The evaluation of a new MRL for prosulfocarb in or on herbs and edible flowers

UK Competent Authority Evaluation Report and Reasoned Opinion

- Prepared under Article 8 of Assimilated Regulation 396/2005 and Data Requirements of Assimilated Regulation 544/2011
- Application Reference Number: COP 2023/01935

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Contents

Summary

In accordance with Article 6 of Assimilated Regulation 396/2005,[1] HSE received an application from Syngenta UK Limited on 19th December 2023 to set import tolerances for the active substance prosulfocarb in or on herbs and edible flowers. This was to accommodate an authorisation in the EU.

The applicant submitted a dossier in accordance with the data requirements outlined in Assimilated Regulation 544/2011.

In accordance with Article 6 of Assimilated Regulation 396/2005, HSE evaluated the dossier in accordance with the uniform principles as outlined in Article 29(6) of Assimilated Regulation 1107/2009.[2]

Based on the assessment HSE prepared an Evaluation Report that included its Reasoned Opinion on the risk to consumers associated with amending the MRLs. HSE also took into account the data assessed for the approval of the active substance and previous Reasoned Opinions.

Sufficiently validated analytical methods for the determination of prosulfocarb in products of plant origin, in line with the residue definition for enforcement, are available to support the uses under consideration in the import tolerance application. Additional method validation data for a multi-residue QuEChERs method was submitted, covering parsley (high water), carrot (high starch) and caraway seeds (high oil) commodities. In principle, the available data may be sufficient to address the data gap covering seed spices and fruit and berries spices. However, this aspect is not related to the current assessment, therefore it will be considered in full at a later date.

Toxicological reference values were established for the approval of the active substance: an ADI of 0.005 mg/kg bw/day and an ARfD of 0.1 mg/kg bw.

Metabolism in primary crops was investigated following foliar spray treatment in wheat and barley (cereals) and soil treatment in potatoes (roots crops) peas (pulses) for the approval of the active substance (DAR, 2005). The metabolic pathway was only identified in early sampling intervals on cereals. Significant residues of parent prosulfocarb were identified in field trials on immature carrots, celery, celeriac and caraway seeds (EFSA, 2011).

[1] Assimilated Regulation No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin

[2] Assimilated Regulation No 1107/2009 concerning the placing of plant protection products on the market

Additional information was requested on the metabolism of prosulfocarb in primary crops with a short vegetation period, especially those belonging to the group *Apicaeae.*

Additional data has been submitted for the metabolism of prosulfocarb in carrot roots and leaves and spring barley after foliar application. As there is existing data for foliar application on barley and the proposed uses are not on cereals, the spring barley metabolism study has not been evaluated. The study on carrots was evaluated.

The data gap has not been considered addressed at this time as the data on carrot roots has not been considered in full, in addition, the additional data on barley has not been evaluated. A full consideration of the residue definition shall be made in a future assessment considering all available data. In addition, further residues and/or toxicological data may be required to conclude on a general residue definition in crops.

Nevertheless, the data on carrot tops has been considered to support the authorised use on herbs and edible flowers, in lieu of specific data on leafy crops. For future applications concerning leafy crops, relevant data concerning the metabolism of prosulfocarb in leafy crops may still be required.

The metabolism data on carrot tops indicate that the current (provisional) residue definitions are suitable for herbs and edible flowers for risk assessment and MRL setting purposes.

Therefore, for the use under consideration, the residue definition for risk assessment (RD-RA) and enforcement (RD-Enf) in plants is the same as proposed during the Article 12 review (EFSA, 2011):

- Prosulfocarb (provisional)

The above residue definitions are considered suitable for the current evaluation of an MRL in/on herbs and edible flowers; for additional uses, including those on different leafy vegetables, may require further consideration.

8 outdoor trials on parsley, balm and dill conducted in NEU were submitted to support an MRL for herbs and edible flowers. The trials are supported by validated analytical methods and storage stability data.

Hydrolysis of prosulfocarb under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was evaluated for the approval of the active substance. The hydrolysis data demonstrate that prosulfocarb is stable under standard conditions, therefore specific residue definitions for processed commodities are not required.

No consideration of rotational crops was made as the impact of residues in rotational crops on the import tolerances was not required.

No consideration of residues in products of animal origin is required as the crops are not

The highest UK NEDI was 48% of the ADI (infant). The highest PRIMo IEDI was 47% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with prosulfocarb.

The highest UK NESTI was 13% of the ARfD (vegetarians/parsley). The highest PRIMo IESTI was 15% of the ARfD (BE toddler, chervil). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with prosulfocarb.

HSE concludes that sufficient data have been provided to support the setting of new MRL for the proposed use of prosulfocarb on herbs and edible flowers. This will not result in consumer exposures exceeding the toxicological reference values and therefore harmful effects on human health are not expected. HSE recommends that the MRLs outlined in Table 0.1 are amended in the GB MRL Statutory Register.

Table 0.1 MRLs recommended by HSE

Product code	**Product**	**Existing GB MRL (mg/kg)**	**New or amended GB MRL (mg/kg)**	**Comments**
Enforcement	**residue**	**definition**	**for products**	**of plant origin:** prosulfocarb
0256000	Herbs and edible flowers	0.05*	20	The MRL is sufficiently supported by data. No health effects are expected.

* Indicates that the MRL is set at the limit of quantification/determination

Background

Assimilated Regulation 396/2005 outlines the rules for setting MRLs in GB. Article 6 covers the submission of applications for MRLs, including the parties which can submit an application. Article 7 outlines that a dossier in accordance with the data requirements of Assimilated Regulation 1107/2009 must be provided.

On 19th December 2023 HSE accepted an application from Syngenta UK Limited to set import tolerances for prosulfocarb in or on herbs and edible flowers.

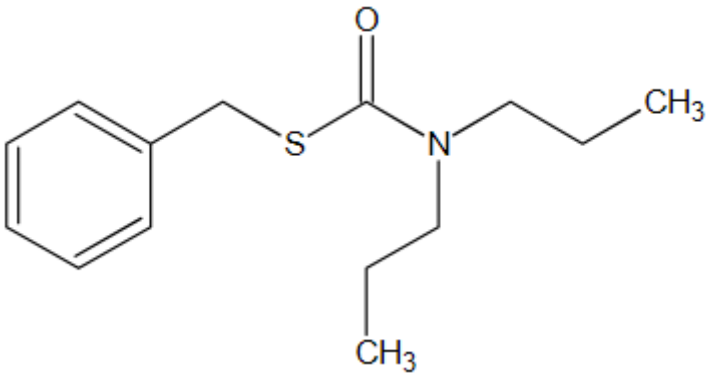
HSE evaluated the information submitted to uniform principles, as defined by Article 8 of Assimilated Regulation 396/2005 and prepared an Evaluation Report. HSE also took into account EFSA Reasoned Opinions and Conclusions on the peer review relating to decisions implemented in GB.

The Evaluation Report is the basis of HSE's Reasoned Opinion.

The active substance and its use pattern

Information on the active substance prosulfocarb is outlined in Table 0.2.

Table 0.2 Information on the active substance

Common name (ISO)	Prosulfocarb
Chemical name (IUPAC)	S-Benzyl dipropylthiocarbamate
CAS number	52888-80-9
Structural formula	
Molecular formula	$C_{14}H_{21}NOS$
Molecular mass	251.4 g/mol

Prosulfocarb is an approved active substance in GB. An EFSA conclusion is available (EFSA, 2007). The MRLs for prosulfocarb were reviewed under Article 12 of Assimilated Regulation 396/2005 (EFSA, 2011). MRLs are established for prosulfocarb in Part 2 of the GB MRL Statutory Register.

A copy of the current national legislation in the exporting country related to the MRLs under consideration and evidence of the authorisation of the respective uses of the plant protection product in [exporting country] was provided by the applicant and is summarised in Appendix E.

Appendix A outlines the GAPs (Good Agricultural Practices) supported in this application.

There are no CXLs available for prosulfocarb.

Assessment

1 Methods of Analysis

1.1 Methods for enforcement and monitoring of residues in food of plant origin

Analytical methods for the determination of prosulfocarb in products of plant origin, in line with the residue definition for enforcement, were assessed for the approval of the active substance (DAR, 2005).

GC-MS method DFG S19 is validated for the high starch (potatoes, wheat grain), high oil (sunflower seed), and high acid (strawberries) matrix groups with an LOQ of 0.01 mg/kg. Acceptable ILV data was provided.

Recovery data for a multi-residue QuEChERS method was provided for the Article 12 review of the MRLs (EFSA, 2011). Although no formal method validation study was available, the results from various EU reference labs demonstrated that prosulfocarb could be enforced with an LOQ of 0.01 mg/kg in high acid, high starch, high oil and high water matrices.

Additional method validation for the QuEChERS method has been provided in the current assessment. The method was validated with an LOQ of 0.005 mg/kg in high water (parsley), high starch (carrot) and high oil (caraway seed) matrices, acceptable ILV in these crops was also provided. A data gap was previously identified regarding the availability of validated methods for enforcement covering seed spices and fruit and berries spices (EFSA, 2011). In principle, the available data may be sufficient to address this data gap covering seed spices and fruit and berries spices. However, this aspect is not related to the current assessment, therefore it will be considered in full at a later date.

Extraction efficiency of the QuEChERS method LC-MS/MS in parsley is sufficiently demonstrated by cross-validation with the extraction method used in metabolism study on carrot leaves (C.3.1.1). Extraction solvents used in the carrot metabolism study and the QuEChERS method are identical. In the metabolism study, at least 98% TRR was extracted from carrot tops. Extraction efficiency is sufficiently addressed with regards to herbs and edible flowers.

The commodities under consideration in the MRL application: herbs and edible flowers (high water) are covered by the analytical methods available.

1.2 Methods for enforcement and monitoring of residues in food of animal origin

Not required as the MRL application does not require the setting or amendment of MRLs in products of animal origin.

2 Mammalian toxicology

The toxicological end points established for the approval of the active substance are summarised in Table 2.1.

Table 2.1 Overview of the toxicological reference values for prosulfocarb

TRVs	Source	Year	Value	Study relied upon	Safety factor
ADI	EFSA	2007	0.005 mg/kg bw/d	2-year oral toxicity study in rats, supported by the multi-generation study in rats	100
ARfD	EFSA	2007	0.1 mg/kg bw	Developmental toxicity study in rats	100

3 Residues in Plants

3.1 Nature of residues in primary crops

Metabolism in primary crops was investigated following foliar spray treatment in wheat and barley (cereals) and soil treatment in potatoes (roots crops) and peas (pulses) for the approval of the active substance (DAR, 2005).

A summary of the available primary crop metabolism data is presented below (EFSA, 2011)

"Immature barley foliage samples were analyzed at BBCH 12-22 (7 and 14 PHI); barley straw and grain samples were analyzed at full maturity 237 PHI. Results indicated that parent prosulfocarb was the major component of the TRR in immature foliage 7 PHI (10.9 % TRR or 4.6 mg/kg, in hexane fraction) along with several metabolites in aqueous phase (2B (10.5 % TRR), 2C (6.9 % TRR), 2D (6.9 % TRR)). Results with immature barley indicated that amount of parent prosulfocarb tends to decrease with longer PHI (3.7 % TRR or 1.85 mg/kg at 14 PHI) while the number of metabolites, due to extensive metabolism, tends to increase at 14 DAT. At the PHI of 161 days the amount of metabolites has significantly decreased, being below 10 % TRR. Results indicated no presence of prosulfocarb and any prosulfocarb specific metabolites in mature grain and straw".

Additional metabolism data has been submitted in the framework of the current assessment for prosulfocarb (carrots, and barley); however, as data is already available for foliar uses on barley, and as the uses under consideration are not cereals, the new barley metabolism study has not been evaluated.

Table 3.1-1 Summary of the primary plant metabolism studies

Crop group	Crop(s)	Applications	DAT[(a)] (days)
Existing data	**(EFSA, 2007)**		
Root crops	Potato	Soil, outdoor, 1 x 3.42 kg a.s./ha, pre-emergence	105
Cereals/grass crops	Wheat	Foliar, outdoor, 1 x 3.64 kg a.s./ha, BBCH 10-12	283
	Barley	Foliar, outdoor, 1 x 4.00 kg a.s./ha, BBCH 10-12	Immature barley: 7, 14 & 161 Grain and straw: 237 days post sowing

Pulses/Oilseeds	Peas	Soil, greenhouse, 1 x 4.05 kg a.s./ha, pre-emergence	At maturity
New data			
Root crops	Carrots	Foliar, outdoor, 1 x 4.18 kg a.s./ha, BBCH 14	Roots & leaves: 21 & 58

For the approval of the active substance, the metabolism of primary crops was considered in potato (root crops) and peas (pulses and oilseeds) after pre-emergence application to soil. The metabolic pathway could not be identified in either crop group as residues were too low for identification. The metabolic pathway of prosulfocarb in wheat and barley after foliar application was partially elucidated, with parent prosulfocarb identified in immature foliage (7 DAT), alongside a variety of metabolites. However, no residues could be identified in the harvest sampling of mature grain and straw. Hence, the residue definition for both enforcement and risk assessment was set provisionally as parent prosulfocarb only.

Significant residues of parent prosulfocarb were identified in field trials on immature carrots, celery, celeriac and caraway seeds (EFSA, 2011). Additional information was requested on the metabolism of prosulfocarb in primary crops with a short vegetation period, especially those belonging to the group *Apicaeae.* This data gap was translated into a footnote in Regulation (EU) No 777/2013 for the substantive MRLs on root and stem crops.

The current residue definition for risk assessment (RD-RA) and enforcement (RD- Enf) in plants has been provisionally agreed as (EFSA, 2011):

- Prosulfocarb (provisional)

The above residue definition is provisional pending the submission of a ‘metabolism study investigating primary crop metabolism in short cycle crops, in particular those belonging to the botanical family of Apiaceae’.

New metabolism data

In the newly submitted study on carrots, prosulfocarb was applied at 4.18 kg a.s/ha, as a post-emergence (BBCH 18) foliar spray, carrot roots and leaves were harvested at 21 and 58 days after treatment. Parent prosulfocarb was identified as the major residue in roots at both sampling intervals (33-48% TRR). Metabolite SYN545179 was identified in carrot roots, comprising 9.2% TRR (0.101 mg/kg) in 21 DAA samples and 14.1% TRR (0.060 mg/kg) in 58 DAA samples.

Metabolite R1331405 was also identified in carrot roots in 21 DAA samples only, contributing 0.3% TRR (0.003 mg/kg). Three further metabolites were characterised in 21 DAA samples, accounting for 7.3% TRR (0.079 mg/kg). Two of these metabolites were characterised in 58 DAA samples, accounting for 9.0% TRR (0.038 mg/kg).

In carrot tops, parent prosulfocarb was the major residue at both sampling intervals (72-79% TRR). R393096 was tentatively identified in minor amounts at between 1.3-1.7% TRR (0.017-0.022x that of parent prosulfocarb). This metabolite was not confirmed by subsequent 2D-TLC or HPLC analysis. As such, R393096 is considered a minor tentatively identified metabolite, no further consideration has been made at this time.

In carrot leaves, R331405 was tentatively identified using 2D-TLC. R331282, R331405, and SYN545179 were also tentatively identified by HPLC, but no quantification was done. By comparison between the 2D-TLC and HPLC analysis, R331282 R331405, and SYN545179 are not expected to be present at levels significantly exceeding 0.2% TRR; see appendix C.3.1.1 for further details.

Overall, based on the initial 1D-TLC and the subsequent 2D-TLC and HPLC analysis, parent prosulfocarb is clearly the predominant residue in carrot leaves – comprising between 72-79% TRR based on 1D-TLC and between 87-90% TRR based on the 2D-TLC follow up.

Overall, sufficient metabolism data is available to conclude on the use under consideration. Parent prosulfocarb is the predominant residue, and no other residues were robustly identified – those which were tentatively identified are expected in very minor amounts, which are insignificant compared to parent prosulfocarb.

On this basis, the available primary crop metabolism data is sufficient to support the authorised uses in the EU for herbs and edible flowers; further consideration is required for any additional uses, including those on other leafy crops.

The data gap has not been addressed in full, as the data from carrot roots has not been fully considered and the new metabolism study on barley was not evaluated. This data shall be considered in full in a future assessment to address the data gaps for prosulfocarb. Additional residue and/or toxicological data may also be required to conclude on a general residue definition for all crops.

Nevertheless, for the current assessment, the following residue definitions (risk assessment (RD-RA) and enforcement (RD-Enf)) are considered appropriate for herbs and edible flowers:

- Prosulfocarb (provisional)

3.2 Magnitude of residues in primary crops

The uses notified in the current application are outlined in Appendix A.

Residue trials

0256000 Herbs and edible flowers

The authorised outdoor GAP in NEU is 1 x 1.6 kg a.s./ha (post-emergence) with a PHI of 21 days.

The applicant has submitted nine trials on herbs (dill leaves, balm and parsley) in the context of this application to support the UK cGAP. A full analysis of the trials can be found in section C.3.1.2.

Nine outdoor trials on parsley, balm and dill were undertaken in NEU using an EC formulation, as tabulated below. The trials were conducted at BBCH 10-47, 1 x 1.6 kg a.s./ha, PHI 21-22 days, which is in line with the authorised GAP. Trials MUE-01 and MUE-02 cannot be considered independent from each other, therefore only trial MUE-01 residues were considered as they represent a worst case. As a consequence of these trials being excluded, a total of eight trials were considered to support the MRL.

The trials were conducted in accordance with the relevant guidance documents (OECD 509), and no significant deviations were noted in the trials. Control residues greater than LOQ (0.005 mg/kg) were recorded in two of the six trials relied upon, for which no explanation was provided. As the control residues in relevant samples are insignificant in comparison with the residues from the associated treated sample, the trials have been included.

The cGAP on herbs and edible flowers is after the formation of the edible part, therefore half of the trials should be decline trials. All six trials show a decline in residues, which is sufficient to support the use.

At least four trials are required to support an MRL increase for a group containing only minor crops. As eight trials are available (four on parsley and four on other fresh herbs), this is sufficient to support the use.

Storage stability

Sufficient storage stability in high water commodities is available from the approval of prosulfocarb to support the maximum storage period of 8 months for herbs and edible flowers.

Storage stability of prosulfocarb in high water commodities was demonstrated for at least 18 months at < -18 ºC.

Analytical methods

Analysis for residues of prosulfocarb was completed using LC-MS/MS method SAA/C/PSM 040 (see section C.1.3 for validation data). The analytical method was satisfactorily validated in accordance with SANCO 3029/99 rev. 4. Extraction efficiency was not sufficiently addressed – however, this is not expected to impact the consumer risk assessment or the derived MRL.

Table 3.2 Overview of the available residue trials data

Commodity	Region/ Indoor (a)	Residue levels (mg/kg) observed in the trials representative for the intended GAPs (b)	Recommendations/ comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
RD-RA/ RD-Enf:	**Prosulfocarb**					
Dill leaves, balm and parsley → herbs and edible flowers	NEU	0.389, 0.431, 0.535, 0.777, 0.907, 1.896, 3.928 11.799	Trials on balm whole plant (1), dill leaves (3) and parsley whole plant (4) from NEU data; extrapolated to cover herbs and edible flowers crop group. Herbs and edible flowers is a minor crop therefore a minimum of 4 trials are required. MRL_{OECD}: 18.216 (unrounded MRL)	**20**	11.799	0.842

(a) GB or the country for an import tolerance and whether the GAP is for an outdoor use or an indoor/protected/glasshouse use.

(b) Residue levels in trials conducted according to GAPs reported in ascending order. When residue definitions for enforcement and risk assessment differ, **Enf/RA** differentiate data expressed according to the residue definition for **Enf**orcement and **R**isk **A**ssessment.

(c) **HR**: Highest residue, according to the residue for risk assessment, (within brackets when expressed according to the residue definition for enforcement: HR_{Enf})

(d) **STMR**: Supervised Trials Median Residue according to the residue definition risk assessment (within brackets when expressed according to the residue definition for enforcement: $STMR_{Enf}$)

3.3 Conversion factors for risk assessment for products of plant origin

As the residue definitions for enforcement (RD-Enf) and risk assessment (RD-RA) are equivalent, conversion factors (CFs) for enforcement to risk assessment are not required.

3.4 Effect of industrial processing and/or household preparation

3.4.1 Nature of the residues in processed commodities

Data on the nature and magnitude of residues in processed commodities was not required for the approval of the active substance as residues in raw agricultural commodities were all <0.1 mg/kg (EFSA, 2007).

A data gap for studies covering prosulfocarb residues in processed commodities was identified by EFSA for the modification of the existing prosulfocarb MRL in fennel (EFSA, 2011), as residues in the RAC exceeded 0.1 mg/kg and the TMDI for all commodities exceeds 10%. However, fennel was a minor contributor to the TMDI and the fennel input alone did not exceed 10%, therefore it was not expected to significantly impact the EFSA MRL evaluation.

In principle no consideration of residues in processed commodities is required in the current evaluation as the crops concerned are not consumed processed (beyond simple physical processes such as washing).

However, for completeness, a study assessing the hydrolysis of prosulfocarb under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was submitted and has been evaluated as part of this application (see C.3.2.1 for the full study).

A summary of the available hydrolysis data is presented below

Table 3.4.1 Overview of the available hydrolysis studies

% applied radioactivity	**Study on prosulfocarb**	
Conditions	**Prosulfocarb**	**Non-discrete regions**
20 min, 90°C, pH 4	99.6%	0.4%
60 min, 100°C, pH 5	99.2%	0.8%
20 min, 120°C, pH 6	98.6%	1.4%

The hydrolysis data demonstrates that prosulfocarb is stable across the standard conditions, therefore specific residue definitions for processed commodities are not required.

3.4.2 Magnitude of the residues in processed commodities

No consideration of residues in processed commodities is required, as the crops concerned are not consumed processed.

3.5 Rotational crops

No consideration of rotational crops was made as the impact of residues in rotational crops on the import tolerances was not required and the potential for residues in rotational crops was considered minimal.

Additional studies were submitted by the applicant and checked for adverse data. The study was not expected to impact the consumer risk assessment or calculated MRLs.

4 Residues in livestock

No consideration of residues in products of animal origin is required as the crops are not used as animal feedstuffs.

5 Residues in honey

No consideration of residues in honey is required, as the application is to ‘old’ data requirements set out under Assimilated Regulation 544/2011. Not applicable to import tolerances where no MRLs for the import of honey have been requested.

6 MRLs for products not covered in Sections 3 and 4

This section is to cover MRLs that can be extrapolated to other products included in Part 1 of the GB MRL Statutory Register but are not covered in Sections 3 and 4 of this ER/RO. Examples include MRLs for edible offals (other than liver and kidney) or MRLs to cover products derived from other species such as goat or equine.

No MRL extrapolations are recommended on the basis of this assessment.

7 Consumer risk assessment

7.1 Dietary Exposure

Consumer intake calculations have been performed using the UK chronic and acute dietary exposure models and the EFSA PRIMo.

The chronic risk assessments have been estimated based on the uses of prosulfocarb considered in this application, the uses considered in previous assessments supporting existing GB MRLs (EFSA, 2007; EFSA 2011 and EFSA, 2013) and, for the remaining commodities, the existing MRLs established in the GB MRL Statutory Register.

The acute risk assessments have only been estimated for the uses of prosulfocarb considered in this application.

UK NEDIs and NESTIs

The UK NEDIs and NESTIs for the active substance and commodities listed in Table 7.1-1 have been calculated for ten consumer groups using the UK chronic and acute models (versions 1.1 and 1.2 respectively) as detailed in Regulatory Update 21/2005. The following assumptions have been made:

- For the NESTIs, upper range of normal (97.5th percentile) consumption of each individual crop which may have been treated.
- For the NEDIs, the 'Rees-Day' approach is taken which sums the two highest 97.5th percentile intakes and the mean intakes for all remaining commodities.
- All produce eaten which may have been treated has been treated and contains residues at the levels given in Table 7.1-1.
- There is no loss of residue during transport, storage or processing of foods prior to consumption.

As there is only consumption data for parsley in UK models, parsley will be used to represent all herbs and edible flowers used in the consumer risk assessments. This approach is supplemented by PRIMo, which has consumption data for all commodities in the herbs and edible flowers group.

The input values for the UK consumer risk assessment are given in Table 7.1-1.

Table 7.1-1 Input values for the UK consumer risk assessment

Commodity	**Chronic risk assessment**		**Acute risk assessment**	
	Input (mg/kg)	**Comment**	**Input (mg/kg)**	**Comment**
Risk assessment residue definition: prosulfocarb				
Herbs and edible flowers**	**0.84**	**STMR (current assessment)**	**11.80**	**HR (current assessment)**
Strawberries	0.05*	GB MRL	Acute risk assessment undertaken only for the uses proposed as part of the current assessment	
Potatoes	0.01	STMR (EFSA, 2011)		
Carrots	0.34	STMR (EFSA, 2011)		
Celeriac	0.03	STMR (EFSA, 2011)		
Horseradishes	0.01	STMR (EFSA, 2011)		
Parsnips	0.01	STMR (EFSA, 2011)		
Salsifies	0.01	STMR (EFSA, 2011)		
Onions	0.01	STMR (EFSA, 2011)		
Spring onions	0.02	STMR (EFSA, 2011)		
Beans (with pods)	0.01	STMR (EFSA, 2011)		
Beans (without pods)	0.01	STMR (EFSA, 2011)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Peas (with pods)	0.01	STMR (EFSA, 2011)		
Peas (without pods)	0.01	STMR (EFSA, 2011)		
Asparagus	0.01	STMR (EFSA, 2011)		
Celeries	0.19	STMR (EFSA, 2011)		
Globe artichokes	0.01	STMR (EFSA, 2011)		
Leeks	0.01	STMR (EFSA, 2011)		
Beans	0.01	STMR (EFSA, 2011)		
Peas	0.01	STMR (EFSA, 2011)		
Barley	0.01	STMR (EFSA, 2011)		
Oat	0.01	STMR (EFSA, 2011)		
Rye	0.01	STMR (EFSA, 2011)		
All other commodities	MRL	MRL†		

* indicates residues at the LOQ

†GB MRL Statutory Register and Regulation (EU) 777/2013

In bold uses proposed as part of the current assessment.

** Parsley used as a surrogate for herbs and edible flowers

Model outputs for the UK chronic and acute models (versions 1.1 and 1.2 respectively) are presented in Appendix B.

PRIMo

The PRIMo IEDIs and IESTIs for the active substance and commodities listed in Table 7.1-2 have been calculated using PRIMo revision 3.1 – Pesticide Residues Intake Model.

The following assumptions have been made:

- All produce eaten which may have been treated, has been treated and contains residues at the levels as given in Table 7.1-2.
- There is no loss of residue during transport, storage or processing of foods prior to consumption.

The input values for the PRIMo risk assessment are given in Table 7.1-2.

Table 7.1-2 Input values for the PRIMo consumer risk assessment

Commodity	**Chronic risk**	**assessment**	**Acute risk**	**assessment**
	Input (mg/kg)	**Comment**	**Input (mg/kg)**	**Comment**
Risk	**assessment**	**residue**	**definition:**	prosulfocarb
Herbs and edible flowers	**0.84**	**STMR (current assessment)**	**11.799**	**HR (current assessment)**
Strawberries	0.05*	GB MRL	Acute risk assessment undertaken only for the uses proposed as part of the current assessment	
Potatoes	0.01	STMR (EFSA, 2011)		
Carrots	0.34	STMR (EFSA, 2011)		
Celeriacs/turnip rooted celeries	0.03	STMR (EFSA, 2011)		
Horseradishes	0.01	STMR (EFSA, 2011)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Parsnips	0.01	STMR (EFSA, 2011)		
Parsley roots	0.01	STMR (EFSA, 2011)		
Salsifies	0.01	STMR (EFSA, 2011)		
Onions	0.01	STMR (EFSA, 2011)		
Shallots	0.01	STMR (EFSA, 2011)		
Spring, green, Welsh onions	0.02	STMR (EFSA, 2011)		
Beans (with pods)	0.01	STMR (EFSA, 2011)		
Beans (without pods)	0.01	STMR (EFSA, 2011)		
Peas (with pods)	0.01	STMR (EFSA, 2011)		
Peas (without pods)	0.01	STMR (EFSA, 2011)		
Asparagus	0.01	STMR (EFSA, 2011)		
Celeries	0.19	STMR (EFSA, 2011)		
Globe artichokes	0.01	STMR (EFSA, 2011)		
Leeks	0.01	STMR (EFSA, 2011)		
Beans	0.01	STMR (EFSA, 2011)		
Peas	0.01	STMR (EFSA, 2011)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Poppy seeds	0.01	STMR (EFSA, 2011)		
Sunflower seeds	0.01	STMR (EFSA, 2011)		
Barley	0.01	STMR (EFSA, 2011)		
Oat	0.01	STMR (EFSA, 2011)		
Rye	0.01	STMR (EFSA, 2011)		
Aniseed	0.05	STMR (EFSA, 2011)		
Black caraway	0.05	STMR (EFSA, 2011)		
Celery seed	0.05	STMR (EFSA, 2011)		
Coriander seed	0.05	STMR (EFSA, 2011)		
Cumin seed	0.05	STMR (EFSA, 2011)		
Dill seed	0.05	STMR (EFSA, 2011)		
Fennel seed	0.05	STMR (EFSA, 2011)		
Fenugreek	0.05	STMR (EFSA, 2011)		
Nutmeg	0.05	STMR (EFSA, 2011)		
Other spices (seeds)	0.05	STMR (EFSA, 2011)		
Allspice	0.05	STMR (EFSA, 2011)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Sichuan pepper	0.05	STMR (EFSA, 2011)		
Caraway	0.05	STMR (EFSA, 2011)		
Cardamom	0.05	STMR (EFSA, 2011)		
Juniper berry	0.05	STMR (EFSA, 2011)		
Peppercorn	0.05	STMR (EFSA, 2011)		
Vanilla pods	0.05	STMR (EFSA, 2011)		
Tamarind	0.05	STMR (EFSA, 2011)		
Other spices (fruits)	0.05	STMR (EFSA, 2011)		
All other commodities	MRL	MRL†		

* indicates residues at the LOQ
In bold uses proposed as part of the current assessment.
Model outputs for EFSA PRIMo revision 3.1 are presented in Appendix B.

Conclusions

The highest UK NEDI was 48% of the ADI (infant). The highest PRIMo IEDI was 47% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with prosulfocarb.

The highest UK NESTI was 13% of the ARfD (vegetarians/parsley). The highest PRIMo IESTI was 15% of the ARfD (BE toddler, chervil). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with prosulfocarb.

7.2 Other routes of exposure

Not applicable

8 The conclusion of the competent authority

Sufficiently validated analytical methods for the determination of prosulfocarb in products of plant origin, in line with the residue definition for enforcement, are available to support the uses under consideration in the import tolerance application. Additional method validation data for a multi-residue QuEChERs method was submitted, covering parsley (high water), carrot (high starch) and caraway seeds (high oil) commodities. In principle, the available data may be sufficient to address the data gap covering seed spices and fruit and berries spices. However, this aspect is not related to the current assessment, therefore it will be considered in full at a later date.

Toxicological reference values were established for the approval of the active substance: an ADI of 0.005 mg/kg bw/day and an ARfD of 0.1 mg/kg bw.

Metabolism in primary crops was investigated following foliar spray treatment in wheat and barley (cereals) and soil treatment in potatoes (roots crops) peas (pulses) for the approval of the active substance (DAR, 2005). The metabolic pathway was only identified in early sampling intervals on cereals. Significant residues of parent prosulfocarb were identified in field trials on immature carrots, celery, celeriac and caraway seeds (EFSA, 2011). Additional information was requested on the metabolism of prosulfocarb in primary crops with a short vegetation period, especially those belonging to the group *Apicaeae.*

Additional data has been submitted for the metabolism of prosulfocarb in carrot roots and leaves and spring barley after foliar application. As there is existing data for foliar application on barley and the proposed uses are not on cereals, the spring barley metabolism study has not been evaluated. The study on carrots was evaluated.

The data gap has not been considered addressed at this time as the data on carrot roots has not been considered in full, in addition, the additional data on barley has not been evaluated. A full consideration of the residue definition shall be made in a future assessment considering all available data. In addition, further residues and/or toxicological data may be required to conclude on a general residue definition in crops.

Nevertheless, the data on carrot tops has been considered to support the authorised use on herbs and edible flowers, in lieu of specific data on leafy crops. For future applications concerning leafy crops, relevant data concerning the metabolism of prosulfocarb in leafy crops may still be required.

The metabolism data on carrot tops indicate that the current (provisional) residue definitions are suitable for herbs and edible flowers for risk assessment and MRL setting purposes.

Therefore, for the use under consideration, the residue definition for risk assessment (RD-RA) and enforcement (RD-Enf) in plants is the same as proposed during the Article 12 review (EFSA, 2011):

- Prosulfocarb (provisional)

The above residue definitions are considered suitable for the current evaluation of an MRL in/on herbs and edible flowers; for additional uses, including those on different leafy vegetables, may require further consideration.

8 outdoor trials on parsley, balm and dill conducted in NEU were submitted to support an MRL for herbs and edible flowers. The trials are supported by validated analytical methods and storage stability data.

Hydrolysis of prosulfocarb under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was evaluated in the current assessment. The hydrolysis data demonstrate that prosulfocarb is stable under standard conditions, therefore specific residue definitions for processed commodities are not required.

No consideration of rotational crops was made as the impact of residues in rotational crops on the import tolerances was not required. A nature of residues study was submitted, this was checked for adverse data, but was not fully evaluated. The study was not expected to impact the consumer risk assessment or calculated MRLs.

No consideration of residues in products of animal origin is required as the crops are not routinely fed to livestock.

The highest UK NEDI was 48% of the ADI (infant). The highest PRIMo IEDI was 47% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with prosulfocarb.

The highest UK NESTI was 13% of the ARfD (vegetarians/parsley). The highest PRIMo IESTI was 15% of the ARfD (BE toddler, chervil). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with prosulfocarb.

HSE concludes that sufficient data have been provided to support the setting of new MRL for the proposed use of prosulfocarb on herbs and edible flowers. This will not result in consumer exposures exceeding the toxicological reference values and therefore harmful effects on human health are not expected. HSE recommends that the MRLs outlined in Table 8.1 are amended in the GB MRL Statutory Register.

Table 8.1 MRLs recommended by HSE

Product code	**Product**	**Existing GB MRL (mg/kg)**	**New or amended GB MRL (mg/kg)**	**Comments**
Enforcement	**residue**	**definition**	**for products**	**of plant origin:** prosulfocarb
0256000	Herbs and edible flowers	0.05*	20	The MRL is sufficiently supported by data. No health effects are expected.

* Indicates that the MRL is set at the limit of quantification/determination

References

Sweden, 2005. Draft Assessment Report (DAR) on the active substance prosulfocarb, prepared by the rapporteur Member State Swdenin the framework of framework of Assimilated Regulation 1107/2009, April 2005

EFSA (European Food Safety Authority), 2007. Conclusion on the peer review of the pesticide risk assessment of the active substance prosulfocarb, EFSA Journal 2007; 5(8):RN-111

EFSA (European Food Safety Authority), 2011. Reasoned opinion of EFSA: 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

Appendix A – GAPs notified in the MRL application

Crop and/or situation (a)	GB or Country For Import Tolerance	Product name	F,G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water (L/ha) min-max	kg a.s./ha min-max (l)		
Herbs and edible flowers	EU NEU/ /NL	Boxer	F	Weeds	EC	800 g/l	Foliar spray	Post emergence	1	n/a		300-400	1.6 kg ai/ha	21	

(a) For crops, the GB and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) State if the use is outdoor, field use (F) or glasshouse (G) or indoor use (I).
(c) *e.g.* biting and sucking insects, soil borne insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Appendix B – UK models and Pesticide Residues Intake Model (PRIMo)

Table B.1 Chronic risk assessment undertaken using UK model version 1.1

Active substance: Prosulfocarb **ADI:** 0.005 mg/kg bw/day

			TOTAL INTAKE based on 97.5th percentile									
			ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
	mg/kg bw/day		0.00054	0.00240	0.001674	0.001220	0.00082	0.00056	0.00056	0.00063	0.00061	0.00074
	% of ADI		11%	48%	33%	24%	16%	11%	11%	13%	12%	15%
	STMR	P	COMMODITY INTAKES									
Commodity	(mg/kg)		(mg/kg bw/day)									
Grapefruit	0.01		0.00002	0.00002	0.00006	0.00005	0.00012	0.00002	0.00001	0.00002	0.00002	0.00002
Lemons	0.01		0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Limes	0.01		0.00000	L/C	0.00002	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001
Mandarins	0.01		0.00001	L/C	0.00006	0.00004	0.00003	0.00002	0.00002	0.00001	0.00002	0.00001
Oranges	0.01		0.00004	0.00011	0.00016	0.00011	0.00008	0.00008	0.00007	0.00005	0.00004	0.00003
Almonds	0.02		0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Brazil nuts	0.02		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Cashew nuts	0.02		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Chestnuts	0.02		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00001	0.00000	L/C

Coconuts	0.02		0.00000	0.00000	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Hazelnuts	0.02		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Pecan nuts	0.02		0.00000	L/C	0.00000	L/C	0.00000	0.00000	L/C	0.00001	0.00000	L/C
Pistachios	0.02		0.00001	L/C	0.00001	L/C	0.00000	L/C	L/C	0.00000	L/C	L/C
Walnuts	0.02		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Peanuts	0.02		0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Apples	0.01		0.00003	0.00008	0.00015	0.00009	0.00008	0.00004	0.00004	0.00003	0.00002	0.00001
Pears	0.01		0.00001	0.00003	0.00007	0.00004	0.00002	0.00002	0.00001	0.00002	0.00002	0.00001
Apricots	0.01		0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Peaches	0.01		0.00001	0.00001	0.00003	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00000
Plums	0.01		0.00001	0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Cherries	0.01		0.00000	0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000
Table grapes	0.01		0.00001	0.00002	0.00005	0.00002	0.00003	0.00001	0.00001	0.00002	0.00001	0.00000
Wine grapes	0.01		0.00010	0.00001	0.00001	0.00001	0.00000	0.00001	0.00004	0.00010	0.00007	0.00001
Strawberries	0.05		0.00003	0.00010	0.00010	0.00007	0.00004	0.00003	0.00003	0.00005	0.00005	0.00003
Blackberries	0.01		0.00000	L/C	0.00002	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Loganberries	0.01		0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
Raspberries	0.01		0.00000	L/C	0.00002	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Gooseberries	0.01		0.00000	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00001	0.00000
Blackcurrants	0.01		0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00000	0.00001	0.00000
Red currants	0.01		0.00000	L/C	0.00001	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
White currants	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Avocados	0.01		0.00001	L/C	0.00001	L/C	L/C	L/C	0.00000	0.00001	0.00001	L/C
Bananas	0.01		0.00002	0.00007	0.00007	0.00004	0.00003	0.00002	0.00001	0.00002	0.00002	0.00002
Dates	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00001	0.00000
Figs	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000

Kiwi fruit	0.01		0.00001	L/C	0.00002	0.00002	0.00001	0.00001	0.00002	0.00001	0.00001	0.00000
Lychees	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Mangoes	0.01		0.00001	L/C	0.00002	0.00001	0.00002	0.00001	0.00004	0.00001	0.00000	L/C
Olives	0.01		0.00000	L/C	0.00001	0.00001	L/C	0.00000	L/C	0.00000	0.00000	L/C
Passion fruit	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Pineapples	0.01		0.00001	0.00005	0.00005	0.00007	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001
Pomegranates	0.01		0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000	0.00001	0.00001	0.00001
Beetroot	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Carrots	0.34		0.00024	0.00120	0.00084	0.00065	0.00042	0.00029	0.00033	0.00030	0.00033	0.00026
Celeriac	0.03		0.00001	L/C	L/C	0.00000	0.00000	L/C	L/C	L/C	L/C	L/C
Horseradish	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C
Jerusalem artichokes	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Parsnips	0.01		0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Radishes	0.01		0.000003	L/C	0.000010	L/C	0.00000	0.000001	0.000001	0.000003	0.000002	0.000001
Salsify	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Swedes	0.01		0.00000	0.00003	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Turnips	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Yam	0.01		0.00003	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Garlic	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Onions	0.01		0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Spring onions	0.02		0.00001	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00001	0.00001	0.00000
Tomatoes	0.01		0.00001	0.00002	0.00003	0.00002	0.00002	0.00001	0.00001	0.00002	0.00001	0.00001
Peppers	0.01		0.00000	L/C	0.00001	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Aubergines	0.01		0.00000	L/C	0.00002	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000	L/C
Marrows	0.01		0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001
Cucumbers	0.01		0.00000	0.00000	0.00002	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000

Gourd	0.01		0.00001	L/C	L/C	L/C	L/C	0.00000	L/C	0.00000	L/C	L/C
Courgettes	0.01		0.00000	0.00001	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Melons	0.01		0.00002	0.00003	0.00005	0.00004	0.00003	0.00002	0.00003	0.00003	0.00003	0.00001
Sweet corn	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000
Broccoli	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Cauliflower	0.01		0.00001	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Brussels sprouts	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Head cabbage	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Chinese cabbage	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00001	0.00000	L/C
Kohl Rabi	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Cress	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Lettuce	0.01		0.00001	0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Spinach	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00000	0.00001	0.00001	0.00000
Watercress	0.01		0.00000	L/C	L/C	0.00000	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Parsley	0.842		0.00014	L/C	0.00009	L/C	0.00013	0.00004	0.00001	0.00014	0.00015	0.00031
Beans with pods	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000
Runner Beans	0.01		0.00001	L/C	0.00001	0.00000	0.00001	0.00001	0.00000	0.00002	0.00001	0.00001
Beans without pods	0.01		0.00000	0.00001	0.00002	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001
Peas with pods	0.01		0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	L/C
Peas without pods	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Beansprouts	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Asparagus	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00001	0.00000	L/C
Bamboo shoots	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Celery	0.19		0.00006	0.00008	0.00008	0.00005	0.00003	0.00005	0.00003	0.00009	0.00009	0.00002
Fennel	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Globe artichokes	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C

Leeks	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Rhubarb	0.01		0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Cultivated mushrooms	0.01		0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Beans	0.01		0.00002	0.00006	0.00005	0.00003	0.00003	0.00002	0.00002	0.00002	0.00001	0.00001
Lentils	0.01		0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
dried Peas	0.01		0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Oilseeds	0.02		0.00006	0.00013	0.00014	0.00014	0.00011	0.00008	0.00007	0.00009	0.00006	0.00008
Potatoes	0.01		0.00003	0.00011	0.00009	0.00008	0.00007	0.00005	0.00005	0.00004	0.00003	0.00003
Oats	0.01		0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001	0.00001
Barley	0.01		0.00000	L/C	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
Millet	0.01		L/C	L/C	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Buckwheat	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Maize	0.01		0.00000	0.00005	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Wheat	0.01		0.00004	0.00003	0.00008	0.00009	0.00007	0.00005	0.00004	0.00004	0.00003	0.00003
Rice	0.01		0.00002	0.00003	0.00005	0.00004	0.00005	0.00004	0.00003	0.00002	0.00001	0.00000
Rye	0.01		0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Poultry	0.01		0.00002	0.00002	0.00003	0.00003	0.00002	0.00002	0.00002	0.00002	0.00002	0.00001
Meat fat	0.01		0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Meat excl. poultry & offal	0.01		0.00002	0.00004	0.00004	0.00003	0.00003	0.00002	0.00002	0.00000	0.00002	0.00002
All types of kidney	0.01		0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00000
All types of Liver	0.01		0.00000	0.00002	0.00002	0.00000	0.00000	0.00001	0.00000	L/C	0.00001	0.00000
Other types of offal	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001
Eggs	0.01		0.00001	0.00005	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001
Milk	0.01		0.00008	0.00098	0.00056	0.00029	0.00018	0.00012	0.00009	0.00010	0.00009	0.00012

Table B.2 Chronic risk assessment undertaken using PRIMo revision 3.1

Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
				No of diets exceeding the ADI : ---						Exposure resulting from	
	Calculated exposure (% of ADI)	MS Diet	Expsoure (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)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food	47.0%	NL toddler	2.35	21.3%	Carrots	11.9%	Milk: Cattle	2.2%	Apples	24.2%	
	38.6%	UK infant	1.93	26.4%	Carrots	7.7%	Milk: Cattle	0.7%	Potatoes	11.1%	
	36.4%	DE child	1.82	36.4%	Carrots	4.0%	Milk: Cattle	2.5%	Apples	12.0%	
	35.5%	DK child	1.78	35.5%	Carrots	2.5%	Milk: Cattle	1.1%	Rye	6.3%	
	28.5%	FR infant	1.42	28.5%	Carrots	3.4%	Milk: Cattle	0.4%	Potatoes	5.2%	
	25.9%	FR toddler 2 3 yr	1.29	25.9%	Carrots	5.9%	Milk: Cattle	0.6%	Apples	10.6%	
	24.7%	SE general	1.24	24.7%	Carrots	2.5%	Milk: Cattle	0.9%	Bovine: Muscle/meat	6.3%	
	24.6%	GEMS/Food G11	1.23	24.6%	Carrots	1.6%	Milk: Cattle	1.5%	Soyabeans	7.9%	
	21.7%	NL child	1.08	21.7%	Carrots	4.6%	Milk: Cattle	0.9%	Wheat	10.7%	
	21.6%	FR child 3 15 yr	1.08	21.6%	Carrots	4.9%	Milk: Cattle	1.7%	Sugar beet roots	13.1%	
	20.5%	FI 3 yr	1.02	20.5%	Carrots	0.9%	Potatoes	0.4%	Strawberries	2.4%	
	19.4%	UK toddler	0.97	19.4%	Carrots	4.1%	Milk: Cattle	0.8%	Wheat	8.0%	
	18.2%	GEMS/Food G08	0.91	18.2%	Carrots	1.1%	Milk: Cattle	1.0%	Parsley	7.0%	

	18.1%	GEMS/Food G07	0.90	18.1%	Carrots	1.3%	Milk: Cattle	0.8%	Wheat	7.2%	
	17.7%	PT general	0.88	17.7%	Carrots	1.4%	Milk: Cattle	0.9%	Wheat	7.0%	
	17.4%	GEMS/Food G15	0.87	17.4%	Carrots	1.1%	Potatoes	0.8%	Wheat	2.9%	
	16.7%	RO general	0.83	16.7%	Carrots	2.3%	Milk: Cattle	1.0%	Wheat	6.7%	
	15.1%	FI 6 yr	0.75	15.1%	Carrots	1.3%	Soyabeans	1.1%	Parsley	7.4%	
	14.7%	GEMS/Food G10	0.74	14.7%	Carrots	0.8%	Potatoes	0.3%	Strawberries	1.9%	
	14.6%	DE women 14-50 yr	0.73	14.6%	Carrots	2.5%	Milk: Cattle	0.9%	Sugar beet roots	7.1%	
	14.1%	IE adult	0.70	14.1%	Carrots	0.9%	Basil and edible flowers	0.9%	Milk: Cattle	5.9%	
	13.7%	FI adult	0.68	13.7%	Carrots	5.6%	Coffee beans	0.2%	Potatoes	6.6%	
	13.4%	DE general	0.67	13.4%	Carrots	2.5%	Milk: Cattle	0.8%	Sugar beet roots	6.8%	
	13.2%	DK adult	0.66	13.2%	Carrots	1.1%	Milk: Cattle	0.3%	Potatoes	2.8%	
	11.3%	ES child	0.56	11.3%	Carrots	2.5%	Milk: Cattle	0.9%	Wheat	7.2%	
	10.8%	GEMS/Food G06	0.54	10.8%	Carrots	1.4%	Wheat	0.7%	Tomatoes	7.4%	
	10.8%	NL general	0.54	10.8%	Carrots	1.7%	Milk: Cattle	0.6%	Sugar beet roots	5.6%	
	8.7%	FR adult	0.44	8.7%	Carrots	0.9%	Milk: Cattle	0.5%	Wine grapes	4.2%	
	8.2%	PL general	0.41	8.2%	Carrots	0.7%	Potatoes	0.4%	Apples	1.1%	
	7.5%	UK vegetarian	0.38	7.5%	Carrots	1.3%	Wheat	0.3%	Other herbs	3.1%	
	7.4%	IT toddler	0.37	7.4%	Carrots	0.7%	Milk: Cattle	0.4%	Wheat	2.5%	
	7.1%	ES adult	0.36	7.1%	Carrots	1.0%	Milk: Cattle	0.5%	Wheat	3.8%	
	6.7%	LT adult	0.34	6.7%	Carrots	0.8%	Milk: Cattle	0.6%	Potatoes	2.4%	

	6.4%	UK adult	0.32	6.4%	Carrots	0.6%	Milk: Cattle	0.3%	Wheat	2.4%	
	5.7%	IT adult	0.29	5.7%	Carrots	0.8%	Wheat	0.4%	Other herbs	2.2%	
	5.1%	IE child	0.25	5.1%	Carrots	0.7%	Milk: Cattle	0.2%	Wheat	1.4%	

Table B.3 Acute risk assessment undertaken using UK model version 1.2

Acute Intakes (97.5th percentiles)

			adult		infant		toddler		4-6 year old child		7-10 year old child	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Parsley	11.80		0.00772	7.7	0.00000	0.0	0.00366	3.7	0.00345	3.5	0.01291	12.9

			11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Parsley	11.80		0.00342	3.4	0.00118	1.2	0.01413	14.1	0.00513	5.1	0.00494	4.9

Table B.4 Acute risk assessment undertaken using PRIMo revision 3.1

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
15.25%	Chervil	0 / 11.8	15.25
12.91%	Parsley	0 / 11.8	12.91
9.68%	Chives	0 / 11.8	9.68
8.93%	Sage	0 / 11.8	8.93
8.61%	Basil and edible flowers	0 / 11.8	8.61
5.66%	Celery leaves	0 / 11.8	5.66
0.71%	Thyme	0 / 11.8	0.71
0.35%	Rosemary	0 / 11.8	0.35
0.12%	Laurel/bay leaves	0 / 11.8	0.12

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
14.13%	Parsley	0 / 11.8	14.13
3.85%	Celery leaves	0 / 11.8	3.85
2.36%	Sage	0 / 11.8	2.36
2.01%	Chives	0 / 11.8	2.01
1.45%	Basil and edible flowers	0 / 11.8	1.45
1.18%	Rosemary	0 / 11.8	1.18
1.18%	Rosemary	0 / 11.8	1.18
1.18%	Rosemary	0 / 11.8	1.18
1.18%	Tarragon	0 / 11.8	1.18
0.95%	Chervil	0 / 11.8	0.95

Appendix C - Detailed evaluation of the additional studies relied on

C.1 Methods of analysis

C.1.1 Methods for enforcement and monitoring of residues in food and feed of plant origin

C.1.1.1 Method validation

Reference:	Prosulfocarb - Validation of the QuEChERS Method for the Determination of Residues of Prosulfocarb in Crop Matrices by LC-MS/MS., [redacted] 2015, Syngenta File No. ICI574_10135, Syngenta Report No. S14-05734
GLP:	Yes
Acceptability of the method:	Acceptable

Principle of the method

Samples of parsley, carrot root and carraway seeds were homogenised using the appropriate methods. Homogenised sub-samples of each test commodity (10 g for parsley and carrot, 2 g for caraway seeds) were added to a 50 mL centrifuge tube, with water added if sample moisture content was below 80% (water was added to give a total water content of 10 ml – e.g. for a 10 g sub-sample with 30% natural water content add 10 mL – (10 x 30/100) mL = 7 mL). Samples were fortified with standard solutions of prosulfocarb in acetonitrile. QuEChERS citrate (EN) material added to each sample, shaken manually then centrifuged for 5 minutes at 3500 rpm. For parsley and carrot, extracts diluted by a factor of 10 with 0.05% formic acid in acetonitrile and shaken to homogenise prior to analysis by LC-MS/MS. Sample concentration for analysis was 0.1 g/mL. For carraway seeds, extracts diluted with 5% formic acid in acetonitrile and shaken to homogenise prior to analysis by LC-MS/MS. Sample concentration for analysis was 0.2 g/mL.

LC-MS/MS Conditions

HPLC system:	AB Sciex 5500
Pumps:	Spark and Holland V20 (Agilent 1200 Binary Pump for parsley extract stability)
Column Oven:	Spark and Holland Mistral (Agilent 1200 for parsley extract stability)
Detector:	AB Sciex 5500 QTrap tandem quadrupole mass spectrometer with Analyst™ software version 1.5.2
Autosampler:	Spark and Holland Symbiosis (CTC Analytics HTS PAL for parsley extract stability)
Column:	ACE C18, 100 x 4.6 mm, 3 µm particle size

Mobile phase:

Time	%A	%B
0.0	90	10
1.0	90	10
4.0	10	90
7.0	10	90
7.1	90	10
10.0	90	10

Mobile phase for parsley:

Time	%A	%B
0.0	90	10
1.0	90	10
7.0	10	90
10.0	10	90
10.1	90	10
13.0	90	10

A: 0.1% formic acid in water
B: 0.1% formic acid in acetonitrile

Flow rate:	0.8 mL/min
Column oven temperature:	40°C
Injection volume:	5-10 µL
Retention time:	Prosulfocarb: approximately 4.9 min

Detector:	Ionisation mode:	ESI
	Source polarity:	Positive
	Curtain gas (CUR):	35 (arbitrary units)
	Gas 1 (GSI):	35 (arbitrary units)
	Gas 2 (GSI):	45 (arbitrary units)
	Temperature (TEM):	550°C
	Interface heater (IHE):	On
	Ionspray voltage (IS):	3500 V
	Collision gas setting (CAD):	9-10 (arbitrary units)
	Entrance potential (EP):	10 V

Dwell time: 100 msec
Resolution Q1 and Q3: Unit

Source and detection parameters for MS/MS experiments:

Compound	Parent ion (*m/z*)	Fragment ions (*m/z*)	CE (V)	DP (V)	CXP (V)	
Prosulfocarb	252.0 252.0	91.1 128.1	40 18	80 80	10 15	Quantification Confirmation

CE: Collision energy; CXP: Collision cell exit potential; DP: Declustering Potential

Quantification: Peak areas of fragment ion at m/z = 91.1, external standards in matrix

Confirmation: Peak areas of fragment ion at m/z = 128.1, external standards in matrix

Results and discussion

Table C.1.1.1-1 Recovery Results from prosulfocarb (Primary transition 252 m/z → 91 m/z)

Matrix	**level (mg/kg)**	**No samples per level**	**Range of recoveries (%)**	**Mean recovery**	**RSD (%)**	**Comments**
Parsley	0.01	5	101-106	104	2.3	0.00025-0.025 µg/mL, equivalent to 0.0025-0.25 mg/kg R >0.999
	0.05	5	103-108	106	1.8	
Carrot	0.01	5	92-110	100	1.6	0.00025-0.025 µg/mL, equivalent to 0.0025-0.25 mg/kg R >0.999
	1.0	5	98-109	101	4.4	

Matrix	level (mg/kg)	No samples per level	Range of recoveries (%)	Mean recovery	RSD (%)	Comments
Carraway seeds	0.01	5	83-90	88	3.5	0.0005-0.05 µg/mL, equivalent to 0.0025-0.25 mg/kg R >0.999
	0.3	5	86-90	88	1.9	

Table C.1.1.1-2 Recovery Results from prosulfocarb (Confirmatory transition 252 m/z → 128 m/z)

Matrix	level (mg/kg)	No samples per level	Range of recoveries (%)	Mean recovery	RSD (%)	Comments
Parsley	0.01	5	104-108	107	1.6	0.00025-0.025 µg/mL, equivalent to 0.0025-0.25 mg/kg R >0.999
	0.05	5	97-108	105	4.4	
Carrot	0.01	5	87-107	101	8.1	0.00025-0.025 µg/mL, equivalent to 0.0025-0.25 mg/kg R >0.999
	1.0	5	90-109	101	7.7	

Matrix	level (mg/kg)	No samples per level	Range of recoveries (%)	Mean recovery	RSD (%)	Comments
Carraway seeds	0.01	5	83-94	89	5.4	0.0005-0.05 µg/mL, equivalent to 0.0025-0.25 mg/kg R >0.999
	0.3	5	88-92	89	1.9	

Specificity

Specificity was demonstrated by retention time match with a reference standard. Analysis of unfortified control samples and reagent blanks demonstrated no significant interference (> 30% of the LOQ) at the retention time of interest.

Due to the presence of interferences in parsley in retention time of interest, an extended gradient was used for parsley analysis in order to separate the interference from the peak of interest.

Matrix effects

Matrix-matched standards were used for quantification. Matrix effects were investigated and were shown as significant in carraway seeds.

Linearity

Linearity was demonstrated by the analysis of five standards of increasing concentration. The range of standard concentrations used for carrot and parsley was 0.00025-0.025 µg/mL, equivalent to 0.0025-0.25 mg/kg prosulfocarb in the samples. The range of standard concentrations used for carraway seeds was 0.0005-0.05 µg/mL, equivalent to 0.0025-0.25 mg/kg prosulfocarb in the samples. The response was linear with a correlation coefficient (r) of > 0.999.

Accuracy

Recovery samples were prepared by spiking blank formulation with active substance standard at concentrations of 0.01 and 0.05 in parsley, 0.01 and 1.0 in carrot and 0.01 and 0.3 in carraway seeds and analysing them by the method described. 5 samples were prepared at each fortification, recovery values were calculated as a percentage of

measured concentration relative to fortified concentration. Mean recovery levels were within the range 70 to 110%.

Precision

Precision was determined from the accuracy recovery data. A minimum of five samples were prepared at each fortification level. % RSD at each fortification level was < 20%.

Extraction efficiency

Extraction solvents used in the metabolism study on carrots demonstrated sufficient extraction efficiency in carrot tops (minimum 98% TRR extracted). As 'identical' extraction solvents are used in the metabolism study (see C.3.1.1, ACN/water, 80/20, v/v) and in the QuEChERS method (ACN/water, 90/10, v/v), this is sufficient to consider extraction efficiency as addressed in accordance with SANTE 2017/10632.

(NB – water content ratio in QuEChERS method is estimated based on herbs and edible flowers containing 90% water by weight; 'identical' solvents are defined as those which do not vary compositionally by more than 20% by volume - SANTE 2017/10632 rev. 3)).

Conclusion

The method is satisfactorily validated in accordance with SANCO/825/00 rev. 8.1 and acceptable to support the study on herbs and edible flowers with a limit of quantification of 0.01 mg/kg. Sufficiently similar extraction solvents to those used in metabolism study (C.3.1.1) to consider extraction efficiency satisfactorily addressed.

C.1.1.2 Independent laboratory validation

Reference:	Prosulfocarb –Validation of the QuEChERS Method for the Determination of Residues of Prosulfocarb in Crop Matrices by LC-MS/MS., [redacted] 2015, Syngenta File No. ICI574_10135, Syngenta Report No. S14-05734
GLP:	Yes
Acceptability of the method:	Acceptable

Principle of the method:

Samples of parsley, carrot and carraway seeds were homogenised using the appropriate methods. Homogenised sub-samples of each test commodity (10 g for parsley and carrot, 2 g for caraway seeds) were added to a 50 mL centrifuge tube, with water added if sample moisture content was below 80%. Samples were fortified with standard solutions of prosulfocarb in acetonitrile. QuEChERS citrate (EN) material added to each sample,

shaken manually then centrifuged for 5 minutes at 3500 rpm. For parsley and carrot, extracts diluted by a factor of 10 with 0.05% formic acid in acetonitrile and shaken to homogenise prior to analysis by LC-MS/MS. Sample concentration for analysis was 0.1 g/mL. For carraway seeds, extracts diluted with 5% formic acid in acetonitrile and shaken to homogenise prior to analysis by LC-MS/MS. Sample concentration for analysis was 0.2 g/mL.

HPLC-MS/MS Conditions

HPLC system:	Sciex API 5500 QTRAP
Pumps:	Shimadzu LC20AD or LC20ADXR
Column Oven:	Shimadzu CTO-20AC
Detector:	API 4000 (AB Sciex) with Analyst™ software version 1.5.1
Autosampler:	Shimadzu SIL20AC
Column:	ACE C18, 100 x 4.6 mm, 3 µm particle size
Mobile phase:	

Time	%A	%B
0.0	90	10
1.0	90	10
4.0	10	90
7.0	10	90
7.1	90	10
10.0	90	10

Mobile phase for parsley:

Time	%A	%B
0.0	90	10
1.0	90	10
7.0	10	90
10.0	10	90
10.1	90	10
13.0	90	10

A: 0.1% formic acid in water
B: 0.1% formic acid in acetonitrile

Flow rate:	0.8 mL/min
Column oven temperature:	40°C
Injection volume:	5 µL
Retention time:	Prosulfocarb: approximately 6.5 min (8.9 min for parsley)

Detector:	Ionisation mode:	ESI
	Source polarity:	Positive
	Curtain gas (CUR):	35 (arbitrary units)
	Gas 1 (GSI):	35 (arbitrary units)
	Gas 2 (GSI):	45 (arbitrary units)
	Temperature (TEM):	550°C
	Interface heater (IHC):	Not reported
	Ionspray voltage (IS):	3500 V
	Collision gas setting (CAD):	9-10 (arbitrary units)

Entrance potential (EP): 10 V
Dwell time: 100 msec
Resolution Q1 and Q3: Unit

Source and detection parameters for MS/MS experiments:

Compound	Parent ion (*m/z*)	Fragment ions (*m/z*)	CE (V)	DP (V)	CXP (V)	
Prosulfocarb	252.0 252.0	91.1 128.1	40 18	80 80	10 15	Quantification Confirmation

CE: Collision energy; CXP: Collision cell exit potential; DP: Declustering Potential

Quantification: Peak areas of fragment ion at m/z = 91.1, external standards in matrix

Confirmation: Peak areas of fragment ion at m/z = 128.1, external standards in matrix

Results and discussion

Table C.1.1.2-1 Recovery Results from prosulfocarb (Primary transition 252 m/z → 91 m/z)

Matrix	level (mg/kg)	No samples per level	Range of recoveries (%)	Mean recovery	RSD (%)	Comments
Parsley	0.01	5	82-89	85	3	0.00025-0.25 µg/mL, equivalent to 0.0025-0.025 mg/kg R >0.998
	0.05	5	83-87	85	2	
Carrot	0.01	5	88-92	91	2	0.00025-0.025 µg/mL, equivalent to 0.0025-0.25 mg/kg R >0.998
	1.0	5	89-91	90	1	

Matrix	level (mg/kg)	No samples per level	Range of recoveries (%)	Mean recovery	RSD (%)	Comments
Carraway seeds	0.01	5	81-91	83	5	0.0005-0.05 µg/mL, equivalent to 0.0025-0.25 mg/kg R >0.998
	0.3	5	81-85	83	2	

Table C.1.1.2-2 Recovery Results from prosulfocarb (Confirmatory transition 252 m/z → 128 m/z)

Matrix	level (mg/kg)	No samples per level	Range of recoveries (%)	Mean recovery	RSD (%)	Comments
Parsley	0.01	5	83-90	86	4	0.0025-0.25 µg/mL, equivalent to 0.0025-0.25 mg/kg R >0.998
	0.05	5	79-83	81	2	
Carrot	0.01	5	85-94	89	4	0.0025-0.25 µg/mL, equivalent to 0.0025-0.25 mg/kg R >0.998
	1.0	5	87-91	89	2	

Matrix	level (mg/kg)	No samples per level	Range of recoveries (%)	Mean recovery	RSD (%)	Comments
Carraway seeds	0.01	5	82-86	84	2	0.0005-0.05 µg/mL, equivalent to 0.0025-0.25 mg/kg R >0.998
	0.3	5	83-85	84	1	

Specificity

Specificity was demonstrated by retention time match with a reference standard. Analysis of unfortified control samples and reagent blanks demonstrated no significant interference (> 30% of the LOQ) at the retention time of interest.

Due to the presence of interferences in parsley in retention time of interest, an extended gradient was used for parsley analysis in order to separate the interference from the peak of interest.

Matrix effects

Matrix-matched standards were used for quantification. Matrix effects were investigated and were shown as significant in carraway seeds.

Linearity

Linearity was demonstrated by the analysis of five standards of increasing concentration. The range of standard concentrations used for carrot and parsley was 0.00025-0.025 µg/mL, equivalent to 0.00025-0.025 mg/kg prosulfocarb in the samples. The range of standard concentrations used for carraway seeds was 0.0005-0.05 µg/mL, equivalent to 0.0025-0.25 mg/kg prosulfocarb in the samples. The response was linear with a correlation coefficient (r) of > 0.999.

Accuracy

Recovery samples were prepared by spiking blank formulation with active substance standard at concentrations of 0.01 and 0.05 in parsley, 0.01 and 1.0 in carrot and 0.01 and 0.3 in carraway seeds and analysing them by the method described. 5 samples were prepared at each fortification, recovery values were calculated as a percentage of

measured concentration relative to fortified concentration. Mean recovery levels were within the range 70 to 110%.

Precision

Precision was determined from the accuracy recovery data. A minimum of five samples were prepared at each fortification level. % RSD at each fortification level was < 20%.

Extraction efficiency

Extraction solvents used in the metabolism study on carrots demonstrated sufficient extraction efficiency in carrot tops (minimum 98% TRR extracted). As 'identical' extraction solvents are used in the metabolism study (see C.3.1.1, ACN/water, 80/20, v/v) and in the QuEChERS method (ACN/water, 90/10, v/v), this is sufficient to consider extraction efficiency as addressed in accordance with SANTE 2017/10632.

(NB – water content ratio in QuEChERS method is estimated based on herbs and edible flowers containing 90% water by weight; 'identical' solvents are defined as those which do not vary compositionally by more than 20% by volume - SANTE 2017/10632 rev. 3)).

Conclusion

The method is satisfactorily validated in accordance with SANCO/825/00 rev. 8.1 and acceptable to support the study on herbs and edible flowers with a limit of quantification of 0.01 mg/kg. Sufficiently similar extraction solvents to those used in metabolism study (C.3.1.1) to consider extraction efficiency satisfactorily addressed.

C.1.1.3 Confirmatory method (if necessary)

No additional studies submitted.

C.1.2 Methods for enforcement and monitoring of residues in food and feed of animal origin

No consideration of methods for products of animal origin is required as the crops under consideration are not fed to animals.

C.1.3 Methods for risk assessment for residues in food and feed of plant origin

C.1.3.1 Analytical method validation for the determination of residues in herbs

Reference:	Residue Examination for Boxer (Prosulfocarb) in Dill Leaves, Balm and Parsley, [redacted] 2015, Syngenta

File No. VV-413381, Syngenta Report No. RU-P-2014-4-1.

GLP: Yes

Acceptability of the method: Acceptable

Principle of the method

Residues of prosulfocarb were extracted from 10g of sample by adding 20 mL methanol), followed by homogenisation for 3 minutes. Samples were centrifuged at 4500rpm for 10 minutes. 2 mL of 20% sodium chloride solution was added to 6 mL of supernatant and mixed, 5 mL of mixture poured into elution column and eluted into a flask with 25 mL of dichloromethane. Volatiles of the extract removed via a rotational vaporizer, residue re-solved in 0.25 mL of water and 5 mM ammonium formate solution. 1 mL of methanol and 5 mM ammonium formate solution. Extract containing 1g of sample material/mL was transferred into a glass vial for LC/MS-MS analysis.

Results and Discussion

Recovery results of prosulfocarb tabulated below.

Table C.1.3.1-1 Prosulfocarb recovery results – Primary transition (m/z 252.1 → 91.2)

Matrix	Fortification level (mg/kg)	Recovery % range (mean)	Repeatability % RSD (n)	Linearity
Dill Leaves	0.005	67.2-74.2 (71.1)	3.7 (5)	2.5-100 ng/mL, equivalent to 0.0025-0.1 mg/kg, R >0.995
	2	66.8-84.6 (73.7)	9.9 (5)	
Balm	0.005	64.4-82.0 (73.6)	12.0 (3)	2.5-100 ng/mL, equivalent to 0.0025-0.1 mg/kg, R >0.997
	0.2	76.0-82.4 (79.6)	4.1 (3)	
Parsley	0.005	71.0-79.0 (75.7)	5.5 (3)	2.5- 100 ng/mL, equivalent to 0.0025-0.1 mg/kg, R >0.999
	30	90.2-95.3 (92.8)	2.8 (3)	

Specificity

Specificity was demonstrated by retention time match with a reference standard. Analysis of unfortified control samples and reagent blanks demonstrated no significant interference (>30% of the LOQ) at the retention time of interest.

Matrix effects

Matrix-matched standards were used for quantification

Linearity

Linearity was demonstrated by the analysis of five standards of increasing concentration. The range of standard concentrations used was 2.5-100 ng/mL, equivalent to 0.0025-0.1 mg/kg prosulfocarb in the samples. The response was linear with a correlation coefficient (r) of > 0.995. Samples were diluted as necessary to fit within the linear range.

Accuracy

Recovery samples were prepared by spiking blank formulation with active substance standard at concentrations of 0.005 and 2.0 in dill leaves and balm and 0.005 and 30 in parsley and analysing them by the method described. For dill leaves, 5 samples were prepared at each fortification level, with 3 samples prepared at each fortification level for balm and parsley. Recovery values were calculated as a percentage of measured concentration relative to fortified concentration. Mean recovery levels were within the range 70 to 110%.

Precision:

Precision was determined from the accuracy recovery data. A minimum of five samples were prepared at each fortification level for dill leaves, with 3 samples prepared at each fortification level for balm and parsley. % RSD at each fortification level was < 20%. All trial samples were processed and analysed within the same time period as the recovery samples to ensure comparable recovery rates.

Conclusion

The method SAA/C/PSM 040 is satisfactorily validated in accordance with SANCO 825/00 rev 8.1 and SANCO/3029/99 rev.5 and acceptable to support the study on herbs and edible flowers with a limit of quantification of 0.005 mg/kg. Extraction efficiency has not been sufficiently addressed.

C.1.4 Methods for risk assessment for residues in food and feed of animal origin

No additional studies submitted

C.1.5 Methods for risk assessment for toxicological studies

No additional studies submitted

C.2 Mammalian toxicology

No additional studies submitted

C.3 Residue data

C.3.1 Nature and magnitude of residues in primary crops

Two studies on the nature of residues in primary crops were submitted, a post emergence application on carrot (see C.3.1.1) and a post emergence application on barley. As data is already available for post emergence foliar uses on barley and the uses under consideration are not cereals, the barley data has not been evaluated.

C.3.1.1 Nature of residues in carrot

Reference:	Prosulfocarb - Metabolism of [^{14}C]-Prosulfocarb in Carrots, [redacted] 2015, Report No. SYN-006/7-08, Syngenta File No. VV-413414
Guideline(s):	Yes, Regulation (EC) No 1107/2009
Deviations:	No
GLP:	Yes
Validity of the study:	Acceptable

Materials and methods

Materials

C-label prosulfocarb (phenyl-U-^{14}C)
Description: [phenyl-U-^{14}C] – prosulfocarb (spec. activity of a.s. 1.97 MBq/mg)
Batch no.: RDR-XIII-89
Radiochemical Purity: 98.6 %

Methods

A study, investigating the metabolism of prosulfocarb in carrots, was carried out in 2012 at 'Fraunhofer Institute for Molecular Biology and Applied Ecology' in Germany. Carrots were treated with a single foliar spray application using prosulfocarb labelled at the [phenyl-U-^{14}C] position, as shown in Figure 3.1.1-1. The radiolabel was uniform throughout the benzene ring.

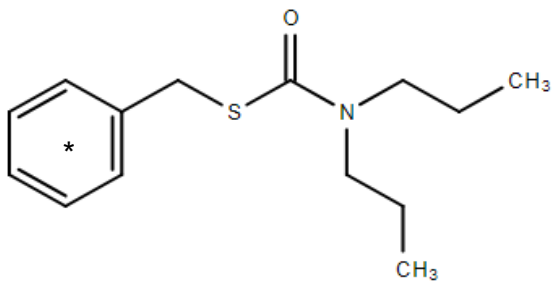


Figure 3.1.1-1 Prosulfocarb (* indicates label position)

Carrot seeds (var. LAGUNA F1) were planted in a 1 m^2 area steel container, filled with sandy loam soil. Two containers were prepared, one was used for treatment with [^{14}C]-prosulfocarb, the second container was used to grow control carrots which did not receive any treatment. The seeds were sown (360 seeds/m^2) and containers were left uncovered outdoors. [^{14}C]-prosulfocarb was applied as a single application at BBCH 14. The target application rate for this study was 4000 g a.s./ha, actual application rate was 4184 g a.s./ha, with a nominal spray concentration of 300 L/ha.

Sampling

Carrot roots and leaves were harvested 21 days after application (BBCH 43) and 58 days after application (BBCH 49). Roots and leaves were homogenised separately to a powder.

Table C.3.1.1-1 Summary of study design

Label		**[phenyl-U-^{14}C]**	
Intended use rate (g as/ha)	**1st application:**	4000	
Actual application rate (g as/ha)	**1st application:**	4184	
Application timing (BBCH)	**1st application:**	14	
Sampling (DALA)†		Roots and leaves:	21 58

† Days after last application; remaining plant was collected but not subjected to any analysis.

Analysis/ general procedures

Subsamples of leaves and roots were separately extracted, homogenised at ambient temperature and extracted using acetonitrile/water (80:20, v/v). Sub-samples of roots harvested 58 days after application were additionally extracted using acetonitrile/water (50/:50, v/v). The solid and liquid phases were separated by filtration under suction. After extraction, the solid phase was air dried at ambient temperature allowing radio-assay of the crop debris to be carried out by combustion analysis and LSC respectively. The radioactivity in the acetonitrile and acetonitrile/water extracts was quantified by LSC.

Principal fractions were subjected to TLC and HPLC chromatographic analysis for quantification and identification/characterisation of the radioactive residues. HPLC was also employed to isolate and purify unknown metabolites as preparation for mass spectrometry. MS was used in conjunction with HPLC for characterisation and identification purposes in carrot roots.

Solid phase extraction (SPE) was carried out via the combination and evaporation of acetonitrile and acetonitrile/water extracts, radioactivity of the extracts was determined by LSC. Polar radioactive fractions were further characterised by ion-pair SPE and hydrolysis procedures and were fractionated by HPLC.

Hydrolysis was undertaken to release residues from polar conjugates and isolated fractions from their conjugated forms. The procedures used covered acid and base hydrolysis as well as a variety of enzyme hydrolysis methods. All hydrolysis methods did not cause significant changes in the chromatographic profile and have not been described further.

Aliquots of the combined extracts of carrot leaves were analysed by TLC for quantification and identification/characterisation of the radioactive residues.

The chromatographic analysis for both crop parts were carried out by comparison with authentic reference standards of parent prosulfocarb and its postulated metabolites.

The following reference standards were used:

- Prosulfocarb
- R331405
- R393096
- SYN545179
- R331282
- SYN545169
- R392042 (non-GLP)
- R012571
- α-toluenesulfonic acid ethylamine salt
- Benzyl alcohol
- Benzaldehyde
- 4-hydroxybenzoic
- 3,4-dihydroxyboenzoic acid
- Gallic acid
- CGA268917 benzyl methyl sulphone
- CGA268918 benzyl methyl sulphoxide
- 1,2,3-Trihydroxybenzene
- 1,3,5-Trihydroxybenzene

- 1,2,4-Trihydroxybenzene
- [U-^{14}C]-D-glucose

The samples were stored (≤-20°C) until required for analysis. The samples were homogenised whilst frozen, and subsequently re-stored at (≤-20°C) until required for analysis. Initial analysis of the carrot root fractions was conducted within 6 months of harvest. The original extracts were re-analysed up to 33 months later. The TLC analysis from each time point were compared for carrot root samples taken at 21 and 58 DALA; the TLC profile in each case was broadly comparable with no significant differences present. No such comparison is available for carrot leaf samples; however, as parent compound was seen to be stable in carrot roots, and as parent compound comprised the majority of the residue in carrot tops, no further information is considered necessary in this case.

Results and discussion

Total radioactive residue (TRR)

The TRR levels in leaves were 74.131 mg/kg 21 days after application and 21.614 mg/kg 58 days after application. TRR levels in roots were 1.091 mg/kg 21 days after application and 0.422 mg/kg 58 days after application. Extractability was high with ≥ 85.0 % TRR extracted from the roots and ≥ 97.6% TRR extracted from the leaves. The extracted radioactivity was analysed by chromatography. The extracted and identified residues are detailed in tables C.3.1.1-1, C.3.1.1-2 and C.3.1.1-3.

Table C.3.1.1-1 Total radioactive residues (TRRs) in carrot

Harvest (DALA)	Crop commodity	Radioactive residues (mg/kg)	
		TRR measured[1]	TRR calculated[2]
21	Roots	0.974	1.091
	Leaves	73.046	74.131
58	Roots	0.334	0.422
	Leaves	19.922	21.614

[1] Quantification from combustion analysis

[2] Sum of extracts and PES

Table C.3.1.1-2 Summary of characterised and identified residues - carrot roots

Compound	Roots (21 DAA)		Roots (58 DAA)	
	% TRR	mg/kg	% TRR	mg/kg
TRR by direct LSC	-	**0.974**	-	**0.334**
Conventional extract				
Prosulfocarb	48.1	0.525	33.0	0.139
R331405	0.3	0.003	ND	ND

SYN545179	9.2	0.101	14.1	0.060
Unassigned 1	5.2	0.057	6.2	0.026
Unassigned 3	1.5	0.016	2.8	0.012
Unassigned 4	0.6	0.006	ND	ND
Polar components[1]	14.1	0.153	26.8	0.113
Remainder	0.2	0.002	1.2	0.005
Losses/gains on fractionation	9.5 (loss)	0.103 (loss)	0.8 (loss)	0.004 (loss)
Total identified	57.6	0.629	47.1	0.199
Total characterised	64.9	0.708	56.1	0.237
Total extracted	**79.2**	**0.863**	**84.1**	**0.355**
Unextracted after conventional extract	11.3	0.124	15.0	0.063
Further extraction of PES (hydrolysis)				
Percent of TRR in debris	11.3	0.124	15.0	0.063
Pectinase hydrolysis	5.4	0.059	5.3	0.022
Mild acid hydrolysis (0.5M)	2.9	0.032	1.7	0.007
Mild base hydrolysis (0.05M)	1.9	0.021	1.0	0.004
Remaining after hydrolysis	8.1	0.089	6.4	0.027
Further extraction of PES (fractionation, after hydrolysis)				
Remaining after hydrolysis	8.1	0.089	6.4	0.027
Lignin	1.8	0.020	1.3	0.006
Hemicellulose	5.2	0.057	3.6	0.015
Acetone rinse	1.1	0.012	1.5	0.006
Remaining unextracted (PES) [2]	2.1	0.023	6.6	0.028
Losses/gains on fractionation	1.2 (loss)	0.013	2.0 (loss)	0.008
Total TRR (by summation)	**100**	**1.091**	**99.9**	**0.422**

[1] 21 DAA – comprised of at least three discrete components, the highest of which being 8.2% TRR, 0.089 mg/kg (component 4, tentatively assigned as ^{14}C glucose)
58 DAA – comprised of at least three discrete components, the highest of which being 15.8% TRR, 0.067 mg/kg (component 3, tentatively assigned as ^{14}C glucose)
[2] Residues remaining after all extraction procedures

Table C.3.1.1-3 Summary of characterisation and identification of residues in carrot leaves

Compound	Leaves (21 DAA)		Leaves (58 DAA)	
	% TRR	mg/kg	% TRR	mg/kg
TRR by direct LSC	**-**	**74.131**	**-**	**21.614**
Prosulfocarb	78.8	58.379	72.3	15.617
R393096	1.7	1.271	1.3	0.270
Unassigned A	0.6	0.445	0.4	0.097
Unassigned B	0.2	0.183	0.1	0.030
Unassigned C	0.3	0.204	0.3	0.065
Polar components	16.6	12.291	23.0	4.970
Remainder	0.4	0.256	0.3	0.072
Losses/gains on fractionation	0.2 (loss)	0.145 (loss)	0.1 (gain)	0.032 (gain)
Total identified	80.5	59.650	73.6	15.887
Total characterised	81.6	60.482	74.4	16.079
Total extracted	**98.6**	**73.029**	**97.7**	**21.121**
Unextracted (PES) [1]	1.3	0.958	2.4	0.525
Total TRR (by summation)	**100.1**	**74.132**	**100**	**21.614**

[1] Residues remaining after all extraction procedures

Carrot roots

The principal component identified was prosulfocarb, which accounted for 48.1% TRR 21 DAA (0.525 mg/kg) and 33.0% TRR 58 DAA (0.139 mg/kg). Metabolite SYN545179 was also identified in both samples, representing 9.2% TRR 21 DAA (0.101 mg/kg) and 14.1% TRR 58 DAA (0.060 mg/kg). Metabolite R331405 was identified in 21 DAA only, 0.3% TRR (0.003 mg/kg).

Three further metabolites were characterised in 21 DAA samples, accounting for 7.3% TRR (0.079 mg/kg). Two of these metabolites were characterised in 58 DAA samples, accounting for 9.0% TRR (0.038 mg/kg).

Unextracted residues after conventional extracts were 11.3% TRR 21 DAA (0.124 mg/kg) and 15.0% TRR 58 DAA (0.525 mg/kg). Various hydrolysis schemes released a further

10.2 and 8% TRR for the 21 and 58 DALA samples, respectively. Residues in bound materials (lignin and hemicellulose, as well as the rinse) were 8.1 and 6.4 % TRR for the the 21 and 58 DALA samples, respectively. After exhaustive extraction, the PES in the cellulose fraction was 2.1 and 6.6% TRR for the 21 and 58 DALA samples, respectively

Carrot leaves

The principal component identified was prosulfocarb, which accounted for 78.8% TRR 21 DAA (58.379 mg/kg) and 72.3% TRR 58 DAA (15.617 mg/kg). Metabolite R393096 was also identified in both samples, representing 1.7% TRR 21 DAA (1.271 mg/kg) and 1.3% TRR 58 DAA (0.270 mg/kg).

Three further metabolites were characterised, accounting for 1.1% TRR 21 DAA (0.832 mg/kg) and 0.8% TRR 58 DAA (0.192 mg/kg).

Unextracted residues were 1.3% TRR 21 DAA (0.958 mg/kg) and 2.40% TRR 58 DAA (0.063 mg/kg).

These TRR values are based on 1D-TLC only. Additional 2D-TLC and HPLC analysis of carrot leaves did not confirm the presence of R393096. The presence of prosulfocarb was confirmed in 2D-TLC at between 84-89% TRR, again indicating that parent prosulfocarb is the principle component in carrot leaves.

The further 2D-TLC analysis indicated potential occurrence of R331405 (0.02% TRR for both sampling times) – no other metabolites were identified in this analysis, a number of unidentified components were detected, none of which exceeded 4.1% TRR.

The retention time associated with SYN545179 was detected by HPLC analysis; the retention time associated with R393096 was not detected by HPLC. Only parent prosulfocarb was detected in the ‘combined SPE eluate/wash’ for both sampling times – this extract comprised 87-90% of the TRR.

In the ‘combined load/rinse extract’ (minor fraction), SYN545179, R331282 and R331405 were detected. Quantification was not performed on these extracts; however, by inference to the 2D-TLC analysis, each of these tentatively identified metabolites is not expected to comprise significantly greater than 0.02% TRR.

Conclusions

The present study describes the metabolism of prosulfocarb in carrot, following a single foliar spray application. Samples of leaves and roots were collected 21 and 58 days after application.

The main observations from the identification work are the following:

- Parent prosulfocarb was the principal residue detected in both samples, accounting for 33.0-48.1% TRR (0.139-0.525 mg/kg) in the root samples and 72.3-78.8% TRR (15.617-58.379 mg/kg) leaves samples.
- R331405 was identified in minor amounts in root samples (21 DAA only), 0.3% TRR (0.003 mg/kg).
- Metabolite SYN545179 was identified in both root samples, representing 9.2% TRR at 21 DAA (0.101 mg/kg) and 14.1% TRR at 58 DAA (0.060 mg/kg).
- Metabolite R393096 was tentatively identified in both leaf samples, representing 1.7% TRR at 21 DAA (1.271 mg/kg) and 1.3% TRR at 58 DAA (0.270 mg/kg); however, this metabolite was not confirmed by 2D-TLC or HPLC.
- In roots, polar components remaining after the initial extraction contained at least three discrete components, of which components tentatively ^{14}C glucose comprised the largest portion in both harvest intervals. The highest % TRR was 15.8% TRR (0.067 mg/kg, 58 DAA).
- Three minor metabolites were also characterised in minor amounts – accounting for 11.3% TRR 21 DAA (0.124 mg/kg) and 15.0% TRR 58 DAA (0.525 mg/kg) in roots and 1.3% TRR 21 DAA (0.958 mg/kg) and 2.40% TRR 58 DAA (0.063 mg/kg) in leaves.
- Remaining radioactivity in roots was identified as polar components, tentatively assigned as glucose and other endogenous plant material

The principle biotransformations observed were:

- Oxidation
- Loss of the propyl side chain through N-dealkylation
- Mineralisation to CO_2 and incorporation into endogenous plant matrix

See figure C.3.1.1-2 for the proposed metabolic pathway in carrots

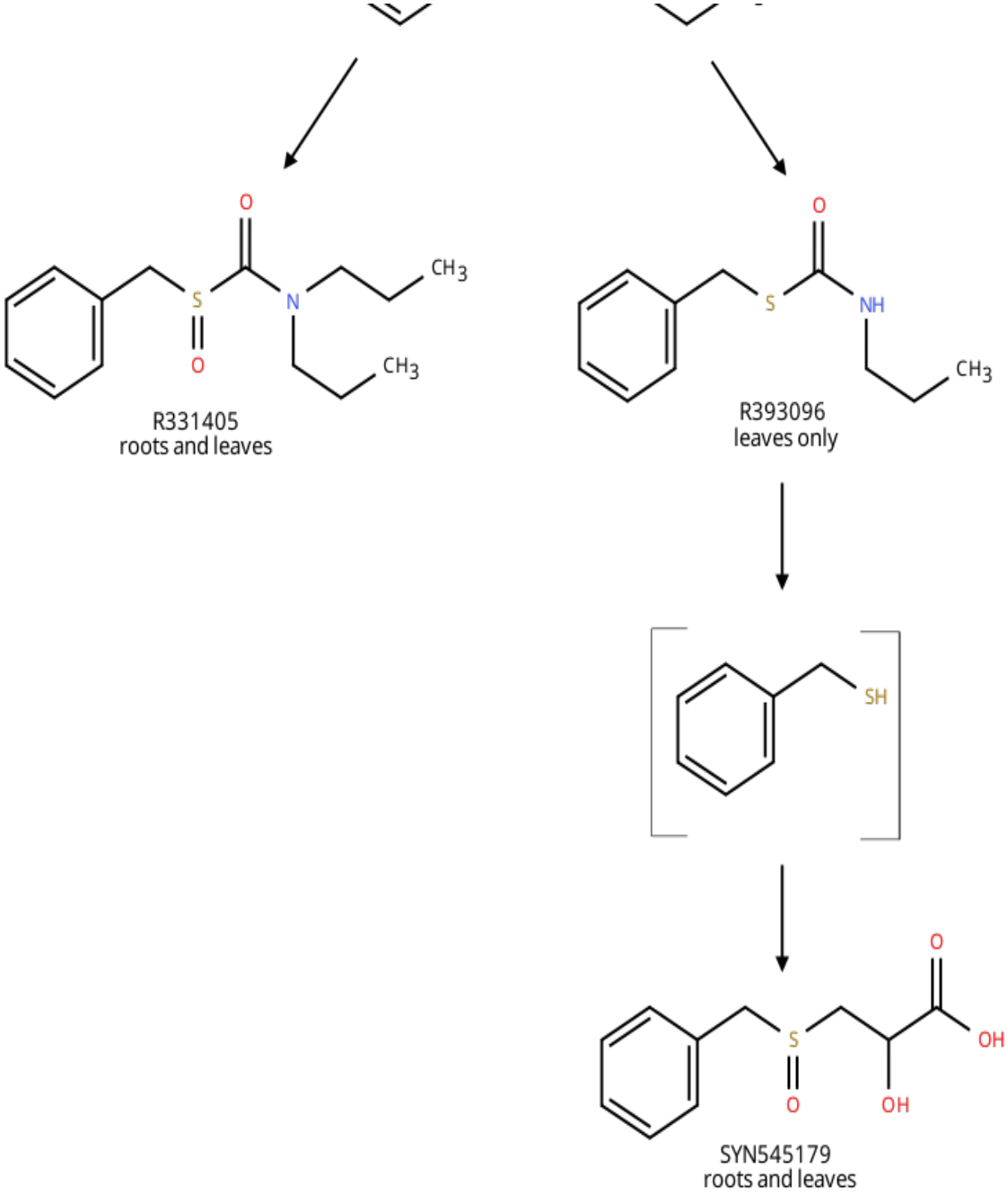


Figure C.3.1.1-2 Proposed metabolic pathway of prosulfocarb in carrots

C.3.1.2 Magnitude of residues

C.3.1.2.1 Dill leaves, Balm and Parsley

Reference:	Residue Examination for Boxer (Prosulfocarb) in Dill Leaves, Balm and Parsley, [redacted] 2015, Syngenta File No. VV-41381, RU-P-2014-4-1
Guideline(s):	Yes, SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Validity of the study:	Acceptable

Materials and methods

Nine at harvest field trials for prosulfocarb on edible herbs and flowers, three on dill leaves, one on balm and five on parsley, were conducted with a EC formulation containing 800 g/L prosulfocarb in Germany during the 2014 growing season.

Two trials on parsley (MUE-01 and MUE-02) are within 20 km of each other and do not have sufficiently separate planting and treatment dates (separation of > 30 days required). Therefore, the trials cannot be considered independent of one another. Trial MUE-01 will be considered in this application as it represents a worst case.

At five sites the treated plot received one foliar application and at four sites the treated plots received two foliar applications of the EC formulation ‘Boxer’ (EC800). For the trials in which two sprays were applied, samples were taken prior to the second spray – therefore, these samples are representative of a single application. The samples taken after the second spray are not relevant to the GAP under consideration.

The nominal rate of prosulfocarb per application was 1600 g a.s./ha. The actual rates ranged from 1483 to 1604 g a.s./ha per application. The retreatment intervals between applications ranged from 31 to 54 days. Spray volumes ranged from 300-401 L/ha.

Weather data were reported for the trials and no exceptional events were noted. Samples were collected at 21 and 28 days after the last application (DALA), as well as 21 days after first application in trials with two applications. No sample weights were recorded and a minimum weight requirement was not specified in the study.

Samples were transported frozen and stored at a temperature of < -18°C until preparation. Samples were frozen for a period of approximately 8 months prior to analysis and were analysed within 2 days of homogenisation. Prosulfocarb residues have been shown to be stable in various matrices including high water commodities for 18 months at <-18°C.

Samples of balm and parsley were taken as whole plant; samples of dill were taken as the leaves only. This is representative of the crops as marketed/consumed and is appropriate.

Residues of prosulfocarb were analysed by analytical method SAA/C/PSM 040 with a LOQ of 0.005 mg/kg. Full details and validation for this method can be found in section C.1.1.

Results and discussions

The analytical method (SAA/C/PSM 040) was satisfactorily validated in section C.1.3. The LOQ of the method is 0.005 mg/kg. Acceptable procedural recovery data for prosulfocarb using an appropriate number of samples were presented.

Residues greater than LOQ (0.005 mg/kg) were detected in five of the nine control samples, between 0.007- 0.047 mg/kg. No explanation was provided for the control residue; nevertheless, the control residues did not exceed 8% of the residues observed in the treated samples – this is considered a minor deficiency.

As trials MUE-01 and MUE-02 cannot be considered sufficiently independent, only trial MUE-01 results were considered as they represent a worst case. Trials HAM-01 and NIS-01 were also excluded due to treatment at an earlier growth stage (BBCH 10-14) than the other trials, and the authorised GAP (BBCH 40-47).

Residues of prosulfocarb in herb leaves and whole plant 21-22 days after one application, but before the 2nd application, were 0.389-11.799 mg/kg.

Residues of prosulfocarb in herb leaves 21 days after two applications were 0.404-4.973 mg/kg.

Table C.3.1.2.1-1 Residue trials on dill leaves, balm and parsley

Reference:	Residue Examination for Boxer (Prosulfocarb) in Dill Leaves, Balm and Parsley, [redacted] 2015, Syngenta File No. VV-41381, RU-P-2014-4-1		
GLP:	Yes	Sample storage conditions:	8 months, <-18°C
Crop/crop group:	Dill leaves, balm and parsley	Analytical method:	SAA/C/PSM 040, validated
Indoor/outdoor:	Outdoor	Limit of Quantification (mg/kg):	0.005
Formulation:	EC	Residues calculated as:	Prosulfocarb
Content of active substance:	800 g/L		

Trial No Location Year	Commodity Variety	Date of 1.Sowing or planting 2.Flowering 3.Harvest	Application rate per treatment			Dates of treatment or number and last date	Interval between applications (days)	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			g a.s./ ha	Water (L/ha)	g a.s./ hL							
RU-P-2014-4-1 LR-K-14-FK-H-06-HAM-01 GERMANY (Europe North)	Dill (GreenSleeves)	1. 02 Jul 14	1600	400	-	30 Jul 14	-	BBCH 14	Leaves	0.535 0.260	21 28	

RU-P-2014-4-1 LR-K-14-FK-H-06-NIS-01 GERMANY (Europe North)	Dill (Blattreich)	1. 23 Jul 14	1600	400	-	08 Aug 14	-	BBCH 10-12	Leaves	0.907 0.362	21 28	
RU-P-2014-4-1 LR-K-14-FK-H-06-SCH-01 GERMANY (Europe North)	Dill (Goldkrone)	1.08 Aug 2014	1604	401	-	02 Oct 14	-	BBCH 46-47	Leaves	3.928 1.654	21 28	Field

RU-P-2014-4-1 LR-K-14-FK-H-07-EFK-01 GERMANY (Europe North)	Balm (Quedlinburger N)	1. 27 Jun 13	1600 1600	300 300	-	22 Jul 14 01 Sep 14	-	BBCH 44-45 BBCH 41-42	Plant	<u>0.389</u> 0.370 0.404	22 (after 1st application) 28 (after 1st application) 21 (after 2nd application)	Field
RU-P-2014-4-1 LR-K-14-FK-H-07-FRE-01 GERMANY (Europe North)	Parsley (einf. Schnitt)	1. 24 Apr 14	1600 1600	400 400	-	25 Jul 14 25 Aug 14	-	BBCH 43-44 BBCH 41	Plant	<u>11.799</u> 3.104 3.188	21 (after 1st application) 28 (after 1st application) 21 (after 2nd application)	Field

RU-P-2014-4-1 LR-K-14-FK-H-07-NIS-01 GERMANY (Europe North)	Parsley (Petra)	1. 19 Jun 14	1600 1600	400 400	-	13 Aug 14 15 Sept 14	-	BBCH 40 BBCH 40	Plant	1.896 0.417 4.973	21 (after 1st application) 28 (after 1st application) 21 (after 2nd application)	Field
RU-P-2014-4-1 LR-K-14-FK-H-07-MUE-01 GERMANY (Europe North)	Parsley (Smaragd-Mooskra)	1. 24 Apr 14	1600	400	-	05 Aug 14	-	BBCH 40	Plant	0.777 0.112	21 28	Field

RU-P-2014-4-1 LR-K-14-FK-H-07-MUE-02 GERMANY (Europe North)	Parsley (Smaragd-Mooskra)	1. 24 Apr 14	1600	400	-	06 Aug 14	-	BBCH 40	Plant	0.712 0.038	21 28	Field – trial not sufficiently independent of trial MUE-01
RU-P-2014-4-1 LR-K-14-FK-H-07-BBG-01 GERMANY (Europe North)	Parsley (Mooskrause)	1. 09 Apr 14	1483 1586	400 400	-	04 Jul 14 15 Aug 14	-	BBCH 41 BBCH 41	Plant	0.431 0.170 3.805	21 (after 1st application) 28 (after 1st application) 21 (after 2nd application)	Field

C.3.2 Nature and magnitude of residues in processed commodities

C.3.2.1 Nature of residues (Standard hydrolysis study)

Reference: Prosulfocarb - Aqueous Hydrolysis at 90, 100 and 120°C, [redacted] 2015, Syngenta File No. ICI574_10111, Syngenta Report No. 8267089

Guideline(s): Yes, OECD Guideline for the Testing of Chemicals, 507.

Deviations: No

GLP: Yes

Validity of the study: Acceptable

Materials and methods

The aim of the study was to investigate the hydrolytic stability of [phenyl-U-^{14}C]-prosulfocarb under conditions representative of pasteurisation, baking, brewing, boiling and sterilisation, identifying and characterising any major components produced. The conditions are summarised below:

Temperature (°C)	Time (min)	pH	Process Represented
90	20	4	Pasteurisation
100	60	5	Baking, Brewing, Boiling
120	20	6	Sterilisation

Materials

Test item: [phenyl-U-^{14}C] prosulfocarb
Lot/ batch #: RDR-XV-17
Specific activity: 2.7676 MBq/mg
Radiochemical purity: 98.8%

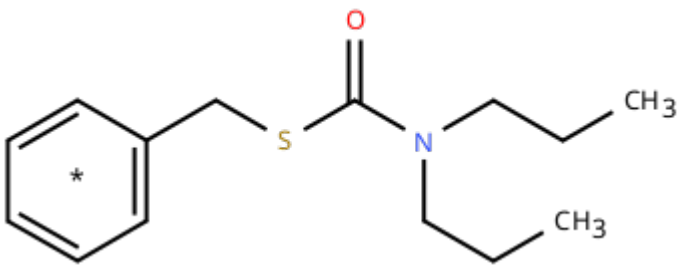


Figure C.3.2.1-1 – Prosulfocarb (* indicates radiolabel position)

Duplicate samples of test solutions were prepared for each of the test conditions (replicate A and B). Preliminary analysis showed that prosulfocarb was insufficiently soluble in buffer solutions prepared at the concentration of 1 mg/L recommended in OECD 507. Therefore, test solutions were prepared at a lower concentration of 0.5 mg/L.

Test substance was dissolved in acetonitrile and an aliquot added to sterile aqueous buffered solutions. The final volume of acetonitrile was <1% v/v in each test solution. Test solutions were sonicated to ensure complete dissolution and homogeneity of test compound within the solution. The actual application rate was 0.501 mg/L (pH 4 and 5 units) and 0.509 mg/L (pH 6 units).

Test conditions

Aliquots of 4 mL of the three test solutions were incubated at the following three representative sets of conditions to investigate the effects of the hydrolysis:

Process represented	**Temperature (°C)**	**pH**
Pasteurisation	90 ± 2	4.04
Baking, brewing and boiling	100 ± 2	4.99
Sterilisation	120 ± 2	6.02

Methods

Following application, each of the samples was placed into a polyethylene glycol (PEG) bath maintained at 90 ± 2°C, 100 ± 2°C or 120 ± 2°C, respectively. Pasteurisation and baking, brewing and boiling samples were preheated to the planned temperatures before application. For sterilisation, volatilisation of the test item and buffer had been previously observed whilst test item was added at 120°C. As a result, sterilisation samples were preheated to 80°C prior to application, then moved to a 120°C PEG bath. An additional five minutes was added onto the test to account for the time taken for the sample to reach the planned test temperature.

Testing was performed in the dark, 0 hour units were processed immediately after application and maintained at room temperature during that time.

After the appropriate incubation period, samples were removed from PEG bath and allowed to cool to room temperature. Samples were weighed and the pH measured at room temperature. Weighed aliquots were then radioassayed, solutions removed from vessel and transferred to a vial (Extract 1). Vessel was then washed with acetone, analysed for radioactivity and transferred to a vial (Extract 2).

Extract 1 and 2 were analysed separately for radioactivity by LSC and then combined prior to analysis by HPLC and TLC.

Analysis/ general procedures

Radioactivity measurements in samples were carried out by LSC, with Extract 1 and 2 analysed separately. LSC was carried out within one day of sampling. The extracts were combined prior to analysis and quantification by HPLC. Samples were analysed using method based on a reverse phase column and acidified ACN/ methanol gradient. Identification was achieved using co-chromatography for both HPLC and TLC with non-radiolabelled reference compound (reference standards: parent prosulfocarb and potential degradation product SYN521384).

Confirmatory TLC was used to verify the presence and quantification of ^{14}C prosulfocarb. LC-MS was used for analysis of selected samples when TLC showed residues that did not move from the origin. A 1 cm band of silica enveloping the origin was scraped from TLC plates and extracted. Solvent was reduced to 1 mL for LC-MS analysis.

TLC and HPLC samples were stored frozen (<-10°C) for up to 43 days and LC-MS samples were stored frozen (<-10°C) before final analysis. Both the initial TLC and final LC-MS showed 100% parent prosulfocarb without degradation, demonstrating sufficient stability of prosulfocarb under the above conditions.

Results and discussion

The total radioactivity in each test solution was determined by HPLC pre and post incubation. The concentration of the total radioactivity in each test/ replicate, expressed as [phenyl-U-^{14}C] prosulfocarb, ranged from 0.494-0.507 mg/L prior to incubation and 0.497-0.501 mg/L following incubation.

The recovery results indicate there was no significant loss of radioactivity during the reactions. Recoveries for test samples are shown in table C.3.2.1-1.

Table C.3.2.1-1 Standard hydrolysis study for prosulfocarb

Processes represented	T (°C)	Time (min)	pH	Prosulfocarb initial recoveries (% applied radioactivity)	Prosulfocarb post incubation recoveries (% applied radioactivity)
Pasteurisation	90	20	4	98.7	99.6
Baking Brewing Boiling	100	60	5	99.5	99.2
Sterilisation	120	20	6	99.7	98.6

Conclusions

The hydrolytic behaviour of [phenyl-U-^{14}C] prosulfocarb under conditions representative for food processing operations was investigated.

The following conditions were tested:

- pH 4 / 90°C (20 min) – pasteurisation
- pH 5 / 100°C (60 min) – baking, brewing and boiling
- pH 6 / 120°C (20 min) – sterilisation

Each test was performed in duplicate. Samples showed no significant degradation and only the parent prosulfocarb was identified. Prosulfocarb can be considered hydrolytically stable under conditions representative of pasteurisation, baking, brewing and boiling and sterilisation.

C.3.2.2 Magnitude of residues (Processing studies)

No additional studies submitted

C.3.3 Nature and magnitude of residues in rotational crops

C.3.3.1 Nature of residue

The maximum DT_{90} was 48 days for parent prosulfocarb and 13 days for minor soil metabolite prosulfocarb sulfoxide. It was concluded that no studies were required for the approval of the active substance.

Additional studies were submitted by the applicant and have been checked for adverse data. The study is not expected to impact the consumer risk assessment or calculated MRLs.

C.3.3.2 Magnitude of residues (field rotational crop studies)

No additional studies submitted

C.3.4 Nature and magnitude of residues in livestock

No additional studies submitted

C.3.5 Residues in honey

No additional studies submitted

C.3.6 Storage stability

C.3.6.1 Storage stability of residues in plant products

No additional studies submitted

C.3.6.2 Storage stability of residues in animal products

No additional studies submitted

C.3.6.3 Storage stability in honey

Additional studies for the storage stability of prosulfocarb in honey have been submitted but not required. Prosulfocarb is to be assessed under ‘old’ data requirements set out under Assimilated Regulation 544/2011.

Furthermore, consideration of honey is not required for import tolerances where no MRLs for the import of honey have been requested.

Appendix D – List of endpoints

The endpoints have not changed as a result of this assessment; however, a number of metabolism studies have been evaluated, and are summarised below. The full list of endpoints is outlined in EFSA Article 12 review (EFSA, 2011).

Table D.1 Primary crop metabolism

Crop group	Crop(s)	Applications	DAT[(a)] (days)	Source
Root crops	Potato	Soil, outdoor, 1 x 3.42 kg a.s./ha, pre-emergence	105	EFSA, 2007
Cereals/grass crops	Wheat	Foliar, outdoor, 1 x 3.64 kg a.s./ha, BBCH 10-12	283	EFSA, 2007
	Barley	Foliar, outdoor, 1 x 4.00 kg a.s./ha, BBCH 10-12	Immature barley: 7, 14 & 161 Grain and straw: 237 days post sowing	EFSA, 2007
Pulses/Oilseeds	Peas	Soil, greenhouse, 1 x 4.05 kg a.s./ha, pre-emergence	At maturity	EFSA, 2007
Root crops	Carrots	Foliar, outdoor, 1 x 4.18 kg a.s./ha, BBCH 14	Roots & leaves: 21 & 58	Current assessment
Overall conclusion on the metabolism in primary crops	The available metabolism studies are sufficient to support the uses under consideration, and the use on herbs and edible flowers is sufficiently supported. For further uses, additional data and/or considerations may be required.			

Table D.2 Nature of the residue on processing

Conditions	Stability	Comment
Pasteurisation (20 min, 90°C, pH 4)	Stable	Identified compound: Prosulfocarb (99.6%)
Baking, brewing and boiling (60 min, 100°C, pH 5)	Stable	Identified compound: Prosulfocarb (99.2%)
Sterilisation (20 min, 120°C, pH 6)	Stable	Identified compound: Prosulfocarb (98.3-98.9%)

Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes

Appendix E – Import Tolerances

Sufficient information was provided to confirm that the GAPs outlined in Appendix A have been authorised in the Netherlands.

Proof of MRLs in force for the exporting country

MRLs for prosulfocarb were set in the EU Regulation 2023/129 of 18 January 2023 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, prosulfocarb, sedaxane and valifenalate in or on certain products

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R0129&qid=1674119253749

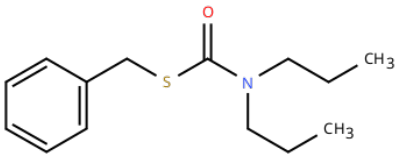
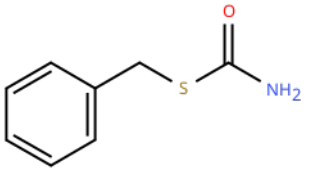
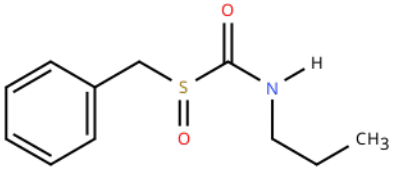
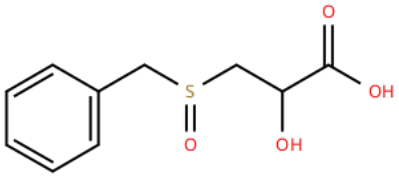
A copy of the current EU legislation in the exporting country related to the MRLs under consideration was provided. The MRLs in force in the exporting country are tabulated in Table E.1.

Table E.1 MRLs in force in the exporting country

Commodity	**MRL in force in the exporting country (mg/kg)**
Enforcement residue	**definition for products of plant origin:** prosulfocarb
Herbs and edible flowers	20

Appendix F – Compound codes

Table F.1 List of metabolites identified in new studies

Code/ name	Chemical name	Structural formula
R331405	(dipropylamino)(phenylmethanesulfinyl) methanone	
R331282	S-benzyl carbamothioate	
R393096	*S*-benzyl N-propylcarbamothiate	
SYN545179	2-hydroxy-3-(phenylmethanesulfinyl)propanoic acid	

Appendix G – Abbreviations

ADI	Acceptable daily intake
ADME	Absorption, distribution, metabolism and excretion
Animal model 2017	EFSA model used to calculate the dietary burden of livestock using the OECD feeding tables
ARfD	Acute reference dose
a.s.	Active substance
BBCH	Growth stages of mono- and dicotyledonous plants
bw	Body weight
CF	Conversion factor
cGAP	Critical GAP
CXL	Codex maximum residue limit
DAR	Draft assessment report
DAT	Days after treatment
DT_{90}	Period required for 90% dissipation (define method of estimation)
DT_{50}	Period required for 50% dissipation (define method of estimation)
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GB	Great Britain
GC-MS	Gas chromatography with mass spectrometry

GLP	Good laboratory practice
HPLC-MS/MS (LC-MS/MS)	High-performance liquid chromatography with tandem mass spectrometry
HR	Highest residue
HSE	Health and Safety Executive
IEDI	International estimate of daily intake
IESTI	International estimate of short-term intake
ILV	Independent laboratory validation
ISO	International Organisation for Standardization
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC_{50}	Lethal concentration, median
LD_{50}	Lethal dose, median
LOAEL	Lowest observed adverse effect level
LOD	Limit of detection or limit of determination (should be defined)
LoEP	List of endpoints
LOQ	Limit of quantification **NB** the limit of quantification and limit of determination are the same. Assimilated Regulation 396/2005 refers to the limit of determination Assimilated Regulation 1107/2009 refers to the limit of quantification MRLs marked with an asterisk (e.g. 0.01* mg/kg) are MRLs set at the limit of determination/quantification
MRL	Maximum residue level
NEDI	National estimate of dietary intake
NESTI	National estimate of short-term intake

NOAEL	No observed adverse effect level
NRL	National reference laboratory
OECD	Organisation for Economic Co-operation and Development
PBI	Plant-back interval
PES	Post-extraction solids
Pf	Processing factor
PHI	Preharvest interval
PRIMo	(EFSA) Pesticide Residue Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	Risk assessment
RD	Residue definition
RD-Enf	Residue definition for enforcement (also referred to as RD-Mo i.e. residue definition for monitoring)
RD-RA	Residue definition for risk assessment
RTI	Re-treatment interval
STMR	Supervised trials median residue
TRR	Total radioactive residue
TTC	Threshold of toxicological concern
WG	Water dispersible granule
WHO	World Health Organization

Additional studies relied upon

Author(s)	Year	Title/Testing Facility/Report No/GLP or GEP Status/Published or not	Submitter
[redacted]	2015	Prosulfocarb –Validation of the QuEChERS Method for the Determination of Residues of Prosulfocarb in Crop Matrices by LC-MS/MS., Syngenta Report No. S14-05734, GLP	Syngenta
	2016	Prosulfocarb – Independent Laboratory Validation of the QuEChERS Method for the Determination of Residues of Prosulfocarb in Crop Matrices by LC-MS/MS, Report number S14-05766, GLP.	Syngenta
	2015	Residue Examination for Boxer (Prosulfocarb) in Dill Leaves, Balm and Parsley, Syngenta Report No. RU-P-2014-4-1, GLP	Syngenta
	2015	Prosulfocarb - Metabolism of [^{14}C]-Prosulfocarb in Carrots, Report No. SYN-006/7-08, GLP	Syngenta
	2015	Prosulfocarb - Aqueous Hydrolysis at 90, 100 and 120°C, Syngenta Report No. 8267089, GLP	Syngenta