REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: CHR/H/MEZO 30 OD

Product names: Vidal 30 OD, Pacyfik 30 OD

Chemical active substance:

Mesosulfuron-methyl, 30 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: December 2023

RMS Assessment: 26/07/2024

MS Finalisation date: 19/11/2024

Version history

When	What
July 2024	zRMS assessment
November 2024	Following commenting period

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10 Relevance of metabolites in groundwater

zRMS comment: Four metabolites of mesosulfuron-methyl: AE F160459, AE F160460, AE F147447 and BCS-CV14885 are predicted to occur in groundwater at the concentrations above 0.1 µg/L (see dRR Part B section 8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.11 is therefore required. All the metabolites cannot be excluded as a product of no concern as they are not:.

- CO2 or an inorganic compound, not containing a heavy metal;
- an organic compound of aliphatic structure, with a chain length of 4 or less, which consists only of C, H, N or O atoms and which has no "alerting structures" such as epoxide, nitros-amine, nitrile or other functional groups of known toxicological concern;
- a substance which is known to be of no toxicological or ecotoxicological concern, and which is naturally occurring at much higher concentrations in the respective compartment.

Mesosulfuron-methyl presented low toxicity following oral, dermal or inhalation routes to rats. It is not a skin or eye irritant. Mesosulfuron-methyl is unlikely to be genotoxic or carcinogenic. No adverse effects were observed on the reproduction, fertility or development of rat or rabbits and there was no evidence for neurotoxicity.
Mesosulfuron-methyl is classified as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) according to CLH Regulation (Index No: 607-729-00-9).
The metabolites: AE F160459, AE F160460, AE F147447 and BCS-CV14885 have no pesticidal activity and are of lower toxicity compared to mesosulfuron-methyl.
The summary of the available information assessed at EU level (EFSA, 2016) is presented in the table below:

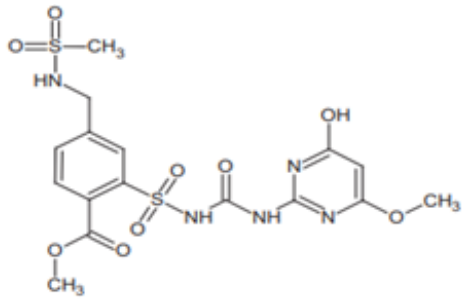
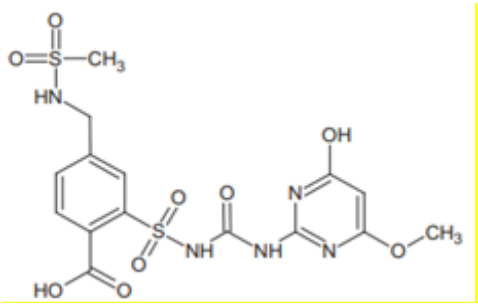
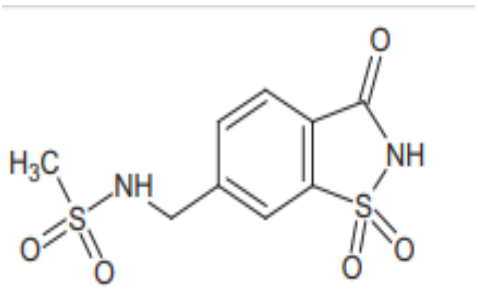
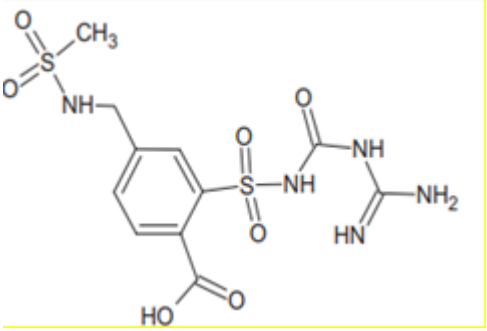
Compound	Pesticidal activity	Toxicological relevance	Ecotoxicology
Mesosulfuron-methyl	Yes	Yes	High risk
AE F160459	No	No Unlikely to be genotoxic	Low risk
AE F160460	No	No Negative Ames test Negative chromosome aberration in vitro Negative gene mutation in vitro in mammalian cells Unlikely to be genotoxic	Low risk
AE F147447	No	No Negative chromosome aberration in vitro Negative gene mutation in vitro in mammalian cells Unlikely to be genotoxic	Low risk
BCS-CV14885	No	No Negative Ames test Negative chromosome aberration in vitro Negative gene mutation in vitro in mammalian cells Unlikely to be genotoxic	Low risk

Taking into account the available information, the metabolites of the active substance are considered non-relevant.

10.1 General information

The metabolites AE F160459, AE F160460, AE F147447, BCS-CV14885 are predicted to occur in groundwater at concentrations above 0.1 µg/L (see Chapter 8.8 in dRR Part 8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document Sanco/221/2000 – rev.11 is therefore required.
General information on the metabolites are provided in Table 10.1-1. The impact of the relevance assessment on whether a particular GAP use leads to acceptable risk or not is presented in the summary of the cGAP evaluation in chapter 8.1 of the dRR Part B, Section 8 (Environmental fate and behaviour).

Table 10.1-1: General information on the metabolite(s)

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Mesosulfuron-methyl (AE F130060)	AE F160459		Max PEC_{gw} Based on:	~~0.284480~~ 0.224703 µg/L FOCUS PEARL 5.5.5, Hamburg scenario
Mesosulfuron-methyl (AE F130060)	AE F160460		Max PEC_{gw} Based on:	~~0.392726~~ 0.703 µg/L FOCUS PELMO 6.6.4, Jokioinen scenario
Mesosulfuron-methyl (AE F130060)	AE F147447		Max PECgw Based on:	~~0.398196~~ 0.320455 µg/L FOCUS PEARL 5.5.5, Jokioinen scenario
Mesosulfuron-methyl (AE F130060)	BCS-CV14885		Max PECgw Based on:	~~0.603020~~ 0.516 µg/L FOCUS ~~PEARL 5.5.5~~, PELMO 6.6.4, Jokioinen scenario

10.2 Relevance assessment of AE F160459 (KCP 10.2)

Summary:

The relevance of the groundwater metabolite AE F160459 has already been assessed and the assessment agreed at EU level (see RAR vol 1 Mesosulfuron-methyl , September 2016) and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). Metabolite AE F160459 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.11. A summary of the relevance assessment is given in Table 10.2-1 and the corresponding studies are listed in the corresponding sections.

Table 10.2-1: Summary of the relevance assessment for AE F160459

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC_{gw}	~~0.284480~~ 0.224703 µg/L
			Based on	FOCUS PEARL 5.5.5, Hamburg scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	non-genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	non-toxic, non-reproductive toxicity properties, non-carcinogenic properties
			Classification of metabolite	non-toxic
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	acceptable (<0.75 µg/L)
	STEP 5		Refined risk assessment	N/A*
			Predicted exposure (% of ADI)	N/A*
			ADI based on	N/A*

* N/A: not applicable

10.2.1 STEP 1: Exclusion of degradation products of no concern (KCP 10.2.1)

AE F160459 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

10.2.2 STEP 2: Quantification of potential groundwater contamination (KCP 10.2.2)

PEC_{gw} calculations after leaching from soil for were performed (see Part B, Section 8, chapter 8.5.2). The

uses for which concentrations of AE F160459 were considered to exceed 0.1 µg/L are listed in Table 10.2-1. Details are given in Part B, Section 8, chapter 8.8.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites (KCP 10.2.3)

10.2.3.1 STEP 3, Stage 1: screening for biological activity (KCP 10.2.3.1)

The biological activity of AE F160459 does not have comparable target activity as the parent active compound as shown in biological screening data. AE F160459 is not considered relevant and is further evaluated in Stage 2.

Full summaries of biological screening studies on the metabolite that have been previously considered within an EU peer review process are described in detail in Appendix 1.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity (KCP 10.2.3.2)

The metabolite AE F160459 was not tested for genotoxicity. AE F160459 is an intermediate metabolite found in the rat metabolic pathway of Mesosulfuron-methyl at trace amounts in the bile, urine and feces of the low and high dose rats (Bile: 0.02 - 0.04% of administered dose in males and females treated at 10 mg/kg bw; Urine: 0.09% and 0.04% of the administered doses in males dosed at 10 and 1000 mg/kg bw respectively; faeces 1.58% - 1.28% of the administered dose in males and females treated at 10 mg/kg bw respectively and 0.13% - 0.21% of the administered dose in males and females treated at 1000 mg/kg bw respectively). This metabolite has a close structure similarity with the parent compound, the only difference between AE F160459 and Mesosulfuron-methyl (AE F130060) is due to a methyl group which is not present in the metabolite. It is structurally also very similar to AE F160460. During the Pesticides Peer Review Meeting TC134 (31 May 2016), the experts agreed that no further genotoxicity testing is necessary for the metabolite AE F160459. Due to structural similarity with the parent compound and the metabolite AE F160460, AE F160459 is unlikely to present genotoxicity property

10.2.3.3 STEP 3, Stage 3: screening for toxicity (KCP 10.2.3.3)

Parent compound Mesosulfuron-methyl is not classified as toxic or very toxic, and has no classification for reproductive toxicity or carcinogenic properties. There are no reasons to expect that AE F160459 may be toxic or highly toxic. AE F160459 has not been subject to targeted testing. AE F160459 is not considered relevant and is further evaluated in Step 4. The genotoxicity studies are evaluated in Part B, Section 6, studies referenced in Table 6.4-1

10.2.4 STEP 4: Exposure assessment – threshold of concern approach (KCP 10.2.4)

AE F160459 was not considered relevant in the hazard assessment of Step 3.
The PEC_{gw} for was AE F160459 < 0.75 µg/L. There is no consumer exposure via other routes. AE F160459 is not considered to exceed the toxicological threshold of concern as defined in EC guidance document SANCO/221/2000 –rev.11.

10.2.5 STEP 5: Refined risk assessment (KCP 10.2.5)

Not necessary for metabolite AE F160459.

10.3 Relevance assessment of AE F160460 (KCP 10.3)

Summary:

The relevance of the groundwater metabolite AE F160460 has already been assessed and the assessment agreed at EU level (see RAR vol 1 Mesosulfuron- methyl, September 2016), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). Metabolite AE F160460 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.11. A summary of the relevance assessment is given in Table 10.3-1 and the corresponding studies are listed in the corresponding sections.

Table 10.3-1: Summary of the relevance assessment for AE F160460

	Assessment step		**Result of assessment**	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC_{gw}	~~0.392726~~ 0.703 µg/L
			Based on	FOCUS PELMO 6.6.4, Jokioinen scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	non-genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	non-toxic, non-reproductive toxicity properties, non-carcinogenic properties
			Classification of metabolite	non-toxic
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	acceptable (<0.75 µg/L)
	STEP 5		Refined risk assessment	N/A*
			Predicted exposure (% of ADI)	N/A*
			ADI based on	N/A*

* N/A: not applicable

10.3.1 STEP 1: Exclusion of degradation products of no concern (KCP 10.3.1)

AE F160460 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

10.3.2 STEP 2: Quantification of potential groundwater contamination (KCP 10.3.2)

PEC_{gw} calculations after leaching from soil for were performed (see Part B, Section 8, chapter 8.5.2). The uses for which concentrations of AE F160460 were considered to exceed 0.1 µg/L are listed in Table 10.3-1. Details are given in Part B, Section 8, chapter 8.8.

10.3.3 STEP 3: Hazard assessment – identification of relevant metabolites (KCP 10.3.3)

10.3.3.1 STEP 3, Stage 1: screening for biological activity (KCP 10.3.3.1)

The biological activity of AE F160460 does not have comparable target activity as the parent active compound as shown in biological screening data. AE F160460 is not considered relevant and is further evaluated in Stage 2.

Full summaries of biological screening studies on the metabolite that have been previously considered within an EU peer review process are described in detail in Appendix 1.

10.3.3.2 STEP 3, Stage 2: screening for genotoxicity (KCP 10.3.3.2)

Metabolite AE F160460 was screened for genotoxic activity by the following data package of in vitro genotoxicity studies: Ames test, gene mutation test with mammalian cells, and a chromosome aberration test. AE F160460 was non-genotoxic as shown by a negative Ames test, negative gene mutation test with mammalian cells, negative chromosome aberration test additional studies and references as required. Metabolite AE F160460 is considered not relevant and is further evaluated in Stage 3. The genotoxicity studies are evaluated in Part B, Section 6, studies referenced in Table 6.4-2.

10.3.3.3 STEP 3, Stage 3: screening for toxicity (KCP 10.3.3.3)

Parent compound Mesosulfuron-methyl is not classified as toxic or very toxic, and has no classification for reproductive toxicity or carcinogenic properties. There are no reasons to expect that AE F160460 may be toxic or highly toxic. AE F160460 has not been subject to targeted testing. AE F160460 is not considered relevant and is further evaluated in Step 4. The toxicity studies are evaluated in Part B, Section 6, studies referenced in Table 6.4-2.

10.3.4 STEP 4: Exposure assessment – threshold of concern approach (KCP 10.3.4)

AE F160460 was not considered relevant in the hazard assessment of Step 3. The PEC_{gw} for AE F160460 was < 0.75 µg/L. There is no consumer exposure via other routes. AE F160460 is not considered to exceed the toxicological threshold of concern as defined in EC guidance document SANCO/221/2000 –rev.11.

10.3.5 STEP 5: Refined risk assessment (KCP 10.3.5)

Not necessary for AE F160460.

10.4 Relevance assessment of AE F147447 (KCP 10.4)

Summary:

The relevance of the groundwater metabolite AE F147447 has already been assessed and the assessment agreed at EU level (see RAR vol 1 Mesosulfuron-methyl, September 2016), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). Metabolite AE F147447 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.11. A summary of the relevance assessment is given in Table 10.4-1 and the corresponding studies are listed in the corresponding sections.

Table 10.4-1: Summary of the relevance assessment for AE F147447

	Assessment step		**Result of assessment**	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC_{gw}	~~0.398196~~ 0.320455 µg/L
			Based on	FOCUS PEARL 5.5.5, Jokioinen scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	non-genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	non-toxic, non-reproductive toxicity properties, non-carcinogenic properties
			Classification of metabolite	non-toxic
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	acceptable (<0.75 µg/L)
	STEP 5		Refined risk assessment	N/A*
			Predicted exposure (% of ADI)	N/A*
			ADI based on	N/A*

* N/A: not applicable

10.4.1 STEP 1: Exclusion of degradation products of no concern (KCP 10.4.1)

AE F147447 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

10.4.2 STEP 2: Quantification of potential groundwater contamination (KCP 10.4.2)

PEC_{gw} calculations after leaching from soil for were performed (see Part B, Section 8, chapter 8.5.2). The

uses for which concentrations of AE F147447 were considered to exceed 0.1 µg/L are listed in Table 10.4-1. Details are given in Part B, Section 8, chapter 8.8.

10.4.3 STEP 3: Hazard assessment – identification of relevant metabolites (KCP 10.4.3)

10.4.3.1 STEP 3, Stage 1: screening for biological activity (KCP 10.4.3.1)

The biological activity of AE F147447 does not have comparable target activity as the parent active compound as shown in biological screening data. AE F147447 is not considered relevant and is further evaluated in Stage 2.

Full summaries of biological screening studies on the metabolite that have been previously considered within an EU peer review process are described in detail in Appendix 1.

10.4.3.2 STEP 3, Stage 2: screening for genotoxicity (KCP 10.4.3.2)

Metabolite AE F147447 was screened for genotoxic activity by the following data package of in vitro genotoxicity studies: Ames test, gene mutation test with mammalian cells, and a chromosome aberration test. AE F147447 was non-genotoxic as shown by a negative Ames test, negative gene mutation test with mammalian cells, negative chromosome aberration test additional studies and references as required. Metabolite 1 is considered not relevant and is further evaluated in Stage 3. The genotoxicity studies are evaluated in Part B, Section 6, studies referenced in Table 6.4-3.

10.4.3.3 STEP 3, Stage 3: screening for toxicity (KCP 10.4.3.3)

Parent compound Mesosulfuron-methyl is not classified as toxic or very toxic, and has no classification for reproductive toxicity or carcinogenic properties.
There are no reasons to expect that AE F147447 may be toxic or highly toxic. AE F147447 has not been subject to targeted testing. AE F147447 is not considered relevant and is further evaluated in Step 4. The toxicity studies are evaluated in Part B, Section 6, studies referenced in Table 6.4-3.

10.4.4 STEP 4: Exposure assessment – threshold of concern approach (KCP 10.4.4)

AE F147447 was not considered relevant in the hazard assessment of Step 3. The PEC_{gw} for AE F147447 was < 0.75 µg/L. There is no consumer exposure via other routes. AE F147447 is not considered to exceed the toxicological threshold of concern as defined in EC guidance document SANCO/221/2000 –rev.11.

10.4.5 STEP 5: Refined risk assessment (KCP 10.4.5)

Not necessary for AE F147447.

10.5 Relevance assessment of BCS-CV14885 (KCP 10.5)

Summary:

The relevance of the groundwater metabolite BCS-CV14885 has already been assessed and the assessment agreed at EU level (see RAR vol 1 Mesosulfuron-methyl, September 2016), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). Metabolite BCS-CV14885 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.11. A summary of the relevance assessment is given in Table 10.5-1 and the corresponding studies are listed in the corresponding sections.

Table 10.5-1: Summary of the relevance assessment for BCS-CV14885

	Assessment step		**Result of assessment**	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC_{gw}	~~0.603020~~ 0.516 µg/L
			Based on	FOCUS PELMO 6.4.4, Jokioinen scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	non-genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	non-toxic, non-reproductive toxicity properties, non-carcinogenic properties
			Classification of metabolite	non-toxic
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	acceptable (<0.75 µg/L)
	STEP 5		Refined risk assessment	N/A*
			Predicted exposure (% of ADI)	N/A*
			ADI based on	N/A*

* N/A: not applicable

10.5.1 STEP 1: Exclusion of degradation products of no concern (KCP 10.5.1)

BCS-CV14885 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

10.5.2 STEP 2: Quantification of potential groundwater contamination (KCP 10.5.2)

PEC_{gw} calculations after leaching from soil for were performed (see Part B, Section 8, chapter 8.5.2). The

uses for which concentrations of BCS-CV14885 were considered to exceed 0.1 µg/L are listed in Table 10.5-1. Details are given in Part B, Section 8, chapter 8.8.

10.5.3 STEP 3: Hazard assessment – identification of relevant metabolites (KCP 10.5.3)

10.5.3.1 STEP 3, Stage 1: screening for biological activity (KCP 10.5.3.1)

The biological activity of BCS-CV14885 does not have comparable target activity as the parent active compound as shown in biological screening data. BCS-CV14885 is not considered relevant and is further evaluated in Stage 2.

Full summaries of biological screening studies on the metabolite that have been previously considered within an EU peer review process are described in detail in Appendix 1.

10.5.3.2 STEP 3, Stage 2: screening for genotoxicity (KCP 10.5.3.2)

Metabolite BCS-CV14885 was screened for genotoxic activity by the following data package of in vitro genotoxicity studies: Ames test, gene mutation test with mammalian cells, and a chromosome aberration test. BCS-CV14885 was non-genotoxic as shown by a negative Ames test, negative gene mutation test with mammalian cells, negative chromosome aberration test additional studies and references as required. Metabolite BCS-CV14885 is considered not relevant and is further evaluated in Stage 3. The genotoxicity studies are evaluated in Part B, Section 6, studies referenced in Table 6.4-4.

10.5.3.3 STEP 3, Stage 3: screening for toxicity (KCP 10.5.3.3)

Parent compound Mesosulfuron-methyl is not classified as toxic or very toxic, and has no classification for reproductive toxicity or carcinogenic properties. There are no reasons to expect that BCS-CV14885 may be toxic or highly toxic. BCS-CV14885 has not been subject to targeted testing. BCS-CV14885 is not considered relevant and is further evaluated in Step 4. The genotoxicity studies are evaluated in Part B, Section 6, studies referenced in Table 6.4-4

10.5.4 STEP 4: Exposure assessment – threshold of concern approach (KCP 10.5.4)

BCS-CV14885 was not considered relevant in the hazard assessment of Step 3. The PEC_{gw} for BCS-CV14885 was < 0.75 µg/L. There is no consumer exposure via other routes. BCS-CV14885 is not considered to exceed the toxicological threshold of concern as defined in EC guidance document SANCO/221/2000 –rev.11.

10.5.5 STEP 5: Refined risk assessment (KCP 10.5.5)

Not necessary for BCS-CV14885.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

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

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

The following tables are to be completed by MS

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	**Owner**
KCP 10.2.3.1 KCP 10.3.3.1 KCP 10.4.3.1	Rosinger C	1999	Report No: M-185253-01-1	N	
KCP 10.5.3.1	Noeding S	2013	Report No: M-460647-01-1	N	
KCP 10.2.3.3		2000a	Rat preliminary toxicokinetics: Metabolism - oral low dose (10 mg/kg body weight) and oral high dose (1000 mg/kg body weight) Code:(2- 14C-pyrimidyl)- AE F13006 [redacted] GLP: yes, unpublished	Y	Bayer CropScience
KCP 10.2.3.3 KCP 10.4.3.3		2000b	Rat metabolism - single oral low dose (10 mg/kg body weight) (U-14C-phenyl)-AE F130060 [redacted], GLP: yes, unpublished	Y	Bayer CropScience
KCP 10.2.3.3 KCP 10.4.3.3		2000c	Rat metabolism - single oral high dose (1000 mg/kg bw); [U14C-phenyl] AE F 130060; [redacted], GLP: yes, unpublished	Y	Bayer CropScience
KCP 10.2.3.3 KCP 10.4.3.3		2000a	Rat metabolism -repeated oral dose (7 x 250) mg/kg body weight) (U-14C-phenyl)-AE F130060 [redacted], GLP yes unpublished	Y	Bayer CropScience
KCP 10.3.3.2	Sokolowski A	2012	*Salmonella typhimurium* reverse mutation assay with AE F160460	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 10.3.3.3			Report No.: 1462301, Harlan CCR, Rossdorf, Germany Bayer CropScience, GLP: yes, unpublished		CropScience
KCP 10.3.3.2 KCP 10.3.3.3	Bohnenberger S	2015	Report amendment - In vitro chromosome aberration test in Chinese hamster V79 cells with AE F160460 Report No.:1462302 Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, GLP yes unpublished	N	Bayer CropScience
KCP 10.4.3.2 KCP 10.4.3.3	Sokolowski, A.	2012	*Salmonella typhimurium* reverse mutation assay with AE F147447 Report No.: 1462101, Harlan CCR, Rossdorf, Germany Bayer CropScience, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.4.3.2 KCP 10.4.3.3	Bohnenberger S	2015	Report amendment - In vitro chromosome aberration test in Chinese hamster V79 cells with AE F147447 Report No.: 1462102, Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.4.3.2 KCP 10.4.3.3	Wollny, H. E.	2012	Gene mutation assay in Chinese hamster V79 cells in vitro (V79 / HPRT) - AE F147447 Report No.: 1462103, Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.5.3.2 KCP 10.5.3.3	Sokolowski, A.	2012	*Salmonella typhimurium* reverse mutation assay with BCS-CV14885 Report No.: 1490201 Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience,	N	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			GLP: yes, unpublished		
KCP 10.5.3.2 KCP 10.5.3.3	Bohnenberger, S.	2015	Report amendment - In vitro chromosome aberration test in Chinese hamster V79 cells with BCS-CV14885 Report No.: 1490202, Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, GLP: yes, unpublished	N	Bayer CropScience
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List of data submitted by the applicant and not relied on

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

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

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