FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 076127 A

Product name(s): PROSIM

Chemical active substances:

Propamocarb hydrochloride, 400 g/L
Cymoxanil, 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Sharda Cropchem España S.L.

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February 2024	Correction in point 7.3.5

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

zRMS comments or modifications to the Applicant's submission are made in grey boxes and/or high-lighted in grey in the text.

Storage stability

Propamocarb

The stability of residues for propamocarb was already addressed during the EU Review process.

Under frozen storage condition, propamocarb residues were demonstrated to be stable in high water content matrices for at least one year.

Potatoes belong to the high starch content matrices. The Applicant did not provide residue stability data for this matrix group (data gap).

Data out of protection documenting stability residues for propamocarb in potato are available. Residues of propamocarb are stable in potatoes samples up to 26 months (EU unprotected data). ~~The Applicant is requested to complete the point 7.2.1 with data on the stability of residues in potatoes.~~

Cymoxanil

The stability of residues for Cymoxanil was already addressed during the EU Review process.

Lettuce	High water content	12 months (-20ºC)	EFSA, 2008
Potato	High starch content	12.5 months (-20ºC)	EFSA, 2008

Metabolism in plant and animal

The metabolism in plant and animal was assessed for annex 1 inclusion (approval) of the actives. The data evaluated is regarded as sufficient to support the proposed use on potato.

The residue definitions agreed for monitoring and risk assessment:

Propamocarb

Plant residue definition for monitoring	Sum of propamocarb and its satls, expressed as propamocarb Regulation (EU) No. 2020/856
Plant residue definition for risk assessment	Sum of propamocarb and its satls, expressed as propamocarb (EFSA, 2013, 2017)
Animal residue definition for monitoring	Pig, milk and ruminant tissues: N-oxide propamocarb only Poultry tissues and eggs: N-desmethyl propamocarb Regulation EU No. 2020/856
Animal residue definition for risk assessment	Milk, pig and ruminant tissues: sum of propamocarb, N-oxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb Poultry tissues: sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb EFSA Journal 2013;11(4):3214
Conversion factor	1.3 for all poultry tissues and eggs 4.25 for milk

	2.2 for ruminant kidney 1.7 for ruminant liver and muscle (EFSA 2013)

Cymoxanil

Plant residue definition for monitoring	Cymoxanil (Regulation (EU) No. 2018/832, Reg. (EU) 2022/1363 - not yet applicable)
Plant residue definition for risk assessment	Cymoxanil (EFSA, 2015)
Animal residue definition for monitoring	Residue definition in animal commodities is not needed but could be set as cymoxanil (for ruminant and pigs) if needed in the future EFSA Journal 2015;13(12):4355
Animal residue definition for risk assessment	Residue definition in animal commodities is not needed but could be set as cymoxanil (for ruminant and pigs) if needed in the future EFSA Journal 2015;13(12):4355

No further data are required.

Magnitude of residues in plants

Proposed GAP: BBCH 21-95; 1-6 applications (interval: 7-14 days); application rate per treatment 1.0 kg as/ha propamocarb + 0.125 kg as/ha cymoxanil; PHI: 14 days

Potatoes

Propamocarb

New acceptable studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

New trials GAP: 6 x 1 kg as/ha, BBCH 93, PHI 14-15d, outdoor

Residues (tuber): 0.06, 3x<0.01, 2x 0.01 mg/kg

Additionally Applicant refers to unprotected EU data

DAR, Ireland, 2005	N-EU	GAP on which MRL/EU a.s. assessment is based: 6-7 x 1-2 kg as/ha, BBCH 48-49 (tuber formation, equivalent BBCH 96.5) , PHI 14-21d, outdoor Tuber: 8 x <0.1 mg/kg

Proposed use is in line with EU representative GAP (SANCO/10057/2006 final); 25 April 2007.

The number of trials is sufficient as to support the use of propamocarb on potatoes according to the proposed GAP in Central Zone.

It can be concluded that the residues arising from the proposed use will not exceed the MRLs for potatoes set at 0.3 mg/kg (Regulation (EU) No. 2020/856).

Cymoxanil

New acceptable studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP: 6 x 0.125 kg as/ha, BBCH 93, PHI 14-15d, outdoor

Residues: 6x<0.01 mg/kg

The number of trials is sufficient as to support the use of cymoxanil on potatoes according to the proposed GAP in Central Zone.

It can be concluded that the residues arising from the proposed use will not exceed the MRLs for potatoes

set at 0.01 mg/kg (Regulation (EU) No. 2018/832)

Magnitude of residues in livestock

Propamocarb

A dietary burden calculation, including the requested use on potato, has already been made by EFSA in the framework of the Art. 12 evaluation of propamocarb-HCl (EFSA Journal 2013;11(4):3214).

zRMS has been performed a new calculation of the dietary burden using the calculator OECD (2017).

The input values for potatoes were changed to 0.1 mg/kg (STMR/HR) according to the data from Table 7.2-9.

Regarding available feeding data, there is no risk for animal MRL to be exceeded.

No new data were submitted and required in the framework of this application.

Cymoxanil

According to EFSA, the previous assessment of residues in livestock (EFSA, 2015) is still valid (EFSA Journal 2019;17(10):5823).

No additional data is required.

Industrial Processing and/or Household Preparation

No supplementary studies on the effects of industrial processing and/or household preparations on residue levels have been conducted or are required.

Succeeding crops

Additional rotational crop residue trials are not required. No waiting periods between application and planting of succeeding crops are necessary.

Consumer risk assessment

The proposed uses of propamocarb and cymoxanil in the formulation PROSIM (SHA 076127 A) do not represent unacceptable acute and chronic risks for the consumer.

Acceptable calculations were made using EFSA PRIMo rev.3.1.

Other / special studies

Potatoes have not melliferous capacity. Studies are not required.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation SHA 076127 A are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central zone for Potato. A list of all intended uses within the Central Zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.3 mg/kg for Propamocarb and 0.01 mg/kg for Cymoxanil as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of Propamocarb and Cymoxanil residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, Poland agrees with the authorization of the intended use(s).

According to available data, no specific mitigation measures should apply.

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

- ~~The Applicant is requested to complete the point 7.2.1 with data on the stability of residues in potatoes.~~
- data gap 2
- data gap 3

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
1	Potato	CEU	SHA 076127 A	F	*Phytophthora infestans*	SC	400 g/L Propamocarb + 50 g/L Cymoxanil	Foliar Spray	BBCH 21-95	1-6	7-10	0.25 propamocarb + 0.03125 cymoxanil – 0.5 propamocarb + 0.0625 cymoxanil	200-400	1.0 propamocarb + 0.125 cymoxanil	14	A

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

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

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

Explanation for Column 11 “Conclusion”

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

7.1.2 Summary of the evaluation

The preparation SHA 076127 A is composed of Propamocarb and Cymoxanil.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of Propamocarb and Cymoxanil

Reference value	Source	Year	Value	Study relied upon	Safety factor
Propamocarb hydrochloride					
ADI	EFSA	2006	0.29 mg/kg bw per day	52 week rat study	100
ARfD	EFSA	2006	1 mg/kg bw	28 days gavage study in rats	100
Propamocarb					
ADI	EFSA	2006	0.244 mg/kg bw per day*	-	-
ARfD	EFSA	2006	0.84 mg/kg bw*	-	-
Cymoxanil					
ADI	EFSA	2008	0.013 mg/kg bw/day	1 year dog study	100
ARfD	EFSA	2008	0.08 mg/kg bw	Rabbit, teratogenicity study	100

*Recalculated by applying molecular weight conversion factor of 0.84 to the toxicological reference values derived for propamocarb hydrochloride

7.1.2.1 Summary for Propamocarb

Table 7.1-3: Summary for Propamocarb

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Potato	Yes	Yes	Yes	Yes	Yes	No	No

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

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

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

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

7.1.2.2 Summary for Cymoxanil

Table 7.1-4: Summary for Cymoxanil

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Potato	Yes	Yes	Yes	Yes	Yes	No	No

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

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

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

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

7.1.2.3 Summary for SHA 076127 A

Table 7.1-5: Information on SHA 076127 A (KCA 6.8)

Crop	PHI for SHA 076127 A proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for SHA 076127 A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Propamocarb	Cymoxanil		
Potato	NR	NR	NR		

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for SHA 076127 A
Crop group	Led by Propamocarb	Led by Cymoxanil	
Root and tuber vegetables	NR	NR	

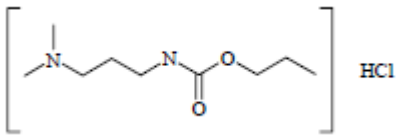
NR: not relevant

Assessment

7.2 Propamocarb

General data on Propamocarb are summarized in the table below (last updated 2020/09/14)

Table 7.2-1: General information on Propamocarb

Active substance (ISO Common Name)	Propamocarb
IUPAC	Propyl 3-(dimethylamino)propylcarbamate (propamocarb)
Chemical structure	
Molecular formula	$C_9H_{21}ClN_2O_2$
Molar mass	224.7
Chemical group	Carbamate
Mode of action (if available)	Lipid synthesis inhibitor
Systemic	Yes
Company (ies)	Bayer CropScience Chimac Agriphar
Rapporteur Member State (RMS)	RMS: Portugal Co-RMS: Belgium
Approval status	Approved Date of (01/10/2007) and reference to decision (COMMISSION DIRECTIVE 07/25/EC - REGULATION (EU) No 540/2011) active hyperlinks.
Restriction	Restricted to use as fungicide
Review Report	SANCO/10057/2006 – final 25/04/2007
Current MRL regulation	Regulation (EU) No 856/2020
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	EFSA Scientific Report (2006) 78, 1-80
EFSA Journal: conclusion on article 12	EFSA Journal 2013;11(4):3214
Current MRL applications on intended uses	EFSA-Q-2008-611 (EMS) Commodities Reasoned opinion available (EFSA Journal 2013;11(4):3214)

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, YYYY - see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Tomato	High water content	12 months	Dr. J. Moede, 1990 Report No. UPSR 48/90 DAR, Ireland, 2005
Tomato		26 months	A. L. Sutton, G. E. Charter, 1999 Report No. RESID/99/18 DAR, Ireland, 2005
Lettuce		14 months	A. Wrede-Rucker, 1990 Report No. UPSR 52/90 DAR, Ireland, 2005
Lettuce		24 months	O. Pigeon, 2003 Report No, Chimac-Agriphar/RE20018/2000 DAR, Ireland, 2005
Cucumber		12 months	O. Pigeon, 2003 Report No. Chimac-Agriphar/RE 20044/2000 DAR, Ireland, 2005
Tomato		12 months	O. Pigeon, 2002 Report No. Chimac-Agriphar/RE 200443/2000 DAR, Ireland, 2005
Brussel sprouts		12 months	O. Pigeon, 2002 Report No. Chimac-Agriphar/RE 20042/2000 DAR, Ireland, 2005
Potato	High starch content	26 months	Everitt, S. L., Charter, G. E., 1998 Report No.: C003683 RAR, Portugal, 2017

Conclusion on stability of residues during storage

Under frozen storage condition, propamocarb residues were demonstrated to be stable in high water content matrices for at least one year.
Residues of propamocarb hydrochloride in potato tubers are stable for a period of at least 26 months when stored deep frozen.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

Not relevant.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Tomatoes	N/A	Soil, G	7.22 g a.s./m^2	4	14, 21, 28, 25		L. E. Daniel, K. K. Rupprecht, 2000 Report No. AV 97E519 DAR, Ireland, 2005
				36.1 g a.s./m^2	4			A. Goodyear, 2002 Report No. CLE 1669/3-D2149 DAR, Ireland, 2005
			Foliar, G	2.166	1	7, 14, 21, 28		
	Cucumbers		Foliar	2.9	1	30		J. Kent, Rupprech, M. Feyerabend, 1998 Report No. U/R 50/94 DAR, Ireland, 2005
			Soil (hydroponic)	53.4 mg/plant	1	21		
Leafy vegetables	Spinach	[^{14}C-carbamate]	Foliar, F	2.53	2	After the first app: 0 after the second: 3		L. E. Daniel, K. K. Rupprecht, 2000 Report No. AV 97E519 DAR, Ire-

								land, 2005
	Lettuce	N/A	Soil, G	Drench: 7.22 g a.s./m^2	3	38		A. Goodyear, 2002 Report No. CLE 1669/6-D2149 DAR, Ireland, 2005
			Foliar, G	Foliar spray: 1.083	3	21		
Root and tuber vegetables	Potatoes	[^{14}C-propyl]	Foliar, F	2.45	3	42		A. Fortsch, 1991 Report No.UPSR 14/91-PA 66752.8/13 DAR, Ireland, 2005
			Foliar, F	2.166	6	7		A. Goodyear, 2002 Report No. CLE 1669/5-D2149 DAR, Ireland, 2005
				10.83				

Summary of plant metabolism studies reported in the EU

Metabolism of propamocarb hydrochloride was investigated for foliar application on fruits and fruiting vegetables (cucumber, tomato), root and tuber vegetables (potato), and leafy vegetables (spinach, lettuce); and for soil application on fruits and fruiting vegetables (tomato) and leafy vegetables (lettuce), using ^{14}C-labelled propamocarb.
After foliar applications, residues are highly extractable (90 % TRR) and consist essentially of propamocarb. Two minor metabolites, accounting for less than 5 % of the TRR were also identified, hydroxypropyl-propamocarb$_{13}$ and N-oxide propamocarb$_{14}$, indicating that the degradation of propamocarb hydrochloride proceeds through hydroxylation and oxidation. A similar pattern was observed in spinach after foliar treatment, with two further metabolites identified (< 4 % TRR), *i.e.* N-desmethyl-propamocarb resulting from N-demethylation and oxazolidine$_{16}$ resulting from the cyclization of the hydroxypropyl-propamocarb. Foliar treatment of tomato plants also resulted in propamocarb being the major constituent in tomato fruits (75 % TRR).
Propamocarb hydrochloride applied hydroponically or as soil treatment in tomatoes or lettuce results in a quite different metabolic pattern in harvested lettuce and tomatoes. The amounts of unchanged parent and of its structurally related metabolites are low, demonstrating a high rate of degradation in plants and in the soil. The total residues are essentially constituted of polar material rather similar for both crops, indicating the incorporation of labelled carbon in the endogenous material. In contrast to the observations made in lettuce and tomatoes, cucumbers grown hydroponically and treated with propamocarb hydrochloride applied in the nutrient solution showed significantly higher levels of parent propamocarb (50 % TRR).

In potato tubers, unchanged propamocarb was present at 2-15 % of the TRR. The vast majority of the radioactivity could be allocated to natural plant constituents (mainly starch), demonstrating the incorporation in plant material of CO_2 produced by the degradation of propamocarb hydrochloride.

Conclusion on metabolism in primary crops

The residue definition for enforcement purposes and risk assessment in all plant commodities is defined

as the sum of propamocarb and its salts, expressed as propamocarb.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	^{14}C-aminopropyl	Bare soil, G	5.96 – 6.16	30, 120, 365	NR	NR	B. N. Meyer, 2000 Report No. AV96E518 DAR, Ireland, 2005
Root and tuber vegetables	Radish							
Cereals	Wheat							

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

In crops planted in the 30 day aged soil, total residues ranged from 0.36 (radish roots) to 2.33 mg/kg (wheat straw), and declined rapidly in crops planted in soil aged 120 days and 365 days to a maximum of 0.09 mg eq/kg. Propamocarb was found in all acidic methanol sample extracts from the 30 day aged soil and was the major component (15.4 % TRR (0.36 mg/kg) in wheat straw to 67.4 % TRR (0.91 mg/kg) in radish tops), except in wheat grain, where the main compound was the oxazolidine metabolite representing 19.9 % TRR (0.13 mg/kg). 2-hydroxy propamocarb, N-oxide and desmethyl propamocarb (wheat only) were not present in any sample at levels exceeding 10 % TRR. The remaining residue was a complex mixture of highly polar components. Residues released after acid and base hydrolysis (< 10 % TRR) indicated a similar pattern of metabolites.

Conclusion on metabolism in rotational crops

Metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not required.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data were submitted in the framework of this application. Not required as no residues are present in raw commodities.

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

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

Endpoints	
Plant groups covered	Leafy crops (spinach and lettuce), fruits (tomatoes and cucumbers) and roob vegetables (potatoes).
Rotational crops covered	Lettuce, radish and wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not required
Residue pattern in processed commodities similar to pattern in raw commodities?	Not relevant.
Plant residue definition for monitoring	Sum of propamocarb and its satls, expressed as propamocarb Regulation (EU) No. 2020/856
Plant residue definition for risk assessment	Sum of propamocarb and its satls, expressed as propamocarb (EFSA, 2013)
Conversion factor from enforcement to RA	None

* If residue pattern in processed commodities is not similar to that in raw commodities
** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).
*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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

Available data

No new data submitted in the framework of this application.

Table 7.2-6: Summary of animal metabolism studies

Group	**Species**	**Label position**	**No of animal**	**Application details**		**Sample details**		**Reference**
				Rate (mg/kg bw/d)	**Duration (days)**	**Commodity**	**Time of sampling**	
EU data								
Lactating ruminants	Cow	^{14}C-carbon	1	2	7	Milk	twice daily	XXXX, 2000 Report No. AV97E521 DAR, Ireland, 2005
						Urine and faeces	twice daily	
						Tissues	at sacrifice	
Laying poultry	Hens		12	1.02	14	Eggs	Once daily	EFSA, 2013
						Excreta	n.r.	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

In cow, over 80 % of the administered dose was excreted in urine and faeces while only 0.7% and 0.46% of the AR remained in tissues and milk, respectively. No quantifiable residues (<0.01 mg/kg) were recovered in fat and no furher metabolites identification was attempted. The highest total radioactive residues were found in liver (0.415 mg eq/kg) and in kidney (0.107 mg eq/kg) and to a minor extent in muscle (0.02 mg eq/kg) and in milk (0.057 mg eq/kg). Propamocarb accounted for 24.6 % TRR in muscle (0.005 mg/kg), 23.5 % TRR in kidney (0.025 mg/kg), 6.2 % TRR in liver (0.026 mg/kg) and 6.0 % TRR in milk (0.003 mg/kg). Parent compound was either oxidized to form N-oxide propamocarb, or hydroxylated at the propyl side chain to form the 2-hydroxy-propamocarb[17] followed by a cyclisation to form the oxazolidine-2-one propamocarb metabolite. Another route of degradation consisted of demethylation of the parent molecule into the N-desmethyl propamocarb. Metabolite N-oxide propamocarb was the predominant metabolite of the total residues found in kidney (41 % TRR – 0.044 mg/kg), liver (49 % TRR – 0.203 mg/kg), muscle (40.5 % TRR – 0.008 mg/kg) and also in milk (21 % TRR – 0.012 mg/kg). Oxazolidine-2-one propamocarb occurred in significant amounts in kidney, liver and milk (14 – 23 % TRR; 0.014 – 0.09 mg/kg). 2-hydroxy propamocarb was the major metabolite of the total residues in milk (37.5 % TRR – 0.022 mg/kg) but was also identified at a lower level in liver (5 % TRR) and kidney (13 % TRR). N-desmethyl propamocarb was either not detected (kidney, liver) or identified at a trace level in milk and muscle (up to 0.002 mg/kg).
In hens, the majority of the residues (92 to 99 % TRR) in the egg and tissues was extractable. The total radioactive residues accounted for 0.254 mg/kg in eggs, 0.492 mg/kg in liver, 0.117 – 0.135 mg/kg in muscle and 0.042 – 0.065 mg/kg in fat. The predominant compound of the total residues was the N-desmethyl propamocarb in eggs (45 % TRR), liver (22 % TRR), muscle (29 % TRR) and to a minor extend in fat (6 % TRR) whilst the parent compound occurred at a lower level in all matrices (2 – 12 % TRR). Bis desmethyl propamocarb[18] and N-oxide propamocarb accounted for less than 10% TRR. It is noted that a significant fraction of the radioactive residues remained uncharacterized in liver and muscle (32 % and 41 % TRR, respectively).

Conclusion on metabolism in livestock

The residue definition for enforcement in pig, milk and ruminant tissues is set as N-oxide propamocarb only and in poultry tissues and eggs as N-desmethyl propamocarb. For risk assessment in milk, pig and ruminant tissues the definition is set as the sum of propamocarb, N-oxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb. For poultry tissues the definition is set as the sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb.

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

Table 7.2-7: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Cow
	Laying hens
Time needed to reach a plateau concentration	28 days in eggs
Animal residue definition for monitoring	Pig, milk and ruminant tissues: N-oxide propamocarb only Poultry tissues and eggs: N-desmethyl propamocarb Regulation EU No. 2020/856
Animal residue definition for risk assessment	Milk, pig and ruminant tissues: sum of propamocarb, N-oxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb

	Poultry tissues: sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb EFSA Journal 2013;11(4):3214
Conversion factor	1.3 for all poultry tissues and eggs 4.25 for milk 2.2 for ruminant kidney 1.7 for ruminant liver and muscle (EFSA 2013)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)
** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.
*** If metabolism in rat and ruminant are not similar

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

~~No new data are submitted in the framework of this application.~~

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of SHA 076127 A and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Potato	DAR, Ireland, 2005	N-EU	GAP on which MRL/EU a.s. assessment is based: 6-7 x 1-2 kg as/ha, BBCH 48-49, PHI 14-21d, outdoor Tuber: 8 x <0.1	N/A				
	New trials	N-EU	Trials GAP: 6 x 1 kg as/ha, BBCH 93, PHI 14-15d, outdoor Tuber: ~~0.059, 3x <0.003 (<LOD), 0.0112, 0.0114~~ 0.06, 3x<0.01, 2x 0.01					
	Overall supporting data for cGAP	N-EU	Tuber: ~~3x <0.003 (<LOD), 0.0112, 0.0114, 0.059,~~ 0.06, 3x<0.01, 2x 0.01, 8 x <0.1	0.1	0.1	0.246	0.3	Yes

* Source of EU MRL: Regulation (EU) No. 2020/856

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on Potato are considered acceptable, for outdoor uses.

The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-9: Input values for the dietary burden calculation (considering the uses authorized within the zone/evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment (EFSA, 2013)	Input value (mg/kg)	Comment (EFSA, 2013)
Sum of propamocarb and its salts, expressed as propamocarb				
Cabbage, heads	0.20	Median residue	0.36	Highest residue
Kale leaves	4.00	Median residue	11.80	Highest residue
Potato culls	0.01	Median residue	0.03	Highest residue
Potato process waste	0.20	Median residue (0.01) * PF (20)	0.20	Median residue (0.01) * PF (20)
Potato dried pulp	0.38	Median residue (0.01) * PF (38)	0.38	Median residue (0.01) * PF (38)

Table 7.2-10: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Sum of propamocarb and its salts, expressed as propamocarb					
Cattle (all diets)	0.225	0.626	Kale leaves	16.45	Y
Cattle (dairy only)	0.225	0.626	Kale leaves	16.28	Y
Sheep (all diets)	0.128	0.350	Kale leaves	8.58	Y
Sheep (ewe only)	0.112	0.286	Kale leaves	8.58	Y
Swine (all diets)	0.070	0.191	Kale leaves	8.28	Y
Poultry (all diets)	0.009	0.014	Cabbage, heads	0.20	Y
Poultry (layer only)	0.009	0.014	Cabbage, heads	0.20	Y

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

zRMS

A dietary burden calculation, including the requested use on potato, has already been made by EFSA in the framework of the Art. 12 evaluation of propamocarb-HCl (EFSA Journal 2013;11(4):3214).
zRMS has been performed a new calculation of the dietary burden using the calculator OECD (2017).
The input values for potatoes were changed to 0.1 mg/kg (STMR/HR) according to the data in Table 7.2-9.

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sum of propamocarb and its salts, expressed as propamocarb				
Cabbage, heads	0.20	Median residue (EFSA, 2013)	0.36	Highest residue (EFSA, 2013)
Kale leaves	4.00	Median residue (EFSA, 2013)	11.80	Highest residue (EFSA, 2013)
Potato culls	0.1	Median residue Residues from field trials	0.1	Highest residue Residues from field trials
Potato process waste	2,0	Median residue (0.01) * PF (20)	2,0	Median residue (0.1) x PF (20)
Potato dried pulp	0.38	Median residue (0.01) * PF (38)	0.38	Median residue (0.1) x PF (38)

Dietary Burden Table:

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,290	0,403	9,22	12,15	Dairy cattle	Kale	leaves	Yes
Cattle (dairy only)	0,290	0,403	7,55	10,48	Dairy cattle	Kale	leaves	Yes
Sheep (all diets)	0,267	0,316	8,02	9,48	Ram/Ewe	Kale	leaves	Yes
Sheep (ewe only)	0,267	0,316	8,02	9,48	Ram/Ewe	Kale	leaves	Yes
Swine (all diets)	0,110	0,144	4,78	6,25	Swine (breeding)	Kale	leaves	Yes
Poultry (all diets)	0,064	0,064	0,91	0,91	Poultry broiler	Potato	dried pulp	Yes
Poultry (layer only)	0,052	0,056	0,76	0,82	Poultry layer	Potato	dried pulp	Yes

Regarding available feeding data, there is no risk for animal MRL to be exceeded.
No new data were submitted and required in the framework of this application.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application.

Table 7.2-11: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	Calculated MRL (mg/kg)	CF for RA[d]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[a]	No	Result for enforce-ment		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (EFSA, 2013)												
Enforcement residue definition: N-oxide propamocarb Risk assessment residue definition: sum of propamocarb, N-oxide propamocarb, oxazolidin-2-one propamocarb and 2-hydroxypropamocarb expressed as propamo-carb												
Pig muscle/meat	0.070	0.191	2	1	NR	0.01	NR	0.01	0.01	0.01	0.01	1.7
Pig fat			2	1	NR	0.01	NR	0.01	0.01	0.01	0.01	1.0
Pig liver			2	1	NR	0.20	NR	0.34	0.02	0.05	0.1	1.7
Pig kidney			2	1	NR	0.04	NR	0.10	0.01	0.01	0.02	2.2
Ruminant meat	0.225	0.626	2	1	NR	0.01	NR	0.01	0.01	0.01	0.01	1.7
Ruminant fat			2	1	NR	0.01	NR	0.01	0.01	0.01	0.01	1.0
Ruminant liver			2	1	NR	0.20	NR	0.34	0.04	0.13	0.2	1.7
Ruminant kidney			2	1	NR	0.04	NR	0.10	0.01	0.03	0.05	
Poultry meat	0.009	0.014	0.26	12	NR	0.02	NR	0.02	0.01	0.02	0.02	1.3
			0.78	12	NR	0.04	NR	0.04				
			2.60	12	NR	0.10	NR	0.12				
Poultry fat	0.009	0.014	0.26	12	NR	0.005	NR	0.01	0.01	0.01	0.01	1.3
			0.78	12	NR	0.01	NR	0.02				
			2.60	12	NR	0.13	NR	0.17				
Poultry liver	0.009	0.014	0.26	12	NR	0.03	NR	0.04	0.01	0.03	0.05	1.3

			0.78	12	NR	0.06	NR	0.08				
			2.60	12	NR	0.11	NR	0.16				
Milk	0.225	0.626	2	1	NR	0.01	NR	0.05	0.01	0.01	0.01	4.25
Eggs	0.009	0.014	0.26	144	NR	0.04	NR	0.05	0.01	0.04	0.05	1.3
			0.78	144	NR	0.09	NR	0.12				
			2.60	288	NR	0.37	NR	0.47				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.
n.r.: Not reported
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): MRL is expressed as mg/kg of fat contained in the whole product.
(a): Based on a 1.9 kg animal consuming 0.12 kg feed DM/day.
(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(d): The median conversion factor for enforcement to risk assessment.

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

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

No new data were submitted in the framework of this application. Not required as no residues are present in raw commodities.

Processing factors for potato were not investigated during the Annex I inclusion process of propamocarb.

As residue of propamocarb is not expected to exceed 0.1 mg/kg in potato tubers following the application of the product, therefore processing studies are not required.

Considering that the contribution of the commodity under consideration to the theoretical maximum daily intake is <10% of the ADI and each of the calculated IESTI values is <10% of the ARfD further investigations are not deemed necessary.

7.2.6 Magnitude of residues in representative succeeding crops

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

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of SHA 076127 A. Therefore, other special studies are not needed.

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

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

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-12: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sum of propamocarb and its salts, expressed as propamocarb				
MRL values Regulation (EU) No. 2020/856				

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-13: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev.3.1	24 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo* rev.3.1	**Raw commodities** Based on children: Potatoes: 5% Based on adults: Potatoes: 1% **Processed commodities** Based on children: Potatoes/fried: 3% Potatoes/dried (flakes): 2% Based on adults: Potatoes/chips: 0.3% Potatoes/dried (flakes): 0.2%
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

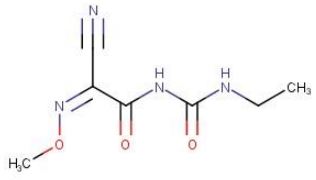
* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of Propamocarb in the formulation PROSIM (SHA 076127 A) do not represent unacceptable acute and chronic risks for the consumer.

7.3 Cymoxanil

General data on Cymoxanil are summarized in the table below (last updated 2020/09/14)

Table 7.3-1: General information on Cymoxanil

Active substance (ISO Common Name)	Cymoxanil
IUPAC	1-[(E/Z)-2-cyano-2-methoxyiminoacetyl]-3-ethylurea
Chemical structure	
Molecular formula	$C_7H_{10}N_4O_3$
Molar mass	198.2 g/mol
Chemical group	Cyanoacetamide oxime

Mode of action (if available)	
Systemic	Yes
Company (ies)	DuPont de Nemours SAS Oxon Italia SpA
Rapporteur Member State (RMS)	RMS: Portugal Co-RMS: Belgium
Approval status	Approved Date of (01/09/2009) and reference to decision (COMMISSION DIRECTIVE 2008/125/EC - REGULATION (EU) No 540/2011) active hyperlinks.
Restriction	Restricted to use as fungicide
Review Report	SANCO/179/08 – final rev. 1, 9 July 2010
Current MRL regulation	Regulation (EU) No 832/2018, Reg. (EU) 2022/1363 not yet applicable
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	EFSA Scientific Report (2008) 16567
EFSA Journal: conclusion on article 12	EFSA Journal 2015;13(12):4355, EFSA Journal 2019;17(10):5823
Current MRL applications on intended uses	~~EFSA-Q-2019-00186~~ ~~All commodities~~ ~~Reasoned opinion available~~ ~~(EFSA Journal 2019;17(10):5823~~ none

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, YYYY - see list of references

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.3-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Lettuce	High water content	12 months	G. Freschi, 2004 Report No. SIP 1379 DAR, Austria, 2007
Potato		12.5 months	C. E. Nathan, 1996 Report No. AMR 3296-95 DAR, Austria, 2007

Conclusion on stability of residues during storage

Residues of cymoxanil are stable under frozen conditions for at least 12 months in lettuce plant and in frozen potato.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

Not relevant.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Tomatoes	N/A	Foliar, F	0.63 kg a.s./ha	3	3		EFSA, 2015
				0.24 kg a.s./ha	4	13		
				0.14 kg a.s./ha	7	7, 14, 21, 35		
	Grapes		Foliar, F	0.21 kg a.s./ha	8	0, 1, 4, 10, 18		
Root and tuber vegetables	Potato	[cyanoacetamide-2-^{14}C]-cymoxanil	Foliar, F	0. 24 kg a.s./ha	8	10		T. Melkebeke, B. van Noorloos, 2003 Report No. 257772 DAR, Austria, 2007
		[2-^{14}C]Cymoxanil		0.40 kg a.s./ha	3	3		Y. Li, 1996 Report No. AMR-3408-95 DAR, Aus-

								tria, 2007
Leafy vegetables	Lettuce	[cyanoacetamide-2-^{14}C]-cymoxanil	Foliar, F	0.24 kg a.s./ha	3	11		T. Melkebeke, B. van Noorloos, 2003 Report No. 257794 DAR, Austria, 2007
		[cyanoacetamide-2-^{14}C]-cymoxanil	Foliar, F	0.84 kg a.s./ha	4	3		G. C. Fox, 1999 Report No. AMR 4375-97 DAR, Austria, 2007

Summary of plant metabolism studies reported in the EU

The metabolism studies on lettuce were conducted with a total of 4 applications at a rate of 840 g a.s./ha (total 3360 g a.s./ha) and sampling 3 days after the last treatment (DuPont) or with 3 applications at 240 g/ha (total 720 g a.s./ha) and a 11-day PHI (Oxon). Total radioactive residue levels in mature lettuce at final harvest were 10.78 mg/kg and 1.07 mg/kg respectively. The parent compound was identified in small amounts only, accounting for 1.4-2.1% of the TRR in leaves. In both studies, conjugated glycine was identified as a main metabolite, in a range of 13.0% to 30.6% of TRR. The other metabolites, only observed in the study submitted by DuPont, were glucose (21.2% TRR), IN-KQ960 (7.4% TRR) and IN-KP533 (2.8 % TRR). An additional metabolite IN-W3595 (up to 18.1% TRR) was also identified, but in the Oxon study only.
On potatoes the two following practices were investigated in the metabolism studies: 3 applications at a rate of 404 g a.s./ha (total 1212 g a.s./ha) and sampling 3 days after the last application (DuPont) and 8 applications at 240 g a.s./ha (total 1920 g a.s./ha) and sampling 10 days after the last application (Oxon). Total radioactive residue levels in mature potato tubers at final harvest were 0.69 mg/kg and 1.07 mg/kg respectively. The parent compound was not detected in relevant concentrations in tuber. The main metabolite was glycine observed after acid hydrolysis of mature potato tuber homogenate.
The released glycine was detected in a concentration range of 27.0% to 78.5% of TRR (0.28 to 0.54 mg eq/kg). Glucose (originating from starch) was also detected as a minor metabolite at a concentration level of 8.1 % of TRR (0.06 mg eq/kg) after acid hydrolysis of mature potato tuber in the DuPont study performed with a significant higher applied rate and a lower PHI.

Conclusion on metabolism in primary crops

The residue definition for enforcement purposes and risk assessment in all plant commodities is defined as Cymoxanil.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	[^{14}C]-cymoxanil	Bare soil, F	1.2 kg a.s./ha	30,120	NR	NR	G. D. Sheftic, H. J. Strek, S. K. Singles, 1996 Report No. AMR 3575-95 DAR, Austria, 2007
Root and tuber vegetables	Sugar beet							
Cereals	Wheat							

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

The study was performer with lettuce, sugar beet and spring wheat grown under greenhouse conditions with two rotational crop intervals (30 and 120 days) and using a single soil treatment equivalent to 1212 g 14C-cymoxanil/ha.
At final harvest, total radioactivity was not significant (<0.01 mg eq/kg) in lettuce heads for both rotational intervals and 0.01 mg/kg and 0.02 mg/kg in mature roots and leaves of sugar beets from the 30-day rotational interval. Significant amounts of TRR were only detected in wheat grain (0.04-0.05 mg eq/kg) and in wheat straw (0.12-0.14 mg eq/kg) for both rotational intervals. Raw agricultural commodities containing more than 0.01 mg eq/kg were extracted and analyzed. The majority of the radioactivity was extractable. No cymoxanil or structurally related metabolites were identified and no individual component that accounted for more than 0.02 mg eq/ha was detected.

Conclusion on metabolism in rotational crops

Metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not required.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data were submitted in the framework of this application. Not required as no residues are present in raw commodities.

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

Table 7.3-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Leafy crops (Lettuce), fruits and fruiting vegetables (grapes,

	tomatoes) and root and tuber vegetables (potatoes).
Rotational crops covered	Lettuce, sugar beet and wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	NR (Not required)
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Cymoxanil (Regulation (EU) No. 2018/832, Reg. (EU) 2022/1363 not yet applicable
Plant residue definition for risk assessment	Cymoxanil (EFSA, 2015)
Conversion factor from enforcement to RA	None

* If residue pattern in processed commodities is not similar to that in raw commodities
** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).
*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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

Available data

No new data submitted in the framework of this application.

Table 7.3-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[2-^{14}C]-cymoxanil	2	10	3	Milk	twice daily	XXXX 1996 Report No. AMR 2084-91 DAR, Austria, 2007
						Urine and faeces	twice daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

The majority of the administered radioactivity was excreted in urine (23.6%) and in faeces (18.3%). In edible parts, recoveries were 6.5% in carcass (0.09 mg/kg for muscle and 0.06 mg/kg for fat), 3.5% in liver (2.1 mg/kg), 2.6% in milk (0.15-0.33 mg/kg) and 0.1% in kidney (0.5 mg/kg). The major 14C-cymoxanil derived residue detected in goat milk was lactose (46% of milk TRR) and fatty acids (i.e. caproic, caprylic, capric, lauric, arachidonic, myristic, lioneleic, oleic acids) that accounted for 5.7 % of milk TRR. In goat liver, formic acid was identified as the primary metabolite, the total formic acid, after acid hydrolysis of extracts or protelyt-ic digestion representing 68.9 % of liver TRR. Additionally, acetic acid was released after protelytic and acid hydrolysis at a concentration level of 14.0 % of liver TRR. Residues in goat muscle or fat fractions were low and remained unidentified. Neither 14C-cymoxanil nor structurally related metabolites were detected in any tissue, milk or in the urine.

Conclusion on metabolism in livestock

The residue definition for monitoring and risk assessment is set as cymoxanil (for ruminants and pigs only).

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

Table 7.3-7: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goat
Time needed to reach a plateau concentration	1 day in eggs
Animal residue definition for monitoring	Residue definition in animal commodities is not needed but could be set as cymoxanil (for ruminant and pigs) if needed in the future EFSA Journal 2015;13(12):4355
Animal residue definition for risk assessment	Residue definition in animal commodities is not needed but could be set as cymoxanil (for ruminant and pigs) if needed in the future EFSA Journal 2015;13(12):4355
Conversion factor	None
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)
** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.
*** If metabolism in rat and ruminant are not similar

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

No new data are submitted in the framework of this application.

Table 7.3-8: Summary of EU reported and new data supporting the intended uses of SHA 076127 A and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Potato	DAR, Austria, 2007	N-EU	GAP on which MRL/EU a.s. assessment is based: 11-12 x 176-211 g as/ha PHI 14d, outdoor and 4 x 116-128 g as/ha, PHI 7 days 10 x <LOQ (<0.05)	N/A				
	New trials	N-EU	Trials GAP: 6 x 0.125 kg as/ha, BBCH 93, PHI 14-15d, outdoor Tuber: 6 x <0.003 (<,LOD)					
	Overall supporting data for cGAP	N-EU	10 x <LOQ, 6 x <0.003 (<LOD)	0.01	0.01	0.01	0.01	Yes

* Source of EU MRL: Regulation (EU) No. 2018/832

7.3.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on Potato are considered acceptable, for outdoor uses.

The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Table 7.3-9: Input values for the dietary burden calculation (considering the uses authorized within the zone/evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment (EFSA, 2015)	Input value (mg/kg)	Comment (EFSA, 2015)
Cymoxanil				
Potato culls	0.01	Median residue	0.01	Median residue
Bean seed (dry)	0.02	Median residue	0.02	Median residue
Lupin seed	0.02	Median residue	0.02	Median residue
Pea seed (dry)	0.02	Median residue	0.02	Median residue
Lupin seed meal	0.02	Median residue (0.02) * PF (1.1)	0.02	Median residue (0.02) * PF (1.1)
Potato process waste	0.01	Median residue (0.01) * PF (1)	0.01	Median residue (0.01) * PF (1)
Potato dried pulp	0.01	Median residue (0.01) * PF (1)	0.01	Median residue (0.01) * PF (1)

Table 7.3-10: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Sum of propamocarb and its salts, expressed as propamocarb					
Cattle (all diets)	0.002	0.002	Potato process waste	0.05	N
Cattle (dairy only)	0.002	0.002	Potato process waste	0.04	N

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Sheep (all diets)	0.002	0.002	Potato process waste	0.05	N
Sheep (ewe only)	0.002	0.002	Potato process waste	0.05	N
Swine (all diets)	0.001	0.001	Potato process waste	0.05	N
Poultry (all diets)	0.001	0.001	Potato culls	0.02	N
Poultry (layer only)	0.001	0.001	Potato culls	0.01	N

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

zRMS
According to EFSA, the previous assessment of residues in livestock (EFSA, 2015) is still valid (EFSA Journal 2019;17(10):5823).
No additional data is required.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application.

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

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

No new data submitted in the framework of this application. Not required as no residues are present in raw commodities.

As residue of ~~propamocarb~~ cymoxanil is not expected to exceed 0.1 mg/kg in potato tubers following the application of the product, therefore processing studies are not required.

Considering that the contribution of the commodity under consideration to the theoretical maximum daily intake is <10% of the ADI and each of the calculated IESTI values is <10% of the ARfD further investigations are not deemed necessary.

7.3.6 Magnitude of residues in representative succeeding crops

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

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of SHA 076127 A. Therefore, other special studies are not needed.

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

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

7.3.8.1 Input values for the consumer risk assessment

Table 7.3-11: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cymoxanil				
MRL values Regulation (EU) No. 2018/832				

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-12: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev.3.1	23 % (based on GEMS/Food G06)
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo* rev.3.1	**Raw commodities** Based on children: Potatoes: 2% Based on adults: Potatoes: 0.4% **Processed commodities** Based on children: Potatoes/fried: 1% Potatoes/dried (flakes): 0.7% Based on adults: Potatoes/chips: 0.1% Potatoes/dried (flakes)
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of cymoxanil in the formulation PROSIM (SHA 076127 A) do not represent unacceptable acute and chronic risks for the consumer.

7.4 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised "scientific methods accepted by the Authority to assess such effects are available."
Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

The product is a mixture of two active substances and for at least two of them an acute reference dose has been allocated. Therefore, combined acute exposure can be considered.

7.5 References

Draft Assessment Report (DAR). Initial risk assessment provided by the rapporteur Member State Ireland for the existing active substance Propamocarb. Ireland, 2005

Draft Assessment Report (DAR). Initial risk assessment provided by the rapporteur Member State Austria for the existing active substance Cymoxanil. Austria, 2007

Conclusion regarding the peer review of the pesticide risk assesment of the active substance cymoxanil. EFSA Scientific Report (2008) 167,1-116

Conclusion regarding the peer review of the pesticide risk assessment of the active substance propamocarb. EFSA Scientific Report (2006) 78, 1-80

Reasoned opinion on the review of the existing maximum residue levels (MRLs) for propamocarb according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(4):3214

Review of the existing maximum residue levels for cymoxanil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(12):4355

Regulation (EU) No. 2018/832

Regulation (EU) No. 2020/856

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.3.1.1	Gabor Wagner	2022	Determination of the residues of cymoxanil in/on potato after six applications of Propamocarb 40 %+ Cymoxanil 5 % SC in Northern Europe - Hungary in 2021, Report No.: 065CPRHU21R26 CPR Europe Kft. GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.1.2	D. Gąszczyk	2022	Quantitative analysis of Propamocarb (sum of Propamocarb and it's salts expressed, as Propamocarb) and Cymoxanil residues in potatoes in field conditions (Raw Agricultural Commodity) after six applications of formulated product Propamocarb 400 g/L + Cymoxamil 50 g/L SC – two harvest trials and one decline trial in Hungary – 2021, Report No.: PB-2022-20 Fertico Sp. z o.o. – Laboratorium GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.1.3	M. Tartanus	2022	Magnitude of the residue of cymoxanil (CAS: 57966-95-7) in potato (Raw Agricultural Commodity – RAC) grown in open field conditions after six applications of a formulated product Propamocarb 400 g*L^{-1} + Cymoxanil 50 g*L^{-1} SC – one harvest trial and one decline curve trial in Northern Europe – Poland (2021), Report No.: 21FRT-19SOLTUPRCY Fertico Sp. z o.o. GLP	N	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 8.3.1.4	D. Gąszczyk	2022	Quantitative analysis of Propamocarb (sum of Propamocarb and it's salts expressed, as Propamocarb) and Cymoxanil residues in potatoes in field conditions (Raw Agricultural Commodity) after six applications of formulated product Propamocarb 400 g/L + Cymoxamil 50 g/L SC – one harvest trial and one decline trial in Poland – 2021, Report No.: PB-2022-19 Fertico Sp. z o.o. – Laboratorium GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.1.5	J. Hrabovsky	2022	Determination of Propamocarb 400 g/L + Cymoxanil 50 g/L SC residues in potato following six sequential applications. Type D under field conditions in The Czech Republic in 2021 – field part, Report No.: KUJ21BR16 Zemědělská zkušební stanice KUJAVY, s.r.o. GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.1.6	D. Gąszczyk	2022	Quantitative analysis of Propamocarb (sum of Propamocarb and it's salts expressed, as Propamocarb) and Cymoxanil residues in potatoes in field conditions (Raw Agricultural Commodity) after six applications of formulated product Propamocarb 400 g/L + Cymoxamil 50 g/L SC – one decline trial in Czech Republic – 2021, Report No.: PB-2022-22 Fertico Sp. z o.o. – Laboratorium GLP Unpublished	N	Sharda Cropchem Ltd.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	J. Moede	1990	STABILITY OF PROPAMOCARB x HCl IN TOMATOES DURING DEEP FREEZE STORAGE Document No: A85300 Non-GLP Published	N	Bayer
	A. L. Sutton, G. E. Charter	1999	TOMATOES: STABILITY DURING DEEP FREEZE STORAGE UP TO 26 MONTHS Propamocarb hydrochloride Active substance Document No: C003740 Non-GLP Published	N	Bayer
	A. Wrede-Rücker	1990	STABILITY OF PROPAMOCARB x HCl IN LETTUCE DURING DEEP FREEZE STORAGE Document No: A85303 Non-GLP Published	N	Bayer
	O. Pigeon	2003	Determination of residues of propamocarb in lettuce after treatments with PROPLANT. Project: Chimac-Agriphar/RE20018/2000. GLP Published	N	Chimac Agriphar
	O. Pigeon	2003	Determination of residues of propamocarb in cucumber growing in greenhouse after treatments with PROPLANT. Project: Chimac-Agriphar/RE 20044/2000 GLP Published	N	Chimac Agriphar
	O. Pigeon	2002	Determination of residues of propamocarb in tomatoes growing in greenhouse after treatments with PROPLANT. Project: Chimac-Agriphar/RE 200443/2000 GLP Published	N	Chimac Agriphar
	O. Pigeon	2002	O. Determination of residues of propamocarb in Brussels sprouts after treatments with	N	Chimac

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			PROPLANT. Project: Chimac-Agriphar/RE 20042/2000 GLP Published		Agriphar
	K. K. Rupprecht, L. E. Daniel	2000	Metabolism of [14C] propamocarb hydrochloride in spinach. (Amended report replacing report AV 97E519, Document A89868)", Report number AV 97E519A, GLP Published	N	Bayer
	A. Fortsch	1991	The fate of propamocarb hydrochloride in potato tubers, Schering report number UPSR 14/91-PA 66752.8/13 of March 1991 Non-GLP Published	N	Bayer
	A. Fortsch	1994	The fate of propamocarb hydrochloride in potato tubers", AgrEvo report number UPSR 14/91of April 1994 Non-GLP Published	N	Bayer
	Feyerabend, M., and Rupprech, J. Kent	1998	Metabolism of propamocarb HCl in cucumber grown in soil and hydroculture", AgrEvo study number U/R 50/94 of July 1998 Non-GLP Published	N	Bayer
	A. Goodyear	2002	(14C)-Propamocarb: Metabolism in potatoes; Covance Labs. Ltd., Harrogate, UK; report # CLE 1669/5-D2149 of 22. March 2002 GLP Published	N	Bayer
	A. Goodyear	2002	(14C)-Propamocarb: Metabolism in lettuce; Covance Labs. Ltd., Harrogate, UK; report # CLE 1669/6-D2149 of 14.. June 2002 GLP Published	N	Bayer
	A. Goodyear	2001	(14C)-Propamocarb: Metabolism in tomatoes; Covance Labs. Ltd., Harrogate, UK; report # CLE 1669/3-	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			D2149 of 29. GLP Published		
	B. N. Meyer	2000	Uptake of propamocarb hydrochloride residues in soil by rotationalcrops under confined conditions (amended report replacing report AV96E518, Document A91264 GLP Published	N	Bayer
	XXXX	2000	Propamocarb: Ruminant (cow)-Metabolism, Distribution and Nature of Residues in Milk and Edible Tissues." Amended Avensis report AV97E521A (replacing report AV97E521) GLP Published	N	Bayer
	G. Freschi	2004	Freezer storage stability of cymoxanil residue in lettuce plants. Report No. SIP1379 GLP Published	N	DuPont
	E. C. Nathan	2004	Magnitude of residues of Cymoxanil in potatoes following application of Curzate M-8 fungicide at maximum label rates and at five times maximum use rates to investigate the need for magnitude of residue data in processed fractions Report No. AMR 3296-95 GLP Published	N	DuPont
	T. Melkebeke, B. van Noorloos	2003	Metabolism, distribution and expression of cymoxanil residues in potatoes. Report No. 257772 GLP Published	N	DuPont
	Y. Li	1996	Plant metabolism of [2-^{14}C]cymoxanil in potatoes. Report No. AMR 3408-95 GLP Published	N	DuPont
	T. Melkebeke, B. van Noorloos	2003	Metabolism, distribution and expression of cymoxanil residues in lettuce. Report No. 257794 GLP	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Published		
	G. C. Fox	1999	Metabolism of [2-^{14}C]cymoxanil in lettuce. Report No. AMR 4375-97 GLP Published	N	DuPont
	G. D. Sheftic, H. J. Strek, S. K. Singles	1996	Accumulation of residues in confined rotational crops: Lettuce, wheat, and beets after treatment with [14C]cymoxanil Report No. AMR 3575-95 GLP Published	N	DuPont
	XXXX	1996	The distribution of [2-^{14}C]-DPX-T3217 (cymoxanil) in the lactating goat (nature of residue study to EPA guidelines Report No. AMR 2084-91 GLP Published	N	DuPont
	L. Duber, K. M. Jernberg	1997	Magnitude of DPX-JE874 and cymoxanil residues in/on soil and potatoes grown in the northern European region-1996 season Battelle Europe-Centre de Recherche de Geneve AMR 3788-96 GLP Published	N	DuPont
	O. Pigeon	2000	Determination of residues of propamocarb in potatoes after treatment with Proplant. Dep. de phytopharmacie, centre de recherche agronomiques de Gembloux, study # 11992; GLP Published	N	Chimac Agriphar
	O. Pigeon	2002	Determination of residues of propamocarb in potatoes after treatments with Proplant (in mixture with DITHANE M 45 WP); Dep. De phytopharmacie, centre de recherche agronomiques de Gembloux, study # 20237; GLP Published	N	Chimac Agriphar
	O. Pigeon	2002	Determination of residues of propamocarb in potatoes after treatment with Proplant (in mixture with mancozeb); Dep. De phytopharmacie, centre de recherche agronomiques de Gembloux, study # 20284;	N	Chimac Agriphar

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

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Propamocarb

A 2.1.1 Stability of residues

No new data submitted in the framework of this application.

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

No new data submitted in the framework of this application.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Potato

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2013)	2-4	0.84 kg a.s./ha	-	BBCH 20-95	7
Intended cGAP (1)	1-6	1 kg a.s./ha	7-10 days	BBCH 21-95	

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

A 2.1.3.1.1 Study 1

Comments of zRMS:	Study is acceptable. Trials are independent and acceptable with regard to available storage stability data. Residues of propamocarb are stable in potatoes samples up to 26 months (EU unprotected data)

Reference:	KCP 8.3.1.1
Report	Determination of the residues of cymoxanil in/on potato after six applications of Propamocarb 40 %+ Cymoxanil 5 % SC in Northern Europe - Hungary in 2021, Gabor Wagner, 2022, Report No.: 065CPRHU21R26
Guideline(s):	Yes - "Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997. - OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009).

Deviations:	No
GLP:	Yes
Acceptability:	Yes

Propamocarb 400 g/L+ Cymoxanil 50 g/L SC is a fungicide developed by Sharda Cropchem Ltd. for pest control in different crops. The objective of this study is to provide results from the magnitude of residues of cymoxanil in/on potato in order to support the registration of the plant protection product applied according to Good Laboratory Practice (GLP).
Three trials were conducted in Hungary in 2021. The field phase was performed in Kőszeg (CPRHU21-263-065FR), in Ják (CPRHU21-264-065FR), and in Zalalövő (CPRHU21-642-065FR).
Six applications (in 7 days' interval, last application at 14 days before harvest) of the formulated product Propamocarb 40 %+ Cymoxanil 5 % SC (containing nominal concentration of 40% propamocarb and 5 % cymoxanil) were applied at a rate of 2.5 L formulated product/ha (1000 g active ingredient of propamocarb/ha + 125 g active ingredient of cymoxanil/ha) onto the crop, under open field condition. Specimens (tubers) were collected at 0, 3, 7, 14 days after last application (DALA) in decline trial and at 14 DALA in harvest trials, frozen and shipped deep frozen to analytical facility of Fertico for residue analysis.

Comments of zRMS:	Analytical method is accepted

Reference:	KCP 8.3.1.2
Report	Quantitative analysis of Propamocarb (sum of Propamocarb and it's salts expressed, as Propamocarb) and Cymoxanil residues in potatoes in field conditions (Raw Agricultural Commodity) after six applications of formulated product Propamocarb 400 g/L + Cymoxamil 50 g/L SC – two harvest trials and one decline trial in Hungary – 2021, D. Gąszczyk, 2022, Report No.: PB-2022-20
Guideline(s):	Yes - SANTE/2020/12830 rev. 1 - SANTE/12682/2019 - PN-EN 15662:2018-06
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Preparation of samples on potato tuber
Portion A was taken for preparation in treated and untreated samples. Analytical samples were prepared for determination of Propamocarb and Cymoxanil residues in potato tuber samples by LC-MS/MS. Two control samples (K1 and K2) from each of untreated sample, three treated samples (T1, T2, T3) from each of treated sample, six fortified samples F1, F2, F3 (at fortification level 0.01 mg/kg) and F4, F5, F6 (at fortification level 0.1 mg/kg) from untreated samples and calibration curves on matrix extract form an untreated sample were prepared.

Weighing
Samples were mixed and weight into 50 ml PP falcones in a weighing room, using a scale Radwag PS 1000.X2. Weighing 10 g +/- 0.05 g of a homogenous sample.

Addition of acetonitrile
To each sample.10 ml of acetonitrile was added. Fortified samples were prepared by addition of 100 µl of Propamocarb and 100 µl of Cymoxanil standard solutions R1 (1 µg/ml) for LOQ level and R0 (10 µg/ml) for level of 10xLOQ. To the spiked samples 9.8 ml of acetonitrile was aded to receive the final volume of 10 ml. Falcones were closed and shaken by hand for 1 minute.

Sample extraction

The QuEChERS buffer salt mixture (4 g $MgSO_4$, 1 g NaCl, 1 g $C_6H_5Na_3O_7$ and 0.5 g $HOC(COOH)(CH_2COONa)_2$ x 1.5 H_2O) has been added to the sample with acetonitrile. The tube was closed and shaken by hand for 1 min, preventing salt lumping and then 5 min on a shaker. After shaking, tube was centrifuged on an MPW-352R centrifuge for 5 min at 5500 rpm, the centrifugation temperature was set using a centrifuge program 20±2°C.

Preparation of analytical sample for chromatographic analysis

The 500 µl of extract was transferred into 1.5 ml Eppendorf tube. The 10 µl of internal standard solution (TPP) at concentration of 10 µg/ml and water were added receive final concentration of 1000 µl. Prepared samples were filtered with 0.22 µm PTFE into the injection vial for LC-MSMS.

Chromatographic parameters

Autosampler with cooling (constant temperature 10°C), injection volume 2 µl, injection mode – 200 µl/min.

Chromatographic column: InfinityLab Poroshell 120 EC-C18 column with dimensions of 3.0 x 150 mm and grain diameter 2.7 µm, series number USCFW17005 and guard column: InfinityLab Poroshell EC-C18 guard column with dimensions of 3.0 x 5 mm and grain diameter 2.7 µm, series number USCEC11811 maintaining a constant temperature of 35°C at the entrance and 35°C at the exit of the chromatographic column.

Binary Pump: solvent A: 5 mM ammonium formate, 0.1% formic acid in water, solvent B: 0.1% formic acid in methanol with LC-MS purity, flow rate 0.5 mL/min.

Parameters of MS-Triple Quadrupole Acquisition Method

Analyte	Rt [min]	Ion Transitions	Collision Energy [V]	Cell Accelerator Voltage	Fragmentor	Polarity
Propamocarb	4.93	189.2 → 144.0	8	5	90	Positive
	4.93	189.2 → 102.0	12	5	90	Positive
Cymoxanil	6.93	199.1 → 128.0	4	5	50	Positive
	6.93	199.1 → 110.9	12	5	50	Positive
TPP	11.33	327.1 → 77.0	52	5	152	Positive
	11.33	327.1 → 51.1	124	5	152	Positive

Table A 2: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Propamocarb (sum of Propamocarb and it's salts expressed, as Propamocarb)		
CPRHU21-263-065FR/ Hungary/ CEU/ 2021 Kőszeg	Potato	1. 30.03.2021 2. late June 2021 3. August 2021	1000	300	-	6 04.08.2021	BBCH 93	Tuber	0.0059 (<LOQ)	14	Analytical method: Report No.: PB-2022-20 LOD= 0.003 mg/kg LOQ = 0.01 mg/kg Time between sampling and extraction: -sampling: 18.08.2021 -extraction: 04.08.2022
CPRHU21-264-065FR/ Hungary/ CEU/ 2021 Ják	Potato	1. 30.03.2021 2. late June 2021 3. August 2021	1000	300	-	6 03.08.2021	BBCH 93	Tuber	0.0132 <0.003 (<LOD) 0.0036 (<LOQ) <0.003 (<LOD)	0 3 7 14	Analytical method: Report No.: PB-2022-20 LOD= 0.003 mg/kg LOQ = 0.01 mg/kg Time between sampling and extraction: -sampling: 17.08.2021 -extraction: 04.08.2022
CPRHU21-642-065FR/ Hungary/ CEU/ 2021 Zalalövő	Potato	1. 30.03.2021 2. late June 2021 3. August 2021	1000	300	-	6 04.08.2021	BBCH 93	Tuber	<0.003 (<LOD)	14	Analytical method: Report No.: PB-2022-20 LOD= 0.003 mg/kg LOQ = 0.01 mg/kg Time between sampling and extraction: -sampling: 18.08.2021 -extraction: 04.08.2022

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

A 2.1.3.1.2 Study 2

Comments of zRMS:	Study is acceptable. Trials are independent and acceptable with regard to available storage stability data. Residues of propamocarb are stable in potatoes samples up to 26 months (EU un-protected data)

Reference:	KCP 8.3.1.3
Report	Magnitude of the residue of cymoxanil (CAS: 57966-95-7) in potato (Raw Agricultural Commodity – RAC) grown in open field conditions after six applications of a formulated product Propamocarb 400 g*L^{-1} + Cymoxanil 50 g*L^{-1} SC – one harvest trial and one decline curve trial in Northern Europe – Poland (2021), M. Tartanus, 2022, Report No.: 21FRT-19SOLTUPRCY
Guideline(s):	Yes -Appendix B: Commission of the European Communities (Directorate General for Agriculture) Doc 7029/VI/95 rev.6. General recommendations for the design, preparation and realization of residue trials. -509 OECD GUIDELINE FOR THE TESTING OF CHEMICALS- CROP FIELD TRIAL. Adopted 7 September 2009.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the field phase was to provide an analytical laboratory with treated specimens resulting from six applications at rate of 2.5 L*ha^{-1} of Propamocarb 400 g/L + Cymoxanil 50 g/L SC (1000 g a.s./ha of propamocarb and 125 g a.s./ha of Cymoxanil), regarding open field conditions. All aspects of a field work was performed in accordance with typical Good Agricultural Practices.
The field phase happened as anticipated in the study plan and amendments. One harvest and one decline trial were established in central Poland. Trials consisted of one untreated plot C and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negatively impacted on the integrity and validity of this study. Six foliar applications of Propamocarb 40% + Cymoxanil 5% SC was performed with a boom sprayer on the treated plot at the target dose rate of 2.5L L/ha. The target spray volume was 200-400 litres per hectare according to Good Agricultural Practices.
The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were calculated to verify delivery rates. The calculations and the delivery rates were verified by the Study Director. RAC specimens for analyses were collected at a 14 DALA in HS and 0,3,7 and 14 DALA in DCS trial.

Comments of zRMS:	Analytical method is accepted

Reference:	KCP 8.3.1.4
Report	Quantitative analysis of Propamocarb (sum of Propamocarb and it's salts expressed, as Propamocarb) and Cymoxanil residues in potatoes in field conditions (Raw Agricultural Commodity) after six applications of formulated product Propamocarb 400 g/L + Cymoxamil 50 g/L SC – one harvest trial and one decline trial in Poland – 2021, D. Gąszczyk, 2022, Report No.: PB-

	2022-19
Guideline(s):	Yes - SANTE/2020/12830 rev. 1 - SANTE/12682/2019 - PN-EN 15662:2018-06
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Preparation of samples on potato tuber

Portion A was taken for preparation in treated and untreated samples. Analytical samples were prepared for determination of Propamocarb and Cymoxanil residues in potato tuber samples by LC-MS/MS. Two control samples (K1 and K2) from each of untreated sample, three treated samples (T1, T2, T3) from each of treated sample, six fortified samples F1, F2, F3 (at fortification level 0.01 mg/kg) and F4, F5, F6 (at fortification level 0.1 mg/kg) from untreated samples and calibration curves on matrix extract form an untreated sample were prepared.

Weighing

Samples were mixed and weight into 50 ml PP falcones in a weighing room, using a scale Radwag PS 1000.X2. Weighing 10 g +/- 0.05 g of a homogenous sample.

Addition of acetonitrile

To each sample.10 ml of acetonitrile was added. Fortified samples were prepared by addition of 100 µl of Propamocarb and 100 µl of Cymoxanil standard solutions R1 (1 µg/ml) for LOQ level and R0 (10 µg/ml) for level of 10xLOQ. To the spiked samples 9.8 ml of acetonitrile was aded to receive the final volume of 10 ml. Falcones were closed and shaken by hand for 1 minute.

Sample extraction

The QuEChERS buffer salt mixture (4 g $MgSO_4$, 1 g NaCl, 1 g $C_6H_5Na_3O_7$ and 0.5 g $HOC(COOH)(CH_2COONa)_2$ x 1.5 H_2O) has been added to the sample with acetonitrile. The tube was closed and shaken by hand for 1 min, preventing salt lumping and then 5 min on a shaker. After shaking, tube was centrifuged on an MPW-352R centrifuge for 5 min at 5500 rpm, the centrifugation temperature was set using a centrifuge program 20±2°C.

Preparation of analytical sample for chromatographic analysis

The 500 µl of extract was transferred into 1.5 ml Eppendorf tube. The 10 µl of internal standard solution (TPP) at concentration of 10 µg/ml and water were added receive final concentration of 1000 µl. Prepared samples were filtered with 0.22 µm PTFE into the injection vial for LC-MSMS.

Chromatographic parameters

Autosampler with cooling (constant temperature 10°C), injection volume 2 µl, injection mode – 200 µl/min.

Chromatographic column: InfinityLab Poroshell 120 EC-C18 column with dimensions of 3.0 x 150 mm and grain diameter 2.7 µm, series number USCFW17005 and guard column: InfinityLab Poroshell EC-C18 guard column with dimensions of 3.0 x 5 mm and grain diameter 2.7 µm, series number USCEC11811 maintaining a constant temperature of 35°C at the entrance and 35°C at the exit of the chromatographic column.

Binary Pump: solvent A: 5 mM ammonium formate, 0.1% formic acid in water, solvent B: 0.1% formic acid in methanol with LC-MS purity, flow rate 0.5 mL/min.

Parameters of MS-Triple Quadrupole Acquisition Method

Analyte	Rt [min]	Ion Transitions	Collision Energy [V]	Cell Accelerator	Fragmentor	Polarity

				Voltage		
Propamocarb	4.93	189.2 → 144.0	8	5	90	Positive
	4.93	189.2 → 102.0	12	5	90	Positive
Cymoxanil	6.93	199.1 → 128.0	4	5	50	Positive
	6.93	199.1 → 110.9	12	5	50	Positive
TPP	11.33	327.1 → 77.0	52	5	152	Positive
	11.33	327.1 → 51.1	124	5	152	Positive

Table A 3: Summary of the study 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Propamocarb (sum of Propamocarb and it's salts expressed, as Propamocarb)		
	(a)	(b)				(c)				(d)	(e)
21FRT-19SOLTUPRCY-01/ Poland/ NEU/ 2021 Pomianowo (Mazowieckie)	Potato	1. 19.04.2021 2. 07-20.07.2021 3. 01.09.2021	1000	300	-	6 28.07.2021	BBCH 44	Tuber	0.0112	15	Analytical method: Report No.: PB-2022-19 LOD= 0.003 mg/kg LOQ = 0.01 mg/kg Time between sampling and extraction: 10 months
21FRT-19SOLTUPRCY-02/ Poland/ NEU/ 2021 Skierniewice (Łódzkie)	Potato	1. 15.04.2021 2. 07-17.07.2021 3. 12-14.09.2021	1000	300	-	6 28.07.2021	BBCH 45	Tuber	0.0190 0.0188 0.0147 (<0.003) <LOD	0 3 8 15	Analytical method: Report No.: PB-2022-19 LOD= 0.003 mg/kg LOQ = 0.01 mg/kg Time between sampling and extraction: 10 months

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

A 2.1.3.1.3 Study 3

Comments of zRMS:	Study is acceptable. Trial is acceptable with regard to available storage stability data. Residues of propamocarb are stable in potatoes samples up to 26 months (EU unprotected data).

Reference:	KCP 8.3.1.5
Report	Determination of Propamocarb 400 g/L + Cymoxanil 50 g/L SC residues in potato following six sequential applications. Type D under field conditions in The Czech Republic in 2021 – field part, J. Hrabovsky, 2022, Report No.: KUJ21BR16
Guideline(s):	Yes -Appendix B: Commission of the European Communities (Directorate General for Agriculture) Doc 7029/VI/95 rev.6. General recommendations for the design, preparation and realization of residue trials. -509 OECD GUIDELINE FOR THE TESTING OF CHEMICALS- CROP FIELD TRIAL. Adopted 7 September 2009. -SANCO 7029/VI/95 rev. 5 22/07/1997
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The purpose of the study was to generate specimens for the determination of residues after six sequential applications with Propamocarb 400 g/L + Cymoxanil 50 g/L SC in potato, variety Antonie in the Czech Republic 2021. The study consisted of a decline trial.
The study was carried out according to the study plan KUJ21BR16, the guideline document SANCO 7029/V1/95 rev. 5, 22.07.1997, and the guidelines mentioned in the "Statement of Compliance".
One decline trial KUJ21BR16 was carried out on the open field in Kujavy (Moravian-Silesian region). Two plots were measured out in the crop potato: one untreated control plot (U) and one treated plot (T). T plot was treated six times with the test item Propamocarb 400 g/L + Cymoxanil 50 g/L SC with the rate of 2,5 l/ha. The used water volume was 200 L/ha. Application A was conducted at BBCH 61 – 65; B at BBCH 69 – 71; C at BBCH 75; D at BBCH 77; E at BBCH 81 and F at BBCH 81 of the crop.

Specimens of the tubers from the untreated and treated plot were collected 0 days after the last application (0 DALA), 3 days after the last application (3 DALA), 7 days after the last application (7 DALA), and 14 days after the last application (14 DALA). The specimens were stored frozen (-18°C to –20.0 °C) at the test facility in ZZS Kujavy.
The specimens were shipped frozen to the analytical laboratory Fertico ul. Mogielnicka 33, 05-600 Grójec, Poland for residue analysis.

Comments of zRMS:	Analytical method is accepted

Reference:	KCP 8.3.1.6
Report	Quantitative analysis of Propamocarb (sum of Propamocarb and it's salts expressed, as Propamocarb) and Cymoxanil residues in potatoes in field conditions (Raw Agricultural Commodity) after six applications of formulated product Propamocarb 400 g/L + Cymoxamil 50 g/L SC – one decline trial

	in Czech Republic – 2021, D. Gąszczyk, 2022, Report No.: PB-2022-22
Guideline(s):	Yes - SANTE/2020/12830 rev. 1 - SANTE/12682/2019 - PN-EN 15662:2018-06
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Preparation of samples on potato tuber

Portion A was taken for preparation in treated and untreated samples. Analytical samples were prepared for determination of Propamocarb and Cymoxanil residues in potato tuber samples by LC-MS/MS. Two control samples (K1 and K2) from each of untreated sample, three treated samples (T1, T2, T3) from each of treated sample, six fortified samples F1, F2, F3 (at fortification level 0.01 mg/kg) and F4, F5, F6 (at fortification level 0.1 mg/kg) from untreated samples and calibration curves on matrix extract form an untreated sample were prepared.

Weighing

Samples were mixed and weight into 50 ml PP falcones in a weighing room, using a scale Radwag PS 1000.X2. Weighing 10 g +/- 0.05 g of a homogenous sample.

Addition of acetonitrile

To each sample.10 ml of acetonitrile was added. Fortified samples were prepared by addition of 100 µl of Propamocarb and 100 µl of Cymoxanil standard solutions R1 (1 µg/ml) for LOQ level and R0 (10 µg/ml) for level of 10xLOQ. To the spiked samples 9.8 ml of acetonitrile was aded to receive the final volume of 10 ml. Falcones were closed and shaken by hand for 1 minute.

Sample extraction

The QuEChERS buffer salt mixture (4 g $MgSO_4$, 1 g NaCl, 1 g $C_6H_5Na_3O_7$ and 0.5 g $HOC(COOH)(CH_2COONa)_2$ x 1.5 H_2O) has been added to the sample with acetonitrile. The tube was closed and shaken by hand for 1 min, preventing salt lumping and then 5 min on a shaker. After shaking, tube was centrifuged on an MPW-352R centrifuge for 5 min at 5500 rpm, the centrifugation temperature was set using a centrifuge program 20±2°C.

Preparation of analytical sample for chromatographic analysis

The 500 µl of extract was transferred into 1.5 ml Eppendorf tube. The 10 µl of internal standard solution (TPP) at concentration of 10 µg/ml and water were added receive final concentration of 1000 µl. Prepared samples were filtered with 0.22 µm PTFE into the injection vial for LC-MSMS.

Chromatographic parameters

Autosampler with cooling (constant temperature 10°C), injection volume 2 µl, injection mode – 200 µl/min.

Chromatographic column: InfinityLab Poroshell 120 EC-C18 column with dimensions of 3.0 x 150 mm and grain diameter 2.7 µm, series number USCFW17005 and guard column: InfinityLab Poroshell EC-C18 guard column with dimensions of 3.0 x 5 mm and grain diameter 2.7 µm, series number USCEC11811 maintaining a constant temperature of 35°C at the entrance and 35°C at the exit of the chromatographic column.

Binary Pump: solvent A: 5 mM ammonium formate, 0.1% formic acid in water, solvent B: 0.1% formic acid in methanol with LC-MS purity, flow rate 0.5 mL/min.

Parameters of MS-Triple Quadrupole Acquisition Method

Analyte	Rt [min]	Ion Transitions	Collision Energy [V]	Cell Accelerator	Fragmentor	Polarity

				Voltage		
Propamocarb	4.93	189.2 → 144.0	8	5	90	Positive
	4.93	189.2 → 102.0	12	5	90	Positive
Cymoxanil	6.93	199.1 → 128.0	4	5	50	Positive
	6.93	199.1 → 110.9	12	5	50	Positive
TPP	11.33	327.1 → 77.0	52	5	152	Positive
	11.33	327.1 → 51.1	124	5	152	Positive

Table A 4: Summary of the study 3 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Propamocarb (sum of Propamocarb and it's salts expressed, as Propamocarb)		
	(a)	(b)				(c)				(d)	(e)
KUJ21BR16-L/ Czech Republic / NEU/ 2021	Potato	1. 30.04.2021 2. 05.06.2021 3. 09.09.2021	1000	300	-	6 16.08.2021	BBCH 81	Tuber	0.0161 0.0113 0.0161 0.0114	0 3 7 14	Analytical method: Report No.: PB-2022-22 LOD= 0.003 mg/kg LOQ = 0.01 mg/kg Time between sampling and extraction: 10 months

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

Summary of the studies in N-EU

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Sum of propamocarb and its salts expressed as propamocarb		
	(a)	(b)				(c)				(d)	(e)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Sum of propamocarb and its salts expressed as propamocarb		
	(a)	(b)				(c)				(d)	(e)
#11992, 994003-02/N-EU/France/2000	Potatoes		7 x 2000			-	BBCH 48-49	Tuber	<0.1	14	
#11992, 99 F PT CH P06N-EU/France/2000	Potatoes		7 x 2000				BBCH 49	Tuber	<0.1	21	
#11992, 994003-01/N-EU/France/2000	Potatoes		7 x 2000				BBCH 48	Tuber	<0.1	14	
#11992, 99 F PT CH P05/N-EU/France/2000	Potatoes		7 x 2000				BBCH 49	Tuber	<0.1	21	
20237/1/N-EU/Belgium/2001	Potatoes		7 x 1000				BBCH 48-49	Tuber	<0.1	14	
20237/2/N-EU/Belgium/2001	Potatoes		7 x 1000				BBCH 48-49	Tuber	<0.1	14	
20234/3/N-EU/Belgium/2001	Potatoes		6 x 1000				BBCH 48-49	Tuber	<0.1	14	
20234/4/N-EU/Belgium/2001	Potatoes		7 x 1000				BBCH 48-49	Tuber	<0.1	14	

A 2.1.4 Magnitude of residues in livestock

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

No new data submitted in the framework of this application.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new data submitted in the framework of this application.

A 2.1.7 Other/Special Studies

No new data submitted in the framework of this application.

A 2.2 Cymoxanil

A 2.2.1 Stability of residues

No new data submitted in the framework of this application.

A 2.2.2 Nature of residues in plants, livestock and processed commodities

No new data submitted in the framework of this application.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Potato

Table A 5: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2015)	1-6	0.13 kg a.s./ha	-	-	7
Intended cGAP (1)	1-6	0.125 kg a.s./ha	7-10 days	BBCH 21-95	

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

A 2.2.3.1.1 Study 1

Comments of zRMS:	Study is acceptable. Trial is acceptable with regard to available storage stability data. Residues of propamocarb are stable in potatoes samples up to 26 months (EU unprotected data).

Reference:	KCP 8.3.1.1
Report	Determination of the residues of cymoxanil in/on potato after six applications of Propamocarb 40 %+ Cymoxanil 5 % SC in Northern Europe - Hungary in 2021, Gabor Wagner, 2022, Report No.: 065CPRHU21R26
Guideline(s):	Yes - "Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997. - OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509

	published in September 2009).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Propamocarb 400 g/L+ Cymoxanil 50 g/L SC is a fungicide developed by Sharda Cropchem Ltd. for pest control in different crops. The objective of this study is to provide results from the magnitude of residues of cymoxanil in/on potato in order to support the registration of the plant protection product applied according to Good Laboratory Practice (GLP).
Three trials were conducted in Hungary in 2021. The field phase was performed in Kőszeg (CPRHU21-263-065FR), in Ják (CPRHU21-264-065FR), and in Zalalövő (CPRHU21-642-065FR).
Six applications (in 7 days' interval, last application at 14 days before harvest) of the formulated product Propamocarb 40 %+ Cymoxanil 5 % SC (containing nominal concentration of 40% propamocarb and 5 % cymoxanil) were applied at a rate of 2.5 L formulated product/ha (1000 g active ingredient of propamocarb/ha + 125 g active ingredient of cymoxanil/ha) onto the crop, under open field condition. Specimens (tubers) were collected at 0, 3, 7, 14 days after last application (DALA) in decline trial and at 14 DALA in harvest trials, frozen and shipped deep frozen to analytical facility of Fertico for residue analysis.

Comments of zRMS:	Analytical method is accepted

Reference:	KCP 8.3.1.2
Report	Quantitative analysis of Propamocarb (sum of Propamocarb and it's salts expressed, as Propamocarb) and Cymoxanil residues in potatoes in field conditions (Raw Agricultural Commodity) after six applications of formulated product Propamocarb 400 g/L + Cymoxamil 50 g/L SC – two harvest trials and one decline trial in Hungary – 2021, D. Gąszczyk, 2022, Report No.: PB-2022-20
Guideline(s):	Yes - SANTE/2020/12830 rev. 1 - SANTE/12682/2019 - PN-EN 15662:2018-06
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Preparation of samples on potato tuber
Portion A was taken for preparation in treated and untreated samples. Analytical samples were prepared for determination of Propamocarb and Cymoxanil residues in potato tuber samples by LC-MS/MS. Two control samples (K1 and K2) from each of untreated sample, three treated samples (T1, T2, T3) from each of treated sample, six fortified samples F1, F2, F3 (at fortification level 0.01 mg/kg) and F4, F5, F6 (at fortification level 0.1 mg/kg) from untreated samples and calibration curves on matrix extract form an untreated sample were prepared.

Weighing
Samples were mixed and weight into 50 ml PP falcones in a weighing room, using a scale Radwag PS 1000.X2. Weighing 10 g +/- 0.05 g of a homogenous sample.

Addition of acetonitrile
To each sample.10 ml of acetonitrile was added. Fortified samples were prepared by addition of 100 µl of Propamocarb and 100 µl of Cymoxanil standard solutions R1 (1 µg/ml) for LOQ level and R0 (10

µg/ml) for level of 10xLOQ. To the spiked samples 9.8 ml of acetonitrile was aded to receive the final volume of 10 ml. Falcones were closed and shaken by hand for 1 minute.

Sample extraction

The QuEChERS buffer salt mixture (4 g $MgSO_4$, 1 g NaCl, 1 g $C_6H_5Na_3O_7$ and 0.5 g $HOC(COOH)(CH_2COONa)_2$ x 1.5 H_2O) has been added to the sample with acetonitrile. The tube was closed and shaken by hand for 1 min, preventing salt lumping and then 5 min on a shaker. After shaking, tube was centrifuged on an MPW-352R centrifuge for 5 min at 5500 rpm, the centrifugation temperature was set using a centrifuge program 20±2°C.

Preparation of analytical sample for chromatographic analysis

The 500 µl of extract was transferred into 1.5 ml Eppendorf tube. The 10 µl of internal standard solution (TPP) at concentration of 10 µg/ml and water were added receive final concentration of 1000 µl. Prepared samples were filtered with 0.22 µm PTFE into the injection vial for LC-MSMS.

Chromatographic parameters

Autosampler with cooling (constant temperature 10°C), injection volume 2 µl, injection mode – 200 µl/min.

Chromatographic column: InfinityLab Poroshell 120 EC-C18 column with dimensions of 3.0 x 150 mm and grain diameter 2.7 µm, series number USCFW17005 and guard column: InfinityLab Poroshell EC-C18 guard column with dimensions of 3.0 x 5 mm and grain diameter 2.7 µm, series number USCEC11811 maintaining a constant temperature of 35°C at the entrance and 35°C at the exit of the chromatographic column.

Binary Pump: solvent A: 5 mM ammonium formate, 0.1% formic acid in water, solvent B: 0.1% formic acid in methanol with LC-MS purity, flow rate 0.5 mL/min.

Parameters of MS-Triple Quadrupole Acquisition Method

Analyte	Rt [min]	Ion Transitions	Collision Energy [V]	Cell Accelerator Voltage	Fragmentor	Polarity
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Cymoxanil	6.93	199.1 → 128.0	4	5	50	Positive
	6.93	199.1 → 110.9	12	5	50	Positive
TPP	11.33	327.1 → 77.0	52	5	152	Positive
	11.33	327.1 → 51.1	124	5	152	Positive

Table A 6: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat-ment or no. of treatments and last date	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil		
	(a)	(b)				(c)				(d)	(e)
CPRHU21-263-065FR/ Hungary/ CEU/ 2021	Potato	1. 30.03.2021 2. late June 2021 3. August 2021	1000	300	-	6 04.08.2021	BBCH 93	Tuber	<0.003 (<LOD)	14	Analytical method: Report No.: PB-2022-20 LOD= 0.003 mg/kg LOQ = 0.01 mg/kg Time between sampling and extraction: -sampling: 18.08.2021 -extraction: 04.08.2022
CPRHU21-264-065FR/ Hungary/ CEU/ 2021	Potato	1. 30.03.2021 2. late June 2021 3. August 2021	1000	300	-	6 03.08.2021	BBCH 93	Tuber	<0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD)	0 3 7 14	Analytical method: Report No.: PB-2022-20 LOD= 0.003 mg/kg LOQ = 0.01 mg/kg Time between sampling and extraction: -sampling: 17.08.2021 -extraction: 04.08.2022
CPRHU21-642-065FR/ Hungary/ CEU/ 2021	Potato	1. 30.03.2021 2. late June 2021 3. August 2021	1000	300	-	6 04.08.2021	BBCH 93	Tuber	<0.003 (<LOD)	14	Analytical method: Report No.: PB-2022-20 LOD= 0.003 mg/kg LOQ = 0.01 mg/kg Time between sampling and extraction: -sampling: 18.08.2021 -extraction: 04.08.2022

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

A 2.2.3.1.2 Study 2

Comments of zRMS:	Study is acceptable. Trial is acceptable with regard to available storage stability data. Residues of propamocarb are stable in potatoes samples up to 26 months (EU unprotected data).

Reference:	KCP 8.3.1.3
Report	Magnitude of the residue of cymoxanil (CAS: 57966-95-7) in potato (Raw Agricultural Commodity – RAC) grown in open field conditions after six applications of a formulated product Propamocarb 400 g*L^{-1} + Cymoxanil 50 g*L^{-1} SC – one harvest trial and one decline curve trial in Northern Europe – Poland (2021), M. Tartanus, 2022, Report No.: 21FRT-19SOLTUPRCY
Guideline(s):	Yes -Appendix B: Commission of the European Communities (Directorate General for Agriculture) Doc 7029/VI/95 rev.6. General recommendations for the design, preparation and realization of residue trials. -509 OECD GUIDELINE FOR THE TESTING OF CHEMICALS- CROP FIELD TRIAL. Adopted 7 September 2009.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the field phase was to provide an analytical laboratory with treated specimens resulting from six applications at rate of 2.5 L*ha^{-1} of Propamocarb 400 g/L + Cymoxanil 50 g/L SC (1000 g a.s./ha of propamocarb and 125 g a.s./ha of Cymoxanil), regarding open field conditions. All aspects of a field work was performed in accordance with typical Good Agricultural Practices.
The field phase happened as anticipated in the study plan and amendments. One harvest and one decline trial were established in central Poland. Trials consisted of one untreated plot C and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negatively impacted on the integrity and validity of this study. Six foliar applications of Propamocarb 40% + Cymoxanil 5% SC was performed with a boom sprayer on the treated plot at the target dose rate of 2.5L L/ha. The target spray volume was 200-400 litres per hectare according to Good Agricultural Practices.
The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were calculated to verify delivery rates. The calculations and the delivery rates were verified by the Study Director. RAC specimens for analyses were collected at a 14 DALA in HS and 0,3,7 and 14 DALA in DCS trial.

Comments of zRMS:	Analytical method is accepted

Reference:	KCP 8.3.1.4
Report	Quantitative analysis of Propamocarb (sum of Propamocarb and it's salts expressed, as Propamocarb) and Cymoxanil residues in potatoes in field conditions (Raw Agricultural Commodity) after six applications of formulated product Propamocarb 400 g/L + Cymoxamil 50 g/L SC – one harvest trial and one decline trial in Poland – 2021, D. Gąszczyk, 2022, Report No.: PB-2022-19

Guideline(s):	Yes - SANTE/2020/12830 rev. 1 - SANTE/12682/2019 - PN-EN 15662:2018-06
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Preparation of samples on potato tuber

Portion A was taken for preparation in treated and untreated samples. Analytical samples were prepared for determination of Propamocarb and Cymoxanil residues in potato tuber samples by LC-MS/MS. Two control samples (K1 and K2) from each of untreated sample, three treated samples (T1, T2, T3) from each of treated sample, six fortified samples F1, F2, F3 (at fortification level 0.01 mg/kg) and F4, F5, F6 (at fortification level 0.1 mg/kg) from untreated samples and calibration curves on matrix extract form an untreated sample were prepared.

Weighing

Samples were mixed and weight into 50 ml PP falcones in a weighing room, using a scale Radwag PS 1000.X2. Weighing 10 g +/- 0.05 g of a homogenous sample.

Addition of acetonitrile

To each sample.10 ml of acetonitrile was added. Fortified samples were prepared by addition of 100 µl of Propamocarb and 100 µl of Cymoxanil standard solutions R1 (1 µg/ml) for LOQ level and R0 (10 µg/ml) for level of 10xLOQ. To the spiked samples 9.8 ml of acetonitrile was aded to receive the final volume of 10 ml. Falcones were closed and shaken by hand for 1 minute.

Sample extraction

The QuEChERS buffer salt mixture (4 g $MgSO_4$, 1 g NaCl, 1 g $C_6H_5Na_3O_7$ and 0.5 g $HOC(COOH)(CH_2COONa)_2$ x 1.5 H_2O) has been added to the sample with acetonitrile. The tube was closed and shaken by hand for 1 min, preventing salt lumping and then 5 min on a shaker. After shaking, tube was centrifuged on an MPW-352R centrifuge for 5 min at 5500 rpm, the centrifugation temperature was set using a centrifuge program 20±2°C.

Preparation of analytical sample for chromatographic analysis

The 500 µl of extract was transferred into 1.5 ml Eppendorf tube. The 10 µl of internal standard solution (TPP) at concentration of 10 µg/ml and water were added receive final concentration of 1000 µl. Prepared samples were filtered with 0.22 µm PTFE into the injection vial for LC-MSMS.

Chromatographic parameters

Autosampler with cooling (constant temperature 10°C), injection volume 2 µl, injection mode – 200 µl/min.

Chromatographic column: InfinityLab Poroshell 120 EC-C18 column with dimensions of 3.0 x 150 mm and grain diameter 2.7 µm, series number USCFW17005 and guard column: InfinityLab Poroshell EC-C18 guard column with dimensions of 3.0 x 5 mm and grain diameter 2.7 µm, series number USCEC11811 maintaining a constant temperature of 35°C at the entrance and 35°C at the exit of the chromatographic column.

Binary Pump: solvent A: 5 mM ammonium formate, 0.1% formic acid in water, solvent B: 0.1% formic acid in methanol with LC-MS purity, flow rate 0.5 mL/min.

Parameters of MS-Triple Quadrupole Acquisition Method

Analyte	Rt [min]	Ion Transitions	Collision Energy [V]	Cell Accelerator Voltage	Fragmentor	Polarity

Propamocarb	4.93	189.2 → 144.0	8	5	90	Positive
	4.93	189.2 → 102.0	12	5	90	Positive
Cymoxanil	6.93	199.1 → 128.0	4	5	50	Positive
	6.93	199.1 → 110.9	12	5	50	Positive
TPP	11.33	327.1 → 77.0	52	5	152	Positive
	11.33	327.1 → 51.1	124	5	152	Positive

Table A 7: Summary of the study 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat-ment or no. of treatments and last date	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil		
	(a)	(b)				(c)				(d)	(e)
21FRT-19SOLTUPRCY-01/ Poland/ NEU/ 2021	Potato	1. 19.04.2021 2. 07-20.07.2021 3. 01.09.2021	1000	300	-	6 28.07.2021	BBCH 44	Tuber	<0.003 (<LOD)	15	Analytical method: Report No.: PB-2022-19 LOD= 0.003 mg/kg LOQ = 0.01 mg/kg Time between sampling and extraction: 10 months
21FRT-19SOLTUPRCY-02/ Poland/ NEU/ 2021	Potato	1. 15.04.2021 2. 07-17.07.2021 3. 12-14.09.2021	1000	300	-	6 28.07.2021	BBCH 45	Tuber	<0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD)	0 3 8 15	Analytical method: Report No.: PB-2022-19 LOD= 0.003 mg/kg LOQ = 0.01 mg/kg Time between sampling and extraction: 10 months

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

A 2.2.3.1.3 Study 3

Comments of zRMS:	Study is acceptable. Trial is acceptable with regard to available storage stability data. Residues of propamocarb are stable in potatoes samples up to 26 months (EU unprotected data).

Reference:	KCP 8.3.1.5
Report	Determination of Propamocarb 400 g/L + Cymoxanil 50 g/L SC residues in potato following six sequential applications. Type D under field conditions in The Czech Republic in 2021 – field part, J. Hrabovsky, 2022, Report No.: KUJ21BR16
Guideline(s):	Yes -Appendix B: Commission of the European Communities (Directorate General for Agriculture) Doc 7029/VI/95 rev.6. General recommendations for the design, preparation and realization of residue trials. -509 OECD GUIDELINE FOR THE TESTING OF CHEMICALS- CROP FIELD TRIAL. Adopted 7 September 2009. -SANCO 7029/VI/95 rev. 5 22/07/1997
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The purpose of the study was to generate specimens for the determination of residues after six sequential applications with Propamocarb 400 g/L + Cymoxanil 50 g/L SC in potato, variety Antonie in the Czech Republic 2021. The study consisted of a decline trial.
The study was carried out according to the study plan KUJ21BR16, the guideline document SANCO 7029/V1/95 rev. 5, 22.07.1997, and the guidelines mentioned in the "Statement of Compliance".
One decline trial KUJ21BR16 was carried out on the open field in Kujavy (Moravian-Silesian region). Two plots were measured out in the crop potato: one untreated control plot (U) and one treated plot (T). T plot was treated six times with the test item Propamocarb 400 g/L + Cymoxanil 50 g/L SC with the rate of 2,5 l/ha. The used water volume was 200 L/ha. Application A was conducted at BBCH 61 – 65; B at BBCH 69 – 71; C at BBCH 75; D at BBCH 77; E at BBCH 81 and F at BBCH 81 of the crop.

Specimens of the tubers from the untreated and treated plot were collected 0 days after the last application (0 DALA), 3 days after the last application (3 DALA), 7 days after the last application (7 DALA), and 14 days after the last application (14 DALA). The specimens were stored frozen (-18°C to –20.0 °C) at the test facility in ZZS Kujavy.
The specimens were shipped frozen to the analytical laboratory Fertico ul. Mogielnicka 33, 05-600 Grójec, Poland for residue analysis.

Comments of zRMS:	Analytical method is accepted

Reference:	KCP 8.3.1.6
Report	Quantitative analysis of Propamocarb (sum of Propamocarb and it's salts expressed, as Propamocarb) and Cymoxanil residues in potatoes in field conditions (Raw Agricultural Commodity) after six applications of formulated product Propamocarb 400 g/L + Cymoxamil 50 g/L SC – one decline trial

	in Czech Republic – 2021, D. Gąszczyk, 2022, Report No.: PB-2022-22
Guideline(s):	Yes - SANTE/2020/12830 rev. 1 - SANTE/12682/2019 - PN-EN 15662:2018-06
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Preparation of samples on potato tuber

Portion A was taken for preparation in treated and untreated samples. Analytical samples were prepared for determination of Propamocarb and Cymoxanil residues in potato tuber samples by LC-MS/MS. Two control samples (K1 and K2) from each of untreated sample, three treated samples (T1, T2, T3) from each of treated sample, six fortified samples F1, F2, F3 (at fortification level 0.01 mg/kg) and F4, F5, F6 (at fortification level 0.1 mg/kg) from untreated samples and calibration curves on matrix extract form an untreated sample were prepared.

Weighing

Samples were mixed and weight into 50 ml PP falcones in a weighing room, using a scale Radwag PS 1000.X2. Weighing 10 g +/- 0.05 g of a homogenous sample.

Addition of acetonitrile

To each sample.10 ml of acetonitrile was added. Fortified samples were prepared by addition of 100 µl of Propamocarb and 100 µl of Cymoxanil standard solutions R1 (1 µg/ml) for LOQ level and R0 (10 µg/ml) for level of 10xLOQ. To the spiked samples 9.8 ml of acetonitrile was aded to receive the final volume of 10 ml. Falcones were closed and shaken by hand for 1 minute.

Sample extraction

The QuEChERS buffer salt mixture (4 g $MgSO_4$, 1 g NaCl, 1 g $C_6H_5Na_3O_7$ and 0.5 g $HOC(COOH)(CH_2COONa)_2$ x 1.5 H_2O) has been added to the sample with acetonitrile. The tube was closed and shaken by hand for 1 min, preventing salt lumping and then 5 min on a shaker. After shaking, tube was centrifuged on an MPW-352R centrifuge for 5 min at 5500 rpm, the centrifugation temperature was set using a centrifuge program 20±2°C.

Preparation of analytical sample for chromatographic analysis

The 500 µl of extract was transferred into 1.5 ml Eppendorf tube. The 10 µl of internal standard solution (TPP) at concentration of 10 µg/ml and water were added receive final concentration of 1000 µl. Prepared samples were filtered with 0.22 µm PTFE into the injection vial for LC-MSMS.

Chromatographic parameters

Autosampler with cooling (constant temperature 10°C), injection volume 2 µl, injection mode – 200 µl/min.

Chromatographic column: InfinityLab Poroshell 120 EC-C18 column with dimensions of 3.0 x 150 mm and grain diameter 2.7 µm, series number USCFW17005 and guard column: InfinityLab Poroshell EC-C18 guard column with dimensions of 3.0 x 5 mm and grain diameter 2.7 µm, series number USCEC11811 maintaining a constant temperature of 35°C at the entrance and 35°C at the exit of the chromatographic column.

Binary Pump: solvent A: 5 mM ammonium formate, 0.1% formic acid in water, solvent B: 0.1% formic acid in methanol with LC-MS purity, flow rate 0.5 mL/min.

Parameters of MS-Triple Quadrupole Acquisition Method

Analyte	Rt [min]	Ion Transi-tions	Collision Energy [V]	Cell Accel-erator	Fragmentor	Polarity

				Voltage		
Propamocarb	4.93	189.2 → 144.0	8	5	90	Positive
	4.93	189.2 → 102.0	12	5	90	Positive
Cymoxanil	6.93	199.1 → 128.0	4	5	50	Positive
	6.93	199.1 → 110.9	12	5	50	Positive
TPP	11.33	327.1 → 77.0	52	5	152	Positive
	11.33	327.1 → 51.1	124	5	152	Positive

Table A 8: Summary of the study 3 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil		
	(a)	(b)				(c)				(d)	(e)
KUJ21BR16-L/ Czech Republic / NEU/ 2021	Potato	1. 30.04.2021 2. 05.06.2021 3. 09.09.2021	1000	300	-	6 16.08.2021	BBCH 81	Tuber	<0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD) <0.003 (<LOD)	0 3 7 14	Analytical method: Report No.: PB-2022-22 LOD= 0.003 mg/kg LOQ = 0.01 mg/kg Time between sampling and extraction: 10 months

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

Summary of the studies in N-EU

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil		
	(a)	(b)				(c)				(d)	(e)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat-ment or no. of treatments and last date	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil		
	(a)	(b)				(c)				(d)	(e)
N-EU/France/1996	Potatoes		11 x 176-211			-		Tuber	<0.05	14	
N-EU/Denmark/1996	Potatoes		12 x 200					Tuber	<0.05	14	
N-EU/Netherlands/1996	Potatoes		12 x 183-209					Tuber	<0.05	14	
N-EU/Germany/1996	Potatoes		12 x 200					Tuber	<0.05	14	
N-EU/Belgium/1996	Potatoes		12 x 203-235					Tuber	<0.05	14	
N-EU/UK/1996	Potatoes		12 x 204-225					Tuber	<0.05	14	
N-EU/France/2000	Potatoes		4 x 122-125					Tuber	<0.05	6	
N-EU/Germany/2002	Potatoes		4 x 116-128					Tuber	<0.05 <0.05 <0.05 <0.05	0 1 3 7	
N-EU/Germany/2002	Potatoes		4 x 120-124					Tuber	<0.05 <0.05 <0.05 <0.05	0 1 3 7	
N-EU/Netherlands/2002	Potatoes		4 x 119-127					Tuber	<0.05	7	

A 2.2.4 Magnitude of residues in livestock

A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new data submitted in the framework of this application.

A 2.2.6 Magnitude of residues in representative succeeding crops

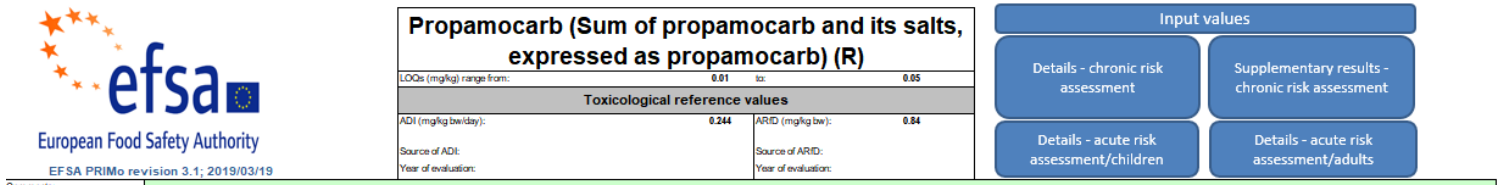
No new data submitted in the framework of this application.

A 2.2.7 Other/Special Studies

No new data submitted in the framework of this application.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations Propamocarb



Propamocarb (Sum of propamocarb and its salts, expressed as propamocarb) (R)

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw/day):	0.244	ARfD (mg/kg bw):	0.84
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
24%	NL toddler	58.44	12%	Spinaches	3%	Cauliflowers	2%	Escaroles/broad-leaved endives	0.2%	0.5%
18%	GEMS/Food G06	44.70	6%	Tomatoes	2%	Watermelons	2%	Lettuces	0.1%	0.2%
16%	SE general	38.77	7%	Lettuces	2%	Chinese cabbages/pe-tsai	1%	Tomatoes	0.0%	0.5%
15%	GEMS/Food G10	37.20	5%	Lettuces	2%	Tomatoes	1%	Chinese cabbages/pe-tsai	0.1%	0.4%
15%	ES adult	35.63	9%	Lettuces	1%	Chards/beet leaves	1%	Tomatoes	0.0%	0.1%
14%	IT adult	34.19	6%	Lettuces	2%	Tomatoes	2%	Spinaches	0.0%	0.1%
13%	ES child	32.51	7%	Lettuces	2%	Tomatoes	1%	Spinaches	0.0%	0.2%
13%	DE child	31.38	3%	Spinaches	2%	Tomatoes	1%	Lettuces	0.1%	0.3%
12%	IT toddler	28.98	5%	Lettuces	2%	Tomatoes	1.0%	Chards/beet leaves	0.0%	0.1%
11%	GEMS/Food G08	27.38	3%	Lettuces	2%	Tomatoes	0.6%	Leeks	0.1%	0.5%
11%	NL child	27.14	4%	Spinaches	1%	Lettuces	0.9%	Tomatoes	0.1%	0.4%
11%	IE adult	26.08	2%	Spinaches	2%	Melons	1%	Lettuces	0.1%	0.3%
10%	GEMS/Food G07	25.46	4%	Lettuces	2%	Tomatoes	0.6%	Spinaches	0.1%	0.5%
10%	FR infant	25.34	4%	Spinaches	2%	Leeks	1%	Cauliflowers	0.0%	0.2%
10%	NL general	24.93	2%	Spinaches	2%	Lettuces	1%	Leeks	0.0%	0.3%
10%	GEMS/Food G11	24.77	2%	Leeks	2%	Spinaches	1%	Tomatoes	0.1%	0.5%
9%	GEMS/Food G15	21.94	2%	Tomatoes	2%	Lettuces	1.0%	Watermelons	0.0%	0.4%
9%	FR toddler 2 3 yr	21.80	3%	Spinaches	2%	Leeks	1.0%	Cauliflowers	0.1%	0.2%
9%	DK child	21.72	3%	Cucumbers	2%	Lettuces	0.9%	Tomatoes	0.0%	0.3%
9%	FR child 3 15 yr	20.95	2%	Spinaches	2%	Leeks	1%	Tomatoes	0.1%	0.2%
8%	RO general	18.55	3%	Tomatoes	1.0%	Watermelons	0.6%	Onions	0.0%	0.5%
7%	DE women 14-50 yr	17.78	2%	Lettuces	1%	Tomatoes	0.8%	Spinaches	0.1%	0.1%
7%	FI 3 yr	17.75	2%	Cucumbers	1%	Spinaches	0.9%	Tomatoes	0.0%	0.6%
7%	DE general	16.13	2%	Lettuces	1%	Tomatoes	0.7%	Spinaches	0.1%	0.2%
7%	FI 6 yr	16.10	1%	Cucumbers	1%	Lettuces	0.9%	Spinaches	0.0%	0.5%
6%	PT general	15.47	2%	Lettuces	2%	Kales	1%	Tomatoes	0.0%	0.7%
6%	UK vegetarian	14.91	2%	Lettuces	1%	Tomatoes	0.8%	Spinaches	0.0%	0.2%
5%	FR adult	13.01	1%	Leeks	0.9%	Spinaches	0.8%	Tomatoes	0.0%	0.1%
5%	FI adult	12.80	2%	Lettuces	0.9%	Tomatoes	0.8%	Cucumbers	0.1%	0.1%
4%	DK adult	10.74	1%	Lettuces	0.8%	Tomatoes	0.5%	Cucumbers	0.0%	0.2%
4%	UK adult	10.42	2%	Lettuces	0.7%	Tomatoes	0.3%	Spinaches	0.0%	0.2%
4%	PL general	9.97	1%	Tomatoes	0.4%	Potatoes	0.4%	Cauliflowers	0.0%	0.4%
4%	UK toddler	8.93	1.0%	Tomatoes	0.4%	Cauliflowers	0.4%	Cauliflowers	0.0%	0.4%
4%	LT adult	8.82	1%	Lettuces	1%	Tomatoes	0.8%	Cucumbers	0.0%	0.4%
3%	UK infant	7.16	1%	Cauliflowers	0.6%	Tomatoes	0.4%	Potatoes	0.0%	0.4%
0.8%	IE child	1.84	0.1%	Lettuces	0.1%	Cauliflowers	0.1%	Tomatoes	0.0%	0.1%

A 3.2 IESTI calculations - Raw commodities Propamocarb

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Potatoes	0.3 / 0.3	46	1%	Potatoes	0.3 / 0.3	9.0
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A 3.3 IESTI calculations - Processed commodities Propamocarb

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Potatoes / fried	0.3 / 0.3	28	0.3%	Potatoes / chips	0.3 / 0.3	2.5
2%	Potatoes / dried (flakes)	0.3 / 1.38	18	0.2%	Potatoes / dried (flakes)	0.3 / 1.38	1.7

A 3.4 TMDI calculations Cymoxanil

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Cymoxanil

LOQs (mg/kg) range from: 0.01 to: 0.10

Toxicological reference values

ADI (mg/kg bw/day):	0.013	ARfD (mg/kg bw):	0.08
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/EDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
23%	GEMS/Food G06	3.05	11%	Tomatoes	3%	Watermelons	2%	Table grapes	1%	0.2%
22%	NL toddler	2.89	6%	Spinaches	5%	Milk: Cattle	4%	Table grapes	8%	0.3%
15%	RO general	1.97	6%	Tomatoes	4%	Wine grapes	1%	Watermelons	2%	0.3%
14%	DE child	1.80	3%	Table grapes	3%	Tomatoes	2%	Spinaches	4%	0.2%
12%	GEMS/Food G07	1.57	3%	Wine grapes	3%	Tomatoes	0.8%	Table grapes	2%	0.3%
12%	GEMS/Food G15	1.57	4%	Tomatoes	2%	Wine grapes	1%	Watermelons	2%	0.3%
12%	IE adult	1.54	3%	Wine grapes	3%	Melons	1%	Tomatoes	2%	0.2%
12%	NL child	1.52	2%	Table grapes	2%	Spinaches	2%	Milk: Cattle	4%	0.3%
11%	GEMS/Food G08	1.48	4%	Tomatoes	2%	Wine grapes	0.8%	Table grapes	2%	0.3%
11%	GEMS/Food G10	1.45	4%	Tomatoes	1.0%	Wine grapes	0.7%	Table grapes	2%	0.2%
11%	FR child 3 15 yr	1.44	3%	Tomatoes	2%	Milk: Cattle	1%	Melons	4%	0.1%
11%	PT general	1.43	6%	Wine grapes	3%	Tomatoes	0.6%	Table grapes	0.4%	0.4%
11%	GEMS/Food G11	1.42	3%	Tomatoes	2%	Wine grapes	1.0%	Table grapes	2%	0.3%
10%	FR adult	1.29	5%	Wine grapes	1%	Tomatoes	0.4%	Melons	1%	0.1%
9%	DE women 14-50 yr	1.14	2%	Tomatoes	2%	Wine grapes	1.0%	Milk: Cattle	3%	0.1%
8%	DE general	1.06	2%	Tomatoes	2%	Wine grapes	0.9%	Milk: Cattle	2%	0.1%
8%	FR toddler 2 3 yr	1.06	2%	Milk: Cattle	1%	Tomatoes	1%	Spinaches	4%	0.1%
8%	ES child	1.06	3%	Tomatoes	1.0%	Milk: Cattle	0.6%	Spinaches	2%	0.1%
8%	FI adult	1.02	4%	Coffee beans	2%	Tomatoes	0.7%	Wine grapes	5%	0.1%
7%	IT toddler	0.94	4%	Tomatoes	0.5%	Wheat	0.4%	Spinaches	0.5%	0.1%
7%	NL general	0.93	1%	Wine grapes	1%	Tomatoes	1%	Spinaches	2%	0.2%
7%	DK child	0.92	2%	Tomatoes	1%	Cucumbers	1.0%	Milk: Cattle	2%	0.2%
7%	SE general	0.90	2%	Tomatoes	1.0%	Milk: Cattle	0.5%	Spinaches	2%	0.3%
7%	ES adult	0.88	2%	Tomatoes	1.0%	Wine grapes	0.6%	Melons	1%	0.1%
7%	IT adult	0.88	4%	Tomatoes	0.7%	Spinaches	0.4%	Melons	0.3%	0.0%
7%	UK toddler	0.86	2%	Tomatoes	2%	Milk: Cattle	0.6%	Table grapes	3%	0.3%
6%	UK infant	0.83	3%	Milk: Cattle	1%	Tomatoes	0.3%	Potatoes	4%	0.3%
6%	DK adult	0.80	2%	Wine grapes	2%	Tomatoes	0.4%	Melons	0.8%	0.1%
6%	UK vegetarian	0.76	2%	Tomatoes	2%	Wine grapes	0.3%	Spinaches	0.6%	0.1%
6%	FR infant	0.73	2%	Spinaches	1%	Milk: Cattle	0.5%	Pumpkins	2%	0.1%
6%	FI 3 yr	0.72	2%	Tomatoes	0.8%	Watermelons	0.6%	Cucumbers	0.7%	0.4%
5%	UK adult	0.70	2%	Wine grapes	1%	Tomatoes	0.2%	Milk: Cattle	0.6%	0.1%
5%	FI 6 yr	0.60	1%	Tomatoes	0.8%	Watermelons	0.4%	Cucumbers	0.6%	0.3%
4%	PL general	0.56	3%	Tomatoes	0.7%	Table grapes	0.3%	Potatoes	0.3%	0.3%
3%	LT adult	0.45	2%	Tomatoes	0.3%	Milk: Cattle	0.2%	Potatoes	0.7%	0.2%
1%	IE child	0.13	0.3%	Milk: Cattle	0.2%	Tomatoes	0.1%	Table grapes	0.4%	0.0%

A 3.5 IESTI calculations - Raw commodities Cymoxanil

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Potatoes	0.01 / 0.01	1.5	0.4%	Potatoes	0.01 / 0.01	0.30
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A 3.6 IESTI calculations - Processed commodities Cymoxanil

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Potatoes / fried	0.01 / 0.01	0.93	0.1%	Potatoes / chips	0.01 / 0.01	0.08
0.7%	Potatoes / dried (flakes)	0.01 / 0.05	0.59	0.07%	Potatoes / dried (flakes)	0.01 / 0.05	0.06

Appendix 4 Additional information provided by the applicant

No new data submitted in the framework of this application.