<b>Duration</b> (days)	<b>N</b> <b>rate/comment</b>
<b>Animals covered</b>	Laying hen	6.25	8	6250

Goat	3.27-3.54	4	3270-3910
Pig	-	-	Not triggered
<p>The major pathways are the oxidation of one of the pyrimidinyl methyl groups to form HO-oxasulfuron (OH-CGA-277476), the hydrolysis of the oxetane ring to form the glycerol ester of HO-oxasulfuron (HO-CGA-310785), prior to sulfonylurea bridge cleavage and further transformation to saccharin (CGA 27913) and pyrimidine amine (C 1801).</p> <p>The metabolism pathways of oxasulfuron in rat and in ruminants are similar.</p>			
Time needed to reach a plateau concentration in milk and eggs (days)	Not provided		
Animal residue definition for monitoring (RD-Mo) <a href="#">OECD Guidance, series on pesticides No 31</a>	Not required		
Animal residue definition for risk assessment (RD-RA)	Not required		
Conversion factor (monitoring to risk assessment)	None		
Metabolism in rat and ruminant similar (Yes/No)	Yes		
Fat soluble residues (Yes/No) <a href="#">(FAO, 2009)</a>	No		

#### Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

<b>Confined rotational crop study</b> (Quantitative aspect) <a href="#">OECD Guideline 502</a>	Data gap: Since CGA 27913 and C 1801 were shown to be low to high persistent in soil (DT <sub>90</sub> of 28.8-788 and 10.8-1560 days, respectively), the potential for residues of these compounds to be present in the rotational crops needs to be investigated. Furthermore and pending upon the outcome of the requested DT <sub>50</sub> /DT <sub>90</sub> values on the metabolites CGA 171895 (M5), M3, CGA 179710, CGA 297691 and MT6 (data gaps in section 4), further rotational crops studies addressing the nature and magnitude of residues in regards to these compounds might be needed.
<b>Field rotational crop study</b> <a href="#">OECD Guideline 504</a>	Open

#### Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)

##### [OECD Guideline 506](#)

Plant products (Category)	Commodity	T (°C)	Stability (Months)
			Oxasulfuron
High water content			
High oil content	Soya bean	-20	24
High protein content			
High starch content			

High acid content			
Other			

Storage stability of oxasulfuron (CGA-277476) was demonstrated for a period of 24 months at -20 °C in soybean seeds and processed fractions (meal, hulls, oil).

Animal	Animal commodity	T (°C)	Stability (Months)
			Oxasulfuron
Beef	Muscle	-20	11
	Liver	-20	7
	Kidney		
	Milk	-20	10
	Egg	-20	12



## Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) **OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator**

Crop	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
<b>Representative uses</b>						
<b>Residue definition for monitoring:</b> Oxasulfuron						
Soyabean	SEU	7x <0.01	MRL <sub>OECD</sub> : 0.01 mg/kg	0.01(*)	0.01	0.01

### MRL application

Not relevant

### Summary of the data on formulation equivalence **OECD Guideline 509**

Crop	Region	Residue data (mg/kg)	Recommendations/comments			
No information provided - Not relevant						

### Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)

Product(s)	Region	Residue data (mg/kg)	Recommendations/comments			
No information provided						

No information provided

Data gap: The determination of the residues in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom with regards to oxasulfuron and relevant metabolites and considering also the outstanding data on rotational crops is requested.

- (a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.
- (b): Residue levels in trials conducted according to GAP reported in ascending order (*e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Monitoring** and **Risk Assessment**.
- (c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR<sub>Mo</sub>).
- (d): **STMR**: Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets (STMR<sub>Mo</sub>).

**Inputs for animal burden calculations**

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
<b>Representative uses</b>				
Soybean seed	0.01	STMR	0.01	STMR
Soybean meal	0.01	STMR	0.01	STMR
Soybean hulls	0.01	STMR	0.01	STMR
<b>MRL application</b>				
Not relevant				

**Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)**  
**OECD Guideline 505 and OECD Guidance, series on pesticides No 73**

MRL calculations	Ruminant				Pig/Swine		Poultry		Fish	
<b>Highest expected intake</b> (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.0001	Ram/Ewe	0.0001	Breeding	0.0001	Broiler	0.0005	Carp	-
	Dairy cattle	0.0001	Lamb	0.0002	Finishing	0.0002	Layer	0.0003	Trout	-
							Turkey	0.0005	Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	No		No		No		No		No	
Feeding study submitted	Not required		Not required		Not required		Not required		Not required	
<b>Representative feeding level</b> (mg/kg bw/d, mg/kg DM for fish) and <b>N rates</b>	Level	Beef: N Dairy: N	Level	Lamb: N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Estimated HR <sup>(a)</sup> at 1N	<b>MRL</b> proposals	Estimated HR <sup>(a)</sup> at 1N	<b>MRL</b> proposals	Estimated HR <sup>(a)</sup> at 1N	<b>MRL</b> proposals	Estimated HR <sup>(a)</sup> at 1N	<b>MRL</b> proposals	Estimated HR <sup>(a)</sup> at 1N	<b>MRL</b> proposals
Muscle										
Fat										
Meat <sup>(b)</sup>										
Liver										
Kidney										
Milk <sup>(a)</sup>										
Eggs										
Method of calculation <sup>(c)</sup>										

<sup>(a)</sup>: Estimated HR calculated at 1N level (**estimated mean level for milk**).

<sup>(b)</sup>: HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

<sup>(c)</sup>: The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

## Conversion Factors (CF) for monitoring to risk assessment

### Animal products

Not relevant (RD-Mo = RD-RA)

### Plant products

Not relevant (RD-Mo = RD-RA)

## Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3) OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

Crop (RAC)/Edible part or Crop (RAC)/Processed product	Number of studies <sup>(a)</sup>	Processing Factor (PF)		Conversion Factor (CF <sub>p</sub> ) for RA <sup>(b)</sup>
		Individual values	Median PF	

### Representative Uses

Processing residue trials are not triggered.

<sup>(a)</sup>: Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)

<sup>(b)</sup>: When the residue definition for risk assessment differs from the residue definition for monitoring

## Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9) Including all uses (representative uses and uses related to an MRL application).

### ADI

TMDI according to EFSA PRIMo

NTMDI, according to (to be specified)

IEDI (% ADI), according to EFSA PRIMo

NEDI (% ADI), according to (to be specified)

Factors included in the calculations

### ARfD

IESTI (% ARfD), according to EFSA PRIMo

NESTI (% ARfD), according to (to be specified)

Factors included in IESTI and NESTI

0.013 mg/kg bw per day

Not relevant

Not provided, not required

Not provided, not required

Not provided, not required

None

Not allocated

-

-

-

## Consumer risk assessment limited to the representative uses<sup>(1)</sup>

TMDI (% ADI), according to EFSA PRIMo

NTMDI (% ADI), according to (to be specified)

IEDI (% ADI), according to EFSA PRIMo

NEDI (% ADI), according to (to be specified)

Factors included in the calculations

IESTI (% ARfD, according to EFSA PRIMo)

NESTI (% ARfD, according to (to be specified)

Factors included in IESTI and NESTI

Highest TMDI: <1% of the ADI (WHO cluster diet F)

Not provided, not required

Not provided, not required

Not provided, not required

None

Not provided, not required

Not provided, not required

None

### Additional contribution to the consumer intakes through drinking water resulting from groundwater metabolite expected to be present above 0.75 µg/L<sup>(1)</sup>

Metabolite	CGA 297691
ADI (mg/kg bw per day)	0.05
Intake of groundwater metabolites (% ADI)	Adult (60 kg bw, 2 L): 0.2 % ADI
WHO Guideline (WHO, 2011)	Child (10 kg bw, 1 L): 0.6 % ADI Infant ( 5 kg bw, 0.75 L): 0.9 % ADI

<sup>(1)</sup>: The overall consumer exposure assessment cannot be finalised in view of the identified data gap for the potential for residues of CGA 27913 and C 1801 to be present in the rotational crops, the outstanding data regarding the metabolism and magnitude of the relevant compounds in rotational crops (see section 4) and the consumer exposure assessment through drinking water with regards to MT6, CGA 171895 (M5) and M3.

### Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

Code <sup>(a)</sup>	Commodity/Group	MRL/Import tolerance <sup>(b)</sup> ( mg/kg) and Comments	
<b>Plant commodities</b>			
<b>Representative uses</b>			
0401070	Soyabeans	0.01(*)	Current MRL Reg EU 289/2014

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005

(b): MRLs proposed at the LOQ, should be annotated by an asterisk (\*) after the figure

### Environmental fate and behaviour

#### Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation after 100 days	0.1-57.4 % after 90-105 d, [ <sup>14</sup> C-phenyl]-label (n=4) 1.3-21.3 % after 90-83 d, [ <sup>14</sup> C-pyrimidinyl]-label (n=3) 80.4 % after 120 d, [ <sup>14</sup> C-oxetan]-label (n=1)
Non-extractable residues after 100 days	1.7-27 % after 90-105 d, [ <sup>14</sup> C-phenyl]-label (n= 4) 25.5-53.9 % after 90-83 d, [ <sup>14</sup> C-pyrimidinyl]-label (n=3) 5.3 % after 120 d, [ <sup>14</sup> C-oxetan]-label (n=1)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	saccharin CGA (27913) – 9-98.5 % at 9-90 d (n=9) [ <sup>14</sup> C-phenyl]-label  M3 – 4.8-25 % at 0-65 d (n=6) [ <sup>14</sup> C-phenyl] & [ <sup>14</sup> C-pyrimidinyl] and [ <sup>14</sup> C-oxetan]-label  M5 – 5.4-10.2 % at 9-2 d (n=2) [ <sup>14</sup> C-phenyl]-label  C1801 – 29.2-54.7 % at 5-14 d (n=4) [ <sup>14</sup> C-pyrimidinyl]-label  CGA 179710 – 1.3-27.5 % at 7-14 d (n=2) [ <sup>14</sup> C-pyrimidinyl]-label  CGA 297691 – about 21 % at 4 d (n=1) [ <sup>14</sup> C-oxetan]-label, field study only

### Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days	0.2-0.3 % at 90-120 d, [ <sup>14</sup> C-phenyl]-label (n=2) 1.1-15.6 % at 90-127 d, [ <sup>14</sup> C-pyrimidinyl]-label (n=2) 6.6 % at 90 d, [ <sup>14</sup> C-oxetan]-label (n=1)
Non-extractable residues after 100 days	3-3.6 % at 90-120 d, [ <sup>14</sup> C-phenyl]-label (n=2) 19.3-50.1 % at 90-127 d, [ <sup>14</sup> C-pyrimidinyl]-label (n=2) 20.2 % at 90 d, [ <sup>14</sup> C-oxetan]-label (n=1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	saccharin (CGA 27913) – 86.5-96.8 % at 120-59 d (n=2) [ <sup>14</sup> C-phenyl]-label  M3 – 30.2 % at 40 d (n=1) [ <sup>14</sup> C-pyrimidinyl]-label  C1801 – 22.7-69 % at 8-59 d (n=2) [ <sup>14</sup> C-pyrimidinyl]-label  CGA 297691 – 87.8 % at 62 d (n=1) [ <sup>14</sup> C-oxetan]-label

### Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	saccharin (CGA 27913) – 90.5 % at 30 d (n=1) [ <sup>14</sup> C-phenyl]-label  CGA 297691 – 58.8 % at 30 d (n=1) [ <sup>14</sup> C-oxetan]-label  C1801 – 51.5 % at 30 d (n=1) [ <sup>14</sup> C-pyrimidinyl]-label
Mineralisation at study end	0.2 % at 30 d, [ <sup>14</sup> C-phenyl]-label (n=1) 0.4 % at 30 d, [ <sup>14</sup> C-pyrimidinyl]-label (n=1) 16.3 % at 30 d, [ <sup>14</sup> C-oxetan]-label (n=1)
Non-extractable residues at study end	0.4 % at 30 d, [ <sup>14</sup> C-phenyl]-label (n=1) 5.5 % at 30 d, [ <sup>14</sup> C-pyrimidinyl]-label (n=1) 7.5 % at 30 d, [ <sup>14</sup> C-oxetan]-label (n=1)

**Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)**

Oxasulfuron			Dark aerobic conditions						
	Soil type	O.C. (%)	pH <sup>a</sup> )	t. °C / % MWHC	DT <sub>50</sub> /DT <sub>90</sub> (d) #	St. (X <sup>2</sup> )	DT <sub>50</sub> (d) 20 °C pF2/10kPa <sup>b</sup> )	St. (X <sup>2</sup> )	Method of calculation §
Gartenacker, Silt loam	2.3	7.2	20°C/40%	8.4/27.9 SFO	3	8.4	3	SFO	
Speyer 2.2, Loamy sand	2.2	5.7	20°C/40%	29.3/97.3 SFO	6.9	29.3	6.9	SFO	
Weide, Sandy loam	1.3	7.6	20°C/40%	11.6/51 FOMC	3.1	15.4	3.1	FOMC (DT <sub>90</sub> /3.32)	
Gartenacker, Silt loam	2.1	7.2	19.8°C/75% of field capacity	5.7/18.9 SFO	3.5	4.6	3.5	SFO	
Collombey, Loamy sand	1.6	7.4	19.8°C/75% of field capacity	6.7/35.5 FOMC	2.5	8.6	2.5	FOMC (DT <sub>90</sub> /3.32)	
USA, Sandy loam a	1.1	6.8	25°C/75% of field capacity at 0.33 bar	4.2/14 SFO	6.1	5.5	6.1	SFO	
USA, Sandy loam b	1.1	6.8	25°C/75% of field capacity at 0.33 bar	3.2/10.6 SFO	9.9	4.2	9.9	SFO	
USA, Sandy loam c	1.5	7	25.5°C/75% of field capacity at 0.33 bar	3.7/20.1 FOMC	6.7	8.3	6.7	FOMC (DT <sub>90</sub> /3.32)	
USA, Sandy loam d	1	7.5	25°C/75% of field capacity at 0.33 bar	7.2/24 SFO	1.4	9.5	1.4	SFO	
USA, Sandy loam e	1	7.5	25°C/75% of field capacity at 0.33 bar	8.3/27.5 SFO	3.7	10.9	3.7	SFO	
USA, Sand	0.5	8.3	25°C/75% of field capacity at 0.33 bar	10/33.3 SFO	3.3	13.1	3.3	SFO	
USA, Loam	1.4	6.7	25°C/75% of field capacity at 0.33 bar	9/29.9 SFO	3	11.8	3	SFO	
USA, Clay	1.2	7.3	25°C/75% of field capacity at 0.33 bar	7.4/24.7 SFO	2.9	9.7	2.9	SFO	
Geometric mean (if not pH dependent)							9.4		
pH dependence, No									

<sup>a</sup>) Measured in water

<sup>b</sup>) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

# Non-normalised for trigger evaluation

§ For modelling purposes

**Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)**

<b>Saccharin (CGA 27913)</b>		<b>Dark aerobic conditions Oxasulfuron dosed from which the f.f. was derived was 0.6</b>							
Soil type	O.C. (%)	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d) #	f. f. k <sub>f</sub> / k <sub>dp</sub>	St. (X <sup>2</sup> )	DT <sub>50</sub> (d) 20 °C pF2/10kP a <sup>b)</sup>	St. (X <sup>2</sup> )	Method of calculation §
Gartenacker, Silt loam	2.3	7.2	20°C/40 %	12.5/111 DFOP (decline phase)	1*	12.9	48	23.7	FOMC (DT <sub>90</sub> /3.32)
Speyer 2.2, Loamy sand	2.2	5.7	20°C/40 %	8.7/28.8 SFO+SFO	0.59	23.8	8.7	23.8	SFO+SFO
Weide, Sandy loam	1.3	7.6	20°C/40 %	4.6/26.1 FOMC (decline phase)	1*	2.6	7.9	2.6	FOMC (DT <sub>90</sub> /3.32)
Sandy loam <sup>§</sup>	-	5.7	20°C/50 %	80.7/269	-	-	80.7	2	SFO
Silt loam-1 <sup>§</sup>	-	7.7	20°C/50 %	34.8/116	-	-	34.8	10	SFO
Silt loam-2 <sup>§</sup>	-	6.4	20°C/50 %	119/661	-	-	119	5	SFO
Mattapex, silt loam <sup>§</sup>	-	6.9	20°C	237.4/788.6	-	-	237.4	4	SFO
Speyer 2.2, loamy sand-1 <sup>§</sup>	-	5.7	20°C	9.69/32.2	-	-	9.69	4.76	Modified HS
Speyer 3A, sandy loam-1 <sup>§</sup>	-	7.3	20°C	10.2/34	-	-	9.53	5.32	Modified HS
Speyer 65, clay-1 <sup>§</sup>	-	7.1	20°C	29.9/99.2	-	-	20.6	5.75	Modified HS
Speyer 2.2, loamy sand-2 <sup>§</sup>	-	5.7	20°C	14.8/49.2	-	-	14.8	-	SFO
Speyer 3A, sandy loam-2 <sup>§</sup>	-	6.88	20°C	9.1/30.1	-	-	8.45	-	SFO
Speyer 65, clay-2 <sup>§</sup>	-	7.23	20°C	27.5/91.2	-	-	20.47	-	SFO
Geometric mean (if not pH dependent)							24.7		
Arithmetic mean					0.86				
pH dependence, No									

<sup>a)</sup> Measured in water

<sup>b)</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

# Non-normalised for trigger evaluation

§ For modelling purposes

\* A worst-case value of 1 has been selected because no acceptable fit could be derived by modelling parent and metabolite together, therefore a suitable estimation of the formation fraction could not be achieved.

§ These values were contained in the endpoints lists from the published finalised EFSA conclusions for the a.s. metsulfuron-methyl <https://www.efsa.europa.eu/it/efsajournal/pub/3936> and ethametsulfuron-methyl <https://www.efsa.europa.eu/it/efsajournal/pub/3508>



<b>M3</b>		<b>Dark aerobic conditions Oxasulfuron dosed from which the f.f. was derived was 0.25</b>							
Soil type	O.C. (%)	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d) #	f. f. k <sub>f</sub> / k <sub>dp</sub>	St. (X <sup>2</sup> )	DT <sub>50</sub> (d) 20 °C pF2/10kPa <sup>b)</sup>	St. (X <sup>2</sup> )	Method of calculation §
Gartenacker, Silt loam	2.3	7.2	20°C/40%	122/406 SFO+SFO	0.25	20.7	122	53.2	SFO+SFO
Geometric mean (if not pH dependent)							122		
Arithmetic mean					0.25				
pH dependence, No									

<sup>e)</sup> Measured in water

<sup>f)</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

# Non-normalised for trigger evaluation

§ For modelling purposes

<b>M5 (CGA 171895)</b>		<b>Dark aerobic conditions Oxasulfuron dosed from which the f.f. was derived was 1</b>							
Soil type	O.C. (%)	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d) #	f. f. k <sub>f</sub> / k <sub>dp</sub>	St. (X <sup>2</sup> )	DT <sub>50</sub> (d) 20 °C pF2/10kPa <sup>b)</sup>	St. (X <sup>2</sup> )	Method of calculation §
Speyer 2.2, Loamy sand	2.2	5.7	20°C/40%	12.7/321 HS (decline phase)	1*	18.3	154	18.3	HS-K2 after lag phase
Weide, Sandy loam	1.3	7.6	20°C/40%	7.4/59.1 FOMC (decline phase)	1*	19.1	17.8	19.1	FOMC (DT <sub>90</sub> /3.32)
Geometric mean (if not pH dependent)							52.4		
Arithmetic mean					1				
pH dependence, No									

<sup>g)</sup> Measured in water

<sup>h)</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

# Non-normalised for trigger evaluation

§ For modelling purposes

\* A worst-case value of 1 has been selected because no acceptable fit could be derived by modelling parent and metabolite together, therefore a suitable estimation of the formation fraction could not be achieved.

<b>C1801</b>		<b>Dark aerobic conditions Oxasulfuron dosed from which the f.f. was derived was 0.6</b>							
Soil type	O.C. (%)	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d) #	f. f. k <sub>f</sub> / k <sub>dp</sub>	St. (X <sup>2</sup> )	DT <sub>50</sub> (d) 20 °C pF2/10kPa <sup>b)</sup>	St. (X <sup>2</sup> )	Method of calculation §
Gartenacker, Silt loam	2.1	7.2	19.8°C/75% of field capacity	3.2/10.8 SFO+SFO	0.3	10.8	2.6	10.8	SFO+SFO
Collombey,	1.6	7.4	19.8°C/75%	14.8/49.2	0.8	10.	11.8	10.4	FOMC+SFO

Loamy sand			of field capacity	FOMC+SF O		4			
USA, Sandy loam b	1.1	6.8	25°C/75% of field capacity at 0.33 bar	468/1560 SFO+SFO	0.61	11.5	611.2	11.5	SFO+SFO
Geometric mean (if not pH dependent)							26.6		
Arithmetic mean					0.57				
pH dependence, No									

<sup>1)</sup> Measured in water

<sup>1)</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

# Non-normalised for trigger evaluation

§ For modelling purposes

<b>CGA 179710</b>		<b>Dark aerobic conditions Oxasulfuron dosed from which the f.f. was derived was 0.3</b>							
Soil type	O.C (%)	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d) #	f. f. k <sub>f</sub> / k <sub>dp</sub>	St. (X <sup>2</sup> )	DT <sub>50</sub> (d) 20 °C pF2/10kPa <sup>b)</sup>	St. (X <sup>2</sup> )	Method of calculation §
USA, Sandy loam b	1.1	6.8	25°C/75% of field capacity at 0.33 bar	298/989 SFO+SFO	0.3	10.8	389.2	10.8	SFO+SFO
Geometric mean (if not pH dependent)							389.2		
Arithmetic mean					0.3				
pH dependence, No									

<sup>k)</sup> Measured in water

<sup>1)</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

# Non-normalised for trigger evaluation

§ For modelling purposes

<b>MT6</b>	Data gap
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### Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

<b>Oxasulfuron</b>	<b>Aerobic conditions</b>								
	Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	O.M. (%)	pH <sup>a)</sup>	Depth (cm)	DT <sub>50</sub> (d) actual	DT <sub>90</sub> (d) actual	C.C.*	DT <sub>50</sub> (d) Norm <sup>b)</sup>
Dewey, bare soil	Illinois	3.4	6.1	7.5	3.2	n.c.	0.989	n.c.	Regression analysis
Loamy sand/sandy loam, cropped soil	North Carolina	< 1	5-6	15	5.9	n.c.	0.916	n.c.	Regression analysis
Geometric mean (if not pH dependent)					4.3				
pH dependence, No									

<sup>a)</sup> Measured in unknown medium

<sup>b)</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix

\* Correlation coefficient

n.c. Not calculated

### Combined laboratory and field kinetic endpoints for modelling (when not from different populations)\*

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)

Not relevant, since field data are not suitable for modelling purposes

Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)

Not relevant

Kinetic formation fraction (f. f.  $k_f / k_{dp}$ ) of transformation products, arithmetic mean

Not relevant

\* Only relevant after implementation of the published EFSA guidance describing how to amalgamate laboratory and field endpoints.

### Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration

Not relevant ( Plateau concentration of 0.000 mg/kg reached after 0 years, based on calculation)

### Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Oxasulfuron	Dark anaerobic conditions. Results not reported since anaerobic DT50 should not be used for the risk assessment						
Soil type	O.C. (%)	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20 °C <sup>b)</sup>	St. (r <sup>2</sup> )	Method of calculation
Gartenacker, Silt loam	2.3	7.2	20°C/40%	-	-	-	-
Gartenacker, Silt loam	2.1	7.2	19.8°C/75% of field capacity	-	-	-	-
USA, Sandy loam a	0.9	7.1	25°C/17.7% of field capacity at 0.33 bar	-	-	-	-
USA, Sandy loam b	0.9	7.1	25°C/17.7% of field capacity at 0.33 bar	-	-	-	-
USA, Sandy loam c	0.8	7.4	25°C/17.2% of field capacity at 0.33 bar	-	-	-	-
Geometric mean (if not pH dependent)							

<sup>a)</sup> Measured in water

<sup>b)</sup> Normalised using a Q10 of 2.58

### Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

C1801	Dark anaerobic conditions. Results not reported since anaerobic DT50 should not be used for the risk assessment
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Soil type	O.C. (%)	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> /DT <sub>90</sub> (d)	f. f. k <sub>f</sub> / k <sub>dp</sub>	DT <sub>50</sub> (d) 20°C <sup>b)</sup>	St. (χ <sup>2</sup> )	Method of calculation
Gartenacker, Silt loam	2.1	7.2	19.8°C/75 % of field capacity	-	-	-	-	-
Geometric mean (if not pH dependent)								
Arithmetic mean								

<sup>a)</sup> Measured in water

<sup>b)</sup> Normalised using a Q10 of 2.58

### Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Parent Soil type	Soil photolysis					
	O.M. (%)	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d) calculated at ??°N	C.C.*	Method of calculation
San Joaquin, Clay loam a	0.8	7.3	25°C/16.91% at 1/3 bar	3.7/n.c.	0.991	Regression analysis with EPISTAT
San Joaquin, Clay loam b	0.8	7.3	25°C/16.91% at 1/3 bar	3.3/n.c.	0.999	Regression analysis with EPISTAT
San Joaquin, Clay loam c	0.8	7.3	25°C/16.91% at 1/3 bar	4.5/n.c.	0.978	Regression analysis with EPISTAT

<sup>a)</sup> Measured in unknown medium

\* Correlation coefficient

### Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

#### Oxasulfuron

Soil Type	OC %	Soil pH <sup>a)</sup>	K <sub>d</sub> (mL/g)	K <sub>doc</sub> (mL/g)	K <sub>F</sub> (mL/g)	K <sub>Foc</sub> (mL/g)	1/n	
Nassau, Silt loam	1.3	6.9	n.c.	n.c.	0.33	26	1.03	
Niagara, Clay loam	1.9	6.8	n.c.	n.c.	0.33	17	0.86	
Sequatchie, Sandy loam	0.9	7.7	n.c.	n.c.	0.16	17	1.36	
Cajon, Loamy sand	0.4	6.4	n.c.	n.c.	0.12	30	0.91	
Geometric mean (if not pH dependent)*								
Arithmetic mean (if not pH dependent)							22.5	1.04
pH dependence, Yes								

<sup>b)</sup> Measured in unknown medium

<sup>c)</sup> \* Only relevant after implementation of the published EFSA guidance.

### Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

#### saccharin (CGA 27913)

Soil Type	OC %	Soil pH <sup>a)</sup>	K <sub>d</sub> (mL/g)	K <sub>doc</sub> (mL/g)	K <sub>F</sub> (mL/g)	K <sub>Foc</sub> (mL/g)	1/n
Maryland, Clay	2.8	5.9	n.c.	n.c.	0.09	3	0.94
Maryland, Sand	0.5	6.5	n.c.	n.c.	0	0	- <sup>b)</sup>
Maryland, Sandy loam	1.1	7.5	n.c.	n.c.	0.03	3	1.05

California, Loam	0.5	6.7	n.c.	n.c.	0.03	6	0.53
Gross-Umstadt, Silt loam	1.2	7.7	-	-	-	20	0.94
Arrow, Sandy loam	2.3	5.7	-	-	-	14	0.88
Mattapex, Silt loam	2.6	6.4	-	-	-	12	0.94
Speyer 2.1, Sand	0.56	6	-	-	-	1.8	0.92
soil 115, Clay loam	1.7	7.4	-	-	-	2.2	0.71
soil 164, Silt loam	3	6.5	-	-	-	4.2	0.93
soil 243, Sandy loam	1.1	4.3	-	-	-	4	1.01
BBA 2.2, Loamy sand	2.5	6.1	-	-	-	5.2	0.95
Hofchen, Silt loam	2.7	7.8	-	-	-	4.6	0.94
Laacherhof, Silt loam	0.86	8.1	-	-	-	5.2	0.97
Ephrata, Loamy sand	0.37	6.8	-	-	-	6.7	0.95
Stilwell, Silty clay loam	1.6	6.7	-	-	-	15.5	0.92
Geometric mean (if not pH dependent)*							
Arithmetic mean (if not pH dependent)						6.7	0.91
pH dependence, No							

<sup>a)</sup> Measured in unknown medium

<sup>b)</sup> Taken into account as 1 for the arithmetic mean

\* Only relevant after implementation of the published EFSA guidance.

### C1801

Soil Type	OC %	Soil pH <sup>a)</sup>	K <sub>d</sub> (mL/g)	K <sub>doc</sub> (mL/g)	K <sub>F</sub> (mL/g)	K <sub>Foc</sub> (mL/g)	1/n
824-3, Sandy loam	1.2	7.4	n.c.	n.c.	0.6	54	0.90
824-4, Loamy sand	0.3	6.2	n.c.	n.c.	6.2	2124	0.75
824-1, Silt loam	1.2	6.7	n.c.	n.c.	2.3	213	0.79
824-2, Clay	1.7	6.5	n.c.	n.c.	2.7	170	0.75
Geometric mean (if not pH dependent)*							
Arithmetic mean (if not pH dependent)						640	0.80
pH dependence, No							

<sup>a)</sup> Measured in unknown medium

\* Only relevant after implementation of the published EFSA guidance.

### CGA 179710

Soil Type	OC %	Soil pH <sup>a)</sup>	K <sub>d</sub> (mL/g)	K <sub>doc</sub> (mL/g)	K <sub>F</sub> (mL/g)	K <sub>Foc</sub> (mL/g)	1/n
824-3, Sandy loam	1.2	7.4	n.c.	n.c.	1.5	143	0.77
824-4, Loamy sand	0.3	6.2	n.c.	n.c.	1.7	601	0.78
824-1, Silt loam	1.2	6.7	n.c.	n.c.	2.0	185	0.82
824-2, Clay	1.7	6.5	n.c.	n.c.	2.3	147	0.76
Geometric mean (if not pH dependent)*							
Arithmetic mean (if not pH dependent)						269	0.78
pH dependence, No							

<sup>a)</sup> Measured in unknown medium

\* Only relevant after implementation of the published EFSA guidance.

### M3

Data gap

### CGA 171895 (M5)

Data gap

### CGA 297691

Data gap

### MT6

Data gap

**Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)**

Column leaching

<p>Elution (mm): 300 mm Time period (d): &lt; 1 d (lowest value of 28 tests)</p>
<p>Leachate: 94.5 % total residues/radioactivity in leachate (highest value of 28 tests) 91.5 % active substance, 2.6 % C1801 0 % total residues/radioactivity retained in top 30 cm (lowest value of 28 tests)</p>

**Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)**

Lysimeter/ field leaching studies

<p>Location: North Carolina Study type (e.g. lysimeter, field): lysimeter Soil properties: texture loamy sand to sandy clay loam, pH 5.6-6.6, OC 0.1-0.8% , Field capacity = 10.37-17.81% Dates of application : June 23, 1993 Number of applications: 1 year, 1 applications per year Duration 367 days. Application rate: 117 g/ha/year Average annual rainfall (mm): 4 mm Average annual leachate volume (mm): 12.9 liters % radioactivity in leachate (maximum/year): 1.2% AR Individual annual maximum: 0.7 µg/L active substance Analyses for individual constituents in the leachates could not be performed. Amount of radioactivity in the soils at the end of the study = 8.4% AR; 0.62 % AR as parent, 7.78 % AR as C1801</p>
<p>Location: North Carolina Study type (e.g. lysimeter, field): field Soil properties: texture , pH=5-6, OC&lt;0.6% , MWHC unknown Dates of application: June 23, 1993 Crop: soybean /Interception estimated: 0% (incorporation into soil)</p>

Number of applications: 1 year, 1 application per year

Duration: 365 d

Application rate: 224 g/ha/year

Average annual rainfall (mm): 741 mm

% radioactivity in leachate (maximum/year): 0 %  
AR

Individual annual maximum concentrations of all the substances were below the limit of detection (0.1 ppb), except for a single sample that was considered as contaminated. That sample was therefore not considered as valid.

Amount of radioactivity in the soils at the end of the study was below the limit of detection

Location: Wisconsin

Study type (e.g. lysimeter, field): field

Soil properties: texture , pH=5.7-6.8, OC<0.7% ,  
MWHC unknown

Dates of application: June 22, 1994

Crop: soybean /Interception estimated: 0%  
(incorporation into soil)

Number of applications: 1 year, 1 application per year

Duration: 763 d

Application rate: 224 g/ha/year

Average annual rainfall (mm): 1002 mm

Oxasulfuron: no detections in any soil-pore water or groundwater samples through 736 DAA.

CGA 177288: no detections in any soil-pore water samples through 736 DAA. A single detection in ground water (0.17 µg/l)

C 1801: one single pore water detection (0.12 µg/l). No groundwater detections.

saccharin (CGA 27913): sporadic low level detections (up to 0.4 µg/l) in soil-pore water at all depths through 490 DAA, as well as prior to the application (0.1 - 0.3 µg/l). Occasionally present in groundwater samples (up to 3 µg/l). 8 out of 12 samples taken before treatment contained residues of up to 1.5 µg/l.

Amount of radioactivity in the soils at the end of the study was below the limit of detection

### Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1)

Hydrolytic degradation of the active substance and metabolites > 10 %

pH 5: 6.3-17.2 d at 25-20 °C (pseudo-1<sup>st</sup> order,  $r^2=0.998$ ,  $\chi^2=2.6$ )

CGA 27913: 95.3 % AR (30 d)

C1801: 95.3 % AR (30d)

CGA 297691: 93 % AR (30d)

pH 7: 8.3-22.7 d at 25-20 °C (pseudo-1<sup>st</sup> order,  $r^2=0.999$ ,  $\chi^2=2.7$ )

CGA 27913: 89.4 % AR (30 d)

C1801: 90.8 % AR (30d)

CGA 297691: 88 % AR (30d)

pH 9: 8.2-22.0 d at 25-20 °C (pseudo-1<sup>st</sup> order,  $r^2=0.997$ ,  $\chi^2=2.4$ )

CGA 27913: 87.2 % AR (30 d)

C1801: 88.2 % AR (30d)

CGA 297691: 88.6 % AR (30d)

### Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %

DT<sub>50</sub>: 3-4 d

C1801: 51 % AR (7 d)

saccharin (CGA 27913): 37 % AR (30 d)

CGA 297691: 91 % AR (30 d)

Estimated DT<sub>50</sub> at 40°N 4.7 days in mid summertime

Estimated DT<sub>50</sub> at 40°N 8.8 days in mid springtime

Estimated DT<sub>50</sub> at 50°N 11.4 days in mid summertime

Estimated DT<sub>50</sub> at 50°N 16.5 days in mid springtime

Quantum yield of direct phototransformation in water at  $\Sigma > 290$  nm

$7.57 \cdot 10^{-3}$  mol · Einstein<sup>-1</sup> at pH 4

$5.33 \cdot 10^{-2}$  mol · Einstein<sup>-1</sup> at pH 9

### 'Ready biodegradability' (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable (yes/no)

No

### Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Oxasulfuron						
System identifier (indicate fresh, estuarine or marine)	pH water phase	t °C <sup>a</sup>	DT <sub>50</sub> /DT <sub>90</sub> Water (pelagic test)		St. (χ <sup>2</sup> )	Method of calculation
			At study temp	Normalised to 20 °C <sup>b</sup>		



Fresh, first label 9.4 µg/L appl	7.9	20	24/81	24/81	7.7	SFO
Fresh, first label 93.1 µg/L appl	7.9	20	22/103	22/103	5.8	DFOP
Fresh, second label 10.3 µg/L appl	7.9	20	18/139	18/139	6.9	FOMC
Fresh, second label 105.9 µg/L appl	7.9	20	18/114	18/114	8.8	FMOC

<sup>a)</sup> Temperature of incubation

<sup>b)</sup> Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

### Mineralisation and non extractable residues (for parent dosed experiments)

System identifier (indicate fresh, estuarine or marine)	pH water phase	Mineralisation x % after 30 d (end of the study).	Non-extractable residues. max x % after n d (suspended sediment test)	Non-extractable residues. max x % after n d (end of the study) (suspended sediment test)
Fresh, first label 9.4 µg/L appl	7.9	3.2	Not reported	Not reported
Fresh, first label 93.1 µg/L appl	7.9	0.4	Not reported	Not reported
Fresh, second label 10.3 µg/L appl	7.9	0.8	Not reported	Not reported
Fresh, second label 105.9 µg/L appl	7.9	0.1	Not reported	Not reported

### Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Oxasulfuron	Distribution (total radiocarbon max in water 101.0% after 0 d. Max. sed 56.4 % after 57 d)										
	Water / sediment system	pH water phase <sup>a)</sup>	pH sed <sup>b)</sup>	t °C <sup>a)</sup>	DT <sub>50</sub> /DT <sub>90</sub> whole sys.	St. (χ <sup>2</sup> )	DT <sub>50</sub> /DT <sub>90</sub> water	St. (χ <sup>2</sup> )	DT <sub>50</sub> /DT <sub>90</sub> sed	St. (χ <sup>2</sup> )	Method of calculation
	Rhine river-a	8.3	7	19.4	20.4/83.1	3	n.c.	n.c.	n.c.	n.c.	FOMC
	Rheinfelden pond	8.6	7.3	19.3	19.5/64.8	5.6	n.c.	n.c.	n.c.	n.c.	SFO
	Rhine river-b	8.6	7.45	19.6	21.5/71.3	5.7	n.c.	n.c.	n.c.	n.c.	SFO
	Geometric mean at 20°C <sup>c)</sup>				21.9 <sup>d)</sup>						

<sup>a)</sup> During equilibration and incubation

<sup>b)</sup> Measured in KCl

<sup>c)</sup> Normalised using a Q10 of 2.58

<sup>d)</sup> For Rhine river-b a value of 25 d (DT90/3.32) has been considered for geomean calculation, since FOMC calculation has been used

<b>Metabolite C1801</b>		<b>Distribution unknown. Max in total system 66.7 % after 120 days, kinetic formation fraction (<math>k_f/k_{dp}</math>): 0.85 in pond experiment, 0.88 in river experiment from oxasulfuron. Whole system calculation.</b>								
Water / sediment system	pH water phase	pH sed <sup>a)</sup>	t. °C	DT <sub>50</sub> /DT <sub>90</sub> whole sys.	St. ( $\chi^2$ )	DT <sub>50</sub> /DT <sub>90</sub> water	St. ( $\chi^2$ )	DT <sub>50</sub> /DT <sub>90</sub> sed	St. ( $\chi^2$ )	Method of calculation
Rheinfelden pond	8.6	7.3	19.3	108/359	7.1	n.c.	n.c.	n.c.	n.c.	SFO+SFO
Rhine river-b	8.6	7.45	19.6	232/772	3.7	n.c.	n.c.	n.c.	n.c.	DFOP+SFO <sup>c)</sup>
Geometric mean at 20°C <sup>b)</sup>				158.3						

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

<sup>b)</sup> Normalised using a Q10 of 2.58

<sup>c)</sup> Excluding latest time-step

### Mineralisation and non extractable residues (from parent dosed experiments)

Water / sediment system	pH water phase <sup>a)</sup>	pH sed <sup>b)</sup>	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Rhine river-a	8.3	7	72.8% after 182 d	24.6% after 56 d	20.9% after 182 d
Rheinfelden pond	8.6	7.3	33.25% after 180 d	24.6% after 180 d	24.6% after 180 d
Rhine river-b	8.6	7.45	53.86% after 180 d	19.65% after 180 d	19.65% after 180 d

<sup>a)</sup> During equilibration and incubation

<sup>b)</sup> Measured in KCl

### Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air	Not studied - no data requested
Photochemical oxidative degradation in air	DT <sub>50</sub> of 3-15 hours derived by the Atkinson model (version unknown). OH (12 h) concentration assumed = $1.5 \cdot 10^6$ OH-radicals . cm <sup>-3</sup>
Volatilisation	from plant surfaces (BBA guideline): considered as not relevant, in agreement with the Henry's law constant of $<3.2 \cdot 10^{-5}$ Pa . m <sup>3</sup> . mole <sup>-1</sup> (20°C, calculated from vapour pressure and water solubility) from soil surfaces (BBA guideline): considered as not relevant, in agreement with the Henry's law constant of $<3.2 \cdot 10^{-5}$ Pa . m <sup>3</sup> . mole <sup>-1</sup> (20°C, calculated from vapour pressure and water solubility)
Metabolites	No metabolites expected

### Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure

Soil: Oxasulfuron, saccharin (CGA 27913), C1801, M3, M5 (CGA 171895), CGA 179710, CGA 297691, MT6  
 Surface water: Oxasulfuron, saccharin (CGA 27913), C1801, M3, M5 (CGA 171895), CGA 179710, CGA 297691, guanidine, 3-guanidine-1-butene, MT6  
 Sediment: Oxasulfuron, saccharin (CGA 27913), C1801, M3, M5 (CGA 171895), CGA 179710, CGA 297691, MT6  
 Ground water: Oxasulfuron, saccharin (CGA 27913), C1801, M3, M5 (CGA 171895), CGA 179710, CGA 297691, MT6  
 Air: Oxasulfuron

### Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

Soil: Oxasulfuron (CGA-277476)  
 Water: Oxasulfuron (CGA-277476)  
 Groundwater: Oxasulfuron (CGA-277476), M3

### Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)

Soil (indicate location and type of study)

None available from formal monitoring requests at EU or national level

Surface water (indicate location and type of study)

None available from formal monitoring requests at EU or national level

Ground water (indicate location and type of study)

None available from formal monitoring requests at EU or national level

Air (indicate location and type of study)

None available from formal monitoring requests at EU or national level

### PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Oxasulfuron  
 Method of calculation

DT<sub>50</sub> (d): 29.3 days  
 Kinetics: SFO  
 Field or Lab: representative worst case from lab studies.

Application data

Crop: soybean  
 Depth of soil layer: 5cm  
 Soil bulk density: 1.5g/cm<sup>3</sup>  
 % plant interception: 35%  
 Number of applications: 1  
 Interval (d): -  
 Application rate(s): 75 g a.s./ha

<b>PEC<sub>(s)</sub> (mg/kg)</b>	<b>Single application Actual</b>	<b>Single application Time weighted average</b>	<b>Multiple application Actual</b>	<b>Multiple application Time weighted average</b>
Initial	0.065	-	-	-
Short term 24h	0.063	0.064	-	-
2d	0.062	0.063	-	-
4d	0.059	0.062	-	-
Long term 7d	0.055	0.060	-	-
28d	0.034	0.048	-	-
50d	0.020	0.038	-	-
100d	0.006	0.025	-	-
Plateau concentration	0.000 mg/kg			

saccharin (CGA 27913)  
 Method of calculation

Molecular weight relative to the parent:  
 183.0/406.4 g/mol  
 DT<sub>50</sub> (d): 237.4 days  
 Kinetics: SFO  
 Field or Lab: representative worst case from lab  
 studies.

Application data

Application rate assumed: 33.27 g/ha (assumed  
 CGA 27913 is formed at a maximum of 98.5 % of  
 the applied dose)

<b>PEC<sub>(s)</sub> (mg/kg)</b>	<b>Single application Actual</b>	<b>Single application Time weighted average</b>	<b>Multiple application Actual</b>	<b>Multiple application Time weighted average</b>
Initial	0.029	-	-	-
Short term 24h	0.029	0.029	-	-
2d	0.029	0.029	-	-
4d	0.028	0.029	-	-
Long term 7d	0.028	0.029	-	-
28d	0.027	0.028	-	-
50d	0.025	0.027	-	-
100d	0.022	0.025	-	-
Plateau concentration	0.004 mg/kg			

C1801  
Method of calculation

Molecular weight relative to the parent:  
123.0/406.4 g/mol  
DT<sub>50</sub> (d): 468 days  
Kinetics: SFO+SFO  
Field or Lab: lab

Application data

Application rate assumed: 12.48 g/ha (assumed C1801 is formed at a maximum of 55 % of the applied dose)

PEC <sub>(s)</sub> (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.011	-	-	-
Short term 24h	0.011	0.011	-	-
2d	0.011	0.011	-	-
4d	0.011	0.011	-	-
Long term 7d	0.011	0.011	-	-
28d	0.010	0.011	-	-
50d	0.010	0.010	-	-
100d	0.010	0.010	-	-
Plateau concentration	0.004 mg/kg after 4 yr			

M3  
Method of calculation

Molecular weight relative to the parent: 436/406.4 g/mol  
DT<sub>50</sub> (d): 1000 days  
Kinetics: -  
Field or Lab: worst case assumption

Application data

Application rate assumed: 20.12 g/ha (assumed M3 is formed at a maximum of 25 % of the applied dose)

PEC <sub>(s)</sub> (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.017	-	-	-
Short term 24h	0.017	0.017	-	-
2d	0.017	0.017	-	-
4d	0.017	0.017	-	-
Long term 7d	0.017	0.017	-	-
28d	0.017	0.017	-	-
50d	0.017	0.017	-	-
100d	0.016	0.017	-	-
Plateau	0.015 mg/kg after 6 yr			

concentration

CGA 171895 (M5)  
Method of calculation

Molecular weight relative to the parent: 124/406.4 g/mol  
DT<sub>50</sub> (d): 1000 days  
Kinetics: -  
Field or Lab: worst case assumption

Application data

Application rate assumed: 2.33 g/ha (assumed M5 is formed at a maximum of 10.2 % of the applied dose)

PEC <sub>(s)</sub> (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.002	-	-	-
Short term 24h	0.002	0.002	-	-
2d	0.002	0.002	-	-
4d	0.002	0.002	-	-
Long term 7d	0.002	0.002	-	-
28d	0.002	0.002	-	-
50d	0.002	0.002	-	-
100d	0.002	0.002	-	-
Plateau concentration	0.002 mg/kg			

CGA 179710  
Method of calculation

Molecular weight relative to the parent: 166/406.4 g/mol  
DT<sub>50</sub> (d): 1000 days  
Kinetics: -  
Field or Lab: worst case assumption

Application data

Application rate assumed: 8.42 g/ha (assumed CGA 179710 is formed at a maximum of 27.5 % of the applied dose)

PEC <sub>(s)</sub> (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.007	-	-	-
Short term 24h	0.007	0.007	-	-
2d	0.007	0.007	-	-
4d	0.007	0.007	-	-
Long term 7d	0.007	0.007	-	-
28d	0.007	0.007	-	-
50d	0.007	0.007	-	-
100d	0.007	0.007	-	-
Plateau concentration	0.006 mg/kg			

CGA 297691  
Method of calculation

Molecular weight relative to the parent: 74.1/406.4 g/mol  
DT<sub>50</sub> (d): 1000 days  
Kinetics: -  
Field or Lab: worst case assumption

Application data

Application rate assumed: 2.87 g/ha (assumed CGA 297691 is formed at a maximum of 21 % of the applied dose)

PEC <sub>(s)</sub> (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.002	-	-	-
Short term 24h	0.002	0.002	-	-
2d	0.002	0.002	-	-
4d	0.002	0.002	-	-
Long term 7d	0.002	0.002	-	-
28d	0.002	0.002	-	-
50d	0.002	0.002	-	-
100d	0.002	0.002	-	-
Plateau concentration	0.002 mg/kg			

MT6

Data gap

### PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)

For FOCUS gw modelling,  
Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.  
Model(s) used: FOCUS PEARL v. 4.4.4, FOCUS PELMO v. 5.5.3  
Crop: soybeans  
Crop uptake factor: 0  
  
Oxasulfuron  
Water solubility (mg/L): 1700 at pH 7 and 25°C  
Vapour pressure: 0 Pa at 25°C  
DT<sub>50 lab</sub>: 9.4 d (geometric mean, normalisation to pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).  
K<sub>OC</sub>: 17 mL/g (worst case),  $1/n = 1.36$  (arithmetic mean).  
  
Metabolites:  
saccharin (CGA 27913)  
DT<sub>50 lab</sub>: 24.7d (geometric mean, normalisation to pF2, 20 °C with Q10 of 2.58 and Walker equation

coefficient 0.7).

$K_{OC}$ : 6.7mL/g (arithmetic mean),  $1/n = 0.91$  (arithmetic mean).

Formation fraction: 0.86 from oxasulfuron

C1801

$DT_{50}$ : 26.6 d (geometric mean).

$K_{OC}$ : 640 mL/g (arithmetic mean),  $1/n = 0.8$  (arithmetic mean).

Formation fraction: 1<sup>a)</sup> from oxasulfuron

CGA 179710

$DT_{50}$ : 1000 d (worst-case default value).

$K_{OC}$ : 269 mL/g (arithmetic mean),  $1/n = 0.78$  (arithmetic mean).

Formation fraction: 1 from oxasulfuron

CGA 297691

$DT_{50}$ : 1000 d (worst-case default value).

$K_{OC}$ : 0 mL/g (worst case default value),  $1/n = 1$ .

Formation fraction: 1 from oxasulfuron

CGA 171895 (M5)

Data gap

M3

Data gap

MT6

Data gap

For field and lysimeter studies

Location: North Carolina

Study type (e.g. lysimeter, field): lysimeter

Soil properties: pH 5.6-6.6, OC 0.1-0.8% , Field capacity = 10.37-17.81%

Dates of application : June 23, 1993

Number of applications: 1 year, 1 application per year

Duration: 367 days.

Average annual rainfall (mm): 4 mm

Average annual leachate volume (mm): 12.9 liters

Location: North Carolina

Study type (e.g. lysimeter, field): field

Soil properties: pH=5-6, OC<0.6% , MWHC unknown

Dates of application: June 23, 1993

Crop: soybean /Interception estimated: 0% (incorporation into soil)

Number of applications: 1 year, 1 application per



Application rate

year Duration: 365 d Average annual rainfall (mm): 741 mm  Location: Wisconsin Study type (e.g. lysimeter, field): field Soil properties: pH=5.7-6.8, OC<0.7% , MWHC unknown Dates of application: June 22, 1994 Crop: soybean /Interception estimated: 0% (incorporation into soil) Number of applications: 1 year, 1 application per year Duration: 763 d Average annual rainfall (mm): 1002 mm
Gross application rate: 75 g/ha. Crop growth stage: BBCH 10-14 Canopy interception %: 35 <sup>b)</sup> Application rate net of interception: 48.75 g/ha. No. of applications: 1 Time of application (absolute or relative application dates): 1, 10 and 20 days after emergence (relative applications)

<sup>a)</sup> a value of 0.57 should be used for future calculations

<sup>b)</sup> canopy interception was specified in calculations performed by the applicant, while was calculated by the model in PECgw calculations for M3 (one application every third year) and CGA 297691 performed by the RMS

### PEC(gw) - FOCUS modelling results (80<sup>th</sup> percentile annual average concentration at 1m)

PELMO 5.5.3 /Soybeans	Scenario (annual appl)	Oxasulfuro n (µg/L)	Metabolites (µg/L)	
			CGA 27913	C1801
	Piacenza, 1 day after emergence	0.007	0.449	0.000
	Piacenza, 10 days after emergence	0.005	0.472	0.000
	Piacenza, 20 days after emergence	0.006	0.471	0.000

PELMO 5.5.3 /Sovbeans	Scenario (appl every third year)	Oxasulfuro n (µg/L)	Metabolites (µg/L)	
			CGA 27913	C1801
	Piacenza, 1 day after emergence	n.c.	0.182	n.c.
	Piacenza, 10 days after emergence	n.c.	0.177	n.c.
	Piacenza, 20 days after emergence	n.c.	0.184	n.c.
PEARL 4.4.4 /Sovbeans	Scenario (annual appl)	Oxasulfuro n (µg/L)	Metabolites (µg/L)	
			CGA 27913	C1801
	Piacenza, 1 day after emergence	0.005	0.291	0.002
	Piacenza, 10 days after emergence	0.004	0.362	0.002
	Piacenza, 20 days after emergence	0.005	0.208	0.004
PEARL 4.4.4 /Sovbeans	Scenario (appl every third year)	Oxasulfuro n (µg/L)	Metabolites (µg/L)	
			CGA 27913	C1801
	Piacenza, 1 day after emergence	n.c.	0.075	n.c.
	Piacenza, 10 days after emergence	n.c.	0.099	n.c.
	Piacenza, 20 days after emergence	n.c.	0.132	n.c.
n.c. not calculated since an acceptable risk was found with annual applications				
PELMO 5.5.3 /Sovbeans	Scenario (annual appl)	Metabolites (µg/L)		
		CGA 179710	CGA 297691	
	Piacenza, 1 day after emergence	0.042	2.436	
	Piacenza, 10 days after emergence	0.038	2.437	
	Piacenza, 20 days after emergence	0.050	2.448	
PELMO 5.5.3 /Sovbeans	Scenario (appl every third year)	Metabolites (µg/L)		
		CGA 179710	CGA 297691	
	Piacenza, 1 day after emergence	n.c.	1.270	
	Piacenza, 10 days after emergence	n.c.	1.251	
	Piacenza, 20 days after emergence	n.c.	1.251	

PEARL 4.4.4 /Soybeans	Scenario (annual appl)	Metabolites (µg/L)	
		CGA 179710	CGA 297691
PEARL 4.4.4 /Soybeans	Piacenza, 1 day after emergence	0.039	2.982
	Piacenza, 10 days after emergence	0.039	2.989
	Piacenza, 20 days after emergence	0.048	3.004
PEARL 4.4.4 /Soybeans	Scenario (appl every third year)	Metabolites (µg/L)	
		CGA 179710	CGA 297691
PEARL 4.4.4 /Soybeans	Piacenza, 1 day after emergence	n.c.	1.029
	Piacenza, 10 days after emergence	n.c.	1.033
	Piacenza, 20 days after emergence	n.c.	1.039

n.c. not calculated since an acceptable risk was found with annual applications

### PEC<sub>(gw)</sub> From lysimeter / field studies

Oxasulfuron	1 <sup>st</sup> year	2 <sup>nd</sup> year	3 <sup>rd</sup> year
Annual average (µg/L)	Not detected	Not detected	Not detected

CGA 27913	1 <sup>st</sup> year	2 <sup>nd</sup> year	3 <sup>rd</sup> year
Annual average (µg/L)	< 0.1	n.p.	n.p.

n.p.: not performed, since study duration was too short

### PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Oxasulfuron

Parameters used in FOCUSsw step 1 and 2

Version control no. of FOCUS calculator: STEPS 1-2 in FOCUS v. 3.2

Molecular weight (g/mol): 406.4

K<sub>OC</sub>/K<sub>OM</sub> (mL/g): 17/9.86 (worst case to take into account the pH effects)

DT<sub>50</sub> soil (d): 9.4 (geometric mean from lab)

DT<sub>50</sub> water/sediment system (d): 21.9 (geometric mean from sediment water studies)

DT<sub>50</sub> water (d): 21.9 (whole system)

DT<sub>50</sub> sediment (d): 1000 (worst-case)

Crop interception (%): 35 % (minimal crop cover)

Parameters used in FOCUSsw step 3 and 4

Version control no.'s of FOCUS software: SPIN v. 2.2, SWASH v. 5.3, Drift calculator v. 1.1, MACRO v. 5.5.4, PRZM v. 4.3.1, TOXSWA v. 4.4.3

Water solubility (mg/L): 1700

Application rate

Vapour pressure:  $2 \times 10^{-6}$  Pa at 25°C  
 $K_{OC}/K_{OM}$  (mL/g): 17/9.86 (worst case to take into account the pH effects)  
 $1/n$ : 1.36 (worst case to take into account the pH effects)  
 $Q_{10}=2.58$ , Walker equation coefficient 0.7  
 Crop uptake factor: 0

Crop and growth stage: soybeans BBCH 10-14  
 Number of applications: 1  
 Interval (d): -  
 Application rate(s): 75 g a.s./ha  
 Application window:  
 Step 1-2: Mar-May (worst-case).  
 Step 3:

Scenario	Timing	
	Early	Late
R3	11 May-10 Jun	21 May-20 Jun
R4	11 Mar-11 Apr	21 Mar-20 Apr

FOCUS STEP 1 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	25.1356	--	4.1558	---
	24 h	24.3377	24.7367	4.1374	4.1466
	2 d	23.5795	24.3467	4.0085	4.1096
	4 d	22.1331	23.5977	3.7626	3.9969
	7 d	20.1283	22.5336	3.4218	3.8223
	14 d	16.1282	20.2940	2.7418	3.4458
	21 d	12.9231	18.3515	2.1969	3.1170
	28 d	10.3549	16.6616	1.7603	2.8304
	42 d	6.6483	13.8961	1.1302	2.3609

## Treatments during March to May

FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	6.4240	---	1.0906	---
	24 h	6.2199	6.3219	1.0574	1.0740
	2 d	6.0303	6.2235	1.0251	1.0576
	4 d	5.6683	6.0357	0.9636	1.0259
	7 d	5.1656	5.7690	0.8782	0.9806
	14 d	4.1593	5.2068	0.7071	0.8851
	21 d	3.3490	4.7178	0.5693	0.8020
	28 d	2.6966	4.2912	0.4584	0.7295

	42 d	1.7483	3.5903	0.2972	0.6103
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**Early application**

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
R3	stream	0 h	2.621	--	0.1506	--
		24 h	0.0027	1.511	0.064	0.117
		2 d	0.0005	0.758	0.046	0.090
		4 d	0.347	0.379	0.049	0.066
		7 d	0.000	0.239	0.028	0.054
		14 d	0.000	0.128	0.017	0.038
		21 d	0.000	0.085	0.011	0.030
		28 d	0.000	0.064	0.008	0.025
		42 d	0.000	0.043	0.005	0.019
R4	stream	0 h	0.272	--	0.008	--
		24 h	0.000	0.049	0.002	0.004
		2 d	0.000	0.024	0.001	0.003
		4 d	0.000	0.012	0.001	0.002
		7 d	0.000	0.007	0.001	0.002
		14 d	< 1e-6	0.003	0.000	0.001
		21 d	< 1e-6	0.002	0.000	0.001
		28 d	< 1e-6	0.002	0.000	0.001
		42 d	< 1e-6	0.001	0.000	0.000

**Late application**

FOCUS STEP 3 -Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
R3	stream	0 h	0.5222	--	0.0387	--
		24 h	0.0024	0.4397	0.0209	0.0332
		2 d	0.0002	0.2338	0.0151	0.0271
		4 d	0.0001	0.1170	0.0108	0.0205
		7 d	0.0000	0.0669	0.0081	0.0160
		14 d	0.0000	0.0372	0.0060	0.0120
		21 d	0.0022	0.0292	0.0042	0.0097
		28 d	0.0000	0.0237	0.0030	0.0082
		42 d	0.0000	0.0159	0.0019	0.0065
R4	stream	0 h	0.2715	--	0.0078	--
		24 h	0.0000	0.0489	0.0021	0.0040
		2 d	0.0000	0.0245	0.0015	0.0029
		4 d	0.0000	0.0122	0.0010	0.0021
		7 d	< 1e-6	0.0070	0.0007	0.0016
		14 d	< 1e-6	0.0035	0.0005	0.0011
		21 d	< 1e-6	0.0023	0.0003	0.0008
		28 d	< 1e-6	0.0017	0.0002	0.0007
		42 d	< 1e-6	0.0012	0.0001	0.0005

### Early application

FOCUS STEP 4 Scenario (20m vegetated filter strips)	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
R3	stream	0 h	0.6203	--	0.0346	--
		24 h	0.0006	0.356	0.0146	0.0267
		2 d	0.0001	0.1788	0.0105	0.0021
		4 d	0.0770	0.08942	0.0110	0.0151
		7 d	0.0000	0.05589	0.0063	0.0122
		14 d	0.0000	0.02892	0.0038	0.0086
		21d	0.0000	0.01928	0.0026	0.0068
		28 d	0.0000	0.01446	0.0019	0.0057
		42 d	0.0000	0.009667	0.0012	0.0043
R4	stream	0 h	0.0316	--	0.0009	--
		24 h	0.0000	0.0057	0.0002	0.0005
		2 d	< 1e-6	0.0028	0.0002	0.0003
		4 d	< 1e-6	0.0014	0.0001	0.0002
		7 d	< 1e-6	0.0008	0.0001	0.0002
		14 d	< 1e-6	0.0004	0.0000	0.0001
		21 d	< 1e-6	0.0003	0.0000	0.0001
		28 d	< 1e-6	0.0002	0.0000	0.0001
		42 d	< 1e-6	0.0001	0.0000	0.0001

### Late application

FOCUS STEP 4 Scenario (20m vegetated filter strips)	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
R3	stream	0 h	0.1249	--	0.0088	--
		24 h	0.0278	0.1061	0.0048	0.0076
		2 d	0.0001	0.0564	0.0034	0.0062
		4 d	0.0000	0.0282	0.0024	0.0047
		7 d	0.0000	0.0161	0.0018	0.0036
		14 d	0.0000	0.0090	0.0013	0.0027
		21d	0.0000	0.0062	0.0009	0.0022
		28 d	0.0000	0.0051	0.0006	0.0018
		42 d	< 1e-6	0.0034	0.0004	0.0014
R4	stream	0 h	0.0316	--	0.0009	--
		24 h	0.0000	0.0057	0.0002	0.0005
		2 d	< 1e-6	0.0028	0.0002	0.0003
		4 d	< 1e-6	0.0014	0.0001	0.0002
		7 d	< 1e-6	0.0008	0.0001	0.0002

14 d	< 1e-6	0.0004	0.0000	0.0001
21 d	< 1e-6	0.0003	0.0000	0.0001
28 d	< 1e-6	0.0002	0.0000	0.0001
42 d	< 1e-6	0.0001	0.0000	0.0001

Metabolite saccharin (CGA 27913)  
Parameters used in FOCUSsw step 1 and 2

Molecular weight: 183.0  
Soil or water metabolite: soil and water  
Koc/Kom (mL/g): 6.7/3.9  
Water solubility (mg/L): 1700  
DT<sub>50</sub> soil (d): 24.7 (geometric mean from lab)  
DT<sub>50</sub> water/sediment system (d): 1000 (worst case)  
DT<sub>50</sub> water (d): 1000 (worst case)  
DT<sub>50</sub> sediment (d): 1000 (worst case)  
Crop interception (%): 35% (minimal crop cover)  
Maximum occurrence observed (% molar basis with respect to the parent)  
Total Water and Sediment: 54%  
Soil: 98.5%

Application rate

Crop and growth stage: soybeans BBCH 10-14  
Number of applications: 1  
Interval (d): -  
Application rate(s): 75 g a.s./ha  
Application window: Mar-May and Jun-Sep.

FOCUS STEP 1 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	17.2176		1.1423	
	24 h	17.2042	17.2109	1.1527	1.1475
	2 d	17.1923	17.2046	1.1519	1.1499
	4 d	17.1685	17.1925	1.1503	1.1505
	7 d	17.1328	17.1745	1.1479	1.1499
	14 d	17.0499	17.1329	1.1423	1.1475
	21 d	16.9673	17.0915	1.1368	1.1449
	28 d	16.8852	17.0502	1.1313	1.1422
	42 d	16.7222	16.9680	1.1204	1.1367

#### Treatments during March to May

FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	4.7542	---	0.3183	---
	24 h	4.7504	4.7523	0.3181	0.3182
	2 d	4.7471	4.7505	0.3178	0.3181
	4 d	4.7406	4.7472	0.3174	0.3178

7 d	4.7307	4.7422	0.3167	0.3175
14 d	4.7078	4.7307	0.3152	0.3167
21 d	4.6850	4.7193	0.3137	0.3160
28 d	4.6623	4.7079	0.3122	0.3152
42 d	4.6173	4.6852	0.3091	0.3137

## Metabolite C1801

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 123.0  
 Soil or water metabolite: soil and water  
 Koc/Kom (mL/g): 640/371.2  
 Water solubility (mg/L): 1700  
 DT<sub>50</sub> soil (d): 26.6 days (geometric mean from lab studies)  
 DT<sub>50</sub> water/sediment system (d): 158.3 (geometric mean from sediment water studies)<sup>a)</sup>  
 DT<sub>50</sub> water (d): 158.3 (whole system)  
 DT<sub>50</sub> sediment (d): 1000 (worst case)  
 Crop interception (%): 35 (minimal crop cover)  
 Maximum occurrence observed (% molar basis with respect to the parent):  
 Total Water and Sediment: 67%  
 Soil: 55%

Parameters used in FOCUSsw step 3

Vapour pressure: 0 Pa at 20°C  
 Koc/Kom (mL/g): 640/371.2  
 1/n: 0.8  
 Q10=2.58, Walker equation coefficient 0.7  
 Crop uptake factor: 0  
 Metabolite kinetically generated in simulation (yes/no): yes  
 Formation fraction in soil ( $k_f/k_{dp}$ ): 1  
 Formation fraction in sediment water ( $k_f/k_{dp}$ ): 1

Application rate

Crop and growth stage: soybeans BBCH 10-14  
 Number of applications: 1  
 Interval (d): -  
 Application rate(s): 75 g a.s./ha  
 Application window:  
 Step 1-2: Mar-May.  
 Step 3:

Scenario	Timing	
	Early	Late
R3	11 May-10 Jun	21 May-20 Jun
R4	11 Mar-11 Apr	21 Mar-20 Apr

Main routes of entry

Runoff

<sup>a)</sup> Simulation with DT<sub>50</sub>water=1000d and DT<sub>50</sub>sed=158.3d is not reported since it gave higher PEC<sub>sed</sub>, but no risk assessment for the sediment compartment is needed for



metabolite C1801

FOCUS STEP 1 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	5.0955		31.7202	
	24 h	5.0094	5.0525	32.0604	31.8903
	2 d	4.9875	5.0255	31.9203	31.9403
	4 d	4.9441	4.9956	31.6420	31.8606
	7 d	4.8795	4.9597	31.2291	31.6783
	14 d	4.7322	4.8826	30.2864	31.2168
	21 d	4.5894	4.8085	29.3722	30.7535
	28 d	4.4509	4.7364	28.4855	30.2968
	42 d	4.1862	4.5966	26.7918	29.4079

## Treatments during March to May

FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	1.3802	---	8.7421	---
	24 h	1.3609	1.3706	8.7187	8.7304
	2 d	1.3573	1.3648	8.6953	8.7187
	4 d	1.3500	1.3592	8.6489	8.6954
	7 d	1.3392	1.3530	8.5796	8.6606
	14 d	1.3143	1.3399	8.4201	8.5801
	21 d	1.2899	1.3273	8.2636	8.5006
	28 d	1.2659	1.3149	8.1101	8.4221
	42 d	1.2193	1.2908	7.8114	8.2680

## Early application

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
R3	stream	0 h	0.1351	--	0.0609	--
		24 h	0.0003	0.0781	0.0559	0.0593
		2 d	0.0002	0.0393	0.0513	0.0571
		4 d	0.0261	0.0197	0.0527	0.0534
		7 d	0.0001	0.0130	0.0434	0.0514
		14 d	0.0000	0.0066	0.0323	0.0446
		21 d	0.0000	0.0044	0.0270	0.0397
		28 d	0.0000	0.0035	0.0345	0.0378
		42 d	0.0000	0.0025	0.0347	0.0371
R4	stream	0 h	0.0030	--	0.0086	--
		24 h	< 1e-6	0.0025	0.0084	0.0085

	2 d	< 1e-6	0.0021	0.0082	0.0084
	4 d	0.0026	0.0011	0.0078	0.0083
	7 d	0.0000	0.0008	0.0074	0.0081
	14 d	0.0000	0.0005	0.0067	0.0079
	21 d	0.0000	0.0004	0.0062	0.0076
	28 d	0.0000	0.0003	0.0059	0.0073
	42 d	< 1e-6	0.0002	0.0054	0.0068

### Late application

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>Sw</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
R3	stream	0 h	0.0563	--	0.1006	--
		24 h	0.0004	0.0475	0.0991	0.1002
		2 d	0.0001	0.0253	0.0976	0.0996
		4 d	0.0001	0.0127	0.0950	0.0983
		7 d	0.0001	0.0073	0.0920	0.0965
		14 d	0.0001	0.0055	0.0902	0.0943
		21 d	0.0127	0.0037	0.0913	0.0935
		28 d	0.0000	0.0032	0.0902	0.0930
		42 d	0.0000	0.0024	0.0853	0.0924
R4	stream	0 h	0.0071	--	0.0179	--
		24 h	0.0000	0.0057	0.0173	0.0177
		2 d	0.0000	0.0049	0.0167	0.0174
		4 d	0.0058	0.0025	0.0158	0.0171
		7 d	0.0000	0.0020	0.0170	0.0169
		14 d	0.0000	0.0013	0.0146	0.0164
		21 d	0.0000	0.0008	0.0132	0.0156
		28 d	0.0000	0.0006	0.0123	0.0149
		42 d	0.0000	0.0004	0.0112	0.0138

#### Metabolite M3

Parameters used in FOCUS<sub>sw</sub> step 1 and 2

Molecular weight: 436  
 Soil or water metabolite: soil  
 Koc/Kom (mL/g): 0/0  
 Water solubility (mg/L): 1700  
 DT<sub>50</sub> soil (d): 1000 (worst case)  
 DT<sub>50</sub> water/sediment system (d): 1000 (worst case)  
 DT<sub>50</sub> water (d): 1000 (worst case)  
 DT<sub>50</sub> sediment (d): 1000 (worst case)  
 Crop interception (%): 35 (minimal crop cover)  
 Maximum occurrence observed (% molar basis with respect to the parent):  
 Total Water and Sediment: 0.001% (default as M3 was not listed in water/sediment studies but FOCUS Steps 1-2 will not accept 0 as input)

Parameters used in FOCUSsw step 3 and 4

Soil: 25%											
Vapour pressure: 0 Pa at 20°C Kom/Koc (mL/g): 0/0 1/n: 1 Q10=2.58, Walker equation coefficient 0.7 Crop uptake factor: 0 Metabolite kinetically generated in simulation (yes/no): yes Formation fraction in soil ( $k_f/k_{dp}$ ): 1 Formation fraction in sediment water ( $k_f/k_{dp}$ ): 0											
Application rate											
Crop and growth stage: soybeans BBCH 10-14 Number of applications: 1 Interval (d): - Application rate(s): 75 g a.s./ha Application window: Step 1-2: Mar-May and Jun-Sep. Step 3-4:											
<table border="1"> <thead> <tr> <th rowspan="2">Scenario</th> <th colspan="2">Timing</th> </tr> <tr> <th>Early</th> <th>Late</th> </tr> </thead> <tbody> <tr> <td>R3</td> <td>11 May-10 Jun</td> <td>21 May-20 Jun</td> </tr> <tr> <td>R4</td> <td>11 Mar-11 Apr</td> <td>21 Mar-20 Apr</td> </tr> </tbody> </table>	Scenario	Timing		Early	Late	R3	11 May-10 Jun	21 May-20 Jun	R4	11 Mar-11 Apr	21 Mar-20 Apr
Scenario		Timing									
	Early	Late									
R3	11 May-10 Jun	21 May-20 Jun									
R4	11 Mar-11 Apr	21 Mar-20 Apr									
Main routes of entry											
Runoff											

FOCUS STEP 1 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	6.7055	--	0.0000	--
	24 h	6.7008	6.7032	0.0000	0.0000
	2 d	6.6962	6.7008	0.0000	0.0000
	4 d	6.6869	6.6962	0.0000	0.0000
	7 d	6.6730	6.6893	0.0000	0.0000
	14 d	6.6407	6.6731	0.0000	0.0000
	21 d	6.6086	6.6569	0.0000	0.0000
	28 d	6.5766	6.6408	0.0000	0.0000
	42 d	6.5131	6.6088	0.0000	0.0000

## Treatments during March to May

FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	2.1398	--	0.0000	--
	24 h	2.1383	2.1391	0.0000	0.0000
	2 d	2.1368	2.1383	0.0000	0.0000
	4 d	2.1339	2.1368	0.0000	0.0000

7 d	2.1294	2.1346	0.0000	0.0000
14 d	2.1191	2.1295	0.0000	0.0000
21 d	2.1089	2.1243	0.0000	0.0000
28 d	2.0987	2.1192	0.0000	0.0000
42 d	2.0784	2.1090	0.0000	0.0000

**Early application**

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
R3	stream	0 h	0.5241	--	0.02806	--
		24 h	0.0005	0.3024	0.0119	0.0218
		2 d	0.0001	0.1518	0.0086	0.0167
		4 d	0.1199	0.0759	0.0116	0.0123
		7 d	0.0000	0.0511	0.0057	0.0104
		14 d	0.0000	0.0255	0.0034	0.0075
		21d	0.0000	0.0170	0.0023	0.0059
		28 d	0.0000	0.0129	0.0017	0.0050
		42 d	0.0000	0.0086	0.0010	0.0038
R4	stream	0 h	0.000198	--	0.0000	--
		24 h	< 1e-6	0.000116	0.0000	0.0000
		2 d	< 1e-6	0.0001	0.0000	0.0000
		4 d	< 1e-6	0.0000	0.0000	0.0000
		7 d	< 1e-6	0.0000	0.0000	0.0000
		14 d	< 1e-6	0.0000	0.0000	0.0000
		21 d	< 1e-6	0.0000	< 1e-6	0.0000
		28 d	< 1e-6	0.0000	< 1e-6	0.0000
		42 d	< 1e-6	0.0000	< 1e-6	0.0000

**Late application**

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
R3	stream	0 h	0.5408	--	0.0368	--
		24 h	0.002508	0.4558	0.0196	0.0315
		2 d	0.000185	0.2425	0.0138	0.0256
		4 d	0.000062	0.1213	0.0098	0.0207
		7 d	0.000026	0.0694	0.0072	0.0148
		14 d	0.000016	0.0400	0.0057	0.0112
		21d	0.002374	0.0267	0.0039	0.0091
		28 d	0.000004	0.0201	0.0027	0.0076
		42 d	0.000002	0.0134	0.0016	0.0058
R4	stream	0 h	0.0081	--	0.0005	--
		24 h	0.0000	0.0047	0.0002	0.0003

	2 d	< 1e-6	0.0024	0.0001	0.0003
	4 d	0.0000	0.0013	0.0001	0.0002
	7 d	< 1e-6	0.0007	0.0001	0.0001
	14 d	< 1e-6	0.0004	0.0000	0.0001
	21 d	< 1e-6	0.0002	0.0000	0.0001
	28 d	< 1e-6	0.0002	0.0000	0.0001
	42 d	< 1e-6	0.0001	0.0000	0.0000

### Early application

FOCUS STEP 4 Scenario (20m vegetated filter strips)	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
R3	stream	0 h	0.1241	--	0.0066	--
		24 h	0.000128	0.0713	0.0028	0.0051
		2 d	0.000021	0.0358	0.0020	0.0039
		4 d	0.02665	0.0179	0.0026	0.0029
		7 d	0.000005	0.0119	0.0013	0.0024
		14 d	0.000002	0.0059	0.0008	0.0017
		21 d	< 1e-6	0.0040	0.0005	0.0014
		28 d	< 1e-6	0.0030	0.0004	0.0012
		42 d	< 1e-6	0.0020	0.0002	0.0009
R4	stream	0 h	0.00005	--	0.000003	--
		24 h	< 1e-6	0.00003	0.000001	0.000002
		2 d	< 1e-6	0.00001	< 1e-6	0.000001
		4 d	< 1e-6	0.00001	< 1e-6	0.000001
		7 d	< 1e-6	0.00000	< 1e-6	< 1e-6
		14 d	< 1e-6	0.00000	< 1e-6	< 1e-6
		21 d	< 1e-6	0.00000	< 1e-6	< 1e-6
		28 d	< 1e-6	0.00000	< 1e-6	< 1e-6
		42 d	< 1e-6	< 1e-6	< 1e-6	< 1e-6

### Late application

FOCUS STEP 4 Scenario (20m vegetated filter strips)	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
R3	stream	0 h	0.1294	--	0.0088	--
		24 h	0.0291	0.1100	0.0047	0.0076
		2 d	0.0001	0.0586	0.0033	0.0062
		4 d	0.0000	0.0293	0.0024	0.0046
		7 d	0.0000	0.0167	0.0017	0.0036

		14 d	0.0000	0.0096	0.0014	0.0027
		21d	0.0006	0.0064	0.0009	0.0022
		28 d	0.0000	0.0048	0.0006	0.0018
		42 d	< 1e-6	0.0032	0.0004	0.0014
R4	stream	0 h	0.001893	--	0.000113	--
		24 h	< 1e-6	0.0011	0.000043	0.00008
		2 d	< 1e-6	0.0005	0.000031	0.00006
		4 d	0.000004	0.0003	0.000025	0.00005
		7 d	< 1e-6	0.0002	0.000018	0.00004
		14 d	< 1e-6	0.0001	0.000011	0.00002
		21 d	< 1e-6	0.0001	0.000007	0.00002
		28 d	< 1e-6	0.0000	0.000005	0.00002
		42 d	< 1e-6	0.0000	0.000003	0.00001

Metabolite CGA 297691

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 74.08  
 Soil or water metabolite: water  
 Koc/Kom (mL/g): 0/0  
 Water solubility (mg/L): 1700  
 DT<sub>50</sub> soil (d): 1000 (worst case)  
 DT<sub>50</sub> water/sediment system (d): 1000 (worst case)  
 DT<sub>50</sub> water (d): 1000 (worst case)  
 DT<sub>50</sub> sediment (d): 1000 (worst case)  
 Crop interception (%): 35 (minimal crop cover)  
 Maximum occurrence observed (% molar basis with respect to the parent):  
 Total Water and Sediment: 93%  
 Soil: 21%

Application rate

Crop and growth stage: soybeans BBCH 10-14  
 Number of applications: 1  
 Interval (d): -  
 Application rate(s): 75 g a.s./ha  
 Application window: Mar-May and Jun-Sep.

FOCUS STEP 1 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	5.3134		0.0000	
	24 h	5.3098	5.3116	0.0000	0.0000
	2 d	5.3061	5.3098	0.0000	0.0000
	4 d	5.2987	5.3061	0.0000	0.0000
	7 d	5.2877	5.3006	0.0000	0.0000
	14 d	5.2621	5.2877	0.0000	0.0000
	21 d	5.2367	5.2750	0.0000	0.0000
	28 d	5.2113	5.2622	0.0000	0.0000
	42 d	5.1610	5.2368	0.0000	0.0000

## Treatments during March to May

FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	1.4321	---	0.0000	---
	24 h	1.4312	1.4317	0.0000	0.0000
	2 d	1.4302	1.4312	0.0000	0.0000
	4 d	1.4282	1.4302	0.0000	0.0000
	7 d	1.4252	1.4287	0.0000	0.0000
	14 d	1.4183	1.4252	0.0000	0.0000
	21 d	1.4115	1.4218	0.0000	0.0000
	28 d	1.4046	1.4183	0.0000	0.0000
	42 d	1.3911	1.4115	0.0000	0.0000

Metabolite CGA 171895 (M5)

Data gap

Metabolite CGA 179710

Parameters used in FOCUS<sub>sw</sub> step 1 and 2

Molecular weight: 166.2  
 Soil or water metabolite: soil  
 Koc/Kom (mL/g): 269/156  
 Water solubility (mg/L): 1700  
 DT<sub>50</sub> soil (d): 1000 (worst case)  
 DT<sub>50</sub> water/sediment system (d): 1000 (worst case)  
 DT<sub>50</sub> water (d): 1000 (worst case)  
 DT<sub>50</sub> sediment (d): 1000 (worst case)  
 Crop interception (%): 3 (minimal crop cover)  
 Maximum occurrence observed (% molar basis with respect to the parent):  
 Total Water and Sediment: 2.4%  
 Soil: 27.5%

Application rate

Crop and growth stage: soybeans BBCH 10-14  
 Number of applications: 1  
 Interval (d): -  
 Application rate(s): 75 g a.s./ha  
 Application window: Mar-May.

FOCUS STEP 1 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	2.2567		6.0524	
	24 h	2.2534	2.2551	6.0616	6.0570
	2 d	2.2518	2.2538	6.0574	6.0583
	4 d	2.2487	2.2520	6.0490	6.0557
	7 d	2.2440	2.2496	6.0364	6.0502
	14 d	2.2332	2.2441	6.0072	6.0360
	21 d	2.2224	2.2387	5.9782	6.0216

28 d	2.2116	2.2332	5.9492	6.0071
42 d	2.1902	2.2225	5.8918	5.9782

### Treatments during March to May

FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	0.7088	---	1.9042	---
	24 h	0.7079	0.7084	1.9029	1.9035
	2 d	0.7074	0.7080	1.9015	1.9029
	4 d	0.7064	0.7074	1.8989	1.9015
	7 d	0.7049	0.7067	1.8950	1.8996
	14 d	0.7015	0.7050	1.8858	1.8950
	21 d	0.6981	0.7032	1.8767	1.8904
	28 d	0.6947	0.7015	1.8676	1.8858
	42 d	0.6880	0.6982	1.8495	1.8767

### Early application

FOCUS STEP 3	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
R3	stream	0 h	0.0541	--	0.0518	--
		24 h	0.0001	0.0391	0.0480	0.0508
		2 d	0.0001	0.0208	0.0480	0.0497
		4 d	0.0378	0.0105	0.0424	0.0480
		7 d	0.0001	0.0069	0.0375	0.0449
		14 d	0.0000	0.0058	0.0456	0.0438
		21 d	0.0000	0.0039	0.0373	0.0432
		28 d	0.0001	0.0038	0.0391	0.0430
		42 d	0.0000	0.0033	0.0411	0.0427
R4	stream	0 h	0.0149	--	0.0172	--
		24 h	0.0000	0.0094	0.0153	0.0166
		2 d	0.0000	0.0087	0.0139	0.0159
		4 d	0.0097	0.0044	0.0118	0.0146
		7 d	0.0000	0.0037	0.0129	0.0140
		14 d	0.0000	0.0023	0.0095	0.0127
		21 d	0.0000	0.0015	0.0080	0.0115
		28 d	0.0000	0.0011	0.0072	0.0106
		42 d	0.0000	0.0008	0.0061	0.0093



## Late application

FOCUS STEP 3	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
R3	stream	0 h	0.1507	..	0.1555	--
		24 h	0.0014	0.1267	0.1411	0.1518
		2 d	0.0006	0.0675	0.1402	0.1474
		4 d	0.0003	0.0340	0.1224	0.1412
		7 d	0.0001	0.0195	0.1083	0.1312
		14 d	0.0003	0.0190	0.1342	0.1279
		21d	0.0882	0.0127	0.1105	0.1266
		28 d	0.0001	0.0124	0.1152	0.1265
		42 d	0.0002	0.0106	0.1195	0.149
R4	stream	0 h	0.03477	--	0.0366	--
		24 h	0.0000	0.0203	0.0321	0.0351
		2 d	0.0000	0.0192	0.0286	0.0335
		4 d	0.0208	0.0098	0.0241	0.0307
		7 d	0.0000	0.0085	0.0261	0.0291
		14 d	0.0000	0.0051	0.0191	0.0261
		21 d	0.0000	0.0034	0.0163	0.0235
		28 d	0.0000	0.0025	0.0146	0.0216
		42 d	0.0000	0.0017	0.0126	0.0190

Metabolite MT6

Data gap

Metabolites guanidine and 3-guanidine-1-butene

PEC<sub>SW</sub> and PEC<sub>SED</sub> calculation assumptions

PEC<sub>sw</sub> were calculated for water phase metabolites guanidine and 3-guanidine-1-butene based on their maximum observed formation in water, the maximum Step 2 PEC<sub>sw</sub> and PEC<sub>SED</sub> for oxasulfuron (6.4 µg/L and 1.1 µg/kg) and assuming the same molecular weight as oxasulfuron in the absence of specific data for 3-guanidine-1-butene.

Results

	Max occ %	Molecular weight	PEC <sub>sw</sub> µg/L	PEC <sub>sed</sub> µg/kg
Oxasulfuron	-	406.4	6.4	1.1
guanidine	33	59.07	0.31	0.05
3-guanidine-1-butene	24	406.4	1.54	0.26

### Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation

PEC calculation from other routes of exposure is not necessary

#### PEC

Maximum concentration

PEC calculation from other routes of exposure is not necessary

## Ecotoxicology

### Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
Bobwhite quail	a.s.	Acute	LD <sub>50</sub>	>2250
Mallard duck	a.s.	Acute	LD <sub>50</sub>	>2250
Bobwhite quail	a.s.	Short-term	LD <sub>50</sub>	>1613
Mallard duck	a.s.	Short-term	LD <sub>50</sub>	>1831
Bobwhite quail	a.s.	Long-term	NOEL	6.91
Mallard duck	a.s.	Long-term	NOEL	12.67
Mammals				
Rat	a.s.	Acute	LD <sub>50</sub>	>5000
Rat	a.s.	Long-term	NOAEL	8.3
Endocrine disrupting properties (Annex Part A, points 8.1.5)				
No indication for potential endocrine disrupting properties from the data available in the section of ecotoxicology				
Additional higher tier studies (Annex Part A, points 10.1.1.2):				
No higher tier studies submitted				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):				
No available data				

### Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

**Soybean (BBCH 10-14): 0.1 kg formulated product/ha corresponding to 75 g oxasulfuron/ha**

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
BBCH 10-14	Small omnivorous bird	Acute	11.91	>189	10
BBCH 10-14	Small omnivorous bird	Long-term	2.58	<b>2.68</b>	5
Tier 1 (Birds)					
BBCH 10-14	Small granivorous bird (finch)	Long-term	0.453	15.25	5
BBCH 10-14	Small omnivorous bird (lark)	Long-term	0.433	15.96	5
BBCH 10-14	Medium herbivorous/granivorous bird (pigeon)	Long-term	0.902	7.66	5
BBCH 10-14	Small insectivorous bird (wagtail)	Long-term	0.449	15.40	5
Screening Step (Mammals)					
BBCH 10-	Small herbivorous mammal	Acute	10.23	>489	10

14					
BBCH 10-14	Small herbivorous mammal	Long-term	2.87	<b>2.9</b>	5
Tier 1 (Mammals)					
BBCH 10-14	Large herbivorous mammal "lagomorph"	Long-term	0.57	14.6	5
BBCH 10-14	Small omnivore mammal "mouse"	Long-term	0.31	26.8	5
BBCH 10-14	Small insectivore mammal "shrew"	Long-term	0.17	49.7	5

**Risk from bioaccumulation and food chain behaviour** – not necessary ( $\log K_{ow} < 3$  for active substance and metabolites)

**Risk from consumption of contaminated water**

**Puddle scenario, Screening step**

Application rate (g a.s./ha)/relevant endpoint  $\leq 50$  (koc < 500 L/kg), TER calculation not needed

**Bold values** do not meet the trigger

### Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)\*

\* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

<sup>1</sup> (<sub>(nom)</sub> nominal concentration; (<sub>(im)</sub> initial measured concentration; (<sub>(mm)</sub> mean measured concentration; prep.: preparation; a.s.: active substance

Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup>
Laboratory tests				
Fish				
<i>Lepomis macrochirus</i>	a.s.	96 hr (flow-through)	Mortality, LC <sub>50</sub>	<b>&gt; 111 (mm)</b>
<i>Oncorhynchus mykiss</i>	a.s.	96 hr (flow-through)	Mortality, LC <sub>50</sub>	> 116 (mm)
<i>Cyprinodon variegatus</i>	a.s.	96 hr (flow-through)	Mortality, LC <sub>50</sub>	> 113 (mm)
<i>Pimephales promelas</i>	a.s.	35 d (flow-through)	Survival and Growth NOEC	<b>114 (mm)</b>
<i>Oncorhynchus mykiss</i>	CGA 297691 (CA2013A)	96 hr (flow-through)	Mortality, LC <sub>50</sub>	<b>&gt; 100 (nom)</b>
<i>Oncorhynchus mykiss</i>	C1801 (CA2006A)	96 hr (static)	Mortality, $\epsilon$ LC <sub>50</sub>	<b>&gt; 100 (nom)</b>
Aquatic invertebrates				
<i>Daphnia magna</i>	a.s.	48 h (flow-through)	Immobility, EC <sub>50</sub>	>89.4 (mm)
<i>Crassostrea virginica</i>	a.s.	96 h (flow-through)	Shell deposition, EC <sub>50</sub>	>132 (mm)
<i>Mysidopsis bahia</i>	a.s.	48 h (flow-through) 96 h (flow-through)	Mortality, LC <sub>50</sub> Mortality, LC <sub>50</sub>	<b>&gt;109 (mm)</b> <b>82.6 (mm)</b>
<i>Daphnia magna</i>	a.s.*	48 h (flow-through)	Immobility, EC <sub>50</sub>	>136 (mm)
<i>Daphnia magna</i>	a.s.	21 d (flow-through)	Reproduction, NOEC Reproduction, EC <sub>10</sub>	<b>14 (mm)</b> 14.3 (mm) 28.85 (mm)

Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup>
			Reproduction, EC <sub>20</sub>	
<i>Daphnia magna</i>	CGA 297691 (CA2013A)	48 h (static)	Immobility, EC <sub>50</sub>	<b>&gt;100 (nom)</b>
<i>Daphnia magna</i>	C1801 (CA2006A)	48 h (static)	Immobility, EC <sub>50</sub>	<b>&gt;100 (nom)</b>
Algae^^				
<i>Navicula pelliculosa</i>	a.s.	72 h (static)	72h E <sub>v</sub> C <sub>50</sub> 72h E <sub>r</sub> C <sub>50</sub>	>100 (nom) >100 (nom)
<i>Pseudokirchneriella subcapitata</i>	a.s.	72 h (static)	72h E <sub>v</sub> C <sub>50</sub> 72h E <sub>r</sub> C <sub>50</sub>	0.256 (mm) <b>1.30 (mm)</b>
<i>Pseudokirchneriella subcapitata</i>	Laguna 75 WG	72 h (static)	E <sub>r</sub> C <sub>50</sub> 72 h E <sub>v</sub> C <sub>50</sub>	2.25 (a.s., mm) 0.225 (a.s., mm)
<i>Pseudokirchneriella subcapitata</i>	CGA 297691 (CA2013A)*	120h (static)	72h E <sub>b</sub> C <sub>50</sub> 120h E <sub>b</sub> C <sub>50</sub> 72h E <sub>r</sub> C <sub>50</sub> 120h E <sub>r</sub> C <sub>50</sub>	<b>&gt;0.097 (mm)</b> <b>&gt;0.097 (mm)</b> <b>&gt;0.097 (mm)</b> <b>&gt;0.097 (mm)</b>
<i>Selenastrum capricornutum</i>	CGA 297691 (CA2013A)	72 h (static)	72h E <sub>b</sub> C <sub>50</sub> 72h E <sub>r</sub> C <sub>50</sub>	>96.8 (mm) >96.8 (mm)
Higher plant				
<i>Lemna gibba</i>	a.s.*	14 d (static)	7d , frond count E <sub>b</sub> C <sub>50</sub> 7d , frond count E <sub>r</sub> C <sub>50</sub> 14d, frond count NOEC	0.0015 (mm) <b>0.00324 (mm)</b> <b>0.00020 (mm)</b>
<i>Lemna gibba</i>	Laguna 75 WG	7 d (semi-static)	Biomass: E <sub>v</sub> C <sub>50</sub> Growth rate: E <sub>r</sub> C <sub>50</sub>	2.23 (mm) 5.59 (mm)
<i>Lemna gibba</i>	CGA 297691 (CA2013A)*	14 d (static)	Frond count, dry weight, EC <sub>50</sub>	<b>&gt;0.08 (mm)</b>

Further testing on aquatic organisms

No further tests submitted

Potential endocrine disrupting properties (Annex Part A, point 8.2.3)

No indication for potential endocrine disrupting properties from the data available in the section of ecotoxicology

<sup>1</sup> (nom) nominal concentration; (mm) mean measured concentration; (im) initial measured concentration; prep.: preparation; a.s.: active substance

\* radiolabelled active substance.

Endpoint marked in bold used in the risk assessment

### Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Active substance	C1801 (CA2006A)	CGA 297691 (CA2013A)	CGA 171895	CGA 179710	CGA 297691
logP <sub>O/W</sub>	-0.81	0.97*	0.45*	1.30*	0.835*	-1.09*
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	Not required	Not required	Not required	Not required	Not required	Not required
Uptake/depuration kinetics BCF	Not performed	Not performed	Not performed	Not performed	Not performed	Not performed

(total wet weight/normalised to 5% lipid content)						
Annex VI Trigger for the bioconcentration factor						
Clearance time (days) (CT <sub>50</sub> )	Not performed	Not performed	Not performed	Not performed	Not performed	Not performed
(CT <sub>90</sub> )	Not performed	Not performed	Not performed	Not performed	Not performed	Not performed
Level and nature of residues (%) in organisms after the 14 day depuration phase						
Higher tier study						
No higher tier studies submitted						

\*Values estimated by the WSKOWWIN V1.67 program contained in the US EPA's EPISUITE package of predictive models

**Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)**
**Maximum PEC<sub>sw</sub> values and TER values for oxasulfuron for FOCUS Step 1 Scenario – application to Soybean (BBCH 10-14):  
0.1 Ł kg formulated product/ha corresponding to 75 g oxasulfuron/ha**

Scenario	PEC Step 1 (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Aquatic plants
		<i>L. macrochirus</i>	<i>P. promelas</i>	<i>Mysidopsis bahia</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>L. gibba</i>
		LC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	E <sub>r</sub> C <sub>50</sub>	E <sub>r</sub> C <sub>50</sub>
		>111000 µg/L	114000 µg/L	82600 µg/L	14000 µg/L	1300µg/L	3.24µg/L
<b>oxasulfuron</b>	25.1	>4422	4542	3290	558	51.8	<b>0.13</b>
		<i>O. mykiss</i>	<i>n.a.</i>	<i>D. magna</i>	<i>n.a.</i>	<i>P. subcapitata</i>	<i>L. gibba</i>
		LC <sub>50</sub>		EC <sub>50</sub>		E <sub>r</sub> C <sub>50</sub>	E <sub>r</sub> C <sub>50</sub>
		>100000 µg/L		>100000 µg/L		1300 <sup>b</sup> µg/L	3.24 <sup>b</sup> µg/L
<b>C1801 (CA2006A)</b>	5.12	>19607		>19607		254	<b>0.63</b>
		<i>O. mykiss</i>	<i>n.a.</i>	<i>D. magna</i>	<i>n.a.</i>	<i>P. subcapitata</i>	<i>L. gibba</i>
		LC <sub>50</sub>		EC <sub>50</sub>		E <sub>r</sub> C <sub>50</sub>	EC <sub>50</sub>
		>100000 µg/L		>100000 µg/L		>97 µg/L	>80 µg/L
<b>CGA 297691 (CA2013A)</b>	5.31	>18832		>18832		>18.27	>15.1
		<i>P. promelas</i>	<i>n.a.</i>	<i>D. magna</i>	<i>n.a.</i>	<i>P. subcapitata</i>	<i>L. gibba</i>
		LC <sub>50</sub>		EC <sub>50</sub>		E <sub>r</sub> C <sub>50</sub>	E <sub>r</sub> C <sub>50</sub>
		17300 µg/L		86200 <sup>b</sup> µg/L		1300 <sup>b</sup> µg/L	3.24 <sup>b</sup> µg/L
<b>CGA 27913</b>	17.22	1004		5000		75	<b>0.19</b>
		<i>L. macrochirus</i>	<i>n.a.</i>	<i>Mysidopsis bahia</i>	<i>n.a.</i>	<i>P. subcapitata</i>	<i>L. gibba</i>
		LC <sub>50</sub>		EC <sub>50</sub>		E <sub>r</sub> C <sub>50</sub>	E <sub>r</sub> C <sub>50</sub>
		>111000 <sup>b</sup> µg/L		82600 <sup>b</sup> µg/L		1300 <sup>b</sup> µg/L	3.24 <sup>b</sup> µg/L
<b>CGA 179710</b>	2.26	>49115		36415		575	<b>1.43</b>
		<i>L. macrochirus</i>	<i>n.a.</i>	<i>Mysidopsis bahia</i>	<i>n.a.</i>	<i>P. subcapitata</i>	<i>L. gibba</i>
		LC <sub>50</sub>		EC <sub>50</sub>		E <sub>r</sub> C <sub>50</sub>	E <sub>r</sub> C <sub>50</sub>
		>11100 <sup>a</sup> µg/L		8260 <sup>a</sup> µg/L		130 <sup>a</sup> µg/L	0.324 <sup>a</sup> µg/L
<b>M3</b>	6.71	>1654		1230		19.37	<b>0.05</b>
Annex VI Trigger		100	10	100	10	10	10

<sup>a</sup> Surrogate value, conservatively assuming acute toxicity to be  $\times 10$  higher than that of the parent active substance.

<sup>b</sup> Surrogate value, conservatively assuming toxicity to be equal to that of the parent active substance.

**Bold values** do not meet the trigger

### Maximum PEC<sub>sw</sub> values and TER values for oxasulfuron for FOCUS Step 2 Scenario – application to Soybean (BBCH 10-14): 0.1 kg formulated producta corresponding to 75 g oxasulfuron/ha

Scenario	PEC Step 2 (SEU) (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Aquatic plants
		<i>L. macrochirus</i>	<i>P. promelas</i>	<i>Mysidopsis bahia</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>L. gibba</i>
		LC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	E <sub>r</sub> C <sub>50</sub>	E <sub>r</sub> C <sub>50</sub>
		>111000 µg/L	114000 µg/L	82600 µg/L	14000 µg/L	1300µg/L	3.24µg/L
<b>oxasulfuron</b>	<b>6.42</b>	>17290	17757	12866	2181	202	<b>0.50</b>
		<i>O. mykiss</i>	<i>n.a.</i>	<i>D. magna</i>	<i>n.a.</i>	<i>P. subcapitata</i>	<i>L. gibba</i>
		LC <sub>50</sub>		EC <sub>50</sub>		E <sub>r</sub> C <sub>50</sub>	E <sub>r</sub> C <sub>50</sub>
		>100000 µg/L		>100000 µg/L		1300 <sup>b</sup> µg/L	3.24 <sup>b</sup> µg/L
<b>C1801 (CA2006A)</b>	<b>1.38</b>	>72464		>72464		942	<b>2.35</b>
		<i>O. mykiss</i>	<i>n.a.</i>	<i>D. magna</i>	<i>n.a.</i>	<i>P. subcapitata</i>	<i>L. gibba</i>
		LC <sub>50</sub>		EC <sub>50</sub>		E <sub>r</sub> C <sub>50</sub>	EC <sub>50</sub>
		>100000 µg/L		>100000 µg/L		>97 µg/L	>80 µg/L
<b>CGA 297691 (CA2013A)</b>	<b>1.43</b>	>69930		>69930		>68	>56
		<i>P. promelas</i>	<i>n.a.</i>	<i>D. magna</i>	<i>n.a.</i>	<i>P. subcapitata</i>	<i>L. gibba</i>
		LC <sub>50</sub>		EC <sub>50</sub>		E <sub>r</sub> C <sub>50</sub>	E <sub>r</sub> C <sub>50</sub>
		17300 µg/L		86200 <sup>b</sup> µg/L		1300 <sup>b</sup> µg/L	3.24 <sup>b</sup> µg/L
<b>CGA 27913 (saccharin)</b>	<b>4.75</b>	3642		18147		273	<b>0.68</b>
		<i>L. macrochirus</i>	<i>n.a.</i>	<i>Mysidopsis bahia</i>	<i>n.a.</i>	<i>P. subcapitata</i>	<i>L. gibba</i>
		LC <sub>50</sub>		EC <sub>50</sub>		E <sub>r</sub> C <sub>50</sub>	E <sub>r</sub> C <sub>50</sub>
		>111000 <sup>b</sup> µg/L		82600 <sup>b</sup> µg/L		1300 <sup>b</sup> µg/L	3.24 <sup>b</sup> µg/L
<b>CGA 179710</b>	<b>0.71</b>	>156338		116338		1831	<b>4.56</b>
		<i>L. macrochirus</i>	<i>n.a.</i>	<i>Mysidopsis bahia</i>	<i>n.a.</i>	<i>P. subcapitata</i>	<i>L. gibba</i>
		LC <sub>50</sub>		EC <sub>50</sub>		E <sub>r</sub> C <sub>50</sub>	E <sub>r</sub> C <sub>50</sub>
		>11100 <sup>a</sup> µg/L		8260 <sup>a</sup> µg/L		130 <sup>a</sup> µg/L	0.324 <sup>a</sup> µg/L



<b>M3</b>	2.14	>5187		3859		61	<b>0.15</b>
<b>Annex VI Trigger</b>		<b>100</b>	<b>10</b>	<b>100</b>	<b>10</b>	<b>10</b>	<b>10</b>

<sup>a</sup> Surrogate value, conservatively assuming acute toxicity to be ×10 higher than that of the parent active substance.

<sup>b</sup> Surrogate value, conservatively assuming toxicity to be equal to that of the parent active substance.

### TER calculation for FOCUS Step 3-4 (20m VFS) Scenario for oxasulfuron– application to Soybean (BBCH 10-14): 0.1 Ł kg formulated product/ha corresponding to 75 g oxasulfuron/ha (worst case between early and late application)

Scenario	PEC (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Aquatic plants
		<i>L. macrochirus</i>	<i>P. promelas</i>	<i>Mysidopsis bahia</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>L. gibba</i>
		LC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	E <sub>r</sub> C <sub>50</sub>	E <sub>r</sub> C <sub>50</sub>
		>111000 µg/L	114000 µg/L	82600 µg/L	14000 µg/L	1300µg/L	3.24µg/L
<b>Step 3</b>							
R3	2.621	42350	43495	31515	5341	496	<b>1.24</b>
R4	0.272	408088	419118	303676	51471	4779	11.91
<b>Step 4 (20m VFS)</b>							
R3	0.620	179032	183871	133226	22581	2097	<b>5.23</b>
R4	0.033	3468750	3562500	2581250	437500	40625	101

**Bold values** do not meet the trigger

### TER calculation for FOCUS Step 3 Scenario for C1801 (CA2006A)– application to Soybean (BBCH 10-14): 0.1 Ł kg formulated product/ha corresponding to 75 g oxasulfuron/ha (worst case between early and late application)

Scenario	PEC (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Aquatic plants
		<i>O. mykiss</i>	<i>n.a.</i>	<i>D. magna</i>	<i>n.a.</i>	<i>P. subcapitata</i>	<i>L. gibba</i>
		LC <sub>50</sub>		EC <sub>50</sub>		E <sub>r</sub> C <sub>50</sub>	E <sub>r</sub> C <sub>50</sub>
		>100000 µg/L		>100000 µg/L		1300 <sup>b</sup> µg/L	3.24 <sup>b</sup> µg/L
<b>Step 3</b>							
R3	0.135	740741		740741		9630	24
R4	0.007	14285714		14285714		185714	463

<sup>b</sup> Surrogate value, conservatively assuming toxicity to be equal to that of the parent active substance.

**TER calculation for FOCUS Step 3 Scenario for CGA 179710 – application to Soybean (BBCH 10-14): 0.1 L kg formulated product./ha corresponding to 75 g oxasulfuron/ha (worst case between early and late application)**

Scenario	PEC (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Aquatic plants
		<i>L. macrochirus</i>	<i>n.a.</i>	<i>Mysidopsis bahia</i>	<i>n.a.</i>	<i>P. subcapitata</i>	<i>L. gibba</i>
		LC <sub>50</sub>		EC <sub>50</sub>		E <sub>r</sub> C <sub>50</sub>	E <sub>r</sub> C <sub>50</sub>
		>111000 <sup>b</sup> µg/L		82600 <sup>b</sup> µg/L		1300 <sup>b</sup> µg/L	3.24 <sup>b</sup> µg/L
<b>Step 3</b>							
R3	0.151	735099		547020		8609	21
R4	0.035	3171429		2360000		37143	93

<sup>b</sup> Surrogate value, conservatively assuming toxicity to be equal to that of the parent active substance.

**TER calculation for FOCUS Step 3-4 (20m VFS) Scenario for M3– application to Soybean (BBCH 10-14): 0.1 kg formulated product/ha corresponding to 75 g oxasulfuron/ha (worst case between early and late application)**

Scenario	PEC (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Aquatic plants
		<i>L. macrochirus</i>	<i>n.a.</i>	<i>Mysidopsis bahia</i>	<i>n.a.</i>	<i>P. subcapitata</i>	<i>L. gibba</i>
		LC <sub>50</sub>		EC <sub>50</sub>		E <sub>r</sub> C <sub>50</sub>	E <sub>r</sub> C <sub>50</sub>
		>11100 <sup>a</sup> µg/L		8260 <sup>a</sup> µg/L		130 <sup>a</sup> µg/L	0.324 <sup>a</sup> µg/L
<b>Step 3</b>							
R3	0.54	20518		15268		240	<b>0.60</b>
R4	0.008	1387500		1032500		16250	41
<b>Step 4 (20m VFS)</b>							
R3	0.129	86047		64031		1008	<b>2.51</b>
R4	0.002	5550000		4130000		65000	162

<sup>a</sup> Surrogate value, conservatively assuming acute toxicity to be ×10 higher than that of the parent active substance.

**Bold values** do not meet the trigger

## Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)\*

\* This section does not reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

Species	Test substance	Time scale/type of endpoint	End point	toxicity
<i>Apis mellifera</i>	a.s.	Acute	Oral toxicity (LD <sub>50</sub> )	>100 µg/bee
<i>Apis mellifera</i>	a.s.	Acute	Larval toxicity (single exposure)* (LD <sub>50</sub> )	>20 µg/bee
<i>Apis mellifera</i>	Laguna 75 WG	Chronic	LC <sub>50</sub>	>6.847 g product/kg food (5.136 g a.s./kg food)
			NOEC	≥6.847 g product/kg food (5.136 g a.s./kg food)
			LDD <sub>50</sub>	>191.4 µg product/bee/day (>143.5 µg a.s./bee/day)
			NOED	≥191.4 µg product/bee/day (143.5 µg a.s./bee/day)
Semi-field test (Cage and tunnel test)				
No further tests submitted				
Field tests				
No further tests submitted				

\*The study was not used in the risk assessment, since it is not considered suitable

### Risk assessment for bees from contact and oral dietary exposure - application to Soybean (BBCH 10-14): 0.1 kg formulated product./ha corresponding to 75 g oxasulfuron/ha

Species	Test substance	Scenario	Risk quotient	HQ/ETR	Trigger
Consumption of pollen and nectar - Screening level assessment					
<i>Apis mellifera</i>	a.s.	Not relevant	ETR <sub>acute adult oral</sub>	< 0.0057	0.2
<i>Apis mellifera</i>	a.s.	Not relevant	ETR <sub>chronic adult oral</sub>	<0.004	0.03
Consumption of guttation water - Screening level assessment					
<i>Apis mellifera</i>	a.s.	Not relevant	ETR <sub>acute adult oral</sub>	< 0.006	0.2
<i>Apis mellifera</i>	a.s.	Not relevant	ETR <sub>chronic adult oral</sub>	<0.002	0.03
Consumption of surface water* - Screening level assessment					
<i>Apis mellifera</i>	a.s.	Not relevant	ETR <sub>acute adult oral</sub>	< 0.000003	0.2
<i>Apis mellifera</i>	a.s.	Not relevant	ETR <sub>chronic adult oral</sub>	< 0.000002	0.03

\*PEC<sub>sw</sub> calculated at Step1

## Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

### Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
<i>Typhlodromus pyri</i>	Laguna 75 WG	Mortality, LR <sub>50</sub> Reproduction, reduction %	3.23 g a.s./ha <50% at the highest tested rate with sufficient survivors for reproduction assessment (7.8% at 3.19 g a.s./ha)
<i>Aphidius rhopalosiphi</i>	Laguna 75 WG	Mortality LR <sub>50</sub> Reproduction, reduction %	>75 g a.s./ha <50% (25.9% at 37.5 g a.s./ha)
Additional species			
None submitted			

### First tier risk assessment for –Soybean (BBCH 10-14): 0.1 kg formulated product/ha corresponding to 75 g oxasulfuron/ha

Test substance	Species	Effect (LR <sub>50</sub> g/ha)	HQ in-field	HQ off-field (1 m)	Trigger
Laguna 75 WG	<i>Typhlodromus pyri</i>	3.23 g a.s./ha	<b>23.2</b>	0.6	2
Laguna 75 WG	<i>Aphidius rhopalosiphi</i>	>75 g a.s./ha	<1	<0.03	2

### Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g product/ha)	End point	% effect*
<i>Typhlodromus pyri</i>	Protonymphs and adults	Laguna 75 WG, leaf bean discs	14 d of exposure	4.688	reproduction	8
				9.375		8.2
				18.75		0.5
				37.5		3.8
				75		1.3
<i>Poecilus cupreus</i>	Adults	Laguna 75 WG, sandy soil	14 d of exposure	4.688	Food consumption	25.9
				9.375		12.9
				18.75		2.9
				37.5		15.1
				75		12.2

#### Semi-field tests

No studies submitted

#### Field studies

No studies submitted

#### Additional specific test

No studies submitted

\*(positive values = adverse effects)

## Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Application method of test a.s./ OM <sup>1</sup>	Time scale	End point	Toxicity (mg/kg d.w. soil)
Earthworms					
<i>Eisenia foetida</i>	a.s.	Incorporated into soil / 10% OM	Acute (14d)	Mortality	LC <sub>50</sub> > 1000
<i>Eisenia foetida</i>	Laguna 75 WG	Incorporated into soil / 10% OM	Chronic (56d)	Reproduction	NOEC= 2
<i>Eisenia foetida</i>	CGA 27913*	Incorporated into soil / 10% OM	Chronic (56d)	Reproduction	NOEC=0.04
Other soil macroorganisms					
No studies submitted					

\*endpoint (metabolite IN-00581) from the EFSA conclusion on metsulfuron-methyl (EFSA, 2015)

### Higher tier testing (e.g. modelling or field studies)

No studies submitted

Nitrogen transformation	Laguna 75 WG*	Maximum tested rate of 0.5 kg product/ha (0.67 mg test item/kg soil dry weight), corresponding to 375 g a.s./ha (0.50 mg a.s./kg soil dry weight); Sandy loam soil.	11.5% effect at day 70 at 0.50 mg a.s./kg soil dry weight (=375 g a.s./ha)
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\*Considering the length of the study, the DT50 in soil and the % of formation of the metabolites reached the maximum in the degradation studies in soil (both aerobic and anaerobic) in short times, metabolites are covered in the study.

### Toxicity/exposure ratios for soil organisms

#### Soybean (BBCH 10-14): 0.1 kg formulated product/ha corresponding to 75 g oxasulfuron/ha

Test organism	Test substance	Time scale	Soil PEC (actual)	TER	Trigger
Earthworms					
	a.s.	Acute	0.065	15384.62	10
	a.s.	Chronic	0.065	30.77	5

	CGA 27913	Chronic	0.029	<b>1.38<sup>b</sup></b>	5
	C 1801 (CA2006A)	Chronic	0.011	18.18 <sup>a</sup>	5
	CGA171895	Chronic	0.002	100 <sup>a</sup>	5
	CGA 179710	Chronic	0.007	28.6 <sup>a</sup>	5
	CGA 297691 (CA2013A)	Chronic	0.0025	80 <sup>a</sup>	5
	M3	Chronic	0.017	11.76 <sup>a</sup>	5

Other soil macroorganisms

<sup>a</sup> assuming toxicity to be ×10 higher than that of the parent active substance<sup>b</sup> based on worst case toxicity endpoint from EFSA conclusion for metsulfuron-methyl (EFSA Journal 2015;13(1):3936), acceptable risk demonstrated by higher tier risk assessment.

### Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

Not required for herbicides or plant growth regulators as ER<sub>50</sub> tests should be provided

#### Laboratory dose response tests\*

Test substance	Species	ER <sub>50</sub> (g a.s./ha) vegetative vigour	ER <sub>50</sub> ** (g a.s./ha) emergence
Laguna 75 WG	Oat	-	122
	Corn		152
	Ryegrass		24
	Onion		149
	Radish		129
	Cabbage		225
	Lettuce		>75
	Tomato		>75
	Cucumber		>375
	Pea		>215.6

\*Risk assessment for non-target terrestrial plants could not be finalised due to the lack of data on vegetative vigour.

\*\*ER<sub>50</sub>s are based on shoot height. Please note, that for all the tested species, except the most sensitive one (ryegrass) the endpoint based of fresh weight is lower

### Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	end point
Activated sludge	3-hour EC <sub>50</sub> > 1000 mg a.s./L
Activated sludge	3-hour EC <sub>50</sub> > 1000 mg CA 2006A/L
<i>Pseudomonas sp</i>	No data were available

### Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the a.s.

No data available

Available monitoring data concerning effect of the PPP.

No data available

## Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds<sup>1</sup>

Compartment	
soil	Oxasulfuron (CGA-277476), CGA 27913 (saccharin)
water	Oxasulfuron (CGA-277476), M3 (pending), MT6 (pending), CGA 171895 (Pending)
sediment	-
groundwater	-

<sup>1</sup> metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

## Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance	oxasulfuron (ISO) oxetan-3-yl 2-[(4,6-dimethylpyrimidin-2-yl)- carbamoylsulfamoyl]benzoate
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] <sup>6</sup> :	Aquatic Acute 1 – H400 Aquatic Chronic 1 - H410
Peer review proposal <sup>7</sup> for harmonised classification according to Regulation (EC) No 1272/2008:	Aquatic Acute 1 – H400 (M=100) Aquatic Chronic 1 - H410 (M=100) <i>Proposal is based upon the endpoint for aquatic plants</i>

<sup>6</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

<sup>7</sup> It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

## Abbreviations

1/ <i>n</i>	slope of Freundlich isotherm
$\lambda$	wavelength
$\varepsilon$	decadic molar extinction coefficient
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AAOEL	acute acceptable operator exposure level
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AUC	area under the blood concentration/time curve
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony-forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
C <sub>max</sub>	concentration achieved at peak blood level
DAA	days after application
DAT	days after treatment
DDD	daily dietary dose
DM	dry matter
DT <sub>50</sub>	period required for 50% dissipation (define method of estimation)
DT <sub>90</sub>	period required for 90% dissipation (define method of estimation)
dw	dry weight
EbC <sub>50</sub>	effective concentration (biomass)
EC <sub>50</sub>	effective concentration
ECHA	European Chemicals Agency



EEC	European Economic Community
EMDI	estimated maximum daily intake
ER <sub>50</sub>	emergence rate/effective rate, median
ErC <sub>50</sub>	effective concentration (growth rate)
ETR	exposure toxicity ratio
ETR <sub>acute</sub>	exposure toxicity ratio for acute exposure
ETR <sub>larvae</sub>	exposure toxicity ratio for chronic exposure
ETR <sub>larvae</sub>	exposure toxicity ratio for larvae
ETR <sub>HPG</sub>	exposure toxicity ratio for effects on honeybee hypopharygeal glands
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	Time-weighted average factor
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FIR	food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as International Group of National Associations of Manufacturers of Agrochemical Products; GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathione
Hb	haemoglobin
Hct	haematocrit
HPLC	high-pressure liquid chromatography or high-performance liquid chromatography
HPLC-MS	high-pressure liquid chromatography–mass spectrometry
HPG	hypopharygeal glands
HQ	hazard quotient
HQ <sub>contact</sub>	hazard quotient for contact exposure
HR	hazard rate
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
iv	intravenous

JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
$K_{doc}$	organic carbon linear adsorption coefficient
$K_{Foc}$	Freundlich organic carbon adsorption coefficient
LC	liquid chromatography
$LC_{50}$	lethal concentration, median
LC-MS	liquid chromatography–mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
$LD_{50}$	lethal dose, median; dosis letalis media
$LDD_{50}$	lethal dietary dose; median
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mm	millimetre (also used for mean measured concentrations)
mN	milli-newton
MRL	maximum residue level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water-holding capacity
NESTI	national estimated short-term intake
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen–phosphorus detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
$PEC_{air}$	predicted environmental concentration in air

PEC <sub>gw</sub>	predicted environmental concentration in groundwater
PEC <sub>sed</sub>	predicted environmental concentration in sediment
PEC <sub>soil</sub>	predicted environmental concentration in soil
PEC <sub>sw</sub>	predicted environmental concentration in surface water
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK <sub>a</sub>	negative logarithm (to the base 10) of the dissociation constant
P <sub>ow</sub>	partition coefficient between <i>n</i> -octanol and water
PPE	personal protective equipment
ppm	parts per million (10 <sup>-6</sup> )
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure–activity relationship
r <sup>2</sup>	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SMILES	simplified molecular-input line-entry system
SPG	specific protection goal
SSD	species sensitivity distribution
STMR	supervised trials median residue
t <sub>1/2</sub>	half-life (define method of estimation)
TER	toxicity exposure ratio
TER <sub>A</sub>	toxicity exposure ratio for acute exposure
TER <sub>LT</sub>	toxicity exposure ratio following chronic exposure
TER <sub>ST</sub>	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
Tmax	time until peak blood levels achieved
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid-stimulating hormone (thyrotropin)
TWA	time-weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor

UV	ultraviolet
W/S	water/sediment
w/v	weight per unit volume
w/w	weight per unit weight
WBC	white blood cell
WG	water-dispersible granule
WHO	World Health Organization