

**FINAL** REGISTRATION REPORT

**Part B**

**Section 7**

**Metabolism and Residues**

Detailed summary of the risk assessment

Product code: GLOB2106cF

Product name: Revus Pro

Chemical active substances:

Propamocarb-HCl, 450 g/L

Mandipropamid, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

**CORE ASSESSMENT**

(authorization)

Applicant: Globachem NV

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**MS Finalisation date: 06/03/2024**

## Version history

When	What
March 2023	Initial dossier submission by applicant for approval of new product
July 2023	Dossier sent for evaluation
November 2023	zRMS evaluation of dRR
March 2024	Final version prepared by zRMS after Commenting period

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zRMS comments:

This report has been completed by the Applicant.

The text highlighted in grey was provided by the zRMS. The text highlighted in yellow was added by zRMS after the commenting process.

## 7 Metabolism and residue data (KCA section 6)

### 7.1 Summary and zRMS Conclusion

The Applicant did not provide any new studies. The assessment is based on data evaluated at EU level.

Comparison of intended and critical EU GAPs  
 Propamocarb

Type of GAP	Crop	Max number of applications	Method of application	Growth stage at last application	Max appl. rate per treatment (g a.s./ha)	PHI (days)
critical NEU GAP (EFSA Journal 2013;11(4):3214)	Potatoes	4	Foliar treatment-spraying	BBCH 20-95	840	7
Critical NEU and SEU GAP (SANCO/10057/2006 final, 25 April 2007)	Potatoes	6	Foliar spray	As 1 <sup>st</sup> symptoms occur	1083	14
Intended GAP	Potatoes	3	Normal downward spraying	BBCH 21-89	855	14

Mandipropamid

Type of GAP	Crop	Max number of applications	Method of application	Growth stage at last application	Max appl. rate per treatment (g a.s./ha)	PHI (days)
critical NEU GAP (EFSA Journal 2018;16(5):5284)	Potatoes	6	Foliar treatment-spraying	BBCH 31-90	150	3
Intended GAP	Potatoes	3	Normal downward spraying	BBCH 21-89	142.5	14

EU GAPs cover intended GAP.

The proposed uses of Propamocarb-HCl in the formulation GLOB2106cF do not represent unacceptable acute and chronic risks for the consumer.

The proposed uses of mandipropamid in the formulation GLOB2106cF do not represent unacceptable chronic risks for the consumer. No acute risk evaluation was performed as the setting of an ARfD was considered not necessary for mandipropamid.

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.

### **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 GLOB2106cF are presented in Table 7.1-1. They have been selected from the individual GAPs in the NEU for potato. A list of all intended uses within the NEU 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-HCl and 0.1 mg/kg for mandipropamid in potato as laid down in Reg. (EU) 396/2005 is not expected.

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

As far as consumer health protection is concerned, PL, zRMS agrees with the authorization of the intended use.

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

#### **Data gaps**

- None in the framework of this application.

**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)	water L/ha min max	kg as/ha min max		
1	Seed, ware and starch potato (SOLTU), code: 0211000	CEU	GLOB2106cF	F	<i>Phytophthora infestans</i> (PHYTIN)	SC	Propamocarb-HCl 450 g/L Mandipropamid 75 g/L	Normal downward spraying	After emergence to shortly before harvest (BBCH21-89)	Min : 1 Max : 3	7	150-300	Propamocarb-HCl Min : 0.855 Max per season : 2.565  Mandipropamid Min: 0.1425 Max per season: 0.4275	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 GLOB106cF is composed of Propamocarb-HCl and Mandipropamid.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Propamocarb-HCl					
ADI	EFSA	2006	0.29 mg as/kg bw/day	52-week dietary study in rats	100
ARfD	EFSA	2006	1 mg as/kg bw/day	28-day rat study	100
Mandipropamid					
ADI	EFSA	2012	0.15 mg as/kg bw/day	2-year dietary study in rats	100
ARfD	EFSA	2012	Not necessary	-	-

### 7.1.2.1 Summary for Propamocarb-HCl

**Table 7.1-3: Summary for Propamocarb-HCl**

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 (8 NEU + 4 SEU)	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-HCl 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 Mandipropamid

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 (8 NEU + 8 SEU)	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

The effects of processing on the nature of Mandipropamid residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were not considered for risk assessment.

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.

### 7.1.2.3 Summary for GLOB2106cF

**Table 7.1-4: Information on GLOB2106cF (KCA 6.8)**

Crop	PHI for GLOB2106cF proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for GLOB2106cF proposed by zRMS	zRMS Comments (if different PHI proposed)
		Propamocarb- HCl	Mandipropamid		
Potato	14 days	Yes	Yes	14 days	-

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).

#### Waiting periods before planting succeeding crops

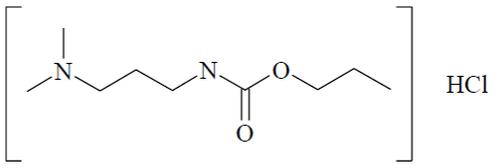
Not relevant.

## Assessment

### 7.2 Propamocarb-HCl

General data on Propamocarb-HCl are summarized in the table below.

**Table 7.2-1: General information on Propamocarb-HCl**

Active substance (ISO Common Name)	Propamocarb (unless otherwise stated, the following data relate to the variant propamocarb hydrochloride)
IUPAC	Propyl 3-(dimethylamino)propylcarbamate (propamocarb) Propyl 3-(dimethylamino) propylcarbamate hydrochloride
Chemical structure	
Molecular formula	C <sub>9</sub> H <sub>21</sub> ClN <sub>2</sub> O <sub>2</sub>
Molar mass	224.7
Chemical group	Carbamate
Mode of action (if available)	Systemic fungicide with protectant, curative and anti-sporulant activity against oomycetes, belonging in the chemical group of the carbamates (FRAC code group 28), which affect the cell membrane permeability (F4).
Systemic	Yes
Company (ies)	Arysta LifeScience Bayer CropScience
Rapporteur Member State (RMS)	1st approval: Ireland Renewal: Portugal
Approval status	Approved 01/10/2007 Commission Directive 2007/25/EC of 23 April 2007 Regulation (EU) No 540/2011
Restriction	Only uses as fungicide may be authorised.
Review Report	SANCO/10057/2006 final 25 April 2007
Current MRL regulation	Reg. (EU) 2020/856
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes EFSA Scientific Report (2006) 78, 1-80
EFSA Journal: conclusion on article 12	Yes EFSA Journal 2013;11(4):3214
Current MRL applications on intended uses	-

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

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

## 7.2.1 Stability of Residues (KCA 6.1)

### 7.2.1.1 Stability of residues during storage of samples

#### Available data

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
<b>Data relied on in EU</b>			
<b>Plant products</b>			
Potato	High starch content	26 months	RAR of Propamocarb Everitt, S.L; Charter, G.E., 1998 (data out of protection)
Tomato	High water content	26 months	EFSA, 2006
Lettuce	High water content	24 months	EFSA, 2006
Cucumber	High water content	12 months	EFSA, 2006
Brussels sprouts	High water content	12 months	EFSA, 2006
<b>Animal Products</b>			
	Muscle	No study available	
	Liver	No study available	
	Kidney	No study available	
	Milk	No study available	
	Egg	No study available	

#### Conclusion on stability of residues during storage

Storage stability studies of Propamocarb-HCl assessed in this section cover the requested use on potato belonging to high starch content commodities for GLOB2106cF.

#### zRMS comments:

The Applicant did not provide any new storage stability studies. The data presented by the Applicant, assessed at EU level, are sufficient and appropriate. Additional studies are not required.

### 7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Not relevant.

#### zRMS comments:

The Applicant did not provide any new studies in this dossier.

## 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.

The data evaluated during the EU Review of Propamocarb-HCl are out of protection and are sufficient to describe the behaviour of the formulated product, so no further studies are required.

Plant metabolism studies had been conducted with tomato, cucumber, spinach, lettuce and potato. The results of the metabolism studies are consistent as they demonstrate that parent Propamocarb is always detected in the treated samples. The studies also suggest that parent Propamocarb is the only residue definition which is suitable for the control of the use of this active substance.

**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	
<b>EU data</b>								
Fruits and fruiting vegetable	Tomatoes	Not reported.	Soil, G	7.22 g a.s./m <sup>2</sup>	4	14, 21, 28, 25	-	EFSA Journal 2013;11(4): 3214
				36.1 g a.s./m <sup>2</sup>	4			
			Foliar, G	2.166	1	7, 14, 21, 28	-	
	Cucumbers	Not reported.	Foliar <sup>(b)</sup>	2.9	1	30	-	
			Soil (hydroponic) <sup>(b)</sup>	53.4 mg/plant (aqueous)	1	21	-	
Leafy vegetables	Spinach	[ <sup>14</sup> C-carbamate]	Foliar, F	2.53	2	after the 1 <sup>st</sup> appl: 0 after the 2 <sup>nd</sup> appl.: 3	-	
	Lettuce	Not reported.	Soil, G	drench: 7.22 g a.s./m <sup>2</sup>	3	38	-	
			Foliar, G	foliar spray: 1.083	3	21	-	
Root and tuber vegetables	Potatoes	[ <sup>14</sup> C-propyl]	Foliar, F	2.45	3	42	-	
			Foliar, F	2.166	6	7	After the 6 <sup>th</sup> application the foliage had died and the spray was sprayed on soil	
				10.83	6			

#### Summary of plant metabolism studies reported in the EU

The metabolism of Propamocarb hydrochloride in plants has been investigated in spinach, potatoes, cucumbers, lettuce and tomatoes. Studies were submitted by both notifiers and as they agreed in

conducting a task-force, the entire information was used independently of its source to understand the behaviour in plants of the compound when applied according to the representative uses supported by both notifiers. The information provided is sufficient with regard to all representative uses. The metabolic pattern found in plants is strongly influenced by the mode of application of the product.

In lettuce, after foliar applications, residues are highly extractable (90% of the Total Radioactive Residues – TRR) and consist essentially in Propamocarb. Two minor metabolites, accounting for less than 5% of the TRR were also identified, hydroxypropyl-propamocarb and propamocarb-N-oxide, indicating that the degradation of propamocarb hydrochloride proceeds through hydroxylation and oxidation. Similar pattern was observed in spinach after foliar treatment, with 2 further metabolites identified, resulting from N-demethylation and cyclization of the hydroxy metabolite identified in lettuce. Foliar treatment of tomato plants also resulted in Propamocarb being the major constituent in tomato fruits (75% of the 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 when present, but the TRR are essentially constituted of polar material rather similar for the 2 plants and indicating the reincorporation in endogenous material of CO<sub>2</sub> resulting from the degradation of Propamocarb hydrochloride by the plant or in the soil. In contrast to the observations made in lettuce and tomatoes, cucumbers grown hydroponically and treated with Propamocarb hydrochloride applied in the nutrient solution showed an important level of parent Propamocarb (50% of the TRR).

Two metabolism studies on potatoes were submitted. Unchanged Propamocarb-anion was present in tubers at 15% of the TRR in one study and at 2% of the TRR in the second study. In both cases, the vast majority of the radioactivity present could be allocated to natural plant constituents (mainly starch), demonstrating the incorporation in plant material of CO<sub>2</sub> produced by the degradation of Propamocarb hydrochloride.

The residue definition in plant commodities for monitoring and risk assessment is proposed to be restricted to Propamocarb and its salts, the sum being expressed as Propamocarb, as no metabolite structurally related to Propamocarb is present at level suggesting a significant contribution to the toxicological burden, whatever the plant or the type of treatment. In addition to this, no metabolite has been identified in plant which was not present in rat metabolism.

### Summary of new plant metabolism studies

No new data is required.

### Conclusion on metabolism in primary crops

The metabolism of Propamocarb hydrochloride in plants has been fully elucidated. Applied by foliar treatment of plants, the compound is degraded through hydroxylation, oxidation, N-demethylation and cyclisation, but however remains the major compound of the residue pattern. Applied by soil treatment or hydroponically with nutritive solution, its levels, as well as those of its structurally related metabolites, resulting from uptake and translocation into edible parts of the plants are low. In this case, the major part of the radioactivity present in plants is due to the incorporation in the plant of the CO<sub>2</sub> produced by complete degradation of the compound. Similar residue pattern is found in potato tubers after foliar treatment of the aerial parts of the plant. The residue definition proposed consists therefore in the sum of Propamocarb and its salts.

#### zRMS comments:

The Applicant did not provide any new metabolism studies. The data presented by the Applicant, assessed at EU level, are sufficient and appropriate. According to the EFSA Journal 2013;11(4):3214: the metabolism of propamocarb hydrochloride in the crops under consideration is sufficiently addressed and **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** since the identified metabolites in all crops were recovered at a low proportion (<10% TRR) and no significant contribution to the toxicological burden is expected. Additional studies are not required.

### 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
<b>EU data</b>								
Leafy vegetables	Lettuce	<sup>14</sup> C-aminopropyl	Bare soil, G	5.96 - 6.16	30, 120, 365	n.r.	-	Ireland, 2004 EFSA, 2006
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.

#### Summary of new plant metabolism studies

No new data submitted in the framework of this application.

#### 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 deemed necessary. Although the oxazolidine metabolite was recovered in significant amounts in wheat straw, this metabolism study was carried out with plants grown in pots with an overdosed application rate. Consequently, it is expected that this metabolite will not be present in significant amounts following realistic application conditions (<0.01 mg eq/kg).

#### zRMS comments:

The Applicant did not provide any new metabolism studies. The data presented by the Applicant, assessed at EU level, are sufficient and appropriate. According to the EFSA Journal 2013;11(4):3214 metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary. Based on data from metabolism studies, the presence of propamocarb residues in rotational crops planted 30 days after treatment cannot be excluded.

### 7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

#### Available data

Residues in processed commodities resulting from the representative uses are not expected (EFSA, 2006).

#### Conclusion on nature of residues in processed commodities

No new data submitted in the framework of this application.

#### zRMS comments:

The Applicant did not provide any new studies on nature of residues in processed commodities. In addition, the effect of processing on the nature of propamocarb was not investigated in the framework of the peer review. According to the Commission Regulation (EU) No 283/2013: studies on the nature of residues in processing shall be provided where residues in products of plant or animal origin subject to processing may occur at a level of or higher than 0.01 mg/kg (based on the residue definition for risk assessment for the raw commodity). As quantifiable residues of propamocarb are not expected in the potato (when used in accordance with the proposed GAP) additional studies are not required in the framework of this registration.

### 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**

<b>Endpoints</b>	
Plant groups covered	Root and tuber vegetables (Potatoes) Fruits and fruiting vegetables (Tomatoes, cucumbers) Leafy vegetables (Spinach, lettuce)
Rotational crops covered	Leafy vegetables (lettuce) Root and tuber vegetables (radish) Cereals (wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes. New metabolite oxazolidine observed but not present in significant amount to be taken into consideration in the residue definition.
Processed commodities	- The residues of Propamocarb are not expected above 0.1 mg/kg in potatoes <del>and tomatoes</del> therefore processing studies are not required.
Residue pattern in processed commodities similar to pattern in raw commodities?	<del>The residues of Propamocarb are not expected above 0.1 mg/kg in potatoes and tomatoes therefore processing studies are not required.</del>
Plant residue definition for monitoring	Sum of Propamocarb and its salts, expressed as Propamocarb EFSA Scientific Report (2006) 78, 1-80; Reg. (EU) 2020/856
Plant residue definition for risk assessment	Sum of Propamocarb and its salts, expressed as Propamocarb EFSA Scientific Report (2006) 78, 1-80 EFSA Journal 2013;11(4):3214
Conversion factor from enforcement to RA	Not applicable

### 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	
<b>EU data</b>								
Lactating ruminants	Cow	<sup>14</sup> C-carbon	1	2	7	Milk	twice daily	Ireland, 2004; EFSA, 2006
						Urine and faeces	twice daily	
						Tissues	at sacrifice	
Laying poultry	Hens		12	1.02	14	Eggs	Once daily	EFSA, 2013 (data under protection)
						Excreta	n.r.	
						Tissues	at sacrifice	

n.r.: Not reported

#### Summary of animal metabolism studies reported in the EU

##### DAR (Ireland, 2004)

###### Ruminants:

Based on the representative uses supported by the notifiers in the DAR (Ireland, 2004), potatoes is the only feed item which may contain residues of Propamocarb. Given the residue levels to expect in practice, the actual exposure of animals is however very low (less than 0.02 and 0.007 mg/kg bw/d for beef and dairy cattle respectively) and no transfer of residues resulting in measurable amounts in animal commodities is expected. However a metabolism study in lactating cow has been submitted. This study was conducted with an exposure rate of animals 3.2 orders of magnitude higher than the expected level of exposure of animals and showed limited transfer of residues to animal commodities. Liver contained the highest levels of TRR (0.4 mg/kg). The metabolic pattern was similar to that observed in rats and plants, and no sign of potential accumulation was identified.

##### Article 12 EFSA Reasoned Opinion (2013)

###### Ruminants:

*“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 further 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 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).”*

#### Hens:

The study was conducted with an exposure rate of animals 3.8 orders of magnitude higher than the expected level of exposure of poultry.

*“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 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).”*

*“Based on these studies, EFSA proposes to limit the residue definition to the best marker compound and to define the residue for enforcement in pig and ruminant tissues and milk as N-oxide propamocarb only and in poultry tissues and eggs as N-desmethyl propamocarb. For risk assessment, EFSA proposes to define the residue in milk, pig and ruminant tissues as the sum of propamocarb, N-oxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb. For poultry tissues, EFSA proposes to define the residue as the sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb.”*

#### **Summary of new animal metabolism studies**

No new data submitted in the framework of this application.

#### **Conclusion on metabolism in livestock**

##### **DAR (Ireland, 2004)**

Taking into account the practical low level of exposure of livestock, there is no need to establish any residue definition nor MRLs for animal commodities.

##### **Article 12 EFSA Reasoned Opinion (2013)**

*“With an additional route of degradation of propamocarb through hydroxylation of the parent molecule at the propyl side chain with further cyclisation of the side chain, the metabolic degradation of propamocarb in cows appears to be more extensive compared to the metabolism depicted in hens. All the major metabolites identified in cow and hens were also observed in the rat metabolism and are therefore assumed to have similar toxicological properties as the parent compound. The general metabolic pathways of propamocarb in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs.*

*Based on these studies, EFSA proposes to limit the residue definition to the best marker compound and to define the residue for enforcement in pig and ruminant tissues and milk as N-oxide propamocarb only and in poultry tissues and eggs as N-desmethyl propamocarb.*

*For risk assessment, EFSA proposes to define the residue in milk, pig and ruminant tissues as the sum of propamocarb, Noxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb. For poultry tissues, EFSA proposes to define the residue as the sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb.*

*Theoretical conversion factors could also be derived as follow: 1.3 for all poultry tissues and eggs, 4.25 for milk, 2.2 for ruminant kidney, 1.7 for ruminant liver and muscle, 1 for ruminant fat. Analytical methods for enforcement of the proposed residue definition are not available (see also section 1.2). The conclusions reached by EFSA are not in line with those of the JMPR (FAO, 2006a) who set a residue definition by default as propamocarb (free base) because the dietary burden was not triggered.”*

**zRMS comments:**

According to the information indicated by the Applicant, data on metabolism evaluated during the review of the MRL values under Article 12 (EFSA Journal 2013;11(4):3214) are still protected and the Applicant has no access to them. Therefore, zRMS recognizes that they have been summarized only as an indication that additional data in this area is available at EU level. In the opinion of zRMS, these data cannot support the dossier. However, considering that the results of field studies indicate the lack of residues of propamocarb in potatoes above the LOQ (for N-EU) and the intended use do not modify the dietary burden calculations completed at EU level, zRMS found that in the framework of this application the lack of access to poultry metabolism study is not critical area of concern and no additional studies are required.

**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**

	<b>Endpoints</b>
Animals covered	A metabolism study was not required. Metabolism studies in the cow and hens were however submitted.
Animal residue definition for monitoring	EFSA Journal 2013;11(4):3214 Reg. (EU) No 2020/856 <u>In milk, pig and ruminant tissues:</u> N-oxide propamocarb <u>In poultry tissues and eggs:</u> N-desmethyl propamocarb
Animal residue definition for risk assessment	EFSA Journal 2013;11(4):3214 <u>In milk, pig and ruminant tissues:</u> the sum of propamocarb, N-oxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxyPropamocarb expressed as propamocarb <u>In poultry tissues and eggs:</u> the sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb
Conversion factor	EFSA Journal 2013;11(4):3214 Theoretical conversion factors could be derived as follow : 1.3 for all poultry tissues and eggs 4.25 for milk 2.2 for ruminant kidney 1.7 for ruminant liver and muscle 1 for ruminant fat
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Non fat soluble.

### 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 propamocarb-HCl 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
Potatoes	DAR of propamocarb-HCl (Ireland, 2004)	N-EU	6 x 1083g/ha, PHI 14d, outdoor E: 8x<0.1 RA: 8x<0.1	0.1	0.1	0.1	0.3	Yes
		S-EU	6 x 1083g/ha, PHI 14d, outdoor E :4x<0.1 RA: 4x<0.1	0.1	0.1	0.1		Yes
	Infinito (France, AMM in France. No. 2090136, unprotected data at MS level)	N-EU	4 x 1000g/ha, PHI 7d, outdoor E: 4x<0.01 RA: 4x<0.01	0.01	0.01	0.01		Yes
		S-EU	4 x 1000g/ha, PHI 7d, outdoor E :4x<0.01 RA: 4x<0.01	0.01	0.01	0.01		Yes
	EFSA Scientific Report (2006) 78, 1-80	N-EU	6 x 1083g/ha, PHI 14d, outdoor E: 8x<0.1 RA: 8x<0.1	0.1	0.1	0.1		Yes
	EFSA review of all MRLs (2013)	NEU	4 x 840 g as/ha, PHI 7d, outdoor E: 8x<0.01 RA: 8x<0.01	0.01	0.01	0.01		Yes

	data under protection	SEU	4 x 840 g as/ha, PHI 7d, outdoor E: 2x<0.01, 0.01, 0.03 RA: 2x<0.01, 0.01, 0.03	0.01	0.03	0.07		Yes
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\*Source of EU MRL: Reg. (EU) No 2020/856

### 7.2.3.2 Effects on the residue level in pollen and bee products

In Regulation (EU) No. 283/2013 for active substances, the residue level in pollen and bee products for human consumption resulting from residues taken up by honeybees needs to be determined. As this determination of residues level in pollen and bee products is an active substance requirement rather than a plant protection product requirement, such active substance studies should be addressed during the annex I renewal of the active substance. Furthermore, The uses of Propamocarb-HCl in GLOB2106cF are on potatoes which are not considered to be a melliferous crop.

**zRMS comments:**

According to the Appendix II of SANTE/11956/2016 rev. 9 potato is a crop which it is not possible to produce honey therefore residues in honey are not expected. Additional studies are not required.

### 7.2.3.3 Conclusion on the magnitude of residues in plants

There are numerous trials available across EU territory with variable GAPs in different years showing practically no difference between North and South EU and absence of significant residue amounts.

According to the available data, the intended uses on potato are considered acceptable as residues found are considerably lower than the existing EU MRL (aligned to the global Codex MRL).

The data submitted show that no exceedance of the MRL will occur when GLOB2106cF is used according to the intended GAP.

**zRMS comments:**

The Applicant did not provide any new studies.  
 Comparison of intended and critical EU GAPs

Type of GAP	Crop	Max number of applications	Method of application	Growth stage at last application	Max appl. rate per treatment (g a.s./ha)	PHI (days)
critical NEU GAP (EFSA Journal 2013;11(4):3214)	Potatoes	4	Foliar treatment-spraying	BBCH 20-95	840	7
Critical NEU and SEU GAP (SANCO/10057/2006 final, 25 April 2007)	Potatoes	6	Foliar spray	As 1 <sup>st</sup> symptoms occur	1083	14
Intended GAP	Potatoes	3	Normal downward spraying	BBCH 21-89	855	14

EU GAP covers GAP proposed for GLOB2106cF.

The field studies evaluated at EU level and presented by the Applicant in this dossier are appropriate and sufficient to conclude that after application of GLOB2106cF, in accordance with the proposed GAP, no residues above the applicable MRL are expected in potatoes.

## 7.2.4 Magnitude of residues in livestock

### 7.2.4.1 Dietary burden calculation

Propamocarb-HCl is already authorised for use on several crops that might be fed to livestock. 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). EU-MRLs on potato were set accordingly and a change of MRL is not needed for this application.

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

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definition:</b> sum of propamocarb and its salts, expressed as propamocarb				
Cabbage	0.2	Median residue (EFSA, 2013)	0.36	Highest residue (EFSA, 2013)
Kale	4	Median residue (EFSA, 2013)	11.8	Highest residue (EFSA, 2013)
Potatoes	0.01	Median residue (EFSA, 2013)	0.03	Highest residue (EFSA, 2013)
Potato processed waste	0.2	Median residue (EFSA, 2013) x EFSA default PF (20)	0.2	Median residue (EFSA, 2013) x EFSA default PF (20)
Potato dried pulp	0.38	Median residue (EFSA, 2013) x EFSA default PF (38)	0.38	Median residue (EFSA, 2013) x EFSA default PF (38)

**Table 7.2-10: Results of the dietary burden calculation**

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			mg/kg DM		
	Median	Maximum	Median	Maximum				
Cattle (all diets)	0,225	0,626	6,02	16,45	Dairy cattle	Kale leaves	Yes	
Cattle (dairy only)	0,225	0,626	5,85	16,28	Dairy cattle	Kale leaves	Yes	
Sheep (all diets)	0,128	0,350	3,35	8,58	Lamb	Kale leaves	Yes	
Sheep (ewe only)	0,112	0,286	3,35	8,58	Ram/Ewe	Kale leaves	Yes	
Swine (all diets)	0,070	0,191	3,03	8,28	Swine (breeding)	Kale leaves	Yes	
Poultry (all diets)	0,009	0,014	0,14	0,20	Poultry layer	Cabbage, heads leaves	Yes	
Poultry (layer only)	0,009	0,014	0,14	0,20	Poultry layer	Cabbage, heads leaves	Yes	

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"  
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

The intended uses of GLOB2106cF are covered by the uses assessed during the review of all existing MRLs for Propamocarb-HCl (EFSA, 2013). The intended uses do not modify the dietary burden calculations completed at European level.

#### zRMS comments:

The calculations presented by the Applicant in Table 7.2-10 were made using an Animal model 2017. The intended use do not modify the dietary burden calculations completed at EU level.

#### **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.

The uses of GLOB2106cF are adequately covered by the animal dietary burden calculations previously presented in the Article 12 Reasoned Opinion (EFSA, 2013); as a consequence, the existing EU MRLs for propamocarb-HCl in livestock products remain valid for the proposed uses.

The available data presented in Article 12 Reasoned Opinion (EFSA,2013) are considered sufficient for deriving MRLs in hens matrices.

*“Considering that an analytical method is required for enforcement purposes and that further clarification on the individual results for propamocarb and its metabolite in the hen metabolism study are still necessary, the MRL proposals should be regarded as tentative only.*

*Regarding ruminants and pigs, tentative MRLs and risk assessment values were derived from the metabolism study and are summarised in [Table 7.2-10]. A representative ruminants feeding study supported by storage stability data is required in order to derive robust MRLs and risk assessment values.”*

zRMS comments:

Additional studies are not required.

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

The effect of processing on the nature of Propamocarb-HCl was not investigated during the peer review and no new studies have been submitted in the framework of this application. Therefore, no data on the effect of processing on Propamocarb-HCl are available.

#### **7.2.4.4 Available data for all crops under consideration**

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

#### **7.2.4.5 Conclusion on processing studies**

During EU review, both notifiers indicated that of the representative crops used in the peer-review, lettuce is not processed and residues of Propamocarb will not exceed 0.1 mg/kg in either potatoes or tomatoes. Consequently processing studies are not required for these crops.

zRMS comments:

Additional studies are not required.

#### **7.2.5 Magnitude of residues in representative succeeding crops**

The crops under consideration can be grown in rotation.

Data dealing with magnitude of residues in succeeding crops are available and are summarized hereafter.

### 7.2.5.1 Field rotational crop studies (KCA 6.6.2)

#### Available data

No new data submitted in the framework of this application.

Rotational crop field trials were evaluated in the framework of the peer review (Ireland, 2004). Propamocarb was applied on bare soil at 4 x 1.68 kg a.s./ha (1 N) and the magnitude of residues was investigated on several succeeding crops (wheat, soybean, sugar beet, table beet and dry beans) sown at three different plant-back intervals (30, 60 and 365 days) following application of the active substance. Wheat was the only crop grown on 30 days aged soils which contained parent residues at or above LOQ. Further rotational crop field trials were submitted where Propamocarb was applied on white cabbage with 2 drench applications at a dose rate of 72.2 kg a.s./ha followed by 2 foliar applications at 3.61 kg a.s./ha (1 N) and the magnitude of residues was investigated on wheat and lamb's lettuce sown at two different plant-back intervals (81 – 102 days for wheat and 52 – 59 days for lamb's lettuce) (Ireland, 2012). No residue was detected (<LOQ of the method) in any of the following crops. In a third set of rotational crop field trials, Propamocarb was sprayed on lettuce as the primary crop at 3 x 1.33 kg a.s./ha (1.8 N) and the magnitude of Propamocarb residues was investigated in lettuce, carrot, winter wheat and barley sown at the 30 day plant-back interval. Residues were < 0.01 mg/kg in all the edible parts of the rotated crops and < 0.05 mg/kg for straw.

Furthermore, we make reference to the following statement (RAR of Propamocarb-HCl, 2017, unprotected data):

Report:	KCA 6.6/01; Gateaud, L.; 2010; M - 359448 - 02 - 1
Title:	Statement concerning the reduction of the plant back interval for products containing propamocarb
Report No.:	M - 359448 - 02 - 1
Document No.:	M - 359448 - 02 - 1
Guideline(s):	not specified
Guideline deviation(s):	not specified
GLP/GEP:	no

Since Annex I Inclusion, no new study has been performed to investigate the metabolism of Propamocarb in rotational crops. Only the magnitude of the residues in the rotational crops has been investigated with new studies:

Report:	KCA 6.6.2/02; Klein, E. H. J.; 2004; M-226597-01-1
Title:	Decline of residues in white cabbage, lamb's lettuce and wheat Field Rotation Crop Study European Union (Northern zone) 2002 propamocarb hydrochloride, AE B066752 Water soluble concentrate (SL); 66.5 percent w/w (= 722 g/L)
Report No.:	C039190
Document No.:	M-226597-01-1
Guideline(s):	Not specified but complies with EU Commission Working Document 7029/VI/95 rev. 5 22/07/97
Guideline deviation(s):	none
GLP/GEP:	yes

Report:	KCA 6.6.2/03; Melrose, I.; Portet, M.; 2010; M-349882-02-1
Title:	Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Netherlands -Rotational crop study
Report No.:	08-2504
Document No.:	M-349882-02-1

Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991,Annex II, part A, section 6 and AnnexIII, part A, section 8Residues in or on Treated Products, Food and FeedEC guidance working document 7029/VI/95 rev. 5 (1997-07-22)EC guidance working document 7524/VI/95 rev. 2 (1997-07-22)OECD Guideline for testing of Chemicals; Residues in rotational crops(limited field studies), No. 504, 8 Jan. 2007
Guideline deviation(s):	none
GLP/GEP:	yes

Report:	KCA 6.6.2/04; Melrose, I.; Portet, M.; 2010; M-349137-02-1
Title:	Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and barley, winter after spraying of fosetyl & propamocarb SL 840 in the field in France (North) -Rotational crop study
Report No.:	08-2505
Document No.:	M-349137-02-1
Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991,Annex II, part A, section 6 and Annex III, part A, section 8Residues in or on Treated Products, Food and FeedEC guidance working document 7029/VI/95 rev. 5 (1997-07-22)EC guidance working document 7524/VI/95 rev. 2 (1997-07-22)OECD Guideline for testing of Chemicals;Residues in rotational crops(limited field studies), No. 504, 8 Jan. 2007
Guideline deviation(s):	none
GLP/GEP:	yes

Report:	KCA 6.6.2/05; Melrose, I.; Portet, M.; 2010; M-361470-01-1
Title:	Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Spain
Report No.:	08-2506
Document No.:	M-361470-01-1
Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991,Annex II, part A, section 6and Annex III, part A, section 8Residues in or on Treated Products, Food and FeedEC guidance working document 7029/VI/95 rev. 5 (1997-07-22)EC guidance working document 7524/VI/95 rev. 2 (1997-07-22)OECD Guideline for testing of Chemicals; Residues inrotational crops(limited field studies), No. 504, 8 Jan. 2007
Guideline deviation(s):	none
GLP/GEP:	yes

Report:	KCA 6.6.2/06; Melrose, I.; Portet, M.; 2010; M-349147-02-1
Title:	Determination of the residues of fosetyl and propamocarb in/on carrot,lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Italy
Report No.:	08-2507
Document No.:	M-349147-02-1
Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22) OECD Guideline for testing of Chemicals; Residues in rotational crops (limited

	field studies), No. 504, 8 Jan. 2007
Guideline deviation(s):	yes, but acceptable, see report
GLP/GEP:	yes

These 5 studies have already been provided to the MS for the re-authorization (Step 2) of Propamocarb-based products as a result of the first Annex I inclusion in 2007 (Step 2 submission: October 2009, Step 2 re-authorization: October 2011 - varying according to each Member State).

Please refer to re-authorization dossier of Propamocarb-based products as those data should also have been used - such as Proplant (Reg. No.: 9500199), Proxanil (Reg. No.: 2080114) and Previcur Energy (Reg. No.: 2070107) attracting no data protection.

Alternatively, those data should have also been used for new registrations obtained after Annex I inclusion of Propamocarb like Infinito (Reg. No.: 2090136) and for which data protection is over.

All of them have been evaluated and peer reviewed within EFSA Journal 2013; 11 (4): 3214 leading to the conclusion that Propamocarb residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that Propamocarb is applied in compliance with the supported GAP. A statement was submitted to support the proposal of a Plant Back Interval of 30 days (M-359448-02-1). EFSA was therefore of the opinion that the label restriction proposed during the peer review (EFSA Scientific Report (2006) 78, 1 - 80) can be cancelled.

**Table 7.2-11: Summary of available studies in field rotational crops**

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
<b>EU data</b>					
Bare soil	6.7 (4x1.68)	Leafy vegetables	Soy bean grain	30 60 365	Ireland, 2004 EFSA, 2006
			Soy bean forage		
			Soy bean hay		
		Root and tuber vegetables	Sugar & table beet top		
			Sugar & table beet root		
		Cereals	Wheat forage		
			Wheat grain		
			Wheat straw		
		Pulses and oilseed	Dry bean grain		
		<b>Data from EFSA Journal 2013;11(4):3214</b>			
Lettuce	3.975 (1.325x3)	Leafy vegetables	Lettuce	30	Melrose I., Portet, M., 2010, report N°08-2504
			Root and tuber vegetables		
		Carrot root			
		Cereals	Wheat forage	30	
			Wheat grain		
			Wheat straw		
Lettuce	3.975 (1.325x3)	Leafy vegetables	Lettuce	35	Melrose I., Portet, M., 2010, report N°08-2505
			Root and tuber vegetables		
		Carrot root			
		Cereals	Barley forage	41	
			Barley grain		
			Barley straw		
Lettuce	3.975 (1.325x3)	Leafy vegetables	Lettuce	98	Melrose I., Portet, M., 2010, report N°08-2506

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
		Root and tuber vegetables	Carrot top	90	
			Carrot root		
		Cereals	Wheat forage	93	
			Wheat grain		
			Wheat straw		
		Lettuce	3.975 (1.325x3)	Leafy vegetables	
Root and tuber vegetables	Carrot top			40	
	Carrot root				
Cereals	Wheat forage			43	
	Wheat grain				
	Wheat straw				
Cabbage	115.42 (cabbage drench treatment BBCH 00-11 at 72.2 kg as/ha + drench treatment BBCH 10-13 at 36 kg as/ha + 2x3.61 kg as/ha as foliar treatment)	Leafy vegetables	Lettuce	52-59	Klein E. H-J., 2004, report N° C039190
		Cereals	Wheat forage	81-102	
			Wheat grain		
			Wheat straw		

### Conclusion on rotational crops studies

As European data are out of protection, the results of the above rotational crop study can be used by the applicant and are sufficient to support the intended use of GLOB2106cF as fungicide in potato. No residue above 0.01 mg/kg is expected in rotational crops.

#### zRMS comments:

zRMS agrees with the data presented by the Applicant. The rotational crop studies evaluated at EU level in the framework of the review of MRLs for propamocarb and presented by the Applicant in the dossier are out of protection. No residue above 0.01 mg/kg is expected in rotational crops. EFSA was of the opinion that the label restriction proposed during the peer review (EFSA Scientific Report (2006) 78, 1 - 80) can be cancelled.

Additional studies are not required.

### 7.2.6 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 GLOB2106cF. Therefore, other special studies are not needed.

## 7.2.7 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).

### 7.2.7.1 Input values for the consumer risk assessment

Consumer risk assessment calculations were performed taking into account all the crops for which an MRL has been set for Propamocarb-HCl under Reg. (EU) ~~No 289/2014~~ No 2020/856. Where the MRL for a particular crop is below the LOQ, calculations have been made with the LOQ for that crop.

**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
<b>Risk assessment residue definition:</b> sum of propamocarb and its salts, expressed as propamocarb				
Potato	MRL	Reg. (EU) No 2020/856	0.01	HR (EFSA, 2006)
Other crops	MRL	Reg. (EU) No 2020/856	Crops not applicable to this submission	
Honey and other apiculture products	0.05	MRL (Reg. (EU) No 2020/856)	Commodities not applicable to this submission	
Potatoes / chips	NA		0.01	STMR (EFSA, 2006)
Potatoes / dried (flakes)	NA		0.046	STMR (EFSA, 2006) x default PF (4.6, OECD, 2008)
Potatoes / fried	NA		0.01	HR (EFSA, 2006)
<b>Risk assessment residue definition:</b> the sum of propamocarb, N-oxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxyPropamocarb expressed as propamocarb				
Swine Muscle/meat	0.017	MRL (Reg. (EU) No 2020/856) x CF(1.7) (EFSA, 2013)	0.02	HR × CF (1.7) (EFSA, 2013)
Swine Fat	0.01	MRL (Reg. (EU) No 2020/856) x CF(1) (EFSA, 2013)	0.01	HR × CF (1) (EFSA, 2013)
Swine Liver	0.17	MRL (Reg. (EU) No 2020/856) x CF(1.7) (EFSA, 2013)	0.09	HR × CF (1.7) (EFSA, 2013)
Swine Kidney	0.044	MRL (Reg. (EU) No 2020/856) x CF(2.2) (EFSA, 2013)	0.02	HR × CF (2.2) (EFSA, 2013)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swine edible offals	0.1	MRL (Reg. (EU) No 2020/856)	0.1	MRL (Reg. (EU) No 2020/856)
Swine Other animal products	0.01	MRL (Reg. (EU) No 2020/856)	0.01	MRL (Reg. (EU) No 2020/856)
Ruminant Muscle/meat	0.017	MRL (Reg. (EU) No 2020/856) x CF(1.7) (EFSA, 2013)	0.02	HR × CF (1.7) (EFSA, 2013)
Ruminant Fat	0.01	MRL (Reg. (EU) No 2020/856) x CF(1) (EFSA, 2013)	0.01	HR × CF (1) (EFSA, 2013)
Ruminant Liver	0.34	MRL (Reg. (EU) No 2020/856) x CF(1.7) (EFSA, 2013)	0.22	HR × CF (1.7) (EFSA, 2013)
Ruminant Kidney	0.11	MRL (Reg. (EU) No 2020/856) x CF(2.2) (EFSA, 2013)	0.06	HR × CF (2.2) (EFSA, 2013)
Ruminant edible offals	0.2	MRL (Reg. (EU) No 2020/856)	0.2	MRL (Reg. (EU) No 2020/856)
Ruminant Milk	0.0425	MRL (Reg. (EU) No 2020/856) x CF(4.25) (EFSA, 2013)	0.04	STMR × CF (4.25) (EFSA, 2013)
Ruminant Other animal products	0.01	MRL (Reg. (EU) No 2020/856)	0.01	MRL (Reg. (EU) No 2020/856)
Other animal product	MRL (Reg. (EU) No 2020/856)		MRL (Reg. (EU) No 2020/856)	
<b>Risk assessment residue definition:</b> the sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb				
Poultry Muscle/meat	0.026	MRL (Reg. (EU) No 2020/856) x CF(1.3) (EFSA, 2013)	0.03	HR × CF (1.3) (EFSA, 2013)
Poultry Fat	0.013	MRL (Reg. (EU) No 2020/856) x CF(1.3) (EFSA, 2013)	0.013	HR × CF (1.3) (EFSA, 2013)
Poultry Liver	0.065	MRL (Reg. (EU) No 2020/856) x CF(1.3) (EFSA, 2013)	0.04	HR × CF (1.3) (EFSA, 2013)
Poultry Kidney	0.01*	MRL (Reg. (EU) No 2020/856)	0.01*	<LOQ MRL
Poultry Edible offals	0.065	MRL (Reg. (EU) No 2020/856) x CF(1.3)	0.065	MRL (Reg. (EU) No 2020/856) x CF(1.3)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Poultry Eggs	0.065	MRL (Reg. (EU) No 2020/856) x CF(1.3) (EFSA, 2013)	0.05	HR × CF (1.3) (EFSA, 2013)
Poultry Other animal products	0.013	MRL (Reg. (EU) No 2020/856) x CF(1.3)	0.013	MRL (Reg. (EU) No 2020/856) x CF(1.3)

### 7.2.7.2 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	21% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	No IEDI calculations were performed as the TMDI calculations using the MRLs were already acceptable. No refinement of the chronic risk assessment is required.
IESTI (% ARfD) according to EFSA PRIMo*	<b>Raw commodities:</b> Potato: 0.2 % for children Milk (Cattle): 0.5% for children <b>Processed commodities:</b> Potatoes, fried: 0.1%, Potatoes, dried (flakes): 0.1%, for children
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-HCl in the formulation GLOB2106cF do not represent unacceptable acute and chronic risks for the consumer.

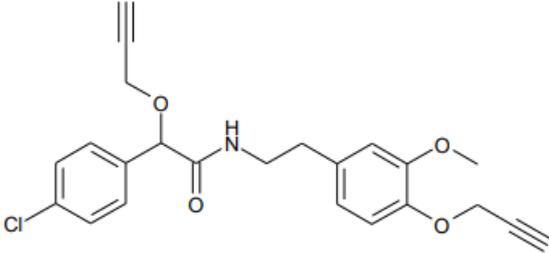
zRMS comments:

The proposed uses of Propamocarb-HCl in the formulation GLOB2106cF do not represent unacceptable acute and chronic risks for the consumer.

### 7.3 Mandipropamid

General data on Mandipropamid are summarized in the table below.

**Table 7.3-1: General information on Mandipropamid**

Active substance (ISO Common Name)	Mandipropamid
IUPAC	( <i>RS</i> )-2-(4-chlorophenyl)-N-[3-methoxy-4-(prop-2-ynyloxy)phenethyl]-2-(prop-2-ynyloxy)acetamide
Chemical structure	
Molecular formula	C <sub>23</sub> H <sub>22</sub> ClNO <sub>4</sub>
Molar mass	411.9
Chemical group	Carboxylic Acid Amide (CAA)
Mode of action (if available)	Fungicide effective against oomycete plant pathogens in a range of crops, i.e. against downy mildews, such as <i>Plasmopara viticola</i> on grapes and potato late blight caused by <i>Phytophthora infestans</i> , belonging in the chemical group of the CAA (FRAC code group 40), which affect phospholipid biosynthesis and cell wall deposition.
Systemic	No (translaminar)
Company (ies)	Syngenta Crop Protection AG
Rapporteur Member State (RMS)	Austria
Approval status	Approved 01/08/2013 Commission Implementing Regulation (EU) No 188/2013 of 5 March 2013 Regulation (EU) No 540/2011
Restriction	Conditions of use shall include risk mitigation measures, where appropriate.
Review Report	SANCO/ 12991/2012 rev 4 23 March 2018
Current MRL regulation	Reg. (EU) <a href="#">2020/1565</a> <a href="#">2024/344</a>
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes EFSA Scientific Report (2012) 78, 1-80
EFSA Journal: conclusion on article 12	Yes EFSA Journal 2018; 16(5):5284
Current MRL applications on intended uses	-

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

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

### 7.3.1 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  $\leq -18^{\circ}\text{C}$  (unless stated otherwise)**

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
<b>Data relied on in EU</b>			
<b>Plant products</b>			
Potato*	High starch content	24 months	EFSA, 2018 (DAR (Austria, 2012): An interim report with data up to 12 months only was reviewed in the DAR)
Tomato	High water content	24 months	
Lettuce	High water content	24 months	
Wheat forage	High water content	24 months	
Wheat straw	Dry	24 months	
Cucumber	High water content	24 months	
Grapes	High acid content	24 months	
Soybean	High oil content	24 months	
<b>Animal Products</b>			
	Muscle	No study available	
	Liver	No study available	
	Kidney	No study available	
	Milk	No study available	
	Egg	No study available	

\*Metabolite SYN 500003 was stable at  $-20^{\circ}\text{C}$  for up to 32 months in potato tubers, granules/flakes, chips and wet peel (EFSA, 2018)

##### Conclusion on stability of residues during storage

Storage stability studies of Mandipropamid assessed in this section cover the requested use on potato belonging to high starch content commodities for GLOB2106cF.

##### zRMS comments:

The Applicant did not provide any new storage stability studies. The data presented by the Applicant, assessed at EU level, are sufficient and appropriate. Additional studies are not required.

#### 7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Not relevant.

zRMS comments:  
 The Applicant did not provide any new studies.

## 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.

The data evaluated during the EU Review of Mandipropamid are out of protection and are sufficient to describe the behaviour of the formulated product, so no further studies are required.

Plant metabolism studies had been conducted with fruits (grapes, tomatoes), leafy vegetables and root crops.

**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	
<b>EU data</b>								
Fruit crops	Grapes	Phenyl (chloro/methoxy)	Spray treatment	0.143-0.150	6	0, 14, 28	Fruits and leaves were sampled	EFSA, 2012
				0.411-0.464		28		
	Tomato	[1-C <sup>14</sup> ]	Spray treatment	0.149-0.276	4	0, 3, 7, 14, 28	-	
Root crops	Potato	Phenyl (chloro/methoxy)	Spray treatment	0.046-0.158	6	7, 21	Tubers and leaves were sampled	
				0.418-0.458				
Leafy crops	Lettuce	Phenyl (chloro/methoxy)	Spray treatment	0.156-0.160	2	3, 14	-	
				0.418-0.458				

#### Summary of plant metabolism studies reported in the EU

The metabolism of mandipropamid was investigated in fruits (grapes, tomatoes), leafy vegetables and root crops in the framework of the peer review (EFSA, 2012). Studies on grapes, lettuce and potatoes were conducted with <sup>14</sup>C-mandipropamid labelled either on the methoxyphenyl or the chlorophenyl ring. The metabolism study on tomato was conducted with [1-C<sup>14</sup>] labelled mandipropamid. After six foliar applications of ca 150 g active substance (a.s.)/ha or six foliar applications of 411–464 g a.s./ha on grapes, mandipropamid was the major component of the residues representing most of the fruit radioactivity 79–89% TRR. All other metabolite fractions in grape fruits were lower than 3.5–3.8% TRR. After two foliar applications of 250 g a.s./ha and two foliar applications of 150 g a.s./ha on tomatoes, mandipropamid was the major component of the residues representing 75% TRR. Mandipropamid showed a slow penetration/translocation of radioactivity into tomato plants. It is slowly metabolised to

many metabolites, which occurred only at very small amount. After two foliar applications of ca 150 g a.s./ha on lettuce, mandipropamid was the major component of the residues representing 94–95% of the TRR. None of the identified metabolites were greater than 0.4% TRR (0.005 mg eq/kg). Potatoes were treated with six foliar applications of 150 g a.s./ha (1N rate) or with six foliar applications of approximately 418–458 g a.s./ha (3N rate). In the 1N rate trials, mandipropamid was detected at amounts lower than 0.01 mg eq/kg in the peel, flesh and whole potato in both labels at pre-harvest interval (PHI) 7 and 21 days. The metabolite SYN 500003 was the only metabolite observed in potato peel (0.002–0.003 mg eq/kg), potato flesh (0.006–0.009 mg eq/kg) and in the whole potato (0.008–0.0115 mg eq/kg). In the 3N rate trials, mandipropamid was observed at 12% TRR in potato peel (0.020 mg eq/kg) and 3% TRR in the whole potato (0.029 mg eq/kg), while SYN 500003 was observed at 11–13% TRR with levels of 0.02 and 0.08 mg eq/kg in potato peel and flesh, and 0.10 mg eq/kg in the whole potato. In conclusion, at the 1N rate the only residues present at significant amounts are of metabolite SYN 500003.

### Summary of new plant metabolism studies

No new data is required.

### Conclusion on metabolism in primary crops

The metabolism of mandipropamid is similar in fruits and leafy vegetables. However, the metabolism observed in roots was different since significant amounts of the metabolite SYN 500003 were observed. In the MRL review (EFSA, 2018), the residue definition for risk assessment for fruits and leafy vegetables is proposed as follows: mandipropamid (any ratio of constituent isomers). For roots, the residue definition for risk assessment is proposed as follows: sum of mandipropamid and SYN 500003. The residue definition for roots is tentative pending on the submission of toxicological information on the metabolite SYN 500003. This is currently being handled by the notifier of the active substance under renewal by testing the genotoxic potential of SYN 500003 via a bacterial mutagenicity study (negative), *in vitro* mammalian mutagenicity assay (negative) and *in vitro* chromosome aberration (IVC) study (positive). To follow up the positive result in the IVC, an *in vivo* micronucleus study was conducted (negative). This test is also supported by a proof of exposure study. On the basis of the available data, SYN 500003 is of no genotoxic concern (VV-731756, 2020). In addition, a 28-day repeat dose study in rats according to OECD 407 is currently in progress for SYN 500003 to address the levels of this metabolite found in potato crops. Nevertheless, the applicant adds information on residue trials assessing the level of this metabolite in the intended crop i.e. potato. Moreover, in the consumer risk assessment, a conversion factor of 2 is used, based on the levels of Mandipropamid and metabolite SYN 500003 detected in the residue trials performed with potatoes (EFSA, 2018).

#### zRMS comments:

The Applicant did not provide any new metabolism studies. The data presented by the Applicant, evaluated at EU level, are sufficient and appropriate. According to the EFSA Journal 2018;16(5):5284: the metabolism of mandipropamid is similar in fruits and leafy vegetables. However, the metabolism observed in roots was different since significant amounts of the metabolite SYN 500003 were observed. The residue definition for risk assessment for fruits and leafy vegetables is proposed as follows: mandipropamid (any ratio of constituent isomers).

For roots, the residue definition for risk assessment is proposed as follows: **sum of mandipropamid and SYN 500003.**

The residue definition for roots is tentative pending on the submission of toxicological information on the metabolite SYN 500003.

For enforcement, the residue definition for all crops under review is proposed as follows: **mandipropamid (any ratio of constituent isomers).**

Additional metabolism studies are not required.

### 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
<b>EU data</b>								
<b>Root/tuber crops</b>	Radish	Phenyl (chloro/methoxy)	Bare soil, G	0.9	29, 58, 120, 365	n.r.	-	EFSA, 2012
<b>Leafy crops</b>	Lettuce							
<b>Cereals (small grain)</b>	Spring wheat							

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

#### Summary of plant metabolism studies reported in the EU

Two confined rotational crop studies were assessed in the framework of the peer review (EFSA, 2012). Mandipropamid labelled either on the chlorophenyl or on the methoxyphenyl ring was applied to bare soil at a rate of ca 900 g a.s./ha. Lettuce, radish and wheat were planted at plant back intervals (PBI) of 29, 58, 120 and 365 days after treatment (DAT). In the methoxyphenyl label study only lettuce and wheat were planted 365 DAT. In the study with mandipropamid labelled on the chlorophenyl ring, the TRR was lower than 0.01 mg eq/kg for mandipropamid and metabolites CGA 380778 and NOA 458422 in all plant commodities with the exception of the wheat straw where residues of mandipropamid were 0.02 and 0.015 mg eq/kg at 29 and 58 DAT, respectively, while metabolite NOA 458422 was detected at 0.016 mg eq/kg at 29 DAT. In the study with mandipropamid labelled on the methoxyphenyl ring the same pattern was observed. The TRR was lower than 0.01 mg eq/kg for mandipropamid and metabolites CGA 380778 and NOA 458422 in all plant commodities with the exception of wheat straw where residues of mandipropamid were 0.021 and 0.023 mg eq/kg at 29 and 58 DAT, respectively, while metabolite NOA 458422 was detected at 0.016 mg eq/kg at 29 and 58 DAT. After 210 DAT, residue levels of mandipropamid and metabolites were below 0.01 mg/kg in all crops. The metabolites formed (CGA 380778 and NOA 458422) were also identified in primary plant metabolism studies as well as in soil metabolism studies (Austria, 2013). The data on metabolism and distribution of mandipropamid in rotational crops indicated that the metabolism of mandipropamid in rotational crops is similar to the pathway observed in primary crops.

#### Summary of new plant metabolism studies

No new data submitted in the framework of this application.

#### 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 deemed necessary.

#### zRMS comments:

The Applicant did not provide any new metabolism studies. The data presented by the Applicant, evaluated at EU level, are sufficient and appropriate. According to the EFSA Journal 2013;11(4):3214

metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary. Additional studies are not required.

### 7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

#### Available data

Studies investigating the nature of residues in processed commodities were assessed in the framework of the peer review (EFSA, 2012). Studies were conducted with radiolabelled mandipropamid simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6). Mandipropamid was stable to hydrolysis under standard conditions of pasteurisation, baking/brewing/boiling and sterilisation.

#### Conclusion on nature of residues in processed commodities

No new data submitted in the framework of this application.

#### zRMS comments:

The Applicant did not provide any new metabolism studies. The data presented by the Applicant, evaluated at EU level, are sufficient and appropriate. Quantifiable residues of mandipropamid are not expected in the treated crops. Additional studies are not required.

### 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**

<b>Endpoints</b>	
Plant groups covered	Root/Tuber vegetables (potato) Fruits (tomato, grape) Leafy vegetables (lettuce)
Rotational crops covered	Radish (root vegetables) Lettuce (leafy vegetables) Spring wheat (cereals)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes.
Processed commodities	Mandipropamid stable under standard hydrolysis conditions (pasteurisation, baking and sterilisation).
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Mandipropamid (sum of isomers) Mandipropamid (any ratio of constituted isomers), Reg. (EU) 2023/1069
Plant residue definition for risk assessment	Mandipropamid except for root/tuber crops where the definition is provisionally proposed as "mandipropamid and SYN 500003", pending the submission of toxicological information on SYN 500003.
Conversion factor from enforcement to RA	Not applicable 2 for potatoes

### 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	
<b>EU data</b>								
Lactating ruminants	Goat	<sup>14</sup> C-carbon	2	0.88-1.54	7	Milk	twice daily	EFSA, 2012; Greece, 2017
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens		5	1.39	14	Eggs	twice daily	EFSA, 2012; Greece, 2017
						Excreta	twice daily	
						Tissues	at sacrifice	

n.r.: Not reported

#### Summary of animal metabolism studies reported in the EU

Although not required, studies to investigate metabolism in livestock were conducted on lactating goats (EFSA, 2012) and laying hens (Greece, 2017).

##### Ruminants:

Lactating goats were dosed with mandipropamid labelled in the chlorophenyl and methoxyphenyl rings over 7 days with 31–54 mg/kg DM. Most of the radioactivity was excreted via urine and faeces and less than 0.23% of the administered radioactivity was recovered in milk and tissues with the highest levels in liver (0.48 mg/kg) and kidney (0.14 mg/kg). Similar residue levels were observed for both radiolabels indicating no amide cleavage of the parent molecule. Mandipropamid was observed as the major component of the residues in fat only (ca. 75% TRR) but was almost not detected in the other matrices. Several metabolites resulting from loss of the methyl group at the methoxyphenyl ring and from the removal of either one or both propargyl chains were identified in liver and kidney, the most abundant being the metabolite NOA458422 accounting for ca. 15% TRR in liver (0.02 mg/kg). Having regard to the very low intakes by animals resulting from the representative uses, no MRLs were proposed for product of animal origin.

##### Hens:

Laying hens were dosed with mandipropamid labelled in the chlorophenyl and methoxyphenyl rings over 14 days with 22–24 mg/kg DM. The majority TRR was detected in excreta (83–85%). The only relevant residues were detected in egg whites, where mandipropamid was observed at 34–37% TRR (0.016–0.018 mg eq/kg). In all other tissues, mandipropamid and metabolites were below 0.01 mg/kg.

#### Summary of new animal metabolism studies

No new data submitted in the framework of this application.

### Conclusion on metabolism in livestock

In the framework of the peer review, the residue definition for enforcement was proposed as mandipropamid (sum of isomers) and the residue definition for risk assessment as mandipropamid only (EFSA, 2012). It is noted however that for this MRL review residue, definitions for livestock are not needed.

**zRMS comments:**

The Applicant did not provide any new storage stability studies. The data presented by the Applicant, assessed at EU level, are sufficient and appropriate. Additional studies are not required.

### 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**

	<b>Endpoints</b>
Animals covered	A metabolism study was not required. Metabolism studies in the goat and hens were however submitted.
Animal residue definition for monitoring	EFSA Journal 2018; 16(5):5284 Reg. (EU) No 2020/1565 Not required Mandipropamid (any ratio of constituted isomers), Reg. (EU) 2023/1069
Animal residue definition for risk assessment	EFSA Journal 2012;10(11):2935 mandipropamid EFSA Journal 2018; 16(5):5284 Not required
Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Non fat soluble.

### 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 Mandipropamid 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
Potatoes	EFSA Scientific Report (2012) 78, 1-80	N-EU	6 x 150g/ha, PHI 2-3d, outdoor E: 8x<0.01 RA: 8x<0.01 Results for metabolite SYN 500003: 8 x < 0.005 mg/kg (LOQ)	0.01	0.01	0.01	0.1	Yes
	EFSA MRL review (2018)	S-EU	6 x 150g/ha, PHI 2-3d, outdoor E: 8x<0.01 RA: <del>8x&lt;0.01</del> 6x0.01; 0.020; 0.021 Results for metabolite SYN 500003: 6 x < 0.005; 0.010; 0.011 mg/kg	0.01	<del>0.01</del> 0.021	<del>0.01</del> 0.038		Yes

\*Source of EU MRL: Reg. (EU) No [2020/1565-2024/344](#)

In addition, the applicant has access to recent residue trials in potatoes that are part of the AIR top-up submission by Syngenta (see table below). For summaries, please refer to Appendix A2.2.3.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner  (SYN = Syngenta)	Previously used Y/N If yes, for which data point?
KCA 6.3.2	Ertus, C.	05/05/2021	Mandipropamid – Residue Study on Potato in Northern France, Czech Republic, Germany, Hungary and Poland in 2020 Report No. C0193 Document No. VV-901800 Test Facility Anadiag S.A. GLP Unpublished	N	Y	The study is necessary for this regulatory decision and eligible for data protection according to O.J. 2019/C 229 in countries of the EU	SYN (LoA for Globachem NV)	N
KCA 6.3.2	Ertus, C.	07/05/2021	Mandipropamid – Residue Study on Potato in Southern France, Greece, Italy and Spain in 2020 Report No. C0194 Document No. VV-901817 Test Facility Anadiag S.A. GLP Unpublished	N	Y	The study is necessary for this regulatory decision and eligible for data protection according to O.J. 2019/C 229 in countries of the EU	SYN (LoA for Globachem NV)	N

**zRMS comments:**

The residue results indicated for NEU in Table 7.3-8 are sufficient for the purposes of this dossier. The Applicant did not provide the study reports listed in Appendix A2.2.3. Therefore, they do not influence the assessment and were considered as informative only.

### 7.3.3.2 Effects on the residue level in pollen and bee products

In Regulation (EU) No. 283/2013 for active substances, the residue level in pollen and bee products for human consumption resulting from residues taken up by honeybees needs to be determined. As this determination of residues level in pollen and bee products is an active substance requirement rather than a plant protection product requirement, such active substance studies should be addressed during the annex I renewal of the active substance. Furthermore, The uses of Mandipropamid in GLOB2106cF are on potatoes which are not considered to be a melliferous crop.

#### zRMS comments:

According to the Appendix II of SANTE/11956/2016 rev. 9 potato is a crop which it is not possible to produce honey therefore residues in honey are not expected. Additional studies are not required.

### 7.3.3.3 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on potato are considered acceptable as residues found are considerably lower than the existing EU MRL (aligned to the global Codex MRL).

The data submitted show that no exceedance of the MRL will occur when GLOB2106cF is used according to the intended GAP.

#### zRMS comments:

##### Comparison of intended and critical EU GAPs

Type of GAP	Crop	Max number of applications	Method of application	Growth stage at last application	Max appl. rate per treatment (g a.s./ha)	PHI (days)
critical NEU GAP (EFSA Journal 2018;16(5):5284)	Potatoes	6	Foliar treatment-spraying	BBCH 31-90	150	3
Intended GAP	Potatoes	3	Normal downward spraying	BBCH 21-89	142.5	14

EU GAP covers GAP proposed for GLOB2106cF.

In support of the proposed GAP the Applicant presented eight residue trails evaluated at EU level (more critical), EFSA Journal 2018;16(5):5284. The residue levels of parent mandipropamid were in all trials below the LOQ of 0.01 mg/kg. Residue levels of the metabolite SYN 500003 in potatoes were in all trials below the LOQ of 0.005 mg/kg. The data submitted show that no exceedance of the MRL will occur when GLOB2106cF is used according to the intended GAP.

Additional studies are not required.

### 7.3.4 Magnitude of residues in livestock

#### 7.3.4.1 Dietary burden calculation

Mandipropamid is authorised for use on potatoes that might be fed to livestock. 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 Mandipropamid (EFSA Journal 2018; 16(5):5284).

EU-MRLs on potato were set accordingly and a change of MRL is not needed for this application.

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

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definition:</b> sum of mandipropamid and metabolite SYN 500003 [tentative; pending on the submission of toxicological information on SYN 500003]				
Potato, culls	0.02	STMR x CF (2)	0.02	HR x CF (2)
Potato, process waste	0.02	STMR x PF x CF	0.02	STMR x PF x CF
Potato, dried pulp	0.02	STMR x PF x CF	0.02	STMR x PF x CF

**Table 7.3-10: Results of the dietary burden calculation**

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No) 0.004 mg/kg bw	Previous assessment Max burden mg/kg bw
	mg/kg bw per day		mg/kg DM						
	Median	Maximum	Median	Maximum					
Cattle (all diets)	0.0031	0.0031	0.0967	0.0967	Dairy cattle	Potato	process waste	No	
Cattle (dairy only)	0.0031	0.0031	0.0800	0.0800	Dairy cattle	Potato	process waste	No	
Sheep (all diets)	0.0032	0.0032	0.0967	0.0967	Ram/Ewe	Potato	process waste	No	
Sheep (ewe only)	0.0032	0.0032	0.0967	0.0967	Ram/Ewe	Potato	process waste	No	
Swine (all diets)	0.0019	0.0019	0.0833	0.0833	Swine (breeding)	Potato	process waste	No	
Poultry (all diets)	0.0014	0.0014	0.0200	0.0200	Turkey	Potato	culls	No	
Poultry (layer only)	0.0009	0.0009	0.0134	0.0134	Poultry layer	Potato	culls	No	

The intended uses of GLOB2106cF are covered by the uses assessed during the review of all existing MRLs for Mandipropamid (EFSA, 2018). The intended uses do not modify the dietary burden calculations completed at European level.

**zRMS comments:**

The intended uses do not modify the dietary burden calculations completed at European level. Additional calculations are not 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.

The uses of GLOB2106cF are adequately covered by the animal dietary burden calculations previously presented in the Article 12 Reasoned Opinion (EFSA, 2018); as a consequence, the existing EU MRLs for Mandipropamid in livestock products remain valid for the proposed uses. MRLs are not necessary as the dietary burdens were found to be below the trigger value.

**zRMS comments:**

Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value, further investigation is unnecessary.

According to the EFSA Journal 2018;16(5):5284: Although not required, studies to investigate metabolism in livestock were conducted on lactating goats (EFSA, 2012) and laying hens (Greece, 2017). Lactating goats were dosed with mandipropamid labelled in the chlorophenyl and methoxyphenyl rings

over 7 days with 31–54 mg/kg DM. Most of the radioactivity was excreted via urine and faeces and less than 0.23% of the administered radioactivity was recovered in milk and tissues with the highest levels in liver (0.48 mg eq/kg) and kidney (0.14 mg eq/kg). Laying hens were dosed with mandipropamid labelled in the chlorophenyl and methoxyphenyl rings over 14 days with 22–24 mg/kg DM. The majority TRR was detected in excreta (83–85%). The only relevant residues were detected in egg whites, where mandipropamid was observed at 34–37% TRR (0.016–0.018 mg eq/kg). In all other tissues, mandipropamid and metabolites were below 0.01 mg/kg.

In the framework of the peer review, the residue definition for enforcement was proposed as mandipropamid (sum of isomers) and the residue definition for risk assessment as mandipropamid only (EFSA, 2012). It is noted however that for MRL review residue definitions for livestock are not needed.

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

The effect of industrial processing and/or household preparation was assessed on studies conducted on apples, citrus, grapes, tomato and rice (EFSA, 2012; Austria, 2013). Robust processing factors could be derived for grapes (pomace (wet and dry), red wine, juice, and raisins), tomato (washed, juice, pomace (wet), canned, puree) and hops (beer) and limited processing factors (not sufficiently supported by data) for potatoes (fried, crisps, granules (flakes) and process waste (wet peel)) and grapes (red wine must heated).

#### 7.3.5.1 Available data for all crops under consideration

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

#### 7.3.5.2 Conclusion on processing studies

Further processing studies are not considered necessary for the intended GAP uses of Mandipropamid in the product GLOB2106cF on potato, since the magnitude of residues in processed commodities has been sufficiently investigated in the studies presented above.

#### zRMS comments:

Considering that the level of residues is less than 0.1 mg/kg and the contribution of the commodity under consideration to the theoretical maximum daily intake (TMDI) is < 10 % of the ADI it is not necessary to carry out processing studies according to the Commission Regulation (EU) No 283/2013.

An overview of the processing studies for potatoes evaluated at EU level is presented below (EFSA Journal 2018;16(5):5284):

Processed commodity	Number of studies <sup>(a)</sup>	Processing factor (PF)		CF <sup>(b)</sup>
		Individual values	Median PF	
Potato/fried	2	0.05; 0.11	0.08	1.6
Potato/crisps (chips)	2	0.03; 0.11	0.07	2.0
Potato/granules or flakes	2	0.03; 0.11	0.07	2.2
Potato/process waste (wet peel)	2	1.1; 3.0	2.0	1.0
Grape/red wine (must heated)	1	0.09	0.09	1

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each residues trial (Greece, 2017).

### **7.3.6 Magnitude of residues in representative succeeding crops**

The crops under consideration can be grown in rotation.

Data dealing with magnitude of residues in succeeding crops are available and are summarized hereafter.

#### **7.3.6.1 Field rotational crop studies (KCA 6.6.2)**

##### **Available data**

No new data submitted in the framework of this application.

There were no studies investigating the magnitude of residues in rotational crops available for the EFSA 2018 MRL review. Greece in its evaluation report mentioned a field rotational crop study; however, no study could be found in the document (Greece, 2017). The maximum application rate proposed for crops that can be grown in rotation is 900 g a.s./ha. It is noted that the application in the confined rotational crop studies was done onto bare soil and thus represents a worst-case scenario of exposure (no foliar interception). A part of mandipropamid is expected to be intercepted by the treated crops since the applications are done until a late growth stage (PHI 3–7 days).

##### **Conclusion on rotational crops studies**

Therefore, it can be concluded that significant residue levels are not expected in succeeding crops provided that mandipropamid is applied according to the current authorisations.

##### **zRMS comments:**

No residues are expected in rotational crops.

#### **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 GLOB2106cF. 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**

Consumer risk assessment calculations were performed taking into account all the crops for which an MRL has been set for Mandipropamid under Reg. (EU) No 2020/1565. Where the MRL for a particular crop is below the LOQ, calculations have been made with the LOQ for that crop. A conversion factor of 2 was applied to root crops, based on the levels of Mandipropamid and metabolite SYN 500003 detected in the residue trials performed with potatoes (EFSA, 2018).

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

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
<b>Risk assessment residue definition:</b> sum of mandipropamid and metabolite SYN 500003 [tentative; pending on the submission of toxicological information on SYN 500003]		
Potato	0.02	STMR x CF
<b>Risk assessment residue definition:</b> mandipropamid (any ratio of constituent isomers)		
Table grapes	0.35	STMR
Wine grapes	0.35	STMR
Tomatoes	0.34	STMR
Aubergines/eggplants	0.34	STMR
Cucumbers	0.05	STMR
Courgettes	0.05	STMR
Melons	0.07	STMR
Pumpkins	0.07	STMR
Lamb's lettuces/corn salads	5.15	STMR
Lettuces	2.75	STMR
Escaroles/broad-leaved endives	2.75	STMR
Cresses and other sprouts and shoots	5.15	STMR
Land cresses	5.15	STMR
Roman rocket/rucola	2.75	STMR
Red mustards	2.75	STMR
Baby leaf crops (including brassica species)	2.75	STMR

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Spinaches	5.15	STMR
Purslanes	5.15	STMR
Chards/beet leaves	2.75	STMR
Chervil	5.15	STMR
Chives	5.15	STMR
Celery leaves	5.15	STMR
Parsley	5.15	STMR
Sage	5.15	STMR
Rosemary	5.15	STMR
Thyme	5.15	STMR
Basil and edible flowers	5.15	STMR
Laurel/bay leave	5.15	STMR
Tarragon	5.15	STMR
Hops	5.15	STMR

### 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	9% (based on NL toddler) -
IEDI (% ADI) according to EFSA PRIMo	9% (based on NL toddler)  No IEDI calculations were performed as the TMDI calculations using the MRLs were already acceptable. No refinement of the chronic risk assessment is required.

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

\*\* if national model is available

The proposed uses of Mandipropamid in the formulation GLOB2106cF do not represent unacceptable chronic risks for the consumer.

**zRMS comments:**

In addition consumer risk assessment calculations were performed using PRIMo rev. 3.1 and taking into account all MRLs in force has been set for mandipropamid under Reg. (EU) No 2023/1069.

Mandipropamid		Input values	
Toxicological reference values		Details - chronic risk assessment	
ADJ (mg/kg bw/day):		Supplementary results - chronic risk assessment	
Source of ADJ: EFSA		Details - acute risk assessment/children	
Year of evaluation: 2018		Details - acute risk assessment/adults	
<p>Comments:</p> <p><b>Normal mode</b></p> <p><b>Chronic risk assessment: JMPR methodology (IEDI/TMDI)</b></p>			
No. of diets exceeding the ADI:			
Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (% of ADI)
25%	NL toddler	38.08	12% Spinaches
18%	GEMS/Food G10	27.19	9% Lettuces
18%	GEMS/Food G06	26.79	7% Tomatoes
18%	IT adult	26.46	6% Lettuces
17%	SE general	26.09	7% Lettuces
15%	DE child	22.74	3% Spinaches
15%	E adult	22.65	3% Other leafy brassica
15%	ES adult	22.50	9% Lettuces
15%	IT toddler	21.98	3% Lettuces
14%	GEMS/Food G11	21.65	4% Celeries
14%	GEMS/Food G07	21.03	4% Lettuces
14%	GEMS/Food G08	20.84	3% Lettuces
13%	ES child	20.03	7% Lettuces
13%	NL child	19.43	4% Spinaches
11%	GEMS/Food G15	17.15	2% Tomatoes
11%	PT general	16.95	3% Wine grapes
11%	RO general	16.18	4% Tomatoes
11%	NL general	16.04	3% Spinaches
10%	FR child 3-15 yr	14.60	2% Other lettuce and other salad plants
10%	FR adult	14.33	3% Wine grapes
8%	DE women 14-50 yr	12.61	2% Lettuces
8%	DE general	11.88	2% Lettuces
7%	FR toddler 2-3 yr	11.22	3% Spinaches
7%	UK vegetables	11.00	2% Lettuces
7%	FR infant	10.62	4% Spinaches
6%	UK adult	9.04	2% Lettuces
5%	FI adult	8.04	2% Lettuces
5%	DK child	7.73	2% Lettuces
5%	DK adult	7.71	2% Lettuces
5%	FI 6 yr	7.33	1% Lettuces
5%	FI 3 yr	6.91	1% Tomatoes
4%	UK toddler	6.69	1% Tomatoes
4%	PL general	6.44	2% Tomatoes
4%	LT adult	5.34	1% Tomatoes
3%	UK infant	4.04	0.7% Tomatoes
0.8%	E child	1.14	0.1% Lettuces
<p><b>Conclusion:</b></p> <p>The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Mandipropamid is unlikely to present a public health concern.</p> <p>DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.</p>			

The highest chronic exposure was calculated for NL toddler representing 25% of the ADI (highest contributor to MS diet was spinaches, 12% ADI). The proposed uses of mandipropamid in the formulation GLOB2106cF do not represent unacceptable chronic risks for the consumer. No acute risk evaluation was performed as the setting of an ARfD was considered not necessary for mandipropamid.

Currently, Regulation No 2024/344 is already in force (applicable from 12/02/2024). Given that it only changes the MRL value for papaya, it should be considered that the risk assessment carried out is still valid.

## 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.

## 7.5 References

European Food Safety Authority, 2013. 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, 72 pp. doi:10.2903/j.efsa.2013.3214

Commission Regulation (EU) 2020/856 of 9 June 2020 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cyazofamid, cyprodinil, fenpyroximate, fludioxonil, fluxapyroxad, imazalil, isofetamid, kresoxim-methyl, lufenuron, mandipropamid, propamocarb, pyraclostrobin, pyriofenone, pyriproxyfen and spinetoram in or on certain products (Text with EEA relevance)

EFSA (European Food Safety Authority), 2006. Conclusion on the peer review of the pesticide risk assessment of the active substance propamocarb. EFSA Journal 2006;4(7):78r, 80 pp. <https://doi.org/10.2903/j.efsa.2006.78r>

Ireland, 2004. Draft assessment report on the active substance propamocarb prepared by the rapporteur Member State Ireland in the framework of Council Directive 91/414/EEC, October 2004. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

EC (European Commission), 2007. Review report for the active substance propamocarb finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 24 November 2006 in view of the inclusion of propamocarb in Annex I of Directive 91/414/EEC

European Food Safety Authority, 2018. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for mandipropamid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(5):5284, 46 pp. doi:10.2903/j.efsa.2018.5284

Commission Regulation (EU) 2020/1565 of Commission Regulation (EU) 2020/1565 of 27 October 2020 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1,4-diaminobutane, 1-methylcyclopropene, ammonium acetate, bifentazate, chlorantraniliprole, chlormequat, cyprodinil, limestone, mandipropamid, pepper, pyridaben, repellants: blood meal, seaweed extracts and trimethylamine hydrochloride in or on certain products (Text with EEA relevance)

EFSA (European Food Safety Authority), 2012. Conclusion on the peer review of the pesticide risk assessment of the active substance mandipropamid. EFSA Journal 2012;10(11):2935, 76 pp. <https://doi.org/10.2903/j.efsa.2012.2935>

Austria, 2006. Draft assessment report on the active substance mandipropamid prepared by the rapporteur Member State Austria in the framework of Council Directive 91/414/EEC, November 2006. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

EC (European Commission), 2018. Review report for the active substance mandipropamid finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 1 February 2013 in view of the inclusion of mandipropamid as active substance in accordance with Regulation (EC) No 1107/2009

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>
KCA 6.3.2	Ertus, C.	2021	Mandipropamid – Residue Study on Potato in Northern France, Czech Republic, Germany, Hungary and Poland in 2020 Report No. C0193 Document No. VV-901800 Test Facility Anadiag S.A. GLP Unpublished	No	Syngenta (LoA Globachem)
KCA 6.3.2	Ertus, C.	2021	Mandipropamid – Residue Study on Potato in Southern France, Greece, Italy and Spain in 2020 Report No. C0194 Document No. VV-901817 Test Facility Anadiag S.A. GLP Unpublished	No	Syngenta (LoA Globachem)

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 6.6.2 /02	Klein, E. H. J.	2004	Decline of residues in white cabbage, lamb's lettuce and wheat Field Rotation Crop Study European Union (Northern zone) 2002 Propamocarb hydrochloride, AE B066752 Water soluble concentrate (SL); 66.5 percent w/w (= 722 g/L) Bayer CropScience GmbH, Frankfurt am Main, Germany TF-BCS-Arysta LifeScience, Report No.: C039190, Edition Number: M-226597-01-1 Date: 2004-03-04 GLP/GEP: yes, unpublished	N	TF-BCS- Arysta LifeScience
KCA 6.6.2 /03	Melrose, I.; Portet, M.	2009	Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Netherlands - Rotational crop study Bayer S.A.S., Bayer CropScience, Lyon, France TF-BCS-Arysta LifeScience, Report No.: 08-2504, Report includes Trial Nos.: 08-2504-01 08-2504-02 08-2504-03 Edition Number: M-349882-02-1 Date: 2009-06-22 <b>...Amended: 2010-01-13</b> GLP/GEP: yes, unpublished	N	TF-BCS- Arysta LifeScience

Data point	Author(s)	Year	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>
KCA 6.6.2 /04	Melrose, I.; Portet, M.	2009	Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and barley, winter after spraying of fosetyl & propamocarb SL 840 in the field in France (North) - Rotational crop study Bayer S.A.S., Bayer CropScience, Lyon, France TF-BCS-Arysta LifeScience, Report No.: 08-2505, Report includes Trial Nos.: 08-2505-01 08-2505-02 08-2505-03 Edition Number: M-349137-02-1 Date: 2009-06-12 <b>...Amended: 2010-01-12</b> GLP/GEP: yes, unpublished	N	TF-BCS-Arysta LifeScience
KCA 6.6.2 /05	Melrose, I.; Portet, M.	2010	Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Spain Bayer S.A.S., Bayer CropScience, Lyon, France TF-BCS-Arysta LifeScience, Report No.: 08-2506, Report includes Trial Nos.: 08-2506-01 08-2506-02 08-2506-03 Edition Number: M-361470-01-1 Date: 2010-01-14 GLP/GEP: yes, unpublished	N	TF-BCS-Arysta LifeScience

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 6.6.2 /06	Melrose, I.; Portet, M.	2009	Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Italy Bayer S.A.S., Bayer CropScience, Lyon, France TF-BCS-Arysta LifeScience, Report No.: 08-2507, Report includes Trial Nos.: 08-2507-01 08-2507-02 08-2507-03 Edition Number: M-349147-02-1 Date: 2009-06-12 Amended: 2010-01-15 GLP/GEP: yes, unpublished	N	TF-BCS-Arysta LifeScience
KCA 6.1	Moede J.	1990	Stability of propamocarb x HCl in tomatoes during deep freeze storage Generated by: Schering AG, Berlin, Germany Document No: A85300 GLP / GEP No un-published	N	Bayer CropScience
KCA 6.1	Sutton A.L., Charter G.E.	1999	Tomatoes: Stability during deep freeze storage up to 26 months Propamocarb hydrochloride Active substance Generated by: AgrEvo UK Limited; Chesterford Park, England Document No: C003740 GLP / GEP Yes un-published	N	Bayer CropScience
KCA 6.1	Wrede-Rücker A.	1990	Stability of propamocarb x HCl in lettuce during deep freeze storage Generated by: Schering AG, Berlin, Germany Document No: A85303 GLP / GEP No un-published	N	Bayer CropScience
KCA 6.2.1	Rupprecht K. J., Daniel L. E.	2000	Metabolism of [14C]-Propamocarb Hydrochloride in Spinach (Amended Report Replacing Report AV97E519, Document A89868) Generated by: Aventis CropScience Environmental Chemistry Department Pikeville, NorthCarolina, USA Document No: B002936 GLP / GEP Yes un-published	N	Bayer CropScience
KCA 6.2.1	Foertsch A.	1991	The fate of Propamocarb x HCl in potato tubers Generated by: Schering AG, Ecochemistry Berlin, Germany Document No: A85140 GLP / GEP Yes un-published	N	Bayer CropScience
KCA 6.2.1	Foertsch A.	1994	The fate of Propamocarb hydrochloride in potato tubers addendum to report UPSR 14/91 Generated by: Schering AG, Ecochemistry Berlin, Germany Document No: A85141 GLP / GEP Yes un-published	N	Bayer CropScience

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 6.2.1	Rupprecht K.J., Feyerabend M.	1998	Metabolism of propamocarb HCL in cucumber grown in soil and hydroculture propamocarb hydrochloride Generated by: Hoechst Schering AgrEvo GmbH; Ecochemistry Frankfurt Germany Document No: A85149 GLP / GEP Yes un-published	N	Bayer CropScience
KCA 6.2.1	Goodyear, A.	2001	(14C)-Propamocarb: Metabolism in tomatoes; Covance Labs. study # 1669/3-D2149, GLP, unpublished	N	Chimac Agriphar
KCA 6.2.1	Goodyear, A.	2002	(14C)-Propamocarb: Metabolism in lettuce; Covance Labs. study # 1669/6-D2149, GLP, unpublished	N	Chimac Agriphar
KCA 6.2.1	Goodyear, A.	2002	(14C)-Propamocarb: Metabolism in potatoes; Covance Labs. study # 1669/5-D2149, GLP, unpublished	N	Chimac Agriphar
KCA 6.2.1	Cooke J.	2002	(14C)-Propamocarb: Identification of metabolites in Tomato, Potato and lettuce plant extracts; Covance Labs. study # 1669/10-D2149, GLP, unpublished	N	Chimac Agriphar
KCA 6.2.2-6.2.5	Rupprecht K. J., Daniel L.E.	2000	Propamocarb: Ruminant (Cow) - Metabolism, Distribution and Nature of the Residues in Milk and Edible Tissues (Amended Report Replacing Report AV97E521, Document A91204) Generated by: Aventis CropScience Environmental Chemistry Department Pikeville, NorthCarolina, USA Document No: B002935 GLP / GEP Yes un-published	N	Bayer CropScience
KCA 6.1	Moede J.	1990	Stability of propamocarb x HCl in tomatoes during deep freeze storage Generated by: Schering AG, Berlin, Germany Document No: A85300 GLP / GEP No un-published	N	Bayer CropScience
KCA 6.3	Pigeon, O.	2000	Determination of residues of propamocarb in potatoes after treatment with Proplant. Dep. de phytopharmacie, centre de recherche agronomiques de Gembloux, study # 11992; GLP, unpublished (season 1999); final report.	N	Chimac Agriphar
KCA 6.3	Pigeon, O.	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, unpublished (season 2001); final report.	N	Chimac Agriphar
KCA 6.3	Pigeon, O.	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; GLP, unpublished (season 2001); final report.	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
KCA 6.6.1	Meyer B.N.	2000	Uptake of [14C]-Propamocarb Hydrochloride Residues in Soil by Rotational Crops Under Confined Conditions (Amended Report Replacing Report AV96E518, Document A91264) Generated by: Aventis CropScience Environmental Chemistry Department Pikeville, NorthCarolina, USA Document No: B002934 GLP / GEP Yes un-published	N	Bayer CropScience
KCA 6.6.2	Singer S.S.	1999	AT HARVEST PROPAMOCARB HYDROCHLORIDE DERIVED RESIDUES IN ROTATIONAL CROPS FOLLOWING SEQUENTIAL APPLICATIONS OF BANOL® TO BARE SOIL AT THE MAXIMUM PROPOSED RATE AND THE SHORTEST ROTATIONAL INTERVAL, USA, 1997 Generated by: Schering AG, Ecochemistry Berlin, Germany Document No: C003451 GLP / GEP Yes un-published	N	Bayer CropScience
KCA 6.3	Sonder K.H.	2003	Residue behaviour in potatoes European Union (Northern zone) 2002 Propamocarb hydrochloride + AE C638206 water miscible suspension concentrate (SC) 625 g/L + 62.5 g/L Code: AE B066752 04 SC61 A102 Bayer CropScience GmbH, Frankfurt, DEU; Residues and Human Exposure, Frankfurt Bayer CropScience AG, Report No.: 02R286 (C032828), Edition Number: M-232144-01-1 Pages: 1-90 Date: 02.09.2003 GLP, unpublished	N	TF-BCS- Arysta LifeScience
KCA 6.3	Sonder K.-H.	2003	Residue behaviour in potatoes European Union (Southern zone) 2002 Propamocarb hydrochloride + AE C638206 water miscible suspension concentrate (SC) 625 g/L + 62.5 g/L Code: AE B066752 04 SC61 A102 Bayer CropScience GmbH, Frankfurt, DEU; Bayer CropScience AG, Report No.: 02R287 (C032829), Edition Number: M-232146-01-1 Pages: 1-100 Date: 04.09.2003 GLP, unpublished	N	TF-BCS- Arysta LifeScience
KCA 6.3	Sonder K.-H.	2003	Residue behaviour in potatoes European Union (Southern zone) 2002 Propamocarb hydrochloride + AE C638206 water miscible suspension concentrate (SC) 625 g/L + 62.5 g/L Code: AE B066752 04 SC61 A102 Bayer CropScience GmbH, Frankfurt, DEU; Bayer CropScience AG, Report No.: 02R287 (C032829), Edition Number: M-232146-01-1 Pages: 1-100 Date: 04.09.2003 GLP, unpublished	N	KCA 6.3
KCA 6.3	Sonder K.-H.	2003	Residue behaviour in potatoes European Union (Southern zone) 2002 Propamocarb hydrochloride + AE C638206 water miscible suspension concentrate (SC) 625 g/L + 62.5 g/L Code: AE B066752 04 SC61 A102 Bayer CropScience GmbH, Frankfurt, DEU; Bayer CropScience AG, Report No.: 02R287 (C032829), Edition Number: M-232146-01-1 Pages: 1-100 Date: 04.09.2003 GLP, unpublished	N	KCA 6.3

**List of data submitted by the applicant and not relied on**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 6.1	Everitt, S. L.; Charter, G. E	1998	Potatoes tubers: Stability during deep freeze storage up to 26 months propamocarb hydrochloride active substance, Code: AE B066752 AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom TF-BCS-Arysta LifeScience, Report No.: C003683, Report includes Trial Nos.: 067/02/004 Edition Number: M-167991-02-1 EPA MRID No.: 45090807 Date: 1998-07-15 ...Amended: 1999-04-29 GLP/GEP: yes, unpublished	N	TF-BCS- Arysta LifeScience
KCA 6.1	Everitt, S. L.; Charter, G. E	2000	Cabbage: Stability during deep freeze storage up to 39 months active substance Propamocarb hydrochloride Code: AE B066752 Aventis CropScience UK Limited, Residues & Human Exposure, Chesterford Park, United Kingdom TF-BCS-Arysta LifeScience, Report No.: C009293, Report includes Trial Nos.: 067/02/005 Edition Number: M-198306-01-1 Date: 2000-11-06 GLP/GEP: yes, unpublished	N	TF-BCS- Arysta LifeScience
KCA 6.6.2	Gateaud, L.	2010	Statement concerning the reduction of the plant back interval for products containing propamocarb Bayer S.A.S., Bayer CropScience, Lyon, France TF-BCS-Arysta LifeScience, Report No.: M-359448-02-1, Edition Number: M-359448-02-1 Date: 2010-01-18 GLP/GEP: n.a., unpublished	N	TF-BCS- Arysta LifeScience
KCA 6.3.2	Ertus, C.	2021	Mandipropamid – Residue Study on Potato in Northern France, Czech Republic, Germany, Hungary and Poland in 2020 Report No. C0193 Document No. VV-901800 Test Facility Anadiag S.A. GLP Unpublished	No	Syngenta (LoA Globachem)
KCA 6.3.2	Ertus, C.	2021	Mandipropamid – Residue Study on Potato in Southern France, Greece, Italy and Spain in 2020 Report No. C0194 Document No. VV-901817 Test Facility Anadiag S.A. GLP Unpublished	No	Syngenta (LoA Globachem)

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 6.2.2-6.2.5	xxxxxxxxxxxxxx	2010	Metabolism of [14c]-propamocarb hydrochloride in the laying hen xxxxxxxxxxxxxxxxxx Edition Number: <a href="#">M-366633-01-1</a> Date: 2010-04-08 GLP, unpublished	Yes	Bayer CropScience

## **Appendix 2 Detailed evaluation of the additional studies relied upon**

### **A 2.1 Propamocarb-HCl**

#### **A 2.1.1 Stability of residues**

##### **A 2.1.1.1 Stability of residues during storage of samples**

###### **A 2.1.1.1.1 Storage stability of residues in plant products**

No new studies were submitted.

###### **A 2.1.1.1.2 Storage stability of residues in animal products**

No new studies were submitted.

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

#### **A 2.1.2.1 Nature of residue in plants**

##### **A 2.1.2.1.1 Nature of residue in primary crops**

No new studies were submitted.

##### **A 2.1.2.1.2 Nature of residue in rotational crops**

No new studies were submitted.

##### **A 2.1.2.1.3 Nature of residues in processed commodities**

No new studies were submitted.

#### **A 2.1.2.2 Nature of residues in livestock**

No new studies were submitted.

**A 2.1.3 Magnitude of residues in plants**

No new studies were submitted.

**A 2.1.4 Magnitude of residues in livestock**

**A 2.1.4.1 Livestock feeding studies**

No new studies were submitted.

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

**A 2.1.5.1 Distribution of the residue in peel/pulp**

No new studies were submitted.

**A 2.1.5.2 Processing studies on a core set of representative processes**

No new studies were submitted.

**A 2.1.6 Magnitude of residues in representative succeeding crops**

No new studies were submitted.

**A 2.1.7 Other/Special Studies**

No new studies were submitted.

**A 2.2 Mandipropamid**

**A 2.2.1 Stability of residues**

**A 2.2.1.1 Stability of residues during storage of samples**

**A 2.2.1.1.1 Storage stability of residues in plant products**

No new studies were submitted.

#### **A 2.2.1.1.2 Storage stability of residues in animal products**

No new studies were submitted.

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

##### **A 2.2.2.1 Nature of residue in plants**

###### **A 2.2.2.1.1 Nature of residue in primary crops**

No new studies were submitted.

###### **A 2.2.2.1.2 Nature of residue in rotational crops**

No new studies were submitted.

###### **A 2.2.2.1.3 Nature of residues in processed commodities**

No new studies were submitted.

###### **A 2.2.2.2 Nature of residues in livestock**

No new studies were submitted.

#### **A 2.2.3 Magnitude of residues in plants**

<b>Data point</b>	K-CA 6.3.2
<b>Report author</b>	Ertus C.
<b>Report year</b>	2021
<b>Report title</b>	Mandipropamid – Residue Study on Potato in Northern France, Czech Republic, Germany, Hungary and Poland in 2020
<b>Report No</b>	C0193
<b>Document No</b>	VV-901800
<b>Guidelines followed in study</b>	<p>Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009.</p> <p>Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).</p> <p>OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009.</p> <p>OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31.</p> <p>OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164,</p>

	<p>ENV/JM/MONO(2011)50.                  European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000).                  OECD GLP ENV/JM/MONO (99) 22.                  The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9.                  The national GLP requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements.</p>
<b>Deviations from current test guideline</b>	None
<b>Previous evaluation</b>	No, not previously submitted
<b>GLP/Officially recognised testing facilities<sup>1,2</sup></b>	Yes, conducted under GLP/Officially recognised testing facilities with the exception of weather and climatic data
<b>Acceptability/Reliability</b>	Yes

<sup>1</sup> See Art.3 of Annex of Regulation No 283/2013 and 284/2013

<sup>2</sup> RMS shall check that the GLP statement has been properly signed in the study report, that the study results are properly reported in accordance with GLP standards and following the relevant guidance by OECD on the review of the GLP status of non-clinical safety data (currently under development).

Field Trials, Crop Residue (Summary): Mandipropamid – Residue Study on Potato in Northern France, Czech Republic, Germany, Hungary and Poland in 2020			
Active Substance (common name):	Mandipropamid	Commercial Product (name):	Revus
Crop/Crop Group:	Potato	Producer of commercial product:	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	Indoor/Glasshouse/Outdoor:	Field
Country:	HUNGARY, POLAND, FRANCE, GERMANY, CZECHIA	Other active substance in the formulation (common name and content):	None
Content of active substance (g/kg or g/L):	A12946B: 250 g/L	Residues calculated as:	mg/kg
Formulation (e.g. WP):	A12946B SC		
Analytical Method:	Mandipropamid (Tubers) GRM001.07B; 0.01 mg/kg SYN500003 (Tubers) GRM001.01B; 0.005 mg/kg		
Recovery data:	Mandipropamid Tubers Mean = 99% RSD = 8% (n = 4 in 0.01 - 0.1 spiking range) SYN500003 Tubers Mean = 81% RSD = 9% (n = 4 in 0.005 - 0.05 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering g 3. Harvest (b)	(4) Method of Treatmen t	(5) Application rate per treatment			(6) Date of treatment(s ) or no of treatment(s ) and last date  Application Interval (days) (c)	(7) Growth Stage at Treatmen t	(8) Portion Analyze d	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Detail s (e)
				Concentratio n	Water	Rate Formulatio n (Additive Type, Rate)				Mandipropa mid (mg/kg)	SYN500003 (mg/kg)			
C0193 C0193 AN1 FRANCE (Europe North) (67240)	Potato / Adora	1.10 Mar 2020 2. – 3. –	-	-	-	-	-	-	Tubers	< 0.01	< 0.005	3	18 Jun 2020/1 8 Jun 2020	Field  SP (max days): 170
	Potato / Adora	1.10 Mar 2020 2. – 3. –	Foliar Foliar Foliar	-	390 L/ha 400 L/ha 413.3 L/ha	146.25 g ai/ha 150 g ai/ha 155 g ai/ha  A12946B  (-)	02 Jun 2020 08 Jun 2020 15 Jun 2020  (6, 7)	BBCH 46- 47 BBCH 48- 48 BBCH 48- 49	Tubers  Tubers  Tubers  Tubers  Tubers	< 0.01  < 0.01  ≤ 0.01  < 0.01  < 0.01	< 0.005  < 0.005  ≤ 0.005  < 0.005  < 0.005	0*  0  3  7  14  21	15 Jun 2020 15 Jun 2020 18 Jun 2020 22 Jun 2020 29 Jun 2020 06 Jul 2020	Field  SP (max days): 173

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatmen t	(5) Application rate per treatment			(6) Date of treatment(s ) or no of treatment(s ) and last date  Application Interval (days) (c)	(7) Growth Stage at Treatmen t	(8) Portion Analyze d	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Detail s (e)
				Concentratio n	Water	Rate Formulatio n (Additive Type, Rate)				Mandipropa mid (mg/kg)	SYN500003 (mg/kg)			
C0193 C0193 BM1 FRANCE (Europe North) (72800)	Potato / Charlotte	1.28 Apr 2020 2. – 3. –	-	-	-	-	-	-	Tubers	< 0.01	< 0.005	3	20 Jul 2020/ -	Field  SP (max days): 138
	Potato / Charlotte	1.28 Apr 2020 2. – 3. –	Foliar Foliar Foliar	-	254.17 7 L/ha 233.33 L/ha 233.33 L/ha	152.5 g ai/ha 140 g ai/ha 140 g ai/ha  A12946B  (-)	03 Jul 2020 09 Jul 2020 17 Jul 2020  (6, 8)	BBCH 45- 47 BBCH 45- 48 BBCH 49-	Tubers	≤ 0.01	≤ 0.005	3	20 Jul 2020	Field  SP (max days): 138
C0193 C0193 BW1 GERMAN Y (Europe North) (79206)	Potato / Colomba	1.18 Mar 2020 2. – 3. –	-	-	-	-	-	-	Tubers	< 0.01	< 0.005	3	13 Jul 2020	Field  SP (max days): 145
	Potato / Colomba	1.18 Mar 2020 2. – 3. –	Foliar Foliar Foliar	-	400 L/ha 386.67 L/ha 400 L/ha	150 g ai/ha 145 g ai/ha 150 g ai/ha  A12946B  (-)	25 Jun 2020 03 Jul 2020 10 Jul 2020  (8, 7)	BBCH 47- 47 BBCH 48- 48 BBCH 49- 49	Tubers	≤ 0.01	≤ 0.005	3	13 Jul 2020	Field  SP (max days): 145
C0193 C0193 CZ1 CZECHIA (Europe North) (51601)	Potato / LAURA	1.15 Apr 2020 2. – 3. –	-	-	-	-	-	-	Tubers	< 0.01	< 0.005	3	24 Aug 2020	Field  SP (max days): 103
	Potato / LAURA	1.15 Apr 2020 2. – 3. –	Foliar Foliar Foliar	-	306.67 L/ha 316.67 L/ha	153.33 g ai/ha 158.33 g ai/ha	06 Aug 2020 13 Aug 2020 21 Aug 2020	BBCH 46- 46 BBCH 46- 47	Tubers  Tubers	< 0.01  < 0.01	< 0.005  < 0.005	0*  0	21 Aug 2020  21 Aug 2020	Field  SP (max

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatmen t	(5) Application rate per treatment			(6) Date of treatment(s ) or no of treatment(s ) and last date  Application Interval (days) (c) (7, 8)	(7) Growth Stage at Treatmen t	(8) Portion Analyze d	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Detail s (e)
				Concentratio n	Water	Rate Formulatio n (Additive Type, Rate)				Mandipropa mid (mg/kg)	SYN500003 (mg/kg)			
					293.33 L/ha	146.67 g ai/ha  A12946B  (-)		BBCH 47- 49	Tubers	≤ 0.01	≤ 0.005	3	24 Aug 2020	days): 106
								Tubers	< 0.01	< 0.005	7	28 Aug 2020		
								Tubers	< 0.01	< 0.005	13	03 Sep 2020		
								Tubers	< 0.01	< 0.005	21	11 Sep 2020		
C0193 C0193 HU1 HUNGARY (Europe North) (H-2921)	Potato / Red Scarlet	1.02 Feb 2020 2. – 3. –	-	-	-	-  (-)	-  (-)	-	Tubers	< 0.01	< 0.005	3	29 Jun 2020	Field  SP (max days): 159
	Potato / Red Scarlet	1.02 Feb 2020 2. – 3. –	Foliar Foliar Foliar	-	306.67 L/ha 281.67 L/ha 283.33 L/ha	153.33 g ai/ha 140.83 g ai/ha 141.67 g ai/ha  A12946B  (-)	11 Jun 2020 19 Jun 2020 26 Jun 2020  (8, 7)	BBCH 42- 43 BBCH 44- 45 BBCH 49- 49	Tubers	< 0.01	< 0.005	0*	26 Jun 2020	Field  SP (max days): 162
								Tubers	< 0.01	< 0.005	0	26 Jun 2020		
								Tubers	≤ 0.01	≤ 0.005	3	29 Jun 2020		
								Tubers	< 0.01	< 0.005	6	02 Jul 2020		
								Tubers	< 0.01	< 0.005	13	09 Jul 2020		
									Tubers	< 0.01	< 0.005	20	16 Jul 2020	
C0193 C0193 MA1 FRANCE (Europe North)	Potato / bernadette	1.11 Apr 2020 2. – 3. –	-	-	-	-  (-)	-  (-)	-	Tubers	< 0.01	< 0.005	3	04 Aug 2020/	Field  SP (max days): 123

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowerin g 3. Harvest (b)	(4) Method of Treatmen t	(5) Application rate per treatment			(6) Date of treatment(s ) or no of treatment(s ) and last date  Application Interval (days) (c)	(7) Growth Stage at Treatmen t	(8) Portion Analyze d	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Detail s (e)	
				Concentratio n	Water	Rate Formulatio n (Additive Type, Rate)				Mandipropa mid (mg/kg)	SYN500003 (mg/kg)				
(57810)	Potato / bernadette	1.11 Apr 2020 2. – 3. –	Foliar Foliar Foliar	-	514.29 L/ha 457.14 L/ha 466.67 L/ha	154.29 g ai/ha 137.14 g ai/ha 140 g ai/ha  A12946B  (-)	17 Jul 2020 25 Jul 2020 01 Aug 2020  (8, 7)	BBCH 44- 44 BBCH 48- 48 BBCH 49- 49	Tubers	≤ 0.01	≤ 0.005	3	04 Aug 2020	Field  SP (max days): 123	
C0193 C0193 ND1 FRANCE (Europe North) (62136)	Potato / ARTEMIS	1.08 Apr 2020 2. – 3. –	-	-	-	-  (-)	-  (-)	-	Tubers	< 0.01	< 0.005	3	14 Jul 2020	Field  SP (max days): 144	
	Potato / ARTEMIS	1.08 Apr 2020 2. – 3. –	Foliar Foliar Foliar	-	-	293.33 L/ha 316.67 L/ha 300 L/ha	146.67 g ai/ha 158.33 g ai/ha 150 g ai/ha  A12946B  (-)	25 Jun 2020 03 Jul 2020 11 Jul 2020  (8, 8)	BBCH 41- 41 BBCH 42- 42 BBCH 47- 47	Tubers	< 0.01	< 0.005	0*	11 Jul 2020	Field  SP (max days): 147
										Tubers	< 0.01	< 0.005	0	11 Jul 2020	
										Tubers	≤ 0.01	≤ 0.005	3	14 Jul 2020	
										Tubers	< 0.01	< 0.005	6	17 Jul 2020	
										Tubers	< 0.01	< 0.005	13	24 Jul 2020	
Tubers	< 0.01	< 0.005	20	31 Jul 2020											
C0193 C0193 PL1 POLAND (Europe North) (99-423)	Potato / TAJFUN	1.17 Apr 2020 2. – 3. –	-	-	-	-  (-)	-  (-)	-	Tubers	< 0.01	< 0.005	3	31 Aug 2020	Field  SP (max days): 96	
	Potato / TAJFUN	1.17 Apr 2020	Foliar Foliar	-	387.5 L/ha	145.31 g ai/ha	13 Aug 2020 20 Aug 2020	BBCH 47- 48	Tubers	< 0.01	< 0.005	0*	28 Aug 2020	Field	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatmen t	(5) Application rate per treatment			(6) Date of treatment(s ) or no of treatment(s ) and last date  Application Interval (days) (c)	(7) Growth Stage at Treatmen t	(8) Portion Analyze d	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Detail s (e)
				Concentratio n	Water	Rate Formulatio n (Additive Type, Rate)				Mandipropa mid (mg/kg)	SYN500003 (mg/kg)			
		2. – 3. –	Foliar		395 L/ha 402.5 L/ha	148.135 g ai/ha 150.94 g ai/ha  A12946B  (-)	28 Aug 2020  (7, 8)	BBCH 48- 48 BBCH 48- 49	Tubers  Tubers  Tubers  Tubers	< 0.01  ≤ 0.01  < 0.01  < 0.01	< 0.005  ≤ 0.005  < 0.005  < 0.005	0  3  7  13  20	28 Aug 2020  31 Aug 2020  04 Sep 2020  10 Sep 2020  17 Sep 2020	SP (max days): 99
C0193 C0193 PL2 POLAND (Europe North) (99-205)	Potato / MICHALIN A	1.20 Mar 2020 2. – 3. –	-	-	-	-  (-)	-  (-)	-	Tubers	< 0.01	< 0.005	3	24 Aug 2020	Field  SP (max days): 103
	Potato / MICHALIN A	1.20 Mar 2020 2. – 3. –	Foliar Foliar Foliar	-	428.33 L/ha 413.33 L/ha 416.67 L/ha	160.63 g ai/ha 155 g ai/ha 156.25 g ai/ha  A12946B  (-)	06 Aug 2020 14 Aug 2020 21 Aug 2020  (8, 7)	BBCH 46- 47 BBCH 47- 48 BBCH 48- 49	Tubers	≤ 0.01	≤ 0.005	3	24 Aug 2020	Field  SP (max days): 103

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of 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.

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

<b>Data point</b>	K-CA 6.3.2
<b>Report author</b>	Ertus C.
<b>Report year</b>	2021
<b>Report title</b>	Mandipropamid – Residue Study on Potato in Southern France, Greece, Italy and Spain in 2020
<b>Report No</b>	C0194
<b>Document No</b>	VV-901817
<b>Guidelines followed in study</b>	<p>Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009.</p> <p>Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).</p> <p>OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009.</p> <p>OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31.</p> <p>OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50.</p> <p>European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000).</p> <p>OECD GLP ENV/JM/MONO (99) 22.</p> <p>The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9.</p> <p>The national GLP requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements.</p>
<b>Deviations from current test guideline</b>	None
<b>Previous evaluation</b>	No, not previously submitted
<b>GLP/Officially recognised testing facilities<sup>1,2</sup></b>	Yes, conducted under GLP/Officially recognised testing facilities with the exception of weather and climatic data
<b>Acceptability/Reliability</b>	Yes

<sup>1</sup> See Art.3 of Annex of Regulation No 283/2013 and 284/2013

<sup>2</sup> RMS shall check that the GLP statement has been properly signed in the study report, that the study results are properly reported in accordance with GLP standards and following the relevant guidance by OECD on the review of the GLP status of non-clinical safety data (currently under development).

Field Trials, Crop Residue (Summary): Mandipropamid – Residue Study on Potato in Southern France, Greece, Italy and Spain in 2020			
Active Substance (common name):	Mandipropamid	Commercial Product (name):	Revus
Crop/Crop Group:	Potato	Producer of commercial product:	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	Indoor/Glasshouse/Outdoor:	Field
Country:	FRANCE, GREECE, ITALY, SPAIN	Other active substance in the formulation (common name and content):	None
Content of active substance (g/kg or g/L):	A12946B: 250 g/L	Residues calculated as:	mg/kg
Formulation (e.g. WP):	A12946B SC		
Analytical Method:	Mandipropamid (Tubers) GRM001.07B; 0.01 mg/kg SYN500003 (Tubers) GRM001.01B; 0.005 mg/kg		
Recovery data:	Mandipropamid Tubers Mean = 89% RSD = 8% (n = 4 in 0.01017 - 0.1017 spiking range) SYN500003 Tubers Mean = 79% RSD = 5% (n = 4 in 0.00529 - 0.05285 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Mandipropamid (mg/kg)	SYN500003 (mg/kg)			
C0194 C0194 AV1 FRANCE (Europe South) (30300)	Potato / Red Pontiac	1.18 May 2020 2. – 3. –	-	-	-	-	-	-	Tubers	< 0.01	< 0.005	3	11 Sep 2020	Field  SP (max days): 92
	Potato / Red Pontiac	1.18 May 2020 2. – 3. –	Foliar Foliar Foliar	-	290 L/ha 316.67 L/ha 306.67 L/ha	145 g ai/ha 158.33 g ai/ha 153.33 g ai/ha  A12946B  (-)	25 Aug 2020 31 Aug 2020 08 Sep 2020  (6, 8)	BBCH 39-39 BBCH 39-39 BBCH 39-49	Tubers	≤ 0.01	≤ 0.005	3	11 Sep 2020	Field  SP (max days): 92
C0194 C0194 BA1 ITALY (Europe)	Potato / Bellini	1.27 Mar 2020 2. – 3. –	-	-	-	-	-	-	Tubers	< 0.01	< 0.005	3	18 Jul 2020	Field  SP (max days): 147

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Mandipropamid (mg/kg)	SYN500003 (mg/kg)			
South) (70043)	Potato / Bellini	1.27 Mar 2020 2. – 3. –	Foliar Foliar Foliar	-	422.22 L/ha 383.33 L/ha 416.67 L/ha	158.33 g ai/ha 143.75 g ai/ha 156.25 g ai/ha  A12946B (-)	01 Jul 2020 08 Jul 2020 15 Jul 2020  (7, 7)	BBCH 48 BBCH 48 BBCH 49	Tubers	≤ 0.01	≤ 0.005	3	18 Jul 2020	Field  SP (max days): 147
C0194 C0194 EF1 FRANCE (Europe South) (47330)	Potato / SPUNTA	1.22 May 2020 2. – 3. –	-	-	-	- (-)	- (-)	-	Tubers	< 0.01	< 0.005	3	10 Sep 2020	Field  SP (max days): 93
C0194 C0194 ES1 SPAIN (Europe South) (17469)	Potato / Agria	1.13 May 2020 2. – 3. –	Foliar Foliar Foliar	-	401.67 L/ha 408.33 L/ha 396.67 L/ha	150.635 g ai/ha 153.135 g ai/ha 148.75 g ai/ha	21 Jul 2020 28 Jul 2020 04 Aug 2020  (7, 7)	BBCH 43-69 BBCH 45-69 BBCH 47-69	Tubers	< 0.01	< 0.005	0*	04 Aug 2020	Field
									Tubers	< 0.01	< 0.005	0	04 Aug 2020	SP (max days): 130
									Tubers	≤ 0.01	≤ 0.005	3	07 Aug 2020	
									Tubers	< 0.01	< 0.005	7	14 Sep 2020	
									Tubers	< 0.01	< 0.005	14	21 Sep 2020	
								Tubers	< 0.01	< 0.005	21	28 Sep 2020		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Mandipropamid (mg/kg)	SYN500003 (mg/kg)			
						A12946B (-)			Tubers	< 0.01	< 0.005	6	10 Aug 2020	
									Tubers	< 0.01	< 0.005	14	18 Aug 2020	
									Tubers	< 0.01	< 0.005	20	24 Aug 2020	
C0194 C0194 GR1 GREECE (Europe South) (50100)	Potato / SPUNTA	1.28 Apr 2020 2. - 3. -	-	-	-	- (-)	-	-	Tubers	< 0.01	< 0.005	3	14 Aug 2020	Field SP (max days): 120
	Potato / SPUNTA	1.28 Apr 2020 2. - 3. -	Foliar Foliar Foliar	-	416.67 L/ha 400 L/ha 413.33 L/ha	156.25 g ai/ha 150 g ai/ha 155 g ai/ha A12946B (-)	28 Jul 2020 04 Aug 2020 11 Aug 2020 (7, 7)	BBCH 45-45 BBCH 47-47 BBCH 48-49	Tubers	< 0.01	< 0.005	0*	11 Aug 2020	Field SP (max days): 123
									Tubers	< 0.01	< 0.005	0	11 Aug 2020	
									Tubers	≤ 0.01	≤ 0.005	3	14 Aug 2020	
									Tubers	< 0.01	< 0.005	6	17 Aug 2020	
									Tubers	< 0.01	< 0.005	13	24 Aug 2020	
Tubers	< 0.01	< 0.005	20	31 Aug 2020										
C0194 C0194 IT1 ITALY (Europe South) (27050)	Potato / Hermes	1.21 Mar 2020 2. - 3. -	-	-	-	- (-)	-	-	Tubers	< 0.01	< 0.005	3	31 Jul 2020	Field SP (max days): 134
	Potato / Hermes	1.21 Mar 2020 2. - 3. -	Foliar Foliar Foliar	-	516.67 L/ha 510 L/ha 533.33 L/ha	155 g ai/ha 153 g ai/ha 160 g ai/ha A12946B (-)	14 Jul 2020 20 Jul 2020 28 Jul 2020 (6, 8)	BBCH 45 BBCH 47 BBCH 47-49	Tubers	< 0.01	< 0.005	0*	28 Jul 2020	Field SP (max days): 137
									Tubers	< 0.01	< 0.005	0	28 Jul 2020	
									Tubers	≤ 0.01	≤ 0.005	3	31 Jul 2020	
									Tubers	< 0.01	< 0.005	6	03 Aug 2020	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Mandipropamid (mg/kg)	SYN500003 (mg/kg)			
									Tubers	< 0.01	< 0.005	13	10 Aug 2020	
									Tubers	< 0.01	< 0.005	20	17 Aug 2020	
C0194 C0194 KR1 GREECE (Europe South) (70200)	Potato / SPUNTA	1.20 Feb 2020 2. – 3. –	-	-	-	-	-	-	Tubers	< 0.01	< 0.005	3	19 Jun 2020	Field SP (max days): 176
	Potato / SPUNTA	1.20 Feb 2020 2. – 3. –	Foliar Foliar Foliar	-	530 L/ha 536.67 L/ha 513.33 L/ha	159 g ai/ha 161 g ai/ha 154 g ai/ha A12946B	02 Jun 2020 09 Jun 2020 16 Jun 2020 (7, 7)	BBCH 45-45 BBCH 46-46 BBCH 48-49	Tubers	≤ 0.01	≤ 0.005	3	19 Jun 2020	Field SP (max days): 176
C0194 C0194 SW1 SPAIN (Europe South) (41520)	Potato / Condor	1.15 Feb 2020 2. – 3. –	-	-	-	-	-	-	Tubers	< 0.01	< 0.005	3	15 Jun 2020	Field SP (max days): 180
	Potato / Condor	1.15 Feb 2020 2. – 3. –	Foliar Foliar Foliar	-	536.11 L/ha 511.11 L/ha 533.33 L/ha	160.83 g ai/ha 153.33 g ai/ha 160 g ai/ha A12946B	29 May 2020 05 Jun 2020 12 Jun 2020 (7, 7)	BBCH 46-47 BBCH 47-48 BBCH 48-49	Tubers	≤ 0.01	≤ 0.005	3	15 Jun 2020	Field SP (max days): 180
C0194 C0194 TL1 FRANCE (Europe South) (31330)	Potato / Agata	1.17 Apr 2020 2. – 3. –	-	-	-	-	-	-	Tubers	< 0.01	< 0.005	3	24 Jul 2020	Field SP (max days): 141
	Potato / Agata	1.17 Apr 2020	Foliar Foliar	-	423.33 L/ha	158.75 g ai/ha 153.75 g ai/ha	07 Jul 2020 15 Jul 2020	BBCH 59-59	Tubers	< 0.01	< 0.005	0*	21 Jul 2020	Field

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Mandipropamid (mg/kg)	SYN500003 (mg/kg)			
		2. – 3. –	Foliar		410 L/ha 415 L/ha	155.63 g ai/ha  A12946B  ( - )	21 Jul 2020  (8, 6)	BBCH 69-69 BBCH 91-95	Tubers	< 0.01	< 0.005	0	21 Jul 2020	SP (max days): 144
								Tubers	≤ 0.01	≤ 0.005	3	24 Jul 2020		
								Tubers	< 0.01	< 0.005	7	28 Jul 2020		
								Tubers	< 0.01	< 0.005	13	03 Aug 2020		
								Tubers	< 0.01	< 0.005	20	10 Aug 2020		

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of 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.

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

**A 2.2.4 Magnitude of residues in livestock**

**A 2.2.4.1 Livestock feeding studies**

No new studies were submitted.

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

**A 2.2.5.1 Distribution of the residue in peel/pulp**

No new studies were submitted.

**A 2.2.5.2 Processing studies on a core set of representative processes**

No new studies were submitted.

**A 2.2.6 Magnitude of residues in representative succeeding crops**

No new studies were submitted.

**A 2.2.7 Other/Special Studies**

No new studies were submitted.

## Appendix 3 Pesticide Residue Intake Model (PRIMO)

### A 3.1 TMDI calculations

#### Propamocarb-HCl:



Propamocarb-HCl			
LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw/day):	0.29	ARID (mg/kg bw):	1
Source of ADI:	EFSA	Source of ARID:	EFSA
Year of evaluation:	2006	Year of evaluation:	2006

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

Chronic risk assessment: JMPR methodology (IED/TMDI)											
No of diets exceeding the ADI: ---											
TMDI(NED) calculation (based on average food consumption)	Calculated exposure (% of ADI)		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)	commodities not under assessment (in % of ADI)
	MS Diet										
	21%	NL toddler	60.43	10%	Spinaches	2%	Cauliflowers	2%	Escaroles/broad-leaved endives	0.1%	
	15%	GEMS/Food G06	44.79	5%	Tomatoes	2%	Watermelons	1%	Lettuces	0.0%	
	14%	SE general	39.18	6%	Lettuces	1%	Chinese cabbages/pe-tsai	1%	Tomatoes	0.0%	
	13%	GEMS/Food G10	37.41	4%	Lettuces	2%	Tomatoes	1%	Chinese cabbages/pe-tsai	0.0%	
	12%	ES adult	35.81	7%	Lettuces	1%	Chards/beet leaves	1%	Tomatoes	0.0%	
	12%	IT adult	34.19	5%	Lettuces	2%	Tomatoes	1%	Spinaches	0.0%	
	11%	ES child	32.95	6%	Lettuces	1%	Tomatoes	1%	Spinaches	0.0%	
	11%	DE child	32.05	3%	Spinaches	1%	Tomatoes	1%	Lettuces	0.1%	
	10%	IT toddler	28.98	4%	Lettuces	2%	Tomatoes	0.8%	Chards/beet leaves	0.0%	
	10%	NL child	27.97	3%	Spinaches	1%	Lettuces	0.8%	Tomatoes	0.1%	
	10%	GEMS/Food G08	27.59	3%	Lettuces	2%	Tomatoes	0.5%	Leeks	0.0%	
	9%	IE adult	26.23	2%	Spinaches	1%	Melons	1%	Lettuces	0.1%	
	9%	FR infant	25.89	4%	Spinaches	2%	Leeks	0.9%	Cauliflowers	0.0%	
	9%	GEMS/Food G07	25.71	3%	Lettuces	1%	Tomatoes	0.5%	Spinaches	0.0%	
	9%	NL general	25.23	2%	Spinaches	1%	Lettuces	0.9%	Leeks	0.0%	
	9%	GEMS/Food G11	25.04	2%	Spinaches	1%	Spinaches	1%	Tomatoes	0.1%	
	8%	FR toddler 2-3 yr	22.78	2%	Spinaches	2%	Leeks	0.8%	Cauliflowers	0.0%	
	8%	GEMS/Food G15	22.20	2%	Tomatoes	2%	Lettuces	0.8%	Watermelons	0.0%	
	8%	DK child	22.17	3%	Cucumbers	2%	Lettuces	0.7%	Tomatoes	0.0%	
	7%	FR child 3-15 yr	21.73	1%	Spinaches	1%	Leeks	1%	Tomatoes	0.0%	
	7%	RO general	18.95	3%	Tomatoes	0.8%	Watermelons	0.5%	Onions	0.0%	
	6%	DE women 14-50 yr	18.19	2%	Lettuces	1%	Tomatoes	0.7%	Spinaches	0.0%	
	6%	FI 3 yr	17.75	2%	Cucumbers	0.9%	Spinaches	0.8%	Tomatoes	0.0%	
	6%	DE general	16.55	1%	Lettuces	0.9%	Tomatoes	0.6%	Spinaches	0.0%	
	6%	FI 6 yr	16.10	1%	Cucumbers	1%	Lettuces	0.8%	Spinaches	0.0%	
	5%	PT general	15.47	1%	Lettuces	1%	Kales	1%	Tomatoes	0.0%	
	5%	UK vegetarian	15.02	2%	Lettuces	0.9%	Tomatoes	0.5%	Spinaches	0.0%	
	5%	FR adult	13.18	0.9%	Leeks	0.7%	Spinaches	0.6%	Tomatoes	0.0%	
	4%	FI adult	12.80	2%	Lettuces	0.8%	Tomatoes	0.6%	Cucumbers	0.1%	
	4%	DK adult	10.93	1%	Lettuces	0.7%	Tomatoes	0.4%	Cucumbers	0.0%	
	4%	UK adult	10.53	2%	Lettuces	0.6%	Tomatoes	0.3%	Spinaches	0.0%	
	3%	PL general	9.97	1%	Tomatoes	0.4%	Potatoes	0.3%	Cauliflowers	0.0%	
	3%	UK toddler	9.62	0.8%	Tomatoes	0.4%	Cauliflowers	0.4%	Cauliflowers	0.0%	
	3%	LT adult	8.97	0.9%	Lettuces	0.9%	Tomatoes	0.7%	Cucumbers	0.0%	
	3%	UK infant	8.45	0.9%	Cauliflowers	0.6%	Milk: Cattle	0.5%	Tomatoes	0.0%	
	0.7%	IE child	1.96	0.1%	Lettuces	0.1%	Cauliflowers	0.1%	Tomatoes	0.0%	

**Conclusion:**  
 The estimated long-term dietary intake (TMDI(NED)/IED) was below the ADI.  
 The long-term intake of residues of Propamocarb-HCl is unlikely to present a public health concern.

**Mandipropamid:**



Mandipropamid			
LOQs (mg/kg) range from:		0.01	to: 0.05
Toxicological reference values			
ADI (mg/kg bw/day):		0.15	ARfD (mg/kg bw): n.n.
Source of ADI:		EFSA	Source of ARfD: EFSA
Year of evaluation:		2012	Year of evaluation: 2012

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 (IED/TMDI)**

			No of diets exceeding the ADI : ---				Exposure resulting from				
TMDI/NEDI 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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
		9%	NL toddler	13.17	2%	Spinaches	2%	Milk: Cattle	1.0%	Kales	0.2%
	8%	SE general	12.15	3%	Chinese cabbages/pe-tsai	1%	Head cabbages	0.8%	Kales	0.0%	0.4%
	8%	IE adult	11.76	3%	Other leafy brassica	2%	Celeries	0.4%	Spinaches	0.1%	0.2%
	7%	GEMS/Food G10	10.01	3%	Chinese cabbages/pe-tsai	0.8%	Head cabbages	0.7%	Celeries	0.1%	0.2%
	7%	IT adult	10.01	3%	Other lettuce and other salad plants	1%	Other spinach and similar	0.7%	Lettuces	0.0%	0.0%
	6%	GEMS/Food G11	9.13	4%	Celeries	0.3%	Spinaches	0.3%	Lamb's lettuce/corn salads	0.1%	0.3%
	5%	IT toddler	7.86	2%	Other lettuce and other salad plants	0.9%	Other spinach and similar	0.5%	Lettuces	0.0%	0.0%
	5%	GEMS/Food G06	7.83	0.8%	Tomatoes	0.6%	Celeries	0.6%	Kales	0.1%	0.1%
	5%	FR child 3 15 yr	7.42	2%	Other lettuce and other salad plants	0.6%	Milk: Cattle	0.5%	Celeries	0.1%	0.7%
	5%	RO general	7.20	3%	Head cabbages	0.4%	Tomatoes	0.4%	Wine grapes	0.0%	0.4%
	5%	GEMS/Food G15	7.15	2%	Head cabbages	1%	Celeries	0.4%	Sweet peppers/bell peppers	0.1%	0.3%
	5%	GEMS/Food G08	6.98	0.9%	Head cabbages	0.9%	Watercress	0.6%	Celeries	0.1%	0.2%
	5%	DE child	6.92	0.7%	Spinaches	0.6%	Milk: Cattle	0.3%	Table grapes	0.2%	0.6%
	5%	PT general	6.77	3%	Kales	0.6%	Wine grapes	0.2%	Tomatoes	0.0%	0.1%
	4%	FR adult	6.73	2%	Other lettuce and other salad plants	0.5%	Wine grapes	0.3%	Celeries	0.0%	0.2%
	4%	NL child	6.71	1%	Kales	0.9%	Spinaches	0.7%	Milk: Cattle	0.1%	0.8%
	4%	GEMS/Food G07	6.46	2%	Celeries	0.4%	Lettuces	0.3%	Wine grapes	0.1%	0.3%
	4%	NL general	5.51	1%	Kales	0.5%	Spinaches	0.4%	Head cabbages	0.0%	0.3%
	4%	FR toddler 2 3 yr	5.35	0.8%	Milk: Cattle	0.5%	Spinaches	0.5%	Beans (with pods)	0.1%	0.9%
	3%	FR infant	4.05	0.9%	Spinaches	0.5%	Milk: Cattle	0.4%	Celeries	0.0%	0.5%
	3%	ES child	3.91	0.8%	Lettuces	0.4%	Milk: Cattle	0.3%	Spinaches	0.0%	0.4%
	3%	ES adult	3.79	1.0%	Lettuces	0.3%	Spinaches	0.2%	Tomatoes	0.0%	0.2%
	2%	DE general	3.60	0.3%	Milk: Cattle	0.3%	Head cabbages	0.2%	Kales	0.1%	0.4%
	2%	DE women 14-50 yr	3.44	0.4%	Milk: Cattle	0.3%	Head cabbages	0.2%	Lettuces	0.1%	0.4%
	2%	UK vegetarian	3.24	0.5%	Celeries	0.3%	Lettuces	0.2%	Head cabbages	0.0%	0.1%
	2%	UK infant	3.23	1%	Milk: Cattle	0.3%	Celeries	0.2%	Head cabbages	0.0%	1%
	2%	UK toddler	3.08	0.6%	Milk: Cattle	0.5%	Celeries	0.2%	Head cabbages	0.0%	0.7%
	2%	DK child	2.58	0.4%	Milk: Cattle	0.3%	Lettuces	0.2%	Chinese cabbages/pe-tsai	0.0%	0.4%
	2%	PL general	2.44	0.7%	Head cabbages	0.3%	Chinese cabbages/pe-tsai	0.2%	Tomatoes	0.0%	0.0%
	2%	UK adult	2.28	0.3%	Wine grapes	0.2%	Lettuces	0.2%	Celeries	0.0%	0.1%
	2%	FI 6 yr	2.26	0.5%	Chinese cabbages/pe-tsai	0.2%	Spinaches	0.2%	Head cabbages	0.0%	0.1%
	1%	FI 3 yr	2.14	0.3%	Chinese cabbages/pe-tsai	0.2%	Spinaches	0.1%	Head cabbages	0.0%	0.1%
	1%	FI adult	2.10	0.3%	Chinese cabbages/pe-tsai	0.3%	Lettuces	0.2%	Head cabbages	0.2%	0.0%
	1%	DK adult	2.02	0.2%	Wine grapes	0.2%	Head cabbages	0.2%	Lettuces	0.0%	0.2%
	1%	LT adult	1.98	0.8%	Head cabbages	0.1%	Tomatoes	0.1%	Lettuces	0.0%	0.2%
	0.4%	IE child	0.65	0.1%	Milk: Cattle	0.1%	Celeries	0.1%	Broccoli	0.0%	0.1%

**Conclusion:**  
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.  
The long-term intake of residues of Mandipropamid is unlikely to present a public health concern.

**A 3.2 IESTI calculations - Raw commodities**

**Propamocarb-HCl:**

<b>Unprocessed commodities</b>	<b>Results for children</b>				<b>Results for adults</b>			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	<b>IESTI</b>				<b>IESTI</b>			
	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)
	0.5%	Milk: Cattle	0.01 / 0.04	5.3	0.2%	Milk: Cattle	0.01 / 0.04	1.6
	0.2%	Bovine: Liver	0.2 / 0.22	1.8	0.09%	Bovine: Liver	0.2 / 0.22	0.88
	0.2%	Potatoes	0.3 / 0.01	1.5	0.07%	Bovine: Edible offals (other	0.2 / 0.2	0.66
	0.1%	Bovine: Edible offals (other	0.2 / 0.2	1.5	0.06%	Sheep: Liver	0.2 / 0.2	0.56
	0.06%	Eggs: Chicken	0.05 / 0.05	0.62	0.04%	Swine: Kidney	0.02 / 0.2	0.44
0.05%	Poultry: Muscle/meat	0.02 / 0.03	0.51	0.04%	Poultry: Muscle	0.02 / 0.03	0.35	
0.03%	Swine: Edible offals (other	0.1 / 0.1	0.30	0.03%	Potatoes	0.3 / 0.01	0.30	
0.03%	Swine: Kidney	0.02 / 0.2	0.25	0.03%	Swine: Edible offals (other	0.1 / 0.1	0.26	
0.02%	Swine: Muscle/meat	0.01 / 0.02	0.24	0.02%	Eggs: Chicken	0.05 / 0.05	0.21	
0.02%	Milk: Goat	0.01 / 0.01	0.24	0.02%	Poultry: Liver	0.05 / 0.04	0.19	
0.02%	Bovine: Kidney	0.05 / 0.06	0.23	0.02%	Milk: Goat	0.01 / 0.01	0.18	
0.02%	Honey and other apiculture	0.05 / 0.05	0.18	0.02%	Milk: Sheep	0.01 / 0.01	0.15	
0.01%	Swine: Liver	0.1 / 0.09	0.11	0.01%	Sheep: Edible offals (other	0.2 / 0.2	0.14	
0.01%	Bovine: Muscle/meat	0.01 / 0.01	0.07	0.01%	Swine: Liver	0.1 / 0.09	0.13	
0.01%	Other farmed animals:	0.01 / 0.01	0.07	0.01%	Bovine: Kidney	0.05 / 0.06	0.13	
Expand/collapse list								
<b>Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)</b>								

**Mandipropamid: not relevant (no ARfD)**

**A 3.3 IESTI calculations - Processed commodities**

**Propamocarb-HCl:**

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	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)	
0.1%	Potatoes / fried	0.3 / 0.01	0.93	0.0%	Potatoes / chips	0.3 / 0.01	0.08	
0.1%	Potatoes / dried (flakes)	0.3 / 0.05	0.59	0.01%	Potatoes / dried (flakes)	0.3 / 0.05	0.06	
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Expand/collapse list								

**Mandipropamid: not relevant (no ARfD)**

## **Appendix 4 Additional information provided by the applicant**

None.