

REGISTRATION REPORT

Part B

Section 5

Analytical Methods

Detailed summary of the risk assessment

Product code: GLOB1913H

Product name: Roxy XL

Chemical active substances:

Prosulfocarb, 900 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: September 2022

Finalisation date: 07/08/2023

After commenting period: 16/11/2023

Version history

When	What
September 2022	Initial submission by applicant for approval of new product.
August 2023	zRMS assessment
November 2023	After commenting period

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5 Analytical methods

5.1 Conclusion and summary of assessment

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

In the context of the residue analytical methods this document was not rewritten. All zRMS comments or/and corrections with regard to the residue analytical methods are within grey boxes/background.

The data are sufficient for evaluation and enforcement of all relevant MRLs/residue levels.

No data gaps were identified in the context of this authorisation request.

Commodity/crop	Supported/ Not supported
Potato	Supported
Sunflower	Supported
Winter Wheat	Supported

5.2 Methods used for the generation of pre-authorization data (KCP 5.1)

5.2.1 Analysis of the plant protection product (KCP 5.1.1)

5.2.1.1 Determination of active substance and/or variant in the plant protection product (KCP 5.1.1)

An overview on the acceptable methods and possible data gaps for analysis of prosulfocarb in plant protection product is provided as follows:

Comments of zRMS:	Described <u>HPLC</u> method validation for the determination of the prosulfocarb in plant protection product has been validated in accordance with SANCO/3030/99 rev. 5. and with Good Laboratory Practice method is acceptable and suitable for the determination of the active substance.
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Reference:	KCP 5.1.1
Report	Validation of the methods of determination of prosulfocarb in an EC formulation, in compliance with good laboratory practice. Sowle J., 2020, DNA5820
Guideline(s):	Yes, SANCO/3030/99 rev.5
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

A sample is diluted in methanol and analysed by HPLC-DAD.

HPLC-DAD Conditions – Prosulfocarb validation

Instrument:	Agilent 1200 HPLC-DAD
Mode:	Isocratic Reverse Phase
Column:	Inertsil ODS-3V (250mm x 4.6mm)
Packing:	ODS-3V, 5µm
Eluent:	65% Acetonitrile 35% Deionised Water adjusted to pH3 with Formic Acid
Wavelength:	235nm
Flow Rate:	1.0 mL/min
Injection Volume:	10µL
Column Temperature:	25°C
Data Collection:	LabSolutions
Retention Time:	Approximately 22.7-23.0 minutes

LCMS Q-ToF Conditions – LC conditions

Instrument:	Agilent 1260 Series HPLC-DAD
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Mode: Isocratic Reverse Phase
Column: Inertsil ODS-3V (250mm x 4.6mm)
Packing: ODS-3V, 5µm
Eluent: 65% Acetonitrile
35% Deionised Water adjusted to pH3 with Formic Acid
Wavelength: 235nm
Flow Rate: 1.0mL/minute
Injection Volume: 10µL
Column Temperature: 25°C

LCMS Q-ToF Conditions – MS conditions

Instrument: Agilent 6500 Series Q-ToF Mass Spectrometer
Mode: Jetstream ESI
Ionisation: Positive
MS Scan Range: 50 to 1000m/z
MS/MS Scan Range: 50-500m/z
Extracted Ions: n/a (Full Scan Mode)
Retention Times: Approximately 24.2 minutes

Gas Temperature: 250°C
Drying Gas Flow: 8L/minute
Nebulizer: 30psig
Sheath Gas: 250°C
Sheath Gas Flow: 8L/minute
Acquisition Rate: 1 Spectra/Second
Acquisition Time: 1000ms/Spectra
Collision Energy: 0-30V
Data Acquisition: Mass Hunter

VCap: 3000V
Nozzle Voltage: 2000V
Fragmentor: 150V
Skimmer: 65V
OCT 1 RF Vpp: 750V

The standards are prepared in methanol.

Validation - Results and discussions

Table 5.2-1: Methods suitable for the determination of the active substance prosulfocarb in plant protection product GLOB1913H

	Prosulfocarb
Author(s), year	Sowle J., 2020
Principle of method	HPLC-DAD
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	0 - 1.0 mg/L r = 1.0000
Precision – Repeatability	Mean: 887.3 ± 1.528 g/L

	Prosulfocarb
Mean n = 6 (%RSD)	%RSD: 0.172
Accuracy n = 6 (% Recovery)	Mean: 100.5 ± 0.575% %RSD: 0.573
Interference/ Specificity	In the specificity chromatograms prosulfocarb eluted at 22.9 min. Other significant peaks were accounted for by assaying a solvent blank and a sample of the formulation blank. There were no other peaks present in these chromatograms at the same elution time as prosulfocarb. This demonstrates that there were no analyte interferences.
Comment	-

Conclusion

The validation parameters for these methodologies have been met for this study under the SAN-CO/3030/99 rev. 5 guidelines.

5.2.1.2 Description of analytical methods for the determination of relevant impurities (KCP 5.1.1)

GLOB1913H does not contain relevant impurities.

5.2.1.3 Description of analytical methods for the determination of formulants (KCP 5.1.1)

GLOB1913H does not contain relevant formulants.

5.2.1.4 Applicability of existing CIPAC methods (KCP 5.1.1)

There are no CIPAC methods available for analysing the active substance in the formulated product.

5.2.2 Methods for the determination of residues (KCP 5.1.2)

An overview on the acceptable methods and possible data gaps for analysis of residues of prosulfocarb for the generation of pre-authorization data is given in the following table. For the detailed evaluation of additional studies it is referred to Appendix 2.

Table 5.2-2: Validated methods for the generation of pre-authorization data

Component of residue definition: Prosulfocarb				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
Plants, plant products,...	Primary	0.01 mg/kg	GC-MSD (multi-residue)	Weber H, Pelz S., 2000/EU agreed

(Residues)	Primary	0.01 mg/kg	LC-MS/MS	Jonchère F., 2010*
	Confirmatory (if required)	-	Not required	-
Soil (Environmental fate)	Primary	0.02 mg/kg	GC-MSD	Crook, 2000/EU agreed
	Confirmatory (if required)	-	Not required	-
Water (Environmental fate)	Primary	0.1 µg/L	GC-MSD	Hargreaves, 1999/EU agreed
	Confirmatory (if required)	-	Not required	-
Air (Exposure)	Primary	0.00015 µg/m³	GC-MSD	Kwaitkowski, 2002/EU agreed
	Confirmatory (if required)	-	Not required	-
Water (Ecotoxicology)	Primary	0.008 mg/L	HPLC-UV	Sacker D., 2008b
		0.01 mg/L	LC-MS/MS	Siche, O., Wydra V., 2021a
		0.002 mg/L	LC-MS/MS	Siche, O., Wydra V., 2021b
		0.009 mg/L	LC-MS/MS	Siche, O., Wydra V., 2021c
		0.004 mg/L (water) ; 0.85 mg/kg (sediment)	LC-MS/MS	Siche, O., Wydra V., 2021d
		0.022 mg/L	HPLC-MS	Juckeland D., 2013a
	Confirmatory (if required)	-	Not required	-
Soil (Ecotoxicology)	Primary	0.1 mg/kg	HPLC-UV	Schulz L., 2015
		0.02 mg/L	HPLC-UV	Sacker D., 2008a
Other (Ecotoxicology)	Primary	9.7 mg/L	HPLC-UV	Chwiesko D., 2021
		6.0 mg/L	HPLC-UV	Chwiesko D., 2021
		4.3 mg/L	HPLC-UV	Berg C., 2021a
		0.43 mg/L	HPLC-DAD	Colli M., 2021
		8.5 mg/L	HPLC-UV	Bützler R., 2021a
		7.7 mg/L	HPLC-UV	Bützler R., 2021b
Metabolites of prosulfocarb: Prosulfocarb sulfoxide				
Water (Ecotoxicology)	Primary	6.21 µg/L	HPLC-MS/MS and UV/VIS	Juckeland D., 2012a
		0.038 mg/L		Juckeland D., 2012b
		0.1002 mg/L		Juckeland D., 2012c
		0.1002 mg/L		Juckeland D., 2012d
		0.01076 mg/L	HPLC-UV/VIS	Juckeland D., 2012e
		2 µg/L	LC-MS/MS	Juckeland D., 2013b

5.3 Methods for post-authorization control and monitoring purposes (KCP 5.2)

5.3.1 Analysis of the plant protection product (KCP 5.2)

Analytical methods for the determination of the active substance and relevant impurities in the plant protection product shall be submitted, unless the applicant shows that these methods already submitted in accordance with the requirements set out in point 5.2.1 can be applied.

5.3.2 Description of analytical methods for the determination of residues prosulfocarb (KCP 5.2)

5.3.2.1 Overview of residue definitions and levels for which compliance is required

Compared to the residue definition proposed in the Draft Assessment Report (incl. its addenda) the current legal residue definition is identical.

Table 5.3-1: Relevant residue definitions for monitoring/enforcement and levels for which compliance is required

Matrix	Residue definition	MRL / limit	Reference for MRL/level Remarks
Plant, high water content	Prosulfocarb	0.01 mg/kg	EFSA, 2007
Plant, high acid content		0.01 mg/kg	EFSA, 2007
Plant, high protein/high starch content (dry commodities)		0.01 mg/kg	EFSA, 2007
Plant, high oil content		0.01 mg/kg	EFSA, 2007
Plant, difficult matrices (hops, spices, tea)		0.01 mg/kg	EFSA, 2007
Muscle	Not required		EFSA, 2007
Milk			
Eggs			
Fat			
Liver, kidney			
Soil (Ecotoxicology)	Prosulfocarb	0.02 mg/kg	EFSA, 2007
Drinking water (Human toxicology)	Prosulfocarb	0.1 µg/L	general limit for drinking water
Surface water (Ecotoxicology)	Prosulfocarb	0.1 µg/L	EFSA, 2007
Air	Prosulfocarb	0.00015 mg/m ³	AOEL: 0.007 mg/kg bw/d
Tissue (meat or liver)	-	Not required	Not classified as T / T+
Body fluids		Not required	Not classified as T / T+

5.3.2.2 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of prosulfocarb in plant matrices is given in the following tables. For the detailed evaluation of additional studies it is referred to Appendix 2.

Table 5.3-2: Validated methods for food and feed of plant origin (required for all matrix types, “difficult” matrix only when indicated by intended GAP)

Component of residue definition: Prosulfocarb				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
High water content	Primary	0.01 mg/kg	GC-MSD (multi-residue)	Weber H, Pelz S., 2000/EU agreed
	ILV	0.01 mg/kg	GC-MSD (multi-residue)	Ryan J, Osborne V., 2000/EU agreed
	Confirmatory (if required)	-	Not required	-
High acid content	Primary	0.01 mg/kg	GC-MSD (multi-residue)	Weber H, Pelz S., 2000/EU agreed
	ILV	0.01 mg/kg	GC-MSD (multi-residue)	Ryan J, Osborne V., 2000/EU agreed
	Confirmatory (if required)	-	Not required	-
High oil content	Primary	0.01 mg/kg	GC-MSD (multi-residue)	Weber H, Pelz S., 2000/EU agreed
	ILV	0.01 mg/kg	GC-MSD (multi-residue)	Ryan J, Osborne V., 2000/EU agreed
	Confirmatory (if required)	-	Not required	-
High protein/high starch content (dry)	Primary	0.01 mg/kg	GC-MSD (multi-residue)	Weber H, Pelz S., 2000/EU agreed
	ILV	0.01 mg/kg	GC-MSD (multi-residue)	Ryan J, Osborne V., 2000/EU agreed
	Confirmatory (if required)	-	Not required	-
Difficult (if required, depends on intended use)	Not required			

For any special comments or remarkable points concerning the analytical methods for the determination of residues in plant matrices, please refer to Appendix 2.

Table 5.3-3: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	The DFG S19 multi-residue method uses mixtures of acetone and water as an extraction solvent. Acetone/water mixtures and acetonitrile/water mixtures are considered to be of similar polarity. Prosulfocarb is equally soluble in both solvent mixtures. The solvent system is considered to be similar to that used in the carrot metabolism study (Derz, 2015). The extraction system is therefore validated and fit-for-purpose.
Not required, because:	-

5.3.2.3 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)

Not required.

5.3.2.4 Description of methods for the analysis of soil (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of prosulfocarb in soil is given in the following tables.

Table 5.3-4: Validated methods for soil (if appropriate)

Component of residue definition: Prosulfocarb			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	0.02 mg/kg	GC-MSD	Crook, 2000/EU agreed
Confirmatory	-	Not required	-

For any special comments or remarkable points concerning the analytical methods for soil please refer to Appendix 2.

5.3.2.5 Description of methods for the analysis of water (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of prosulfocarb in surface and drinking water is given in the following tables. For the detailed valuation of additional studies it is referred to Appendix 2.

Table 5.3-5: Validated methods for water (if appropriate)

Component of residue definition: Prosulfocarb				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Drinking water	Primary	0.1 µg/L	GC-MSD	Hargreaves, 1999/EU agreed
	ILV	missing		
	Confirmatory	-	Not required	-

Component of residue definition: Prosulfocarb				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Surface water	Primary	0.1 µg/L	GC-MSD	Hargreaves, 1999/EU agreed
	Confirmatory	-	Not required	-

For any special comments or remarkable points concerning the analytical methods for water please refer to Appendix 2.

5.3.2.6 Description of methods for the analysis of air (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of prosulfocarb in air is given in the following tables.

Table 5.3-6: Validated methods for air (if appropriate)

Component of residue definition: Prosulfocarb			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	0.00015 µg/m ³	GC-MSD	Kwaitkowski, 2002/EU agreed
Confirmatory	-	Not required	-

For any special comments or remarkable points concerning the analytical methods for air it is referred to Appendix 2.

5.3.2.7 Description of methods for the analysis of body fluids and tissues (KCP 5.2)

Prosulfocarb and prosulfocarb metabolites are not defined as “relevant for monitoring” and are not categorised as toxic or very toxic in any recognised classification system. Consequently, analytical methods for post-approval control of residues in body fluids and tissues are not required.

5.3.2.8 Other studies/ information

No other studies were submitted.

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	Vertebrate study Y/N	Owner
KCP 5.1.1	Sowle J.	2020	Validation of the Methods of Determination of Prosulfocarb in an EC Formulation, in Compliance with Good Laboratory Practice DNA5820 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Globachem NV
KCP 5.1.2 Submitted as KCA 8.2.6.1	Sacker D.	2008b	The growth inhibition of Prosulfocarb Technical to the algae <i>Scenedesmus subspicatus</i> over a 72 hour exposure period Chemex Environmental International Ltd GLP Unpublished	N	Syngenta Globachem access
KCP 5.1.2 Submitted as KCP 10.2.1	Siche, O., Wydra V.	2021a	GLOB1913H: Acute toxicity to <i>Daphnia magna</i> in a static 48-hour immobilization test 155401220 Ibacon GmbH GLP Unpublished	N	Globachem NV
KCP 5.1.2 Submitted as	Siche, O., Wydra V.	2021b	GLOB1913H: Acute toxicity to <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test 155401210	N	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2.1			Ibacon GmbH GLP Unpublished		
KCP 5.1.2 Submitted as KCP 10.2.1	Siche, O., Wydra V.	2021c	GLOB1913H: Toxicity to the aquatic plant <i>Lemna gibba</i> in a static growth inhibition test 155401240 Ibacon GmbH GLP Unpublished	N	Globachem NV
KCP 5.1.2 Submitted as KCP 10.2.1	Siche, O., Wydra V.	2021d	GLOB1913H: Toxicity to the aquatic plant <i>Myriophyllum spicatum</i> in a static growth inhibition test with a prior rooting phase 155401215 Ibacon GmbH GLP Unpublished	N	Globachem NV
KCP 5.1.2 Submitted as KCP 10.2.1	Juckeland, D.	2013a	Effects of Prosulfocarb 800 EC on <i>Myriophyllum spicatum</i> in a growth inhibition test under semi-static test conditions 13 10 48 018 W Biochem Agrar GmbH GLP Unpublished	N	Globachem NV
KCP 5.1.2 Submitted as KCA 8.2.6.1	Juckeland, D.	2012a	Effects of Prosulfocarb sulfoxide on <i>Chlamydomonas reinhardtii</i> in an algal growth inhibition test 12 10 48 057 W Biochem Agrar GmbH GLP Unpublished	N	Globachem NV
KCP 5.1.2 Submitted as KCA 8.2.6.1	Juckeland, D.	2012b	Effects of Prosulfocarb sulfoxide on <i>Chlorella vulgaris</i> in an algal growth inhibition test 12 10 48 059 W Biochem Agrar GmbH GLP Unpublished	N	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 5.1.2 <i>Submitted as KCA 8.2.6.2</i>	Juckeland, D.	2012c	Effects of Prosulfocarb sulfoxide on <i>Anabaena flos-aquae</i> in an algal growth inhibition test 12 10 48 058 W Biochem Agrar GmbH GLP Unpublished	N	Globachem NV
KCP 5.1.2 <i>Submitted as KCA 8.2.6.2</i>	Juckeland, D.	2012d	Effects of Prosulfocarb sulfoxide on <i>Navicula pelliculosa</i> in an algal growth inhibition test 12 10 48 053 W Biochem Agrar GmbH GLP Unpublished	N	Globachem NV
KCP 5.1.2 <i>Submitted as KCA 8.2.6.2</i>	Juckeland, D.	2012e	Effects of Prosulfocarb sulfoxide on <i>Skeletonema costatum</i> in an algal growth inhibition test 12 10 48 060 W Biochem Agrar GmbH GLP Unpublished	N	Globachem NV
KCP 5.1.2 <i>Submitted as KCA 8.2.7</i>	Juckeland, D.	2013b	Effects of prosulfocarb sulfoxide on <i>Myriophyllum spicatum</i> in a growth inhibition test under semi-static conditions 13 10 48 017 W Biochem Agrar GmbH GLP Unpublished	N	Globachem NV
KCP 5.1.2 <i>Submitted as KCP10.3.1.1.1</i>	Chwiesko, D.	2021	GLOB1913H: Acute contact and oral toxicity to bumblebees (<i>Bombus terrestris</i> L.) in the laboratory. 155401105 Ibacon GmbH GLP Unpublished	N	Globachem NV
KCP 5.1.2 <i>Submitted as KCP 10.3.1.2</i>	Berg, C.	2021a	GLOB1913H: Chronic oral toxicity test on the honey bee (<i>Apis mellifera</i> L.) in the laboratory. 155401136 Ibacon GmbH GLP	N	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 5.1.2 <i>Submitted as KCP 10.3.1.3</i>	Colli, M.	2021	Effects of GLOB1913H on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure BT273/20 Biotechnologie BT S.r.l. GLP Unpublished	N	Globachem NV
KCP 5.1.2 <i>Submitted as KCP 10.4.1.2</i>	Schulz, L.	2015	Effects of prosulfocarb 800 g/L EC on earthworms under field conditions. Biochem Agrar Report Number 14 10 48 008 F GLP Unpublished	N	Globachem NV
KCP 5.1.2 <i>Submitted as KCA 8.1.3</i>	Sacker, D.	2008a	The bioaccumulation potential of prosulfocarb in earthworm (<i>Eisenia foetida foetida</i>). ENV8333/040822 Chemex Environmental International Ltd GLP Unpublished	N	Globachem NV
KCP 5.1.2 <i>Submitted as KCP 10.6</i>	Bützler, R.	2021	GLOB1913H: Effects on terrestrial (non-target) plants: seedling emergence and seedling growth test 155401086 Ibacon GmbH GLP Unpublished	N	Globachem NV
KCP 5.1.2 <i>Submitted as KCP 10.6</i>	Bützler, R.	2021	GLOB1913H: Effects on terrestrial (non-target) plants: vegetative vigour test 155401087 Ibacon GmbH GLP Unpublished	N	Globachem NV
KCP 5.1.2	Jonchère F.	2010	Validation of the Analytical Method for the Determination of Prosulfocarb Residues in Potato Tubers, Sunflower Seeds and Winter Wheat Whole Plant + Amendment 1 to final report No R A9085 (2014)	N	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Anadiag R A9085 GLP Unpublished		

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
None					

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

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

Appendix 2 Detailed evaluation of submitted analytical methods

A 2.1 Analytical methods for prosulfocarb

A 2.1.1 Methods used for the generation of pre-authorization data (KCP 5.1)

Reference is made to 5.2.1 for a summary of the method used to determine the active substance in the formulated product.

A 2.1.1.1 Analytical method for prosulfocarb in cereals

A 2.1.1.1.1 Method validation

Comments of zRMS:	The analytical phase of the study No R A9085 is acceptable and suitable for the determination of the active substance Prosulfocarb Residues in Potato Tubers, Sunflower Seeds and Winter Wheat Whole Plant. LOQ was 0.01 mg/kg. The study has been performed in compliance with Good Laboratory Practice and SANCO/825/00 rev. 8.1.
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Reference:	KCP 5.1.2
Report	Validation of the Analytical Method for the Determination of Prosulfocarb Residues in Potato Tubers, Sunflower Seeds and Winter Wheat Whole Plant + Amendment 1 to final report No. R A9085 (2014), Jonchère F, 2010, R A9085.
Guideline(s):	Yes, SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and Methods

The method is based on the following reference: “Foods of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE - QuEChERS-method.”

Residues are extracted with acetonitrile/acetic acid 99.9 : 0.1 % in the presence of magnesium sulfate and sodium chloride. After centrifugation the extract is purified with magnesium sulfate and PSA. The internal standard (triphenylphosphate in acetonitrile) and formic acid are added to the extract before analysis by liquid chromatography using a MS/MS detector with the following conditions:

Apparatus	UPLC /MS /MS
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Column

Description	BEH C18	Supplier	WATERS	Particles	1.7 µm
Internal diam. x length	2.1*100 mm	Supplier reference	186002352	Temperature	40 °C
Development Column ANADIAG Number	130	Stationary Phase	C18	Comment	-

Mobile phase

A =	Methanol HPLC/ H2O HPLC 20:80 + 5 mM ammonium acetate	C =	-
B =	Methanol HPLC/ H2O HPLC 90:10 + 5 mM ammonium acetate	D =	-

Sample temperature	15 ° C
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Elution

Elution	Time min	Flow ml/min	Composition (%)				Curve (type)
			A	B	C	D	
Pg1	0.00	0.40	100	0	-	-	1
Pg2	4.00	0.40	0	100	-	-	1
Pg3	6.40	0.40	0	100	-	-	1
Pg4	6.50	0.40	100	0	-	-	1
Pg5	8.00	0.40	100	0	-	-	1

Detector

IONISATION mode*	ES x	APCI
Polarity*	Pos x	Neg

*make a cross in the right choice

Active ingredient(s)	Cone voltage	Collision Voltage	Dwell time (ms)	TRANSITION 1	TRANSITION 2	RT (min.)
				Parent > Daughter	Parent > Daughter	
Prosulfocarb	20	15	50	252.1 > 91.2	-	≈ 4.8
	25	10		-	252.1 > 128.3	≈ 4.8
Triphenyl phosphate	40	27		327.0 > 215.0	-	≈ 4.5

Results and Discussion

The results of the validation of the 252.1 > 91.2 transition are given below and show that the method meets the requirements of the SANCO 825/00 rev. 8.1:

- Linearity:

The linearity of the method was studied in matrix-matched calibration solutions between 3 ng/mL to 120 ng/mL of Prosulfocarb for potato tubers and sunflower seeds, and between 2 ng/mL to 60 ng/mL of Prosulfocarb for winter wheat whole plant. The linear correlation coefficients were typically > 0.990, showing a good linearity.

- Sensitivity:

The limit of quantification (LOQ) is the lowest validated level where a mean recovery within the range 70-110 % with a RSD less than 20 % could be obtained.

The LOQ was set at 0.01 mg/kg in potato tubers, sunflower seeds and winter wheat whole plant.

- Precision:

Repeatability tests (5 recoveries at each fortification level) were performed at LOQ level and at 10 x LOQ for each matrix.

	Prosulfocarb
RSD for each fortification level	1.2 to 9.3 %
Overall RSD per sample material	2.0 to 10.8 %

All RSD determined were less than 20%, the method therefore fulfills the requirements of residue analytical methods.

- Recovery/accuracy:

The recovery results are presented hereunder. The accuracy of the method fulfills the requirements for residue analytical methods which demand that the mean recoveries per fortification level should be in the range 70-110 %.

Matrix	Active ingredient	Fortification level (mg/kg)	Mean recovery (%)	Standard deviation (SD) (%)	Relative standard deviation (RSD) (%)	Number of fortified samples (n)
Potato tubers	Prosulfocarb	0.01	88.2	8.2	9.3	5
		0.10	101.3	7.6	7.5	5
		All levels	94.7	10.2	10.8	10
Sunflower seeds	Prosulfocarb	0.01	91.4	1.1	1.2	5
		0.10	88.7	1.1	1.3	5
		All levels	90.0	1.8	2.0	10
Winter wheat whole plant	Prosulfocarb	0.01	107.3	1.6	1.5	5
		0.10	105.3	3.9	3.7	5
		All levels	106.3	3.0	2.8	10

- Specificity:

Analysis of Prosulfocarb in LC/MS-MS, with monitoring of two transitions is considered as specific, thus the use of an alternative method was not necessary. However, to meet the requirements of the SANCO 825/00 rev. 8.1, the validation data of a second transition are provided below.

Table A 1: Validation data for a second transition at 0.01 ppm (252.1 > 128.3)

Crop/Matrix	Study	Analytical method
Winter wheat whole plant	Validation	Prosulfocarb in the untreated (n=2): <LOD Linearity: $R^2 = 0.996$ Recovery whole plant (n=5): 99.7-108.1 (mean = 104.6%) Precision whole plant (n=5): 3.3%
Sunflower seeds	Validation	Prosulfocarb in the untreated (n=2): <LOD Linearity: $R^2 = 0.996$ Recovery sunflower (n=5): 84.3-92.2% (mean = 89%) Precision sunflower: RSD (n=5): 3.3%
Potato tubers	Validation	Prosulfocarb in the untreated (n=2): <LOD Linearity: $R^2 = 0.996$ Recovery potato (n=5): 71.4-91.3% (mean = 86.2%) Precision potato: RSD (n=5): 9.7%

Conclusion

The method meets the requirement of the SANCO 825/00 rev. 8.1 and can be used to reliably and accurately determine prosulfocarb in potato tubers, sunflowers and winter wheat to a limit of quantification of 0.01 mg/kg.

A 2.1.1.1.2 Analytical methods in water used in aquatic toxicity studies

A 2.1.1.1.2.1 Method validation

Comments of zRMS:	The analytical method of the study ENV8187/110707 is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of quantitation (LOQ) were 0.008 mg/L.
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Reference: KCP 5.2.1 (Submitted as KCA 8.2.6.1)

Report: The growth inhibition of Prosulfocarb Technical to the alga *Scenedesmus subspicatus* over a 72 hour exposure period, Sacker D., 2008b, ENV8187/110707

Guideline(s): Yes, OECD 201

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

The samples were diluted in deionised water.

Standard solutions were diluted in acetonitrile.

All samples were analysed using HPLC-UV.

Results and discussions

Table A 2: Recovery results from method validation of prosulfocarb using the analytical method

Matrix	Analyte	Fortification level (mg/L) (n = x)	Mean recovery (%)	RSD (%)
Test medium	Prosulfocarb	2.434 (5)	55.8	3.77

Table A 3: Characteristics for the analytical method used for validation of prosulfocarb in test medium

	Prosulfocarb
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	Linear

	Prosulfocarb
	y= 363569x r ² = 1.00 number of data points: 9
Calibration range	0.008-25.974 mg/L
Assessment of matrix effects is presented	yes
Limit of quantification	0.008 mg/L

Conclusion

The method was sufficiently validated according to SANCO/3029/99 Rev. 4 and can be used for analytical determination of prosulfocarb in test medium.

Comments of zRMS:	The analytical method of the study 155401210 is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of detection (LOD) and quantitation (LOQ) were at 0.017 µg/L / 0.01 mg/L, respectively.
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Reference:	KCP 5.2.1 (Submitted as KCP 10.2.1)
Report	GLOB1913H: acute toxicity to <i>Daphnia magna</i> in a static 48-hour immobilisation test, Siche O., Wydra V., 2021a, 155401220
Guideline(s):	Yes, OECD 202 (2004)
Deviations:	Yes, the test item instead of the reference item was used to prepare the chromatographic stock and standard solutions. This has no impact on the study since the identity of the analyte was confirmed by the high specificity of the mass transitions.
GLP:	Yes
Acceptability:	Yes

Materials and methods

The samples were thawed at room temperature, shaken well and treated with ultrasounds for 1 minute to obtain homogenous samples. The samples were already diluted with acetonitrile by factor 2 directly after sampling. The samples were diluted further with acetonitrile/test water (1/1, v/v) to match the calibration range, if necessary.

Standard solutions were dissolved in acetonitrile/test water (1/1, v/v).

All samples were analysed using LC-MS/MS.

Results and discussions

Table A 4: Recovery results from method validation of prosulfocarb using the analytical method

Matrix	Analyte	Fortification level (mg/L) (n = x)	Mean recovery (%)	RSD (%)
Test medium	Prosulfocarb	0.01 (5)	95	2
		2 (5)	94	6
		Overall (10)	95	4

Table A 5: Characteristics for the analytical method used for validation of prosulfocarb in test medium

	Prosulfocarb
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	Linear y= 658144147.65844147 x+107431 r ² = 0.9988 number of data points: 7
Calibration range	0.005 – 0.1 mg/L
Assessment of matrix effects is presented	yes
Limit of detection/quantification	0.017 µg/L / 0.01 mg/L

Conclusion

The method was sufficiently validated according to SANCO/3029/99 Rev. 4 and can be used for analytical determination of prosulfocarb in test medium.

Comments of zRMS:	The analytical method of the study 155401210 is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of detection (LOD) and quantitation (LOQ) were at 0.017 µg/L and 0.002 mg/L, respectively.
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Reference:	KCP 5.2.1 (Submitted as KCP 10.2.1)
Report	GLOB1913H: toxicity to <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test, Siche O., Wydra V., 2021b, 155401210
Guideline(s):	Yes, OECD 201 (2011)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The samples were thawed at room temperature, shaken well and treated with ultrasounds for 1 minute to obtain homogenous samples. The samples were already diluted with acetonitrile by factor 2 directly after

sampling. The samples were diluted further with acetonitrile/test water (1/1, v/v) to match the calibration range, if necessary. The samples were centrifuged before analysis to remove the algae.

Standard solutions were dissolved in acetonitrile/test water (1/1, v/v).

All samples were analysed using LC-MS/MS.

Results and discussions

Table A 6: Recovery results from method validation of prosulfocarb using the analytical method

Matrix	Analyte	Fortification level (mg/L) (n = x)	Mean recovery (%)	RSD (%)
Test medium	Prosulfocarb	0.0025 (5)	83	2
		0.6 (5)	99	3
		Overall (10)	91	9

Table A 7: Characteristics for the analytical method used for validation of prosulfocarb in test medium

	Prosulfocarb
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	Linear y= 166336162x+75775 r ² = 0.9995 number of data points: 6
Calibration range	0.001 – 0.075 mg/L
Assessment of matrix effects is presented	yes
Limit of detection/quantification	0.017 µg/L / 0.002 mg/L

Conclusion

The method was sufficiently validated according to SANCO/3029/99 Rev. 4 and can be used for analytical determination of prosulfocarb in test medium.

Comments of zRMS:	The analytical method of the study 155401240 is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of detection (LOD) and quantitation (LOQ) were at 0.04 µg/L and 0.009 mg/L, respectively.
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Reference: KCP 5.2.1 (Submitted as KCP 10.2.1)

Report GLOB1913H: Toxicity to the aquatic plant *Lemna gibba* in a static growth inhibition test, Siche O., Wydra V., 2021c, 155401240

Guideline(s): Yes, OECD 221 (2006); SANCO/3029/99 Rev. 4

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

The samples were thawed at room temperature, shaken well and treated with ultrasounds for 1 minute to obtain homogenous samples. The samples were already diluted with acetonitrile by factor 2 directly after sampling. The samples were diluted further with acetonitrile/test water (1/1, v/v) to match the calibration range, if necessary.

Standard solutions were dissolved in acetonitrile/test water (1/1, v/v).

All samples were analysed using LC-MS/MS.

Results and discussions

Table A 8: Recovery results from method validation of prosulfocarb using the analytical method

Matrix	Analyte	Fortification level (mg/L) (n = x)	Mean recovery (%)	RSD (%)
Test medium	Prosulfocarb	0.01 (5)	102	4
		2.5 (5)	94	3
		Overall (10)	98	5

Table A 9: Characteristics for the analytical method used for validation of prosulfocarb in test medium

	Prosulfocarb
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	Linear y= 120678984x+37389 r ² = 0.9993 number of data points: 7
Calibration range	0.001 – 0.075 mg/L
Assessment of matrix effects is presented	yes
Limit of detection/quantification	0.04 µg/L / 0.009 mg/L

Conclusion

The method was sufficiently validated according to SANCO/3029/99 Rev. 4 and can be used for analytical determination of prosulfocarb in test medium.

Comments of zRMS:	The analytical method of the study 155401215 is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of detection (LOD) and quantitation (LOQ) were at LOD 0.07 µg/L and LOQ 0.004 mg/L (water); LOQ 0.85 mg/kg (sediment), respectively.
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Reference:	KCP 5.2.1 (Submitted as KCP 10.2.1)
Report	GLOB1913H: Toxicity to the aquatic plant <i>Myriophyllum spicatum</i> in a static growth inhibition test with a prior rooting phase, Siche O., Wydra V., 2021d, 155401215
Guideline(s):	Yes, OECD 239 (2014); SANCO/3029/99 Rev. 4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test media (overlying and pore water):

The samples were thawed at room temperature, shaken well and treated with ultrasounds for 1 minute to obtain homogenous samples. The samples were already diluted with acetonitrile by factor 2 directly after sampling. The samples were diluted further with acetonitrile/test water (1/1, v/v) to match the calibration range, if necessary. The pore water samples were centrifuged before analysis.

Sediment:

To approximately 5 g of sediment, 10 mL of acetonitrile/test water (9/1, v/v) were added and ultrasonicated for 5 min. The mixture was shaken and afterwards centrifuged. The overlying extract was removed. Additional 10 mL of acetonitrile/test water (9/1, v/v) were given to the sediment and ultrasonicated for 5 min. The mixture was shaken and afterwards centrifuged and the extract was removed. An aliquot of the combined extract was diluted with acetonitrile/test water (1/1, v/v) and analysed.

Standard solutions were dissolved in acetonitrile/test water (1/1, v/v).

All samples were analysed using LC-MS/MS.

Results and discussions

Table A 10: Recovery results from method validation of prosulfocarb using the analytical method

Matrix	Analyte	Fortification level (n = x)	Mean recovery (%)	RSD (%)
Test medium	Prosulfocarb	0.005 mg/L (5)	88	6
		3 mg/L (5)	88	3
		Overall (10)	88	5
Sediment		0.005 mg/kg d.w. (5)	82	2
		3 mg/kg d.w. (5)	91	5
		Overall (10)	87	8

Table A 11: Characteristics for the analytical method used for validation of prosulfocarb in test medium

	Prosulfocarb
Specificity	blank value < 30 % LOQ

	Prosulfocarb
Calibration (type, number of data points)	Linear $y = 180084932x + 164281$ $r^2 = 0.9996$ $y = 104518450x + 105543$ $r^2 = 0.9985$ $y = 266603498x + 140988$ $r^2 = 0.9997$ number of data points: 7
Calibration range	0.001 – 0.075 mg/L
Assessment of matrix effects is presented	yes
Limit of detection/quantification	LOD/LOQ 0.07 µg/L / 0.004 mg/L (water) LOQ 0.85 mg/kg (sediment)

Conclusion

The method was sufficiently validated according to SANCO/3029/99 Rev. 4 and can be used for analytical determination of prosulfocarb in test medium (overlying and pore water) and sediment.

Comments of zRMS:	The analytical method of the study 13 10 48 018 W is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of quantitation (LOQ) were 0.022 mg/L.
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Reference:	KCP 5.2.1 (Submitted as KCP 10.2.1)
Report	Effects of prosulfocarb 800 EC on <i>Myriophyllum spicatum</i> in a growth inhibition test under semi-static test conditions, Juckeland D., 2013a, 13 10 48 018 W
Guideline(s):	Yes, ASTM Designated E 1913-04; SANCO/3029/99 rev. 4.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The samples were thawed at room temperature and diluted with test medium.

Standard solutions were dissolved in methanol and diluted in water.

All samples were analysed using HPLC-MS/MS.

Results and discussions

Table A 12: Recovery results from method validation of prosulfocarb using the analytical method

Matrix	Analyte	Fortification level (n = x)	Mean recovery (%)	RSD (%)
Modified	Prosulfocarb	0.022 mg/L (5)	93	7.6

Matrix	Analyte	Fortification level (n = x)	Mean recovery (%)	RSD (%)
Andrew's medium		1.039 mg/L (5)	88	2.8
		11.05 mg/L (5)	80	2.9

Table A 13: Characteristics for the analytical method used for validation of prosulfocarb in test medium

	Prosulfocarb
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	Quadratic $y = 4615.020x^2 + 33176.941x + 53211.83$ $r^2 = 0.9994$ number of data points: 6
Calibration range	0.017 – 1.243 mg/L
Assessment of matrix effects is presented	yes
Limit of quantification	0.022 mg/L

Conclusion

The method was sufficiently validated according to SANCO/3029/99 Rev. 4 and can be used for analytical determination of prosulfocarb in modified Andrew's medium.

Comments of zRMS:	The analytical method of the study 12 10 48 057 W is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of quantitation (LOQ) were 6.21 µg/L.
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Reference:	KCP 5.2.1 (Submitted as KCA 8.2.6.1)
Report	Effects of Prosulfocarb sulfoxide on <i>Chlamydomonas reinhardtii</i> in an algal growth inhibition test, Juckeland D., 2012a, 12 10 48 057 W
Guideline(s):	Yes, OECD 201; SANCO/3029/99 Rev. 4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The samples were thawed at room temperature, homogenized by shaking and aliquots filled into autosampler vials.

Standard solutions were dissolved in methanol and diluted in water.

All samples were analysed using HPLC-MS/MS (m/z 160.1) and UV/VIS (250 nm).

Results and discussions

Table A 14: Recovery results from method validation of prosulfocarb sulfoxide using the analytical method

Matrix	Analyte	Detection method	Fortification level (µg/L) (n = x)	Mean recovery (%)	RSD (%)
Test medium	Prosulfocarb sulfoxide	MS	6.21 (5)	97	2.5
			577.80 (5)	99	1.3
		UV	577.80 (5)	100	0.9
			UV detection could not be successfully validated, the sensitivity was too low. The results of the UV detector are reported as additional information.		

Table A 15: Characteristics for the analytical method used for validation of prosulfocarb sulfoxide residues in test medium

	Prosulfocarb sulfoxide
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	UV: Linear $y = 81.6976x - 83.746$ $r^2 = 0.9999$ MS/MS: Quadratic $y = 2.918629x^2 + 4249.561x + 11575.14$ $r^2 = 0.9993$ number of data points: 7
Calibration range	4.97 – 597.306 µg/L – 597.06 µg/L
Assessment of matrix effects is presented	yes
Limit of quantification	6.21 µg/L

Conclusion

The method was sufficiently validated according to SANCO/3029/99 Rev. 4 and can be used for analytical determination of prosulfocarb sulfoxide in test medium.

Comments of zRMS:	The analytical method of the study 12 10 48 059 W is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of quantitation (LOQ) were 38 µg/L.
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Reference:	KCP 5.2.1 (Submitted as KCA 8.2.6.1)
Report	Effects of Prosulfocarb sulfoxide on <i>Chlorella vulgaris</i> in an algal growth inhibition test, Juckeland D., 2012b, 12 10 48 059 W
Guideline(s):	Yes, OECD 201; SANCO/3029/99 Rev. 4
Deviations:	No

GLP: Yes

Acceptability: Yes

Materials and methods

The samples were thawed at room temperature, homogenized by shaking and aliquots filled into autosampler vials.

Standard solutions were dissolved in methanol and diluted in water.

All samples were analysed using HPLC-MS/MS (m/z 160.1) and UV/VIS (250 nm).

Results and discussions

Table A 16: Recovery results from method validation of prosulfocarb sulfoxide using the analytical method

Matrix	Analyte	Detection method	Fortification level (µg/L) (n = x)	Mean recovery (%)	RSD (%)
Test medium	Prosulfocarb sulfoxide	MS	38.0 (5)	104	3.5
			2003 (5)	98	5.4
		UV	38.0 (5)	89	5.3
			2003 (5)	100	1.0

Table A 17: Characteristics for the analytical method used for validation of prosulfocarb sulfoxide residues in test medium

	Prosulfocarb sulfoxide
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	UV: Linear $y = 44.3018x + 163.337$ $r^2 = 0.9999$ MS/MS: Quadratic $y = 0.2051259x^2 + 1214.308x + 14167.29$ $r^2 = 0.9994$ number of data points: 6
Calibration range	4 – 2407.5 µg/L
Assessment of matrix effects is presented	yes
Limit of quantification	38 µg/L

Conclusion

The method was sufficiently validated according to SANCO/3029/99 Rev. 4 and can be used for analytical determination of prosulfocarb sulfoxide in test medium.

Comments of zRMS:	The analytical method of the study 12 10 48 058 W is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of quantitation (LOQ) were 100.15 µg/L.
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Reference:	KCP 5.2.1 (Submitted as KCA 8.2.6.2)
Report	Effects of Prosulfocarb sulfoxide on <i>Anabaena flos-aquae</i> in an algal growth inhibition test, Juckeland D., 2012c, 12 10 48 058 W
Guideline(s):	Yes, OECD 201; SANCO/3029/99 Rev. 4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The samples were thawed at room temperature, homogenized by shaking and aliquots filled into autot sampler vials.

Standard solutions were dissolved in methanol and diluted in water.

All samples were analysed using HPLC-MS/MS (m/z 160.1) and UV/VIS (250 nm).

Results and discussions

Table A 18: Recovery results from method validation of prosulfocarb sulfoxide using the analytical method

Matrix	Analyte	Detection method	Fortification level (µg/L) (n = x)	Mean recovery (%)	RSD (%)
Test medium	Prosulfocarb sulfoxide	MS	3100.15 (5) 100.15 (5)	101.34	1.9
			1637 (5)	98	3.2
			51039 (5)	92	2.5
		UV	3100.15 (5) 100.15 (5)	93	5.7
			1637 (5)	101	1.5
			51039 (5)	103	0.3

Table A 19: Characteristics for the analytical method used for validation of prosulfocarb sulfoxide residues in test medium

	Prosulfocarb sulfoxide
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	UV: Linear $y = 18.4253x + 129.72$ $r^2 = 0.9999$ MS/MS:

	Prosulfocarb sulfoxide
	Quadratic $y = 0.1192590x^2 + 706.9643x + 32486.08$ $r^2 = 0.9995$ number of data points: 5
Calibration range	80.12 – 2003.04 µg/L
Assessment of matrix effects is presented	yes
Limit of quantification	100.15 µg/L

Conclusion

The method was sufficiently validated according to SANCO/3029/99 Rev. 4 and can be used for analytical determination of prosulfocarb sulfoxide in test medium.

Comments of zRMS:	The analytical method of the study 12 10 48 053 W is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of quantitation (LOQ) were 100.2 µg/L.
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Reference:	KCP 5.2.1 (Submitted as KCA 8.2.6.2)
Report	Effects of Prosulfocarb sulfoxide on <i>Navicula pelliculosa</i> in an algal growth inhibition test, Juckeland D., 2012d, 12 10 48 053 W
Guideline(s):	Yes, OECD 201; SANCO/3029/99 Rev. 4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The samples were thawed at room temperature, homogenized by shaking and aliquots filled into autosampler vials.

Standard solutions were dissolved in methanol and diluted in water.

All samples were analysed using HPLC-MS/MS (m/z 160.1) and UV/VIS (250 nm).

Results and discussions

Table A 20: Recovery results from method validation of prosulfocarb sulfoxide using the analytical method

Matrix	Analyte	Detection method	Fortification level (µg/L) (n = x)	Mean recovery (%)	RSD (%)
Test medium	Prosulfocarb sulfoxide	MS	100.2 (5)	95.9	4.2
			1541 (5)	91	1.3

Matrix	Analyte	Detection method	Fortification level (µg/L) (n = x)	Mean recovery (%)	RSD (%)
			50076 (5)	90	2.7
		UV	100.2 (5)	99	3.1
			15417 (5)	101	1.8
			50076 (5)	97	2

Table A 21: Characteristics for the analytical method used for validation of prosulfocarb sulfoxide residues in test medium

	Prosulfocarb sulfoxide
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	UV: Linear $y = 43.4484x - 290.748$ $r^2 = 0.9998$ MS/MS: Quadratic $y = 0.2507586x^2 + 1328.515x + 88046.21$ $r^2 = 0.9985$ number of data points: 5
Calibration range	78.1 – 2003.0 µg/L
Assessment of matrix effects is presented	yes
Limit of quantification	100.2 µg/L

Conclusion

The method was sufficiently validated according to SANCO/3029/99 Rev. 4 and can be used for analytical determination of prosulfocarb sulfoxide in test medium.

Comments of zRMS:	The analytical method of the study 12 10 48 060 W is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of quantitation (LOQ) were 10.76 µg/L.
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Reference:	KCP 5.2.1 (Submitted as KCA 8.2.6.2)
Report	Effects of Prosulfocarb sulfoxide on <i>Skeletonema costatum</i> in an algal growth inhibition test, Juckeland D., 2012e, 12 10 48 060 W
Guideline(s):	Yes, OECD 201; SANCO/3029/99 Rev. 4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The samples were thawed at room temperature, homogenized by shaking and aliquots filled into autosampler vials.

Standard solutions were dissolved in methanol and diluted in water.

All samples were analysed using HPLC-UV/VIS (250 nm 225 nm).

Results and discussions

Table A 22: Recovery results from method validation of prosulfocarb sulfoxide using the analytical method

Matrix	Analyte	Detection method	Fortification level (µg/L) (n = x)	Mean recovery (%)	RSD (%)
Test medium	Prosulfocarb sulfoxide	UV	10.76 (5)	99	4.5
			606.7 (5)	109	1.7

Table A 23: Characteristics for the analytical method used for validation of prosulfocarb sulfoxide residues in test medium

	Prosulfocarb sulfoxide
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	Linear y= 800.23x – 925.649 r ² = 0.9999 number of data points: 6
Calibration range	8.59 – 722.25 µg/L
Assessment of matrix effects is presented	yes
Limit of quantification	10.76 µg/L

Conclusion

The method was sufficiently validated according to SANCO/3029/99 Rev. 4 and can be used for analytical determination of prosulfocarb sulfoxide in test medium.

Comments of zRMS:	The analytical method of the study 13 10 48 017 W is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of quantitation (LOQ) were 2 µg/L.
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Reference:	KCP 5.2.1 (Submitted as KCA 8.2.7)
Report	Effects of prosulfocarb sulfoxide on <i>Myriophyllum spicatum</i> in a growth inhibition test under semi-static test conditions, Juckeland D., 2013b, 13 10 48 017 W
Guideline(s):	Yes, ASTM Designated E 1913-04; SANCO/3029/99 Rev. 4
Deviations:	No
GLP:	Yes

Acceptability: Yes

Materials and methods

The samples were thawed at room temperature and injected without further treatment.

Standard solutions were dissolved in methanol and diluted in water.

All samples were analysed using HPLC-MS/MS.

Results and discussions

Table A 24: Recovery results from method validation of prosulfocarb sulfoxide using the analytical method

Matrix	Analyte	Fortification level (n = x)	Mean recovery (%)	RSD (%)
Modified Andrew's medium	Prosulfocarb sulfoxide	1.995 µg/L (5)	94	13.1
		137.6 µg/L (5)	87	3.1

Table A 25: Characteristics for the analytical method used for validation of prosulfocarb sulfoxide in test medium

	Prosulfocarb sulfoxide
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	Quadratic $y = 0.0894x^2 + 200.9513x + 39.4073$ $r^2 = 0.9997$ number of data points: 7
Calibration range	1.648 – 164.823 µg/L
Assessment of matrix effects is presented	yes
Limit of quantification	2 µg/L

Conclusion

The method was sufficiently validated according to SANCO/3029/99 Rev. 4 and can be used for analytical determination of prosulfocarb sulfoxide in modified Andrew's medium.

A 2.1.1.1.3 Analytical methods in soil used in ecotoxicological studies

A 2.1.1.1.3.1 Method validation

Comments of zRMS:	The analytical method of the study 14 10 48 008 F is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of detection (LOD) and quantitation (LOQ) were at ≤ 30% of LOQ and 0.1 mg/kg respectively.
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Reference:	KCP 5.2.1 (Submitted as KCP 10.4.1.2)
Report	Effects of Prosulfoarb 800 g/L EC on earthworms under field conditions, Schulz L., Biochem Agrar, 14 10 48 008 F
Guideline(s):	Yes, ISO 11268-3 (1999), Kula <i>et al.</i> , 2006 - Technical recommendations to ISO 11268-3; SANCO/3029/99 Rev.4
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	/

Materials and methods

The soil dry weight was determined by heating soil aliquots to a temperature of 105 °C and keeping them at that temperature until the soil weight was constant. The soil moisture analysis was carried out once for each soil specimen. 10 g of soil were weighed into an evaporating dish and thoroughly blended with 5 g of sea sand. A 22 mL extraction cell was closed at one end of the tube with a screw cap. Two round filters were placed into the bottom of the extraction cell and covered with a 0.5 cm layer of sea sand. The specimen was transferred into the extraction cell using a powder funnel. The evaporating dish and the powder funnel were rinsed with sea sand which was subsequently added to the cell. At this stage, the standard solution was applied to the blended soil/sea sand mixtures destined for fortification. The content of the cell was pressed using a piston to secure a firm consistency and filled up with sea sand to about 1 mm below the top of the cell tube. It was covered with a round filter and screwed hand-tight with another screw cap. The extraction was carried out using ASE (accelerated solvent extraction). The eluate of the ASE cell was transferred into a 50 mL volumetric flask, then filled up to the mark with “dilution solution” (CH₃OH/H₂O/HCOOH; 70/30/0.1; v/v/v) and mixed. An aliquot of approximately 1 mL of this final solution was filtered through an 0.2 µm PTFE filter into an injection vial and analysed using LC-MS/MS. Extracts above the calibration range were diluted with methanol/ultra pure water; 1/1; v/v. Standard solution in methanol were diluted with water in range of 0.251 to 15.06 ng/mL

Results and discussions

Table A 26: Recovery results from method validation of prosulfocarb using the analytical method

Matrix	Analyte	Fortification level (mg/kg) (n = x)	Mean recovery (%)	RSD (%)
Soil	Prosulfocarb	0.1 (5)	101	1.9
		1.0 (5)	103.9	1.3
		Overall (10)	102.4	2.1

Table A 27: Characteristics for the analytical method used for validation of prosulfocarb residues in soil

	Prosulfocarb
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	Linear y = - 6516x + 446.3 r ² = 0.9999

	Prosulfocarb
Specificity	blank value < 30 % LOQ
	number of data points: 8
Calibration range	0.251 – 15.06 ng/mL
Assessment of matrix effects is presented	yes
Limit of determination/quantification	≤ 30% of LOQ / 0.1 mg/kg

Conclusion

The method was sufficiently validated according to SANCO/3029/99, Rev.4 and can be used for analytical determination of prosulfocarb in soil.

Comments of zRMS:	The analytical method of the study ENV8333/040822 is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of detection (LOD) and quantitation (LOQ) were at 0.01 mg/L and 0.02 mg/L respectively.
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Reference:	KCP 5.2.1 (Submitted as KCA 8.1.3)
Report	The bioaccumulation potential of prosulfocarb in earthworm (<i>Eisenia foetida</i>), Sacker D., 2008a, ENV8333/040822
Guideline(s):	Yes, OECD Guideline for Testing of Chemicals 207: Earthworm acute toxicity tests (1984), OECD Guideline for Testing of Chemicals 222: Earthworm Reproduction Test (<i>Eisenia fetida</i> / <i>Eisenia andrei</i>) (2004), OECD Guidelines for Testing of Chemicals 305, Bioconcentration: Flow-through Fish Test. (2006), OECD Guidelines for Testing of Chemicals, Bioaccumulation in sediment-dwelling Benthic Oligochaetes (Proposed December 2007)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Soil samples: extraction of the test sediment with dichloromethane/acetone in presence of sodium sulphate. Evaporation and redissolution in acetonitrile

Earthworm samples: the worms were ground and extracted with acetonitrile/acetone. Evaporation and redissolution in acetonitrile.

Standard solutions were diluted in acetonitrile.

All samples were analysed using HPLC-UV (220 nm) 228nm.

Results and discussions

Table A 28: Recovery results from method validation of prosulfocarb using the analytical method

Matrix	Analyte	Fortification level (mg/L) (n = x)	Mean recovery (%)	RSD (%)
Soil	Prosulfocarb	2.5 (5)	99.9	1.18

Table A 29: Characteristics for the analytical method used for validation of prosulfocarb residues in soil

	Prosulfocarb
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	Linear y= - 363269x + 5923.8 r ² = 1.0 number of data points: 9
Calibration range	0.028 – 25 mg/L
Assessment of matrix effects is presented	yes
Limit of determination/quantification	0.01 mg/L / 0.02 mg/L

Conclusion

The method can be used for analytical determination of prosulfocarb in the earthworm bioaccumulation study.

A 2.1.1.1.4 Analytical methods used in other ecotoxicological studies

A 2.1.1.1.4.1 Method validation

Comments of zRMS:	The analytical method of the study 155401105 is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of detection (LOD) and quantitation (LOQ) were at 0.3 mg/L and 6.0 mg/L, respectively.
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Reference: KCP 5.2.1 (Submitted as KCP 10.3.1.1.1)

Report GLOB1913H: Acute contact and oral toxicity to bumblebees (*Bombus terrestris* L.) in the laboratory, Chwiesko D., 2021, 155401105

Guideline(s): Yes, OECD 246 and OECD 247 (2017); SANCO/3029/99 Rev.4

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

An aliquot of each sample was diluted in acetonitrile/pure water (50/50 v/v) while solutions were stirring.

All samples were analysed by HPLC-UV.

All standards were prepared in acetonitrile/pure water (50/50 v/v).

Results and discussions

Table A 30: Recovery results from method validation of prosulfocarb using the analytical method

Matrix	Analyte	Fortification level (g/L) (<i>n</i> = <i>x</i>)	Mean recovery (%)	RSD (%)
Contact application solution	Prosulfocarb	11 (5)	108	4
		275 (5)	106	4
		Overall (10)	107	4
Oral feeding solution		0.68 (5)	97	10
		17 (5)	100	1
		Overall (10)	98	7

Table A 31: Characteristics for the analytical method used for validation of prosulfocarb residues in the contact application solution

	Prosulfocarb
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	Linear $y = 14194x - 1553$ $r^2 > 0.9996$ number of data points: 6
Calibration range	2 – 20 mg/L
Assessment of matrix effects is presented	yes
Limit of quantification/determination	0.3 mg/L / 9.7 mg/L

Table A 32: Characteristics for the analytical method used for validation of prosulfocarb residues in the oral feeding solution

	Prosulfocarb
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	Linear $y = 14194x - 1553$ $r^2 > 0.9996$ number of data points: 6
Calibration range	2 – 20 mg/L
Assessment of matrix effects is presented	yes
Limit of detection/quantification	0.3 mg/L / 6.0 mg/L

Conclusion

The method was sufficiently validated according to SANCO/3029/99 Rev.4 and can be used for analytical determination of prosulfocarb in the contact application solution and oral feeding solution.

Comments of zRMS:	The analytical method of the study 155401105 155401136 is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of detection (LOD) and quantitation (LOQ) were at 0.2 mg/L and 4.3 mg/L, respectively.
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Reference:	KCP 5.2.1 (Submitted as KCP 10.3.1.2)
Report	GLOB1913H: Chronic oral toxicity test on the honey bees (<i>Apis mellifera</i> L.) in the laboratory, Berg C., 2021, 155401136
Guideline(s):	Yes, OECD 245 (2017); SANCO/3029/99 Rev.4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

An aliquot of each sample was diluted in acetonitrile/pure water (50/50 v/v). For feeding solutions 10000 mg a.i./kg first dilution step was conducted while solutions were stirring.

All samples were analysed by HPLC-UV.

All standards were prepared in acetonitrile/pure water (50/50 v/v).

Results and discussions

Table A 33: Recovery results from method validation of prosulfocarb using the analytical method

Matrix	Analyte	Fortification level (g/L) (n = x)	Mean recovery (%)	RSD (%)
Feeding solution	Prosulfocarb	0.5 (5)	96	5
		17 (5)	97	2
		Overall (10)	97	4

Table A 34: Characteristics for the analytical method used for validation of prosulfocarb residues in feeding solution

	Prosulfocarb
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	Linear

	Prosulfocarb
	$y = 9326x - 9526x + 274$ $r^2 = 0.9996$ number of data points: 6
Calibration range	2.5 – 25 mg/L
Assessment of matrix effects is presented	yes
Limit of detection/quantification	0.2 mg/L / 4.3 mg/L

Conclusion

The method was sufficiently validated according to SANCO/3029/99 Rev.4 and can be used for analytical determination of prosulfocarb in feeding solution.

Comments of zRMS:	<p>The analytical method of the study BT273/20 is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb.</p> <p>The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of detection (LOD) and quantitation (LOQ) were at 1.011 mg/L and 0.44 g/L, respectively.</p>
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Reference:	KCP 5.2.1 (Submitted as KCP 10.3.1.3)
Report	Effects of GLOB1913H on honey bees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure, Colli M., 2020, BT273/20
Guideline(s):	Yes, OECD 239 (2016)
Deviations:	Yes, during the test the temperature was out of the range for more than two hours. The deviations were minimal and did not affect the test results, as is also demonstrated because all the validity criteria were met.
GLP:	Yes
Acceptability:	Yes

Materials and methods

All samples were analysed by HPLC-DAD.

All standards were prepared in acetonitrile.

Results and discussions

Table A 35: Recovery results from method validation of prosulfocarb using the analytical method

Matrix	Analyte	Fortification level (g/L) (n = x)	Mean recovery (%)	RSD (%)
Water stock solution	Prosulfocarb	0.44 (5)	103.7	2.65
		16.4 (5)	106.7	0.47 0.44

Table A 36: Characteristics for the analytical method used for validation of prosulfocarb residues in water stock solution

	Prosulfocarb
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	Linear $y=15.976x+5.0908$ $r^2 = 0.9995$ number of data points: 5
Calibration range	1.011 – 10.1104 mg/L
Assessment of matrix effects is presented	yes
Limit of detection/quantification	1.011 mg/L / 0.44 g/L

Conclusion

The method was sufficiently validated according to SANCO/3029/99 Rev.4 and can be used for analytical determination of prosulfocarb in water stock solution.

Comments of zRMS:	The analytical method of the study 155401086 is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of detection (LOD) and quantitation (LOQ) were at 1 mg/L and 8.5 mg/L, respectively.
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Reference:	KCP 5.2.1 (Submitted as KCP 10.6)
Report	GLOB1913H: Effects on terrestrial (non-target) plant: seedling emergence and seedling growth test, Bützler R., 2021a, 155401086
Guideline(s):	Yes, OECD 208 (2006), SANCO/3029/99, Rev.4
Deviations:	For fresh weight, emergence, mortality, phytotoxicity and growth stages only 9 pots (18 seeds) were evaluated for the control group for <i>Solanum lycopersicum</i> instead of 10 pots with 2 seeds each because the soil of one pot silted up during the application procedure.
GLP:	Yes
Acceptability:	Yes

Materials and methods

An aliquot of each sample was diluted with acetonitrile/pure water (50/50 v/v) while solutions were stirring.

Standard solutions were diluted in acetonitrile.

All samples were analysed using HPLC-UV (210 nm).

Results and discussions

Table A 37: Recovery results from method validation of prosulfocarb using the analytical method

Matrix	Analyte	Fortification level (g/L) (n = x)	Mean recovery (%)	RSD (%)
Stock solution	Prosulfocarb	5 (5)	103	2
		10 (5)	103	2
		18 (4)	102	2
		100 (5)	102	4
		Overall (19)	103	3

Table A 38: Characteristics for the analytical method used for validation of prosulfocarb in stock solution

	Prosulfocarb
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	Linear $y = 13592 x + 3132$ $r^2 = 0.9997$ $y = 13622 x + 2961$ $r^2 = 0.9996$ number of data points: 6
Calibration range	2.5 – 25 mg/L
Assessment of matrix effects is presented	yes
Limit of determination/quantification	1 mg/L / 8.5 mg/L

Conclusion

The method was sufficiently validated according to SANCO/3029/99, Rev.4 and can be used for analytical determination of prosulfocarb in stock solution.

Comments of zRMS:	The analytical method of the study 155401087 is acceptable and suitable for the determination concentrations of the active ingredient Prosulfocarb. The study has been performed in compliance with Good Laboratory Practice and SANCO/3029/99 rev. 4. The limits of detection (LOD) and quantitation (LOQ) were at 0.3 mg/L and 7.7 mg/L, respectively.
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Reference:	KCP 5.2.1 (Submitted as KCP 10.6)
Report	GLOB1913H: Effects on terrestrial (non-target) plants: vegetative vigour test, Bützler R., 2021b, 155401087
Guideline(s):	Yes, OECD 227 (2006); SANCO/3029/99, Rev.4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

An aliquot of each sample was diluted with acetonitrile/pure water (50/50 v/v) while solutions were stirring.

Standard solutions were diluted in acetonitrile.

All samples were analysed using HPLC-UV (210 nm).

Results and discussions

Table A 39: Recovery results from method validation of prosulfocarb using the analytical method

Matrix	Analyte	Fortification level (g/L) (n = x)	Mean recovery (%)	RSD (%)
Stock solution	Prosulfocarb	18 (4)	102	2
		100 (5)	102	4
		Overall (9)	102	3

Table A 40: Characteristics for the analytical method used for validation of prosulfocarb in stock solution

	Prosulfocarb
Specificity	blank value < 30 % LOQ
Calibration (type, number of data points)	Linear $y = 13622 x + 2961$ $r^2 = 0.9996$ number of data points: 6
Calibration range	2.5 – 25 mg/L
Assessment of matrix effects is presented	yes
Limit of determination/quantification	0.3 mg/L / 7.7 mg/L

Conclusion

The method was sufficiently validated according to SANCO/3029/99, Rev.4 and can be used for analytical determination of prosulfocarb in stock solution.

A 2.1.2 Methods for post-authorization control and monitoring purposes (KCP 5.2)

A 2.1.2.1 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.2 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.3 Description of Methods for the Analysis of Soil (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.4 Description of Methods for the Analysis of Water (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.5 Description of Methods for the Analysis of Air (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.6 Description of Methods for the Analysis of Body Fluids and Tissues (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.7 A.2.A.9 Other Studies/ Information

No new or additional studies have been submitted