

REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

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

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After commenting period: 15/11/2023

Version history

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

Table of Contents

7	Metabolism and residue data (KCA section 6).....	5
7.1	Summary and zRMS Conclusion.....	5
7.1.1	Critical GAP(s) and overall conclusion	5
7.1.2	Summary of the evaluation	8
7.1.2.1	Summary for prosulfocarb	8
7.1.2.2	Summary for GLOB1913H.....	9
7.2	Prosulfocarb	10
7.2.1	Stability of Residues (KCA 6.1)	11
7.2.1.1	Stability of residues during storage of samples	11
7.2.1.2	Stability of residues in sample extracts (KCA 6.1).....	11
7.2.2	Nature of residues in plants, livestock and processed commodities	11
7.2.2.1	Nature of residue in primary crops (KCA 6.2.1)	11
7.2.2.2	Nature of residue in rotational crops (KCA 6.6.1).....	13
7.2.2.3	Nature of residues in processed commodities (KCA 6.5.1).....	13
7.2.2.4	Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)	14
7.2.2.5	Nature of residues in livestock (KCA 6.2.2-6.2.5)	14
7.2.2.6	Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)	14
7.2.3	Magnitude of residues in plants (KCA 6.3)	16
7.2.3.1	Summary of European data and new data supporting the intended uses	16
7.2.3.3	Conclusion on the magnitude of residues in plants	18
7.2.4	Magnitude of residues in livestock	19
7.2.4.1	Dietary burden calculation	19
7.2.4.2	Livestock feeding studies (KCA 6.4.1-6.4.3)	20
7.2.5	Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3).....	20
7.2.6	Magnitude of residues in representative succeeding crops.....	20
7.2.7	Other / special studies (KCA6.10, 6.10.1)	21
7.2.8	Estimation of exposure through diet and other means (KCA 6.9).....	21
7.2.8.1	Input values for the consumer risk assessment	21
7.2.8.2	Conclusion on consumer risk assessment	21
7.2.9	Acute consumer risk assessment from combined exposure.....	22
7.2.10	Chronic consumer risk assessment from combined exposure	22
7.3	References	23
Appendix 1	Lists of data considered in support of the evaluation.....	24
Appendix 2	Detailed evaluation of the additional studies relied upon	27
A 2.1	Prosulfocarb	27
A 2.1.1	Stability of residues.....	27
A 2.1.2	Nature of residues in plants, livestock and processed commodities	27
A 2.1.3	Magnitude of residues in plants	27
A 2.1.4	Magnitude of residues in livestock	31
A 2.1.5	Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)	31
A 2.1.6	Magnitude of residues in representative succeeding crops.....	31

A 2.1.7	Other/Special Studies	31
Appendix 3	Pesticide Residue Intake Model (PRIMo).....	44
Appendix 4	TMDI calculations	44
A 4.1	IESTI calculations - Raw commodities	46
A 4.2	IESTI calculations - Processed commodities.....	47

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

The critical GAPs with respect to consumer intake and risk assessment for the preparation GLOB1913H are presented in Table 7.1-1. They have been selected from the individual GAPs in the central EU for wheat and potato. A list of all intended uses within the central EU is given in Part B, Section 0.

Overall conclusion

Storage stability: Storage stability studies of prosulfocarb have been investigated in the framework of the EU peer review. These studies cover the requested uses for GLOB1913H.

Metabolism in plants: Studies demonstrated extensive metabolism of prosulfocarb in primary crops. The results of the confined rotational crop study show that the metabolism of prosulfocarb in rotated crops is similar for all investigated crop groups and indicated that the potential for uptake of prosulfocarb and its degradation products from the soil by the succeeding crops is low.

Processing: As residues of prosulfocarb exceeding 0.1 mg/kg are not expected in treated crops, the contribution of this crop to the TMDI is < 10% and the estimated daily intake is < 10% of the ARfD, investigation of the magnitude of residues in processed commodities is not needed.

Livestock dietary burdens: Due to the low exposure of livestock the MRLs of animal products are not expected to be exceeded after feeding when the product will be applied according to proposed GAP.

Magnitude of residues in plants: The residues arising from the proposed use will not exceed the MRLs for cereals and potato set at 0.01 mg/kg (Reg. (EU) 2023/129).

Residues in bee products: Cereals and potato are considered as non-melliferous crops. Therefore, only the exposure through non-target plants are relevant. Taking into account the application timing of the plant protection product as well as the metabolic pattern of prosulfocarb, no exceedance of the default MRL in honey is expected based on the proposed uses.

Chronic and acute exposure: The estimated long-term dietary intake is below the ADI and the IESTI value is below of ARfD. The proposed uses of prosulfocarb in the formulation GLOB1913H do not represent unacceptable chronic and acute risks for the consumers.

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 mg/kg for prosulfocarb as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of prosulfocarb residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, PL z RMS agrees with the authorization of the intended use(s).

Data gaps

Noticed data gaps are: none

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	Crop and/ or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
1	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	Central	GLOB1913H	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	EC	Prosulfocarb: 900 g/L	Downward spraying	Pre-emergence (BBCH 0-09)	1	-	Prosulfocarb: 1.2-2.3	155-300	Prosulfocarb: 3.6	NR	A
2	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	Central	GLOB1913H	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	EC	Prosulfocarb: 900 g/L	Downward spraying	Pre-emergence (BBCH 0-09)	1	-	Prosulfocarb: 1.05-2.0	155-300	Prosulfocarb: 3.15	NR	A
3	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	Central	GLOB1913H	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	EC	Prosulfocarb: 900 g/L	Downward spraying	BBCH 10-29	1	-	Prosulfocarb: 1.2-2.3	155-300	Prosulfocarb: 3.6	NR	A
4	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW),	Central	GLOB1913H	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	EC	Prosulfocarb: 900 g/L	Downward spraying	BBCH 10-29	1	-	Prosulfocarb: 1.05-2.0	155-300	Prosulfocarb: 3.15	NR	A

	Triticale (TTLWI)															
5	Potato (SOL-TU)	Central	GLOB1913H	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	EC	Prosulfocarb: 900 g/L	Downward spraying	Pre-emergence (BBCH 0-09)	1	-	Prosulfocarb: 1.32-2.55	155-300	Prosulfocarb: 3.96	NR	A
6	Potato (SOL-TU)	Central	GLOB1913H	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	EC	Prosulfocarb: 900 g/L	Downward spraying	Pre-emergence (BBCH 0-09)	1	-	Prosulfocarb: 1.05-2.0	155-300	Prosulfocarb: 3.15	NR	A
7	Winter durum wheat (TRZDW)	Central	GLOB1913H	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	EC	Prosulfocarb: 900 g/L	Downward spraying	Pre-emergence (BBCH 0-09)	1	-	Prosulfocarb: 0.78-1.51	155-300	Prosulfocarb: 2.34	NR	A
8	Winter durum wheat (TRZDW)	Central	GLOB1913H	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	EC	Prosulfocarb: 900 g/L	Downward spraying	BBCH 10-29	1	-	Prosulfocarb: 0.78-1.51	155-300	Prosulfocarb: 2.34	NR	A

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

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 "Conclusion"

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation GLOB1913H is composed of the active substance prosulfocarb.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of prosulfocarb

Reference value	Source	Year	Value	Study relied upon	Safety factor
Prosulfocarb					
ADI	EFSA	2007	0.005 mg/kg bw/d	2-year rat oral toxicity, supported by multi-generation study	100
ARfD	EFSA	2007	0.1 mg/kg bw	Rat, developmental toxicity	100

7.1.2.1 Summary for prosulfocarb

Table 7.1-3: Summary for prosulfocarb

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1-4	Winter cereals	Yes	Yes (36)	N/A	Yes	Yes	No	No
5+6	Potato	Yes	Yes (16)	N/A	Yes	Yes	No	No

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

As residues of prosulfocarb do not exceed the trigger values defined in Reg. (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

7.1.2.2 Summary for GLOB1913H

Table 7.1-4: Information on GLOB1913H (KCA 6.8)

Crop	PHI for GLOB1913H proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for GLOB1913H proposed by zRMS	zRMS Comments (if different PHI proposed)
		Prosulfocarb		
Cereals	NR	NR	-	
Potato	NR	NR	-	

NR: not relevant

* Purpose of withholding period to be specified

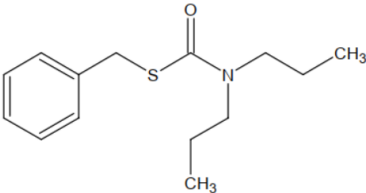
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Assessment

7.2 Prosulfocarb

General data on prosulfocarb are summarized in the table below (last updated 2021/04/19)

Table 7.2-1: General information on prosulfocarb

Active substance (ISO Common Name)	Prosulfocarb
IUPAC	S-benzyl dipropyl(thiocarbamate)
Chemical structure	
Molecular formula	C ₁₄ H ₂₁ NOS
Molar mass	251.4 g/mol
Chemical group	Thiocarbamate
Mode of action (if available)	Inhibition of lipid synthesis in the meristem
Systemic	Yes
Company (ies)	Syngenta*
Rapporteur Member State (RMS)	Sweden
Approval status	Approved Date of 01/11/2009 and reference to decision COMMISSION DIRECTIVE 2007/76/EC - REGULATION (EU) No 2019/1589 - REGULATION (EU) No 540/2011. Extension of the approval period - 31/01/2027 (Commission Implementing Regulation (EU) 2023/1757)
Restriction	Restricted to use as herbicide
Review Report	SANCO/2824/07 – rev. 3 10/09/2007
Current MRL regulation	Regulation (EU) No 777/2013 2023/129
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes, EFSA 2007
EFSA Journal: conclusion on article 12	Yes, EFSA 2011
Current MRL applications on intended uses	-

* Notifier in the EU process to whom the a.s. belong(s)

** If yes: EFSA, YYYY - see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Pea	High water content	18 months	Sweden, 2006
Wheat forage		25 months	Sweden, 2006
Dry bean and pea	High protein content	18 months	Sweden, 2006
Potato	High starch water content	18 months	Sweden, 2006
Wheat grain	High starch content	25 months	Sweden, 2006
Wheat straw	-	25 months	Sweden, 2006

Conclusion on stability of residues during storage

The storage stability of prosulfocarb in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2007, 2011). It was demonstrated that in crops assessed in the framework of this application, residues were stable for at least 18 months when stored at -18°C .

Storage stability studies of prosulfocarb in this section cover the requested uses for GLOB1913H.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Procedural recoveries obtained during residue analysis demonstrate the stability of residues of prosulfocarb in sample extracts and fully support the residue data presented in this submission.

In the DAR (2006) residues of prosulfocarb in sample extracts were considered to be stable within the time frame of whole analytical procedure for potatoes, grain, straw and forage.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Root and tuber vegetables	Potatoes	[¹⁴ C]phenyl	Soil spraying, F	3.42	1	Tubers: 105	-	Sweden, 2006
Pulses and oilseeds	Peas		Soil spraying, G	4.05	1	Shelled peas: maturity	-	Sweden, 2006
Cereals	Winter wheat		Soil spraying, F	3.64	1	Grain, straw: 283	-	Sweden, 2006
	Winter barley			4.00	1	Immature plant: 7, 14, 161 Grain, straw: 237	-	Sweden, 2007

Summary of plant metabolism studies reported in the EU

Metabolism studies conducted with crops representative of three different crop groups (cereal/grass: winter barley; spring barley and wheat; root vegetables: potato and carrot; pulses and oilseed: peas) have provided a detailed understanding of the metabolism of prosulfocarb in food and feed commodities. The metabolic pathways in the studies are similar and consequently the available crop metabolism studies fully support the current proposed uses of prosulfocarb on crops. The metabolism of ¹⁴C-prosulfocarb in plants is extensive.

Levels of organosoluble radioactivity are low in potatoes and contain a multi-component residue with only benzoic acid (3.1% TRR in potato tubers) identified as a prosulfocarb related metabolite. The nature of the residue is dominated by natural incorporation of the radiolabelled carbon. In potatoes, incorporation is associated mainly with starch, with over 70% of the radioactive residue present in this fraction. A similar pattern of metabolism is assumed to occur in wheat grain and straw where high levels (>50%) of radioactive residue are present in aqueous soluble and bound fractions after acid hydrolysis.

The metabolism of prosulfocarb following application to winter barley is complex and extensive. No prosulfocarb or related metabolites were detected in mature grain or straw. All observed chromatographic peaks in the grain and straw were <10% TRR and <0.05 mg/kg. The winter barley study confirms the rapid and extensive metabolism of parent to

natural products resulting in neither prosulfocarb nor structurally related metabolites being present in detectable quantities in mature crop commodities. Characterisation of the residues in immature barley foliage has allowed the identification of a number of prosulfocarb plant metabolites. In peas, incorporation is associated with proteins and carbohydrates, which account for *ca* 78% and *ca* 17% of the radioactive residue, respectively. The incorporation of radioactivity into the plant structure is assumed to be through assimilation of $^{14}\text{CO}_2$ produced from the extensive mineralisation of prosulfocarb in the soil. Soil studies have shown that up to 43% of prosulfocarb is mineralised within two months of application.

Conclusion on metabolism in primary crops

The data reported above are sufficient to support the intended uses of GLOB1913H.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

The metabolism of prosulfocarb in rotational crops was not investigated in the framework of the peer review because the DT_{90} of prosulfocarb and its relevant soil metabolites were below the trigger of 100 days.

Therefore, no residues are expected in rotational crops and no further study is deemed necessary.

Taken from EFSA (2022): “A confined rotational crop study with radiolabelled prosulfocarb was provided. Rotational crops (lettuces, turnips, wheat) were planted at three different plant back intervals (PBI): 30, 169 and 275 days in a sandy loam soil that had been previously treated at 3.52–3.87 kg/ha with [^{14}C] prosulfocarb. The results of the confined rotational crop study show that the metabolism of prosulfocarb in rotated crops is similar for all investigated crop groups and indicated that the potential for uptake of prosulfocarb and its degradation products from the soil by the succeeding crops is low. The findings are in agreement with the results of the field dissipation studies assessed in the EU pesticides peer review (EFSA, 2007), which demonstrated that the degradation rate of prosulfocarb in soil is rapid (maximum DT_{90} of 48 days).”

Conclusion on metabolism in rotational crops

The data reported above are sufficient to support the intended uses of GLOB1913H.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Residues of prosulfocarb in plant products that may be subject to processing are not detected at levels above 0.01 mg/kg. Therefore, a study investigating the nature of residues in processed commodities is not needed.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-4: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Foliar treatment (early post-emergence application): cereals (wheat, barley) Soil treatment: root vegetables (potato) and pulses (pea)
Rotational crops covered	Not required given the low to moderate persistence of prosulfocarb in soil
Metabolism in rotational crops similar to metabolism in primary crops?	Assessment not required
Processed commodities	Not required as no residues are present in raw commodities
Residue pattern in processed commodities similar to pattern in raw commodities?	Assessment not required*
Plant residue definition for monitoring	Prosulfocarb (Regulation (EU) No 777/2013)** 2023/129
Plant residue definition for risk assessment	Prosulfocarb (EFSA 2007)***
Conversion factor from enforcement to RA	None (EFSA 2007)

* If residue pattern in processed commodities is not similar to that in raw commodities

** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).

*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Summary of animal metabolism studies reported in the EU

An animal metabolism study is not required due to the extremely low exposure of livestock.

Conclusion on metabolism in livestock

The data reported above are sufficient to support the intended uses of GLOBAL1913H.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-5: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	No required due to the extremely low exposure of livestock.
Time needed to reach a plateau concentration	Assessment not required.
Animal residue definition for monitoring	Assessment not required.

Animal residue definition for risk assessment	Assessment not required.
Conversion factor	Assessment not required.
Metabolism in rat and ruminant similar	Assessment not required.
Fat soluble residue	Assessment not required.

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)

** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

*** If metabolism in rat and ruminant are not similar

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

Residue trials on cereals were already evaluated in the context of the peer review process. All trials compliant with the intended GAP as well as trials with a GAP that is worst case compared to the intended GAP have been selected from the DAR of prosulfocarb (Sweden, 2006).

Residue trials on potato were already evaluated in the context of the peer review process. Two additional trials have been conducted by the applicant.

Table 7.2-6: Summary of EU reported and new data supporting the intended uses of GLOB1913H and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Cereal grain (winter wheat, winter barley, winter rye)	EFSA, 2007 Sweden, 2006	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 3.0-8.0 kg as/ha, BBCH 11-25, PHI 96-311 d, outdoor 32 x < 0.01 mg/kg	N/A				
	Sweden, 2006	S-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 3.375-6.75 kg as/ha, BBCH 12-13, PHI 132-211 d, outdoor 4 x < 0.01 mg/kg					
	Overall supporting data for cGAP	N-EU + S-EU	36 x < 0.01 mg/kg	0.01	0.01	0.01	0.01	Yes
Cereal straw (winter wheat, winter barley, winter rye)	EFSA, 2007 Sweden, 2006	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 3.0-8.0 kg as/ha, BBCH 11-25, PHI 96-302 d, outdoor 17 x < 0.01 mg/kg	N/A				
	Sweden, 2006	S-EU						
	Overall supporting data for cGAP	N-EU + S-EU	21 x < 0.01 mg/kg	0.01	0.01	-	-	-

Potato	EFSA, 2007 Sweden, 2006	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 3.6-4.0 kg as/ha, BBCH 00-11 10 x < 0.01 mg/kg	N/A				
	EFSA, 2007 Sweden, 2006	S-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 4.0-4.8 kg as/ha, BBCH 00-10 and BBCH 39-40 (1 trial) 4 x < 0.01 mg/kg					
	New	S-EU	GAP: 1 x 4.0 kg a.s./ha; BBCH 00 2 x < 0.01 mg/kg					
	Overall supporting data for cGAP	N-EU + S-EU	16 x < 0.01 mg/kg	0.01	0.01	0.01	0.01	Yes

* Source of EU MRL: Reg. (EU) No ~~777/2013~~ 2023/129

Summary of residues data according to the representative uses (EFSA, 2007):

Crop	Region	Trials results relevant to the critical GAP	STMR	HR
Cereals	Northern and Southern Europe	8x <0.01	0.01	0.01
Potatoes	Northern and Southern Europe	14 x <0.01	0.01	0.01

Comparison of the proposed and already accepted conditions of use:

	No of applications	Max dose [kg as/ha]	BBCH	PHI
Cereals				
EU GAP	1	4.0	21	-
Proposed GAP	1	3.6	09-29	-
Potato				
EU GAP	1	4.0	11	-
Proposed GAP	1	3.96	09	-

zRMS comment: The proposed uses of GLOB1913H are within the uses considered acceptable at EU level.

7.2.3.2 Effects on the residue level in pollen and bee products

Prosulfocarb is a non-systemic herbicide applied in winter cereals and potatoes at early growth stages. Winter cereals and potatoes are considered a non-melliferous crop. In both crops, the application of GLOB1913H is before the flowering stage. Therefore, only the exposure of non-target plants (in-field weeds and adjacent plants) is relevant.

Referring to a recent publication (Maynard *et al.* (2015)¹), it was shown that less than 2% of all weeds recorded in arable crops (wheat, oilseed rape, sugarbeet, sunflower, potatoes, maize, peas and beans) are at flowering growth stage when herbicides are applied. It can therefore be considered that the exposure of bees to in-field flowering weeds resulting shortly after application of an herbicide is not a realistic scenario as flowering weeds are not present in the field in significant quantities in realistic conditions. Similarly, in arable crops, the weeds present during application of the herbicide and which are not yet at the flowering growth stage (< BBCH 60) will not survive cultural practices aimed at eliminating them (i.e. herbicidal treatments themselves) so that exposure will also not occur at significant level.

Therefore, only off field flowering weeds and plants should still be considered, which will only be exposed to a drift rate (and not to the full rate).

It was shown in the plant metabolism studies that the parent prosulfocarb is rapidly and extensively metabolized. Since the residue definition for food of plant origin only includes prosulfocarb, no exceedance of the default MRL in honey is to expected

Moreover, considering that for GLOB1913H only autumn to winter use is intended in winter cereals, the application timing will not coincide with the flowering period of weeds and non-target plants.

The application in potatoes will be made between February and early May, so it also does not coincided for the largest part with the flowering period of non-target plants.

In conclusion, no exceedance of the default MRL in honey is expected based on the intended uses.

zRMS comment: wheat and potato are considered as non-melliferous crops. Therefore, only the exposure through non-target plants are relevant. Taking into account the application timing of the plant protection product as well as the metabolic pattern of prosulfocarb, no exceedance of the default MRL in honey is expected based on the proposed uses.

7.2.3.3 Conclusion on the magnitude of residues in plants

Cereals are a major crop in both northern and southern Europe, so normally 8 trials are required in each region. However, as the primary crop metabolism study on cereals showed that the residues of prosulfocarb were not detected in grain or straw, only 3 trials per region are needed.

According to the EU guideline SANTE/2019/12752, extrapolation from any one of the following barley/oats/rye/triticale/wheats to the remaining four crops is possible as long as the last application is done before consumable parts of the crops have started to form (BBCH 51). Considering the intended uses, the extrapolation is possible.

Potato is a major crop in both northern and southern Europe, so normally 8 trials are required in each

¹ Maynard S.K., Albuquerque R., Weber C., von Mérey G., Geiger M.F., Becker R., Keppler J., Masche J., Brougham K., Coulson M., 1.8 Weeds in the treated field – a realistic scenario for pollinator risk assessment? Hazards of pesticides to bees – 12th International Symposium of the ICP-PR Bee Protection Group, Ghent (Belgium, September 15-17, 2014, Julius-Kühn-Archiv, 450, 2015.

region. However, as residues were all below the LOQ in the tubers, only 4 trials per region are needed.

The data submitted show that no exceedance of the MRL will occur.

According to the available data, the intended uses on cereals and potatoes are considered acceptable, for outdoor uses.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

The input values for the dietary burden calculation are summarised in the following table. Considering the available residue trials and the crop metabolism studies (EFSA Journal 2011;9(8):2346), as well as the application early in the growing season, no significant residues are anticipated in cereals, potato and sunflower seeds. Therefore, no default processing factor was applied to processed products of these commodities.

Table 7.2-7: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Prosulfocarb				
Cereal grain	0.01	Median residue (EFSA, 2011)	0.01	Median residue (EFSA, 2011)
Cereal straw	0.01	Median residue (EFSA, 2011)	0.10	Highest residue (EFSA, 2011)
Peas (dry)	0.01	Median residue (EFSA, 2011)	0.01	Median residue (EFSA, 2011)
Beans (dry)	0.01	Median residue (EFSA, 2011)	0.01	Median residue (EFSA, 2011)
Potatoes	0.01	Median residue (EFSA, 2011)	0.01	Highest residue (EFSA, 2011)
Brewer's grain	0.01	Median residue (EFSA, 2011)	-	-
Distiller's grain	0.01	Median residue (EFSA, 2011)	-	-
Potato process waste	0.01	Median residue (EFSA, 2011)	-	-
Potato dried pulp	0.01	Median residue (EFSA, 2011)	-	-
Sunflower meal	0.01	Median residue (EFSA, 2011)	-	-
Wheat gluten meal	0.01	Median residue (EFSA, 2011)	-	-

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat milled by-products	0.01	Median residue (EFSA, 2011)	-	-

Table 7.2-8: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: prosulfocarb					
Beef cattle*	0.0012	0.002	Barley (straw)	0.08	N
Dairy cattle*	0.0017	0.003	Barley (straw)	0.07	N
Ram/ewe	0.0017	0.003	Barley (straw)	0.1	N
Lamb	0.0014	0.004	Barley (straw)	0.09	N
Breeding swine	0.001	0.001	Potato (process waste)	0.05	N
Finishing swine*	0.001	0.001	Potato (culls)	0.03	N
Broiler poultry	0.001	0.001	Potato (culls)	0.02	N
Layer poultry*	0.001	0.002	Wheat (straw)	0.03	N
Turkey	0.001	0.001	Potato (culls)	0.02	N

* These categories correspond to those (formerly) assessed at EU level.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

The calculated dietary burden is not exceeding the trigger. Further investigations of residues is therefore not required.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

As residues of prosulfocarb exceeding 0.1 mg/kg are not expected in treated ~~cereals~~ crops, the contribution of this crop to the TMDI is < 10% and the estimated daily intake is < 10% of the ARfD, investigation of the magnitude of residues in processed commodities is not needed.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

~~“The results of the confined rotational crop study show that the metabolism of prosulfocarb in rotated crops is similar for all investigated crop groups and indicated that the potential for uptake of prosul-~~

focarb and its degradation products from the soil by the succeeding crops is low. The findings are in agreement with the results of the field dissipation studies assessed in the EU pesticides peer review (EFSA, 2007), which demonstrated that the degradation rate of prosulfocarb in soil is rapid" (EFSA, 2022).

7.2.7 Other / special studies (KCA6.10, 6.10.1)

Five decline curve residue studies were performed to determine the degradation rate of prosulfocarb residue in cereal plants. The purpose of these studies was to refine the risk assessment to mammals. These studies are summarized in Appendix 2.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-9: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Prosulfocarb				
All commodities	MRL	Reg. (EU) No 777/2013 Reg. (EU) 2023/129	MRL	Reg. (EU) No 777/2013 Reg. (EU) 2023/129

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-10: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	47% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	No IEDI calculations were performed as the TMDI calculations using the MRLs were already acceptable. No refinement of the chronic risk assessment is required.
IENTI (% ARfD) according to EFSA PRIMo*	Carrots: 63% (based on UK infant) Celeries: 56% (based on BE toddlers) Carrots/juice: 36% (based on DE child)
NTMDI (% ADI) **	-
NEDI (% ADI) **	-
NESTI (% ARfD) **	-

* include raw and processed commodities if both values are required for PRIMo

** if national model is available

The proposed uses of prosulfocarb in the formulation GLOB1913H do not represent unacceptable acute and chronic risks for the consumer.

zRMS comment: The estimated long-term dietary intake is below the ADI and the IESTI value is below of ARfD. An acute risk assessment performed only for crops under consideration indicated IESTI well below of ARfD. The proposed uses of prosulfocarb in the formulation GLOB1913H do not represent unacceptable chronic and acute risks for the consumers.

7.2.9 Acute consumer risk assessment from combined exposure

Not required.

7.2.10 Chronic consumer risk assessment from combined exposure

The uses under consideration provide only a minor contribution to the overall chronic exposure of consumers to pesticide residues. The issue requires a more universal consideration and possibly the generic usage of monitoring data. A harmonised approach is not yet available, and currently no specific consideration is warranted in the scope of this evaluation.

7.3 References

EFSA (European Food Safety Authority), 2007. Conclusions regarding the peer review of the pesticide risk assessment of the active substance prosulfocarb. EFSA Scientific Report (2007) 111, 1-81.

EFSA (European Food Safety Authority), 2011. Review of the existing maximum residue levels (MRLs) for prosulfocarb according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011;9(8):2346. [39 pp.] doi:10.2903/j.efsa.2011.2346.

EFSA (European Food Safety Authority), 2022. Modification of the existing maximum residue levels for prosulfocarb in herbs and edible flowers. EFSA Journal 2022;20(5):7334.

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
KCA 6.3	Jonchère F.	2010a	Determination of prosulfocarb residues in potato following treatment with Prosulfocarb 800 g/L EC under field conditions in southern Europe in 2009 A9050 Anadiag GLP Unpublished	N	Globachem NV
KCA 6.10	Jonchère F.	2010b	Determination of Prosulfocarb Residues In Winter Wheat RAC Following Treatment with Prosulfocarb 800 g/l EC under Field Conditions in Northern Europe in 2009-2010. A9051 Anadiag GLP Unpublished	N	Globachem NV
KCA 6.10	Perny A.	2010	Determination of Prosulfocarb Residues In Winter Wheat RAC Following Treatment with Prosulfocarb 800 g/l EC under Field Conditions in Northern Europe in 2011-2012. R B1234 Anadiag GLP Unpublished	N	Globachem NV

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 No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on and 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 No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Prosulfocarb

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

No new studies were submitted.

A 2.1.1.1.2 Storage stability of residues in animal products

No new studies were submitted.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No new studies were submitted.

A 2.1.2.1.2 Nature of residue in rotational crops

No new studies were submitted.

A 2.1.2.1.3 Nature of residues in processed commodities

No new studies were submitted.

A 2.1.2.2 Nature of residues in livestock

Now new studies were submitted.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Potatoes

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, Sweden, 2006)	1	4.00 kg prosulfocarb/ha	NA	BBCH 11	NR
cGAP EU (Art. 12, EFSA, 2011)	1	4.00 kg prosulfocarb/ha	NA	BBCH 11	NR
Intended cGAP (3*)	1	3.96 kg prosulfocarb/ha	NA	BBCH 09	NR

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

A 2.1.3.1.1 Study 1

Comments of zRMS:	The study was conducted in the southern zone. It is considered as supporting the use of the prosulfocarb in potato.
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Reference:	KCA 6.3
Report	Determination of prosulfocarb residues in potato following treatment with Prosulfocarb 800 g/L EC under field conditions in southern Europe in 2009, Jonchère F., 2010a, A9050.
Guideline(s):	Yes, 7029/VI/95 rev. 5, SANCO 7525/VI/95 rev. 8, SANCO/825/00 rev. 7, SANCO/3029/99 rev.4
Deviations:	No
GLP:	Yes
Acceptability:	Supplementary

Table A 2: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Analyte 1		
(a)	(a)	(b)				(c)				(d)	(e)
R A9050 A9050 TL01 Ondes 21330 Southern France	Potato/Agata	1) 11/05/2009 2) NA 3) 30/07/2009 to 02/08/2009	42 66	320	1333	11/05/2009	00	Tubers	< 0.01	81	<p>Prosulfocarb 800 EC</p> <p>Analytical method consisted in extraction with acetonitrile/acetic acid. Detection with LC-MS/MS. Method fully validated in A9085.</p> <p>LOQ: 0.01 mg/kg</p> <p>Untreated specimens were all < LOQ.</p> <p>Max. storage interval between sampling and analysis: 138 days</p>

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Analyte 1		
R A9050 A9050 DR1 Duras 47120 Southern France	Potato/Sirtema	1) 30/06/2009 2) 01/08/2009 to 17/08/2009 3) 31/07/2009 to 15/09/2009	4172	313	1333	05/06/2009	00	Tubers	<u>< 0.01</u>	87	Prosulfocarb 800 EC Analytical method consisted in extraction with acetonitrile/acetic acid. Detection with LC- MS/MS. Method fully validated in A9085. LOQ: 0.01 mg/kg Untreated specimens were all < LOQ. Max. storage interval between sampling and analysis: 107 days

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new studies were submitted.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.5.1 Distribution of the residue in peel/pulp

No new studies were submitted.

A 2.1.5.2 Processing studies on a core set of representative processes

No new studies were submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new studies were submitted.

A 2.1.7 Other/Special Studies

A 2.1.7.1 Study 1

Comments of zRMS:	Two studies were conducted according to relevant guidelines and GLP principles. They are accepted. The objective of the studies was to determine the residue levels of prosulfocarb in winter wheat raw agricultural commodity after one foliar application of the formulated product Prosulfocarb 800 g/L EC on the crop. These studies indicate a rapid decline in prosulfocarb residues levels. The average prosulfocarb half-life was 1.59 d and 2.02 d in the first and second study respectively.
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Reference:	KCA 6.10
Report	Determination of Prosulfocarb Residues In Winter Wheat RAC Following Treatment with Prosulfocarb 800 g/l EC under Field Conditions in Northern Europe in 2009-2010, Jonchère F., 2010b, A9051.
Guideline(s):	Yes, 7029/VI/95 rev. 5, SANCO 7525/VI/95 rev. 8, SANCO/825/00 rev. 7, SANCO/3029/99 rev.4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Reference:	KCA 6.10
Report	Determination of Prosulfocarb Residues In Winter Wheat RAC Following Treatment with Prosulfocarb 800 g/l EC under Field Conditions in Northern Europe in 2011-2012, Perny A., 2012, R B1234.
Guideline(s):	Yes, 7029/VI/95 rev. 5, SANCO 7525/VI/95 rev. 8, SANCO/825/00 rev. 8.1, SANCO/3029/99 rev.4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of the studies was to determine the residue levels of prosulfocarb in winter wheat raw agricultural commodity after one foliar application of the formulated product PROSULFOCARB 800 g/L EC on the crop. The study was composed of two phases: the field phase and the analytical phase.

The study was conducted at 5 sites in Northern Europe (Northern France and Germany).

One plot was treated once with PROSULFOCARB 800 g/L EC at the application rate of 5 L/ha with a spray volume of 300 L water/ha at BBCH growth stage 12. A second plot remained untreated.

Wheat samples (whole plants) were taken at 0, 1, 2, 4, 7 (± 1) and 14 (± 1) days after the last application. Prosulfocarb residues were analysed in samples harvested during the field phase using the method developed and validated by ANADIAG in the study A9085 "Validation of the Analytical Method for the Determination of Prosulfocarb residues in Potato Tubers, Sunflower Seeds and Winter Wheat Whole Plant"; Report No. R A9085; GLP study; 07/01/2010" which is summarized in dRR Section B5 and submitted as study KCP 5.1.2.

The results are based on samples sizes of minimum 100 grams of plant material. At this immature stage, 100 gram of immature plants corresponds to the sampling of up to 200 whole plants. This is in accordance with the Guidance Document Sanco7029/VI/95 rev5 that reads on page 56: if immature samples are to be taken, cut no less than 12 short lengths from rows over the entire plot. As can be seen in the final report of the study, this was respected. As the product was applied at BBCH 12 and samplings were taken starting at BBCH 12 up to BBCH 13 (14 days after the last application), a sample size of 1 kg of plant material was not possible however this is accepted by the above guidance.

Although this study was conducted in Northern Europe, the results are valid in Southern Europe too as the study is a higher Tier study used for refinement of the risk assessment to determine the DT₅₀ value of the active ingredient in plants. Conditions in Northern Europe can be colder than in Southern Europe meaning that the study is worst case: under colder conditions, the plants will grow slower and degradation can be slower. Therefore the obtained DT₅₀ value is worst case and thus acceptable.

Results and discussions

Table A 3: Tier 1 tables of the residue studies used for the refinement of the DT₅₀ of prosulfocarb in winter wheat plants

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active ingredient : **Prosulfocarb** Producer of commercial product : GLOBACHEM NV
Crop/crop group : Wheat / Cereals
Responsible body for reporting : ANADIAG, 16 rue Ampère Page : 1/2
(name, address) : 67500 HAGUENAU, France
Country : Northern France Indoor/Glasshouse/Outdoor : Outdoor
Content of active substance (g/kg or g/l) : prosulfocarb 800 g/L Other a.i. in formulation : -
Formulation (e.g. WP) : EC (common name and content) :
Commercial product (name) : **PROSULFOCARB 800 g/L** Residues calculated as : mg/kg prosulfocarb

1	2	3	4	5			6	7	8	9	10	11
Report-No ; Location including Postal code	Commodity /Variety (a)	Date of (b) 1) Sowing 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (actual)			Dates of treatment or n°. of treatm. and last date (d)	Growth stage at last treatm. or date(e)	Portion analysed (a)	Residues (mg/kg)	PHI (days) (f)	Remarks (g)
				g a.i./ha (h)	Water (l/ha)	g a.i./hl (h)						
A9051 AN1 Seebach (67160) Northern France	Wheat / Apache	1) 14/10/09 2)- 3)-	Foliar spray	4093	307	1333	13/11/09	12	Whole plant Whole plant Whole plant Whole plant Whole plant	454.41 316.95 92.47 20.85 10.72 1.59	0 1 2 4 7 13	LOQ prosulfocarb 0.01 mg/kg
A9051 GE1 Neuershausen (79232) Germany	Wheat / Apache	1) 28/10/09 2)- 3)-	Foliar spray	4013	301	1333	01/12/09	12	Whole plant Whole plant Whole plant Whole plant Whole plant	714.54 452.58 327.90 123.23 38.85 5.70	0 1 2 4 6 13	LOQ prosulfocarb 0.01 mg/kg

Remarks:

(a) According to EEC and Codex Classification (both) should be used/

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient	: Prosulfocarb	Producer of commercial product	: GLOBACHEM NV
Crop/crop group	: Wheat / Cereals		
Responsible body for reporting (name, address)	: ANADIAG, 16 rue Ampère 67500 HAGUENAU, France	Page	: 34/3
Country	: Northern France	Indoor/Glasshouse/Outdoor	: Outdoor
Content of active substance (g/kg or g/l)	: prosulfocarb 800 g/L	Other a.i. in formulation	: -
Formulation (e.g. WP)	: EC	(common name and content)	:
Commercial product (name)	: PROSULFOCARB 800 g/L	Residues calculated as	: mg/kg prosulfocarb

1	2	3	4	5			6	7	8	9	10	11
Report-No ; Location including Postal code	Commodity /Variety (a)	Date of (b) 1) Sowing 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (actual)			Dates of treatment or n°. of treatm. and last date (d)	Growth stage at last treatm. or date(e)	Portion analysed (a)	Residues (mg/kg)	PHI (days) (f)	Remarks (g)
				g a.i./ha (h)	Water (l/ha)	g a.i./hl (h)						
B1234 AN1 Seebach (67160) Northern France	Wheat / Premio	1) 11/10/11 2) - 3) -	Foliar spray	3840	288	1333	10/11/11	12	Whole plant	286.5	0	LOQ prosulfocarb 0.01 mg/kg
									Whole plant	233.9	1	
									Whole plant	135.6	2	
									Whole plant	42.5	4	
									Whole plant	29.4	7	
									Whole plant	4.4	14	

Remarks:

- (a) According to EEC and Codex Classification (both) should be used⁷
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting *etc*
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
- (f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
- (g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active ingredient	: Prosulfocarb	Producer of commercial product	: GLOBACHEM NV
Crop/crop group	: Wheat / Cereals	Page	: 35/2
Responsible body for reporting (name, address)	: ANADIAG, 16 rue Ampère 67500 HAGUENAU, France	Indoor/Glasshouse/Outdoor	: Outdoor
Country	: Northern France	Other a.i. in formulation (common name and content)	: -
Content of active substance (g/kg or g/l)	: prosulfocarb 800 g/L	Residues calculated as	: mg/kg prosulfocarb
Formulation (e.g. WP)	: EC		
Commercial product (name)	: PROSULFOCARB 800 g/L		

1	2	3	4	5			6	7	8	9	10	11
Report-No ; Location including Postal code	Commodity /Variety (a)	Date of (b) 1) Sowing 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (actual)			Dates of treatment or n°. of treatm. and last date (d)	Growth stage at last treatm. or date(e)	Portion analysed (a)	Residues (mg/kg)	PHI (days) (f)	Remarks (g)
				g a.i./ha (h)	Water (l/ha)	g a.i./hl (h)						
B1234 BM1 Thorée les Pins (72800) Northern France	Wheat / Premio	1) 18/10/11 2) - 3) -	Foliar spray	4227	317	1333	17/11/11	12	Whole plant	443.6	0	LOQ prosulfocarb 0.01 mg/kg
									Whole plant	280.2	1	
									Whole plant	158.3	2	
									Whole plant	59.8	4	
									Whole plant	28.0	7	
									Whole plant	4.1	14	

Remarks:

- According to EEC and Codex Classification (both) should be used⁷
- Only if relevant
- High or low volume spraying, spreading, dusting *etc*
- Year must be indicated
- BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
- Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
- Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active ingredient	: Prosulfocarb	Producer of commercial product	: GLOBACHEM NV
Crop/crop group	: Wheat / Cereals	Page	: 36/2
Responsible body for reporting (name, address)	: ANADIAG, 16 rue Ampère 67500 HAGUENAU, France	Indoor/Glasshouse/Outdoor	: Outdoor
Country	: Northern France	Other a.i. in formulation (common name and content)	: -
Content of active substance (g/kg or g/l)	: prosulfocarb 800 g/L	Residues calculated as	: mg/kg prosulfocarb
Formulation (e.g. WP)	: EC		
Commercial product (name)	: PROSULFOCARB 800 g/L		

1	2	3	4	5			6	7	8	9	10	11
Report-No ; Location including Postal code	Commodity /Variety (a)	Date of (b) 1) Sowing 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (actual)			Dates of treatment or n°. of treatm. and last date (d)	Growth stage at last treatm. or date(e)	Portion analysed (a)	Residues (mg/kg)	PHI (days) (f)	Remarks (g)
				g a.i./ha (h)	Water (l/ha)	g a.i./hl (h)						
B1234 BP1 Engenville (45300) Northern France	Wheat / Premio	1) 22/10/11 2) - 3) -	Foliar spray	3827	287	1333	14/11/11	12	Whole plant	278.3	0	LOQ prosulfocarb 0.01 mg/kg
									Whole plant	122.4	1	
									Whole plant	74.2	2	
									Whole plant	57.5	4	
									Whole plant	13.7	7	
									Whole plant	2.7	14	

Remarks:

- (a) According to EEC and Codex Classification (both) should be used⁷
- (f) Only if relevant
- (g) High or low volume spraying, spreading, dusting *etc*
- (h) Year must be indicated
- (i) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
- (f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
- (g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included

Table A 4: Summary tables of the residue studies used for the refinement of the DT₅₀ of prosulfocarb in winter wheat plants (including weather data)

Country Year Trial No.	Application					Average T	Rainfall	Residues (prosulfocarb)			DT50
	Formu- lation	N°	kg a.i./ha	L/ha	Growth stage (BBCH)			Commodity and growth stage (BBCH)	PHI (days)	mg/kg	
North France	800 EC	1	4.093	307	12	9.6°C	0 mm	Whole plant (12)	0	454.41	1.43 days
2009						9.9°C	1.1 mm	Whole plant (12)	1	316.95	
A9051 AN1						8.5°C	12.9 mm	Whole plant (12)	2	92.47	
						11.9°C	4.3 mm	Whole plant (12)	4	20.85	
						9°C	0 mm	Whole plant (12/13)	7	10.72	
						11.9°C	0 mm	Whole plant (13)	13	1.59	
Germany	800 EC	1	4.013	301	12	5°C	0 mm	Whole plant (12)	0	714.54	1.75 days
2009						4.6°C	0 mm	Whole plant (12)	1	452.58	
A9051 GE1						6.2°C	2 mm	Whole plant (12)	2	327.9	
						3.8°C	0 mm	Whole plant (12)	4	123.23	
						8.1°C	0 mm	Whole plant (12)	6	38.85	
						-0.7°C	0 mm	Whole plant (12-13)	13	5.7	
North France	800 EC	1	3.84	288	12	6.2°C	0 mm	Whole plant (12)	0	286.5	2.2 days
2011						7.1°C	0 mm	Whole plant (12)	1	233.9	
B1234 AN1						8°C	0 mm	Whole plant (12-13)	2	135.6	
						3.1°C	0.3 mm	Whole plant (12-13)	4	42.5	
						4.4°C	0 mm	Whole plant (12-13)	7	29.4	
						0.2°C	0.3 mm	Whole plant (12-13)	14	4.4	
North France	800 EC	1	4.227	317	12	13.5°C	0.3 mm	Whole plant (12)	0	443.6	1.93 days
2011						10.8°C	0.1 mm	Whole plant (12)	1	280.2	
B1234 BM1						11°C	0.3 mm	Whole plant (12)	2	158.3	
						11.5°C	0.1 mm	Whole plant (12)	4	59.8	
						8.8°C	0 mm	Whole plant (12-13)	7	28	

						9.5°C	1.8 mm	Whole plant (12-13)	14	4.1	
North France	800 EC	1	3.827	287	12	8.3°C	0.3 mm	Whole plant (12)	0	278.3	1.92 days
2011						6.8°C	0.2 mm	Whole plant (12)	1	122.4	
B1234 BP1						6°C	0.1 mm	Whole plant (12)	2	74.2	
						11°C	0.2 mm	Whole plant (12)	4	57.5	
						12.3°C	0.1 mm	Whole plant (13)	7	13.7	
						8.3°C	0.2 mm	Whole plant (13)	14	2.7	

Based on these results, the half-life of prosulfocarb in the five trials was calculated in the table below.

Table A 5: DT₅₀ of prosulfocarb in winter wheat plants

Trial No.	Half-life (days)	Coefficient of determination R ²
A9051 AN1	1.43	0.9042
A9051 GE1	1.75	0.9745
B1234 AN1	2.20	0.9592
B1234 BM1	1.93	0.9595
B1234 BP1	1.92	0.9293
Geometric mean	1.83	
Arithmetic mean	1.85	

Conclusion

The DT₅₀ of prosulfocarb ranged from 1.43 to 2.2 days in five residue trials conducted in winter wheat, with arithmetic and geometric means of 1.85 and 1.83 days respectively.

Kinetic analysis

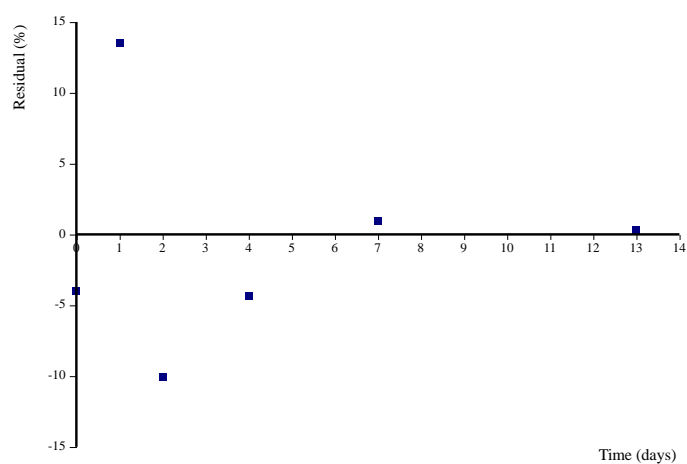
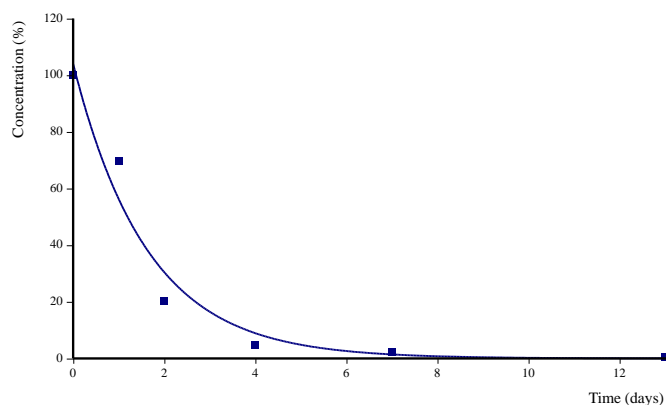
In order to comply with the recommendations of the FOCUS workgroup on degradation kinetics (FOCUS 2006, 2014), a kinetic analysis of the above residue decline data is provided here below.

Residue data were fitted using CAKE v3.3 to determine first order half-lives. The data were directly fitted un-weighted with the complete data set and unconstrained initial concentration (M0) for the parent. The acceptability of the kinetic fits was judged as follows:

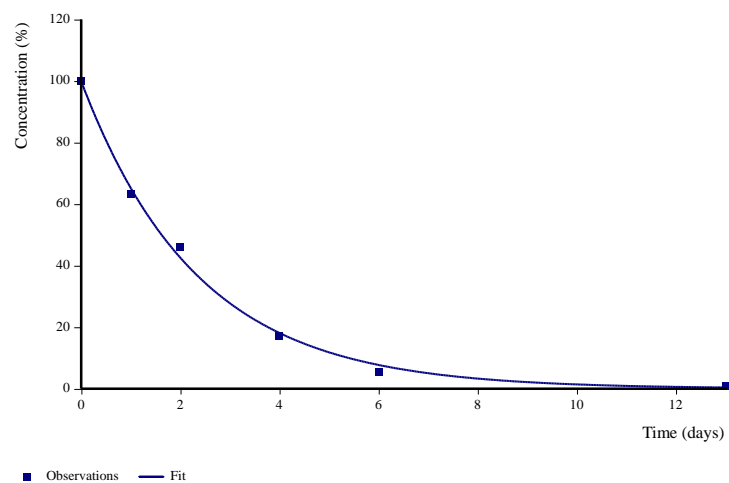
- Visually using a three point scale:
 Poor = an unacceptable fit, the fitted curve does not represent the trend of the data points and residuals show strong deviations from random distribution;
 Acceptable = the fitted curve describes the trend of the data points, residuals may show some deviation from random distribution but it is not significant;
 Good = the fitted curve closely follows all the data points, residuals are randomly distributed.
- Fit to the data points (χ^2 error%):
 It is recommended that a χ^2 error% of 15% or less indicates acceptable fits, although for data that may include intrinsically variable data, higher values can be tolerated if the visual fit is acceptable or good. Where two or more models are acceptable fits to the data, the χ^2 error% parameter has been used to assess goodness of fit. In these cases, the model with the lowest value of this parameter has been chosen as the best fit.

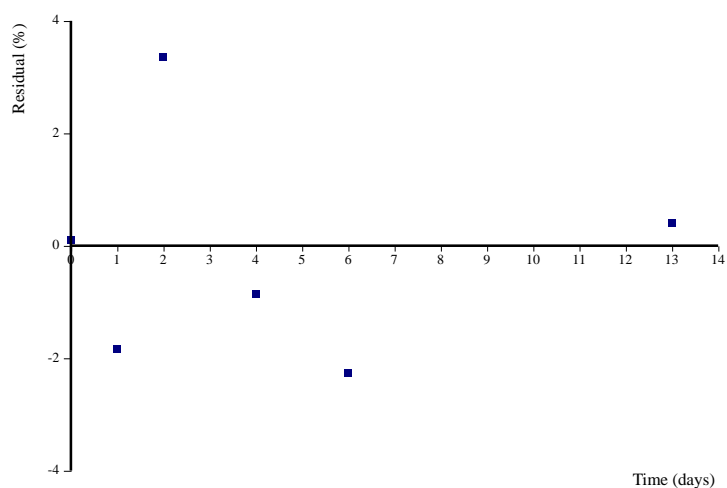
Graphs with the measured residues plotted versus time and with calculated minus measured data (residuals) of the different residue trials are shown in the figures below.

Graphs for trial A9051 AN1

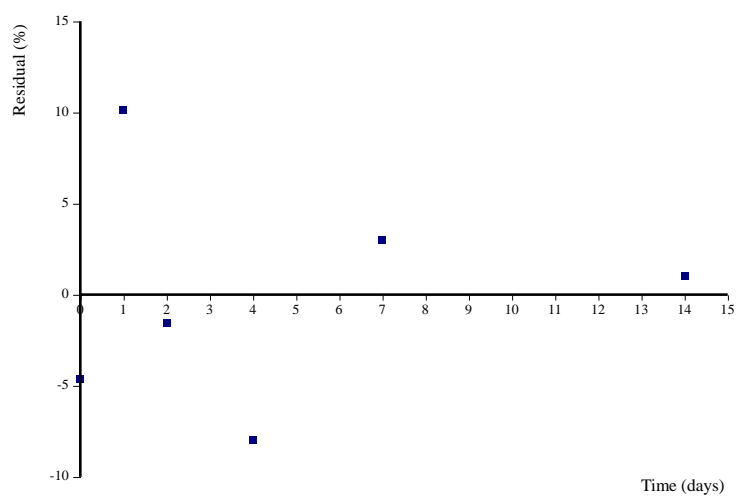
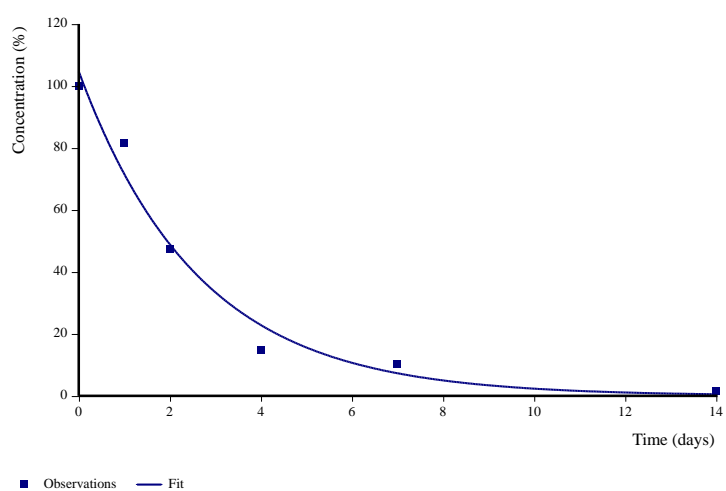


Graphs for trial A9051 GE1

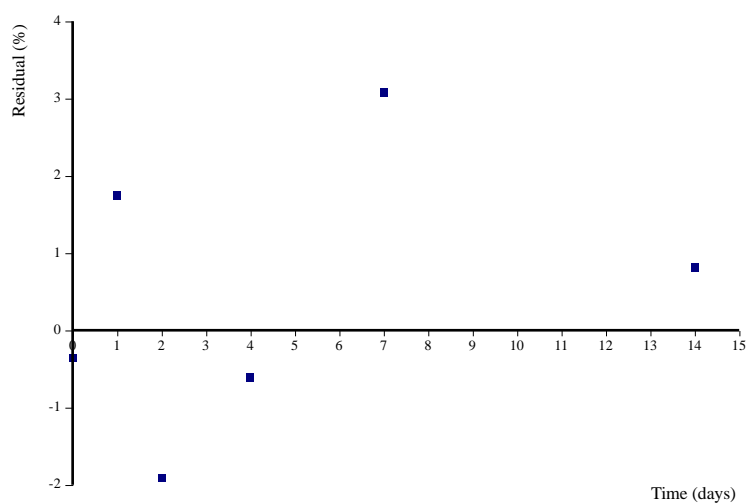
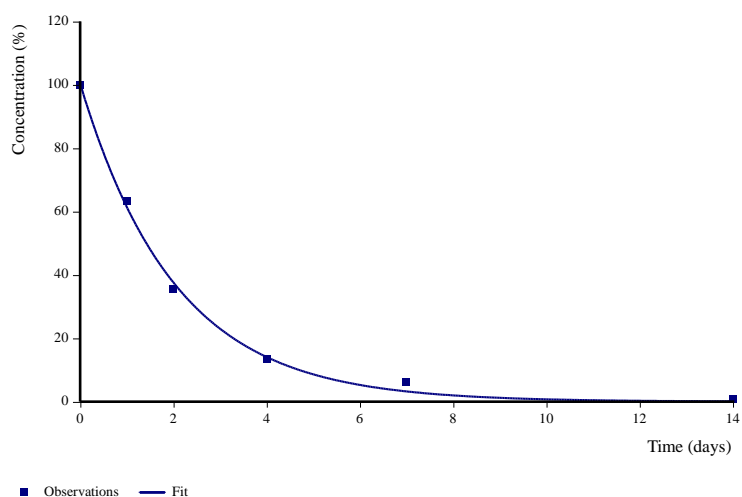




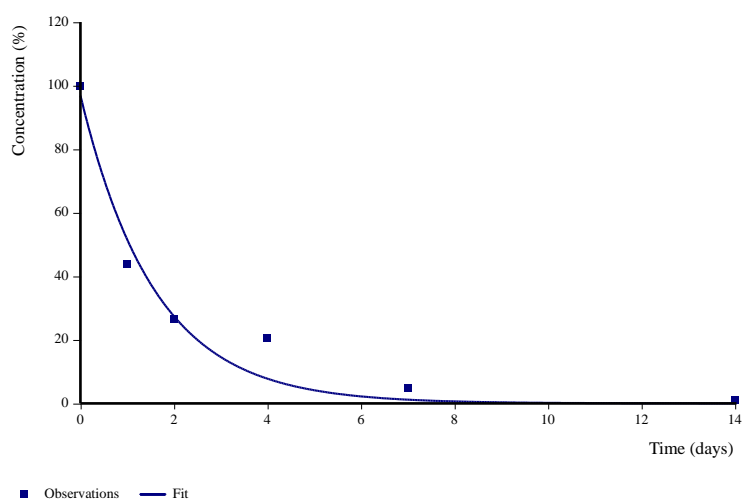
Graphs for trial B1234 AN1

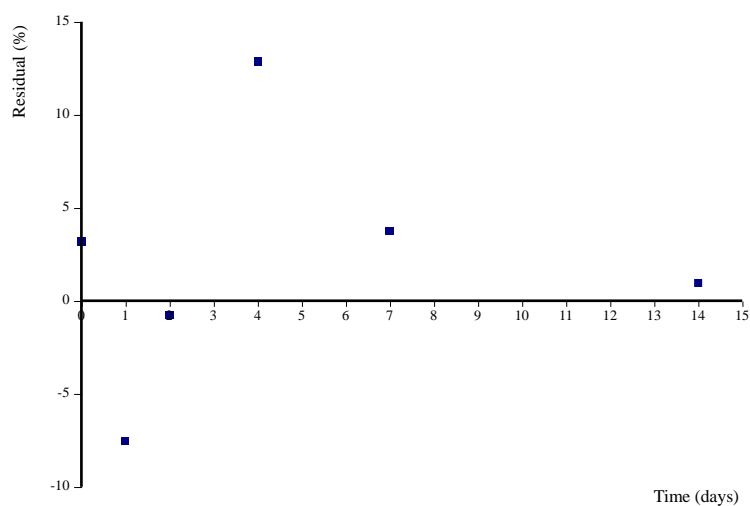


Graphs for trial B1234 BM1



Graphs for trial B1234 BP1





Foliar DT₅₀ values determined by kinetic fitting are summarized in the table below.

Summary of foliar DT₅₀ values

Trial No.	Foliar DT ₅₀ (days)	Foliar DT ₉₀ (days)	Error % (χ^2)	Kinetic model	Reference
A9051 AN1	1.13	3.75	17.6	SFO	Jonchère, 2010
A9051 GE1	1.62	5.39	3.81	SFO	
B1234 AN1	1.82	6.05	10.8	SFO	Perny, 2012
B1234 BM1	1.41	4.69	3.69	SFO	
B1234 BP1	1.10	3.65	15.6	SFO	

Appendix 3 Pesticide Residue Intake Model (PRIMo)

Appendix 4 TMDI calculations



Prosulfocarb			
LOQs (mg/kg) range from:		0.01	to: 0.16
Toxicological reference values			
ADI (mg/kg bw/day):		0.005	ARfD (mg/kg bw): 0.1
Source of ADI:		EFSA	Source of ARfD: EFSA
Year of evaluation:		2007	Year of evaluation: 2007

Input values	
Details - chronic risk assessment	Supplementary results - chronic risk assessment
Details - acute risk assessment/children	Details - acute risk assessment/adults

Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
No of diets exceeding the ADI:				---							
Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)	
47%	NL toddler	2.37	21%	Carrots	12%	Milk: Cattle	2%	Apples	25%		
39%	UK infant	1.97	26%	Carrots	8%	Milk: Cattle	0.7%	Celeries	12%		
36%	DK child	1.80	27%	Carrots	3%	Milk: Cattle	1%	Rye	8%		
36%	DE child	1.79	21%	Carrots	4%	Milk: Cattle	2%	Apples	12%		
33%	GEMS/Food G11	1.66	15%	Carrots	8%	Celeries	2%	Milk: Cattle	9%		
29%	FR infant	1.46	22%	Carrots	3%	Milk: Cattle	1.0%	Celeries	6%		
26%	FR toddler 2-3 yr	1.29	14%	Carrots	6%	Milk: Cattle	0.6%	Apples	11%		
25%	SE general	1.27	17%	Carrots	2%	Milk: Cattle	0.9%	Bovine: Muscle/meat	7%		
23%	FR child 3-15 yr	1.13	10%	Carrots	5%	Milk: Cattle	1%	Celeries	11%		
22%	NL child	1.09	8%	Carrots	5%	Milk: Cattle	2%	Sugar beet roots	14%		
22%	GEMS/Food G07	1.08	9%	Carrots	4%	Celeries	1%	Milk: Cattle	8%		
21%	UK toddler	1.04	10%	Carrots	4%	Milk: Cattle	1%	Celeries	9%		
21%	FI 3 yr	1.04	17%	Carrots	0.9%	Potatoes	0.4%	Strawberries	3%		
20%	GEMS/Food G15	0.99	8%	Carrots	2%	Celeries	1%	Milk: Cattle	8%		
19%	GEMS/Food G08	0.96	9%	Carrots	1%	Celeries	1%	Milk: Cattle	8%		
18%	PT general	0.89	13%	Carrots	1%	Potatoes	0.8%	Wheat	4%		
18%	IE adult	0.88	6%	Carrots	4%	Celeries	0.9%	Milk: Cattle	7%		
17%	RO general	0.85	9%	Carrots	2%	Milk: Cattle	1%	Wheat	7%		
16%	GEMS/Food G10	0.79	5%	Carrots	2%	Celeries	1%	Soyabeans	8%		
15%	FI 6 yr	0.76	12%	Carrots	0.8%	Potatoes	0.3%	Strawberries	3%		
15%	DE women 14-50 yr	0.73	6%	Carrots	2%	Milk: Cattle	0.9%	Sugar beet roots	7%		
14%	FI adult	0.69	7%	Carrots	6%	Coffee beans	0.2%	Potatoes	7%		
13%	DK adult	0.67	10%	Carrots	1%	Milk: Cattle	0.3%	Potatoes	3%		
13%	DE general	0.66	5%	Carrots	2%	Milk: Cattle	0.8%	Sugar beet roots	7%		
12%	GEMS/Food G06	0.61	2%	Carrots	1%	Wheat	1%	Celeries	8%		
12%	ES child	0.58	4%	Carrots	2%	Milk: Cattle	0.9%	Wheat	8%		
11%	NL general	0.55	4%	Carrots	2%	Milk: Cattle	0.6%	Sugar beet roots	6%		
9%	FR adult	0.46	4%	Carrots	0.9%	Milk: Cattle	0.6%	Celeries	4%		
9%	UK vegetarian	0.43	5%	Carrots	1%	Celeries	0.7%	Milk: Cattle	3%		
8%	PL general	0.41	6%	Carrots	0.7%	Potatoes	0.4%	Apples	2%		
8%	IT toddler	0.39	4%	Carrots	1%	Wheat	0.8%	Celeries	3%		
7%	ES adult	0.37	3%	Carrots	1.0%	Milk: Cattle	0.5%	Wheat	4%		
7%	UK adult	0.34	4%	Carrots	0.6%	Milk: Cattle	0.4%	Celeries	3%		
7%	LT adult	0.34	3%	Carrots	0.8%	Milk: Cattle	0.6%	Potatoes	3%		
6%	IT adult	0.30	3%	Carrots	0.8%	Wheat	0.6%	Celeries	2%		
5%	IE child	0.26	3%	Carrots	0.7%	Milk: Cattle	0.2%	Wheat	2%		
Conclusion: The estimated long-term dietary intake (TMDI/NIEDI/IEDI) was below the ADI. The long-term intake of residues of Prosulfocarb is unlikely to present a public health concern.											

A 4.1 IESTI calculations - Raw commodities

Prosulfocarb

Acute risk assessment /children					Acute risk assessment / adults / general population					Acute risk assessment /children					Acute risk assessment / adults / general population					
Details - acute risk assessment /children					Details - acute risk assessment/adults					Hide IESTI new calculations					Show IESTI new calculations					
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.										IESTI new calculations: The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.										
Show results for all crops																				
Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):					Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):					IESTI new Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI new):					IESTI new Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI new):				
	IESTI					IESTI					IESTI new					IESTI new				
	Highest % of ARfD/ADI		Commodities		MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI		Commodities		MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI		Commodities		MRL / input for RA (mg/kg)	Exposure (µg/kg bw)		
	63%	Carrots	1/1	63	24%	Celeries	1.5/1.5	24	34%	Celeries	1.5/1.5	34	14%	Celeries	1.5/1.5	14				
	56%	Celeries	1.5/1.5	56	20%	Carrots	1/1	20	27%	Carrots	1/1	27	12%	Carrots	1/1	12				
	4%	Celeriacs/turnip rooted	0.08/0.08	4.4	1%	Chamomille	2/2	1.2	3%	Celeriacs/turnip rooted	0.08/0.08	2.7	1%	Chamomille	2/2	1.2				
	3%	Parsnips	0.08/0.08	2.9	1%	Chamomille	2/2	1.2	1%	Salsifies	0.08/0.08	1.3	1%	Chamomille	2/2	1.2				
	2%	Salsifies	0.08/0.08	2.5	1%	Chamomille	2/2	1.2	1%	Milk: Cattle	0.01/0.01	1.2	1%	Chamomille	2/2	1.2				
	2%	Potatoes	0.01/0.01	1.5	1%	Chamomille	2/2	1.2	1%	Parsnips	0.08/0.08	1.2	1%	Chamomille	2/2	1.2				
	2%	Melons	0.01/0.01	1.5	1%	Chamomille	2/2	1.2	0.9%	Melons	0.01/0.01	0.91	1%	Chamomille	2/2	1.2				
1%	Pears	0.01/0.01	1.4	1%	Parsnips	0.08/0.08	1.1	0.8%	Strawberries	0.05/0.05	0.82	0.8%	Rooibos	2/2	0.80					
1%	Oranges	0.01/0.01	1.3	0.9%	Celeriacs/turnip rooted	0.08/0.08	0.95	0.7%	Watermelons	0.01/0.01	0.73	0.8%	Rooibos	2/2	0.80					
1%	Milk: Cattle	0.01/0.01	1.2	0.9%	Salsifies	0.08/0.08	0.86	0.7%	Oranges	0.01/0.01	0.67	0.7%	Parsnips	0.08/0.08	0.68					
1%	Watermelons	0.01/0.01	1.2	0.8%	Parsley roots/Hamburg	0.08/0.08	0.82	0.7%	Potatoes	0.01/0.01	0.66	0.6%	Hybiscus/roselle	2/2	0.60					
1%	Apples	0.01/0.01	1.1	0.8%	Rooibos	2/2	0.80	0.6%	Apples	0.01/0.01	0.62	0.6%	Celeriacs/turnip rooted celeries	0.08/0.08	0.57					
1%	Pineapples	0.01/0.01	1.0	0.8%	Rooibos	2/2	0.80	0.6%	Bananas	0.01/0.01	0.61	0.5%	Oranges	0.01/0.01	0.47					
1.0%	Bananas	0.01/0.01	0.97	0.6%	Hybiscus/roselle	2/2	0.60	0.6%	Pineapples	0.01/0.01	0.61	0.5%	Strawberries	0.05/0.05	0.47					
1.0%	Peaches	0.01/0.01	0.95	0.6%	Horseradishes	0.08/0.08	0.58	0.6%	Pears	0.01/0.01	0.59	0.4%	Plums	0.01/0.01	0.39					
Expand/collapse list																				
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)										Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)										

A 4.2 IESTI calculations - Processed commodities

Prosulfocarb

Processed commodities	Results for children			Results for adults			Results for children			Results for adults		
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			No of processed commodities for which ARfD/ADI is exceeded (IESTI):			No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			No of processed commodities for which ARfD/ADI is exceeded (IESTI new):		
	---			---			---			---		
	IESTI			IESTI			IESTI new			IESTI new		
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg) Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg) Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg) Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg) Exposure (µg/kg bw)
	36%	Carrots / juice	1/1 36	51%	Celeriacs / boiled	1.5/1.5 51	36%	Carrots / juice	1/1 36	30%	Celeriacs / boiled	1.5/1.5 30
	4%	Parsnips / boiled	0.08/0.08 4.1	8%	Carrots / canned	1/1 8.2	2%	Salsifies / boiled	0.08/0.08 1.7	8%	Carrots / canned	1/1 8.2
	2%	Salsifies / boiled	0.08/0.08 2.1	2%	Parsnips / boiled	0.08/0.08 1.7	2%	Parsnips / boiled	0.08/0.08 1.7	0.9%	Celeriacs / boiled	0.08/0.08 0.87
	1%	Celeriacs / juice	0.08/0.08 1.2	1%	Celeriacs / boiled	0.08/0.08 1.5	1%	Celeriacs / juice	0.08/0.08 1.2	0.7%	Parsnips / boiled	0.08/0.08 0.73
	1%	Sugar beets (root) / sugar	0.01/0.12 1.1	0.7%	Salsifies / boiled	0.08/0.08 0.66	1%	Sugar beets (root) /	0.01/0.12 1.1	0.7%	Salsifies / boiled	0.08/0.08 0.73
	0.9%	Potatoes / fried	0.01/0.01 0.93	0.6%	Pumpkins / boiled	0.01/0.01 0.55	0.6%	Potatoes / dried (flakes)	0.01/0.05 0.59	0.4%	Sugar beets (root) / sugar	0.01/0.12 0.44
	0.9%	Pumpkins / boiled	0.01/0.01 0.89	0.4%	Sugar beets (root) / sugar	0.01/0.12 0.44	0.5%	Apples / juice	0.01/0.01 0.54	0.4%	Pumpkins / boiled	0.01/0.01 0.40
	0.9%	Witlofs / boiled	0.01/0.01 0.89	0.4%	Cauliflowers / boiled	0.01/0.01 0.42	0.5%	Pumpkins / boiled	0.01/0.01 0.53	0.3%	Apples / juice	0.01/0.01 0.33
	0.8%	Broccoli / boiled	0.01/0.01 0.79	0.4%	Beetroots / boiled	0.01/0.01 0.39	0.5%	Oranges / juice	0.01/0.01 0.53	0.2%	Cauliflowers / boiled	0.01/0.01 0.25
	0.7%	Cauliflowers / boiled	0.01/0.01 0.70	0.3%	Apples / juice	0.01/0.01 0.33	0.5%	Broccoli / boiled	0.01/0.01 0.47	0.2%	Coffee beans / extraction	0.05/0.01 0.24
	0.7%	Escaroles/broad-leaved	0.01/0.01 0.66	0.3%	Onions / boiled	0.03/0.03 0.28	0.5%	Witlofs / boiled	0.01/0.01 0.47	0.2%	Witlofs / boiled	0.01/0.01 0.22
	0.6%	Potatoes / dried (flakes)	0.01/0.05 0.59	0.2%	Broccoli / boiled	0.01/0.01 0.24	0.4%	Potatoes / fried	0.01/0.01 0.44	0.2%	Onions / boiled	0.03/0.03 0.22
	0.6%	Leeks / boiled	0.01/0.01 0.57	0.2%	Coffee beans / extraction	0.05/0.01 0.24	0.4%	Wine grapes / juice	0.01/0.01 0.44	0.2%	Shallots / boiled	0.03/0.03 0.21
	0.5%	Apples / juice	0.01/0.01 0.54	0.2%	Courgettes / boiled	0.01/0.01 0.23	0.4%	Cauliflowers / boiled	0.01/0.01 0.42	0.2%	Wine grapes / juice	0.01/0.01 0.21
	0.5%	Oranges / juice	0.01/0.01 0.53	0.2%	Kohlrabies / boiled	0.01/0.01 0.21	0.4%	Escaroles/broad-leaved	0.01/0.01 0.40	0.2%	Broccoli / boiled	0.01/0.01 0.20
Expand/collapse list												
Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Prosulfocarb is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.												

Acute risk assessment performed only for crops under consideration.

Acute risk assessment /children					Acute risk assessment / adults / general population					Acute risk assessment /children					Acute risk assessment / adults / general population															
Details - acute risk assessment /children					Details - acute risk assessment/adults					Hide IESTI new calculations					Show IESTI new calculations															
Unprocessed commodities	The acute risk assessment is based on the ARID. The calculation is based on the large portion of the most critical consumer group.										IESTI new calculations: The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.																			
	Show results for all crops																													
	Results for children No. of commodities for which ARID/ADI is exceeded (IESTI):				---	Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI):				---	IESTI new Results for children No. of commodities for which ARID/ADI is exceeded (IESTI new):				---	IESTI new Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI new):				---										
	IESTI					IESTI					IESTI new					IESTI new														
	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)		Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)		Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)		Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)											
	2%	Potatoes	0,01 /0,01	1,5		0,3%	Potatoes	0,01 /0,01	0,30		0,7%	Potatoes	0,01 /0,01	0,66		0,3%	Potatoes	0,01 /0,01	0,31											
	0,1%	Wheat	0,01 /0,01	0,14		0,09%	Rice	0,01 /0,01	0,09		0,1%	Wheat	0,01 /0,01	0,14		0,09%	Rice	0,01 /0,01	0,09											
	0,1%	Rice	0,01 /0,01	0,13		0,08%	Wheat	0,01 /0,01	0,08		0,1%	Rice	0,01 /0,01	0,13		0,08%	Wheat	0,01 /0,01	0,08											
	0,07%	Maize/corn	0,01 /0,01	0,07		0,05%	Rye	0,01 /0,01	0,05		0,07%	Maize/corn	0,01 /0,01	0,07		0,05%	Rye	0,01 /0,01	0,05											
	0,06%	Rye	0,01 /0,01	0,06		0,05%	Barley	0,01 /0,01	0,05		0,06%	Rye	0,01 /0,01	0,06		0,05%	Barley	0,01 /0,01	0,05											
	0,06%	Barley	0,01 /0,01	0,06		0,03%	Buckwheat and other	0,01 /0,01	0,03		0,06%	Barley	0,01 /0,01	0,06		0,03%	Buckwheat and other pseudo-	0,01 /0,01	0,03											
	0,05%	Buckwheat and other	0,01 /0,01	0,05		0,02%	Maize/corn	0,01 /0,01	0,02		0,05%	Buckwheat and other	0,01 /0,01	0,05		0,02%	Maize/corn	0,01 /0,01	0,02											
	0,03%	Sorghum	0,01 /0,01	0,03		0,01%	Common millet/proso	0,01 /0,01	0,01		0,03%	Sorghum	0,01 /0,01	0,03		0,01%	Common millet/proso millet	0,01 /0,01	0,01											
	0,01%	Common millet/proso	0,01 /0,01	0,01		0,01%	Oat	0,01 /0,01	0,01		0,01%	Common millet/proso	0,01 /0,01	0,01		0,01%	Oat	0,01 /0,01	0,01											
	0,01%	Oat	0,01 /0,01	0,01		0,00%	Sorghum	0,01 /0,01	0,00		0,01%	Oat	0,01 /0,01	0,01		0,00%	Sorghum	0,01 /0,01	0,00											
	Expand/collapse list																													
	Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)																				Total number of commodities found exceeding the ARID/ADI in children and adult diets (IESTI new calculation)									
Processed commodities	Results for children No. of processed commodities for which ARID/ADI is exceeded (IESTI):				---	Results for adults No. of processed commodities for which ARID/ADI is exceeded (IESTI):				---	Results for children No. of processed commodities for which ARID/ADI is exceeded (IESTI new):				---	Results for adults No. of processed commodities for which ARID/ADI is exceeded (IESTI new):				---										
	IESTI					IESTI					IESTI new					IESTI new														
	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)		Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)		Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)		Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)											
	0,9%	Potatoes / fried	0,01 /0,01	0,93		0,1%	Maize / oil	0,01 /0,25	0,13		0,6%	Potatoes / dried (flakes)	0,01 /0,05	0,59		0,1%	Maize / oil	0,01 /0,25	0,13											
	0,6%	Potatoes / dried (flakes)	0,01 /0,05	0,59		0,08%	Potatoes / chips	0,01 /0,01	0,08		0,4%	Potatoes / fried	0,01 /0,01	0,44		0,08%	Potatoes / chips	0,01 /0,01	0,08											
	0,2%	Maize / oil	0,01 /0,25	0,23		0,07%	Barley / beer	0,01 /0	0,07		0,2%	Maize / oil	0,01 /0,25	0,23		0,07%	Barley / beer	0,01 /0	0,07											
	0,1%	Wheat / milling (flour)	0,01 /0,01	0,12		0,06%	Potatoes / dried (flakes)	0,01 /0,05	0,06		0,1%	Wheat / milling (flour)	0,01 /0,01	0,12		0,06%	Potatoes / dried (flakes)	0,01 /0,05	0,06											
	0,1%	Rice / milling (polishing)	0,01 /0	0,06		0,04%	Wheat / bread/pizza	0,01 /0,01	0,04		0,06%	Rice / milling (polishing)	0,01 /0	0,06		0,04%	Wheat / bread/pizza	0,01 /0,01	0,04											
	0,1%	Wheat / milling (wholemeal)	0,01 /0,01	0,06		0,04%	Rice / milling (polishing)	0,01 /0	0,04		0,06%	Wheat / milling	0,01 /0,01	0,06		0,04%	Rice / milling (polishing)	0,01 /0	0,04											
	0,1%	Millet / boiled	0,01 /0	0,05		0,04%	Wheat / pasta	0,01 /0,01	0,04		0,05%	Millet / boiled	0,01 /0	0,05		0,04%	Wheat / pasta	0,01 /0,01	0,04											
	0,1%	Buckwheat / bulgur and	0,01 /0,01	0,05		0,03%	Wheat / bread	0,01 /0,01	0,03		0,05%	Buckwheat / bulgur and	0,01 /0,01	0,05		0,03%	Wheat / bread (wholemeal)	0,01 /0,01	0,03											
	0,0%	Rye / boiled	0,01 /0,01	0,04		0,02%	Millet / boiled	0,01 /0	0,02		0,04%	Rye / boiled	0,01 /0,01	0,04		0,02%	Millet / boiled	0,01 /0	0,02											
	0,0%	Oat / boiled	0,01 /0,01	0,04		0,02%	Oat / boiled	0,01 /0,01	0,02		0,04%	Oat / boiled	0,01 /0,01	0,04		0,02%	Oat / boiled	0,01 /0,01	0,02											
	0,0%	Buckwheat / boiled	0,01 /0,01	0,04		#LICZBAI	#LICZBAI	#LICZBAI	#LICZBAI		0,04%	Buckwheat / boiled	0,01 /0,01	0,04		#LICZBAI	#LICZBAI	#LICZBAI	#LICZBAI											
	0,0%	Barley / cooked	0,01 /0,01	0,04		#LICZBAI	#LICZBAI	#LICZBAI	#LICZBAI		0,04%	Barley / cooked	0,01 /0,01	0,04		#LICZBAI	#LICZBAI	#LICZBAI	#LICZBAI											
	0,0%	Rye / milling (wholemeal)-l	0,01 /0,01	0,04		#LICZBAI	#LICZBAI	#LICZBAI	#LICZBAI		0,04%	Rye / milling (wholemeal)-	0,01 /0,01	0,04		#LICZBAI	#LICZBAI	#LICZBAI	#LICZBAI											
	0,0%	Oat / milling (flakes)	0,01 /0,01	0,03		#LICZBAI	#LICZBAI	#LICZBAI	#LICZBAI		0,03%	Oat / milling (flakes)	0,01 /0,01	0,03		#LICZBAI	#LICZBAI	#LICZBAI	#LICZBAI											
	0,0%	Maize / processed (not spe	0,01 /0,01	0,02		#LICZBAI	#LICZBAI	#LICZBAI	#LICZBAI		0,02%	Maize / processed (not	0,01 /0,01	0,02		#LICZBAI	#LICZBAI	#LICZBAI	#LICZBAI											
		Expand/collapse list																												
	Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Prosulfocarb, is unlikely to present a public health risk For processed commodities, no exceedance of the ARID/ADI was identified.																													