

# REGISTRATION REPORT

## Part B

### Section 7

#### Metabolism and Residues

Detailed summary of the risk assessment

Product code: GLOB2011I

Product name(s): SANKARI

Chemical active substance: Pelargonic Acid

650 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

Submission date: 31/07/2023

RMS Assessment: 15/01/2024

After commenting period: 15/04/2024

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Update list studies: 28/05/2024

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## Version history

When	What
January 2024	RMS assessment
April 2024	After commenting period
May 2024	Update list studies

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

In EFSA Journal 2013;11(1):3023, it is concluded:

*“From the mammalian toxicology section, it is postulated that the fatty salts used as plant protection products on the edible crops are of low toxicological concern if it is demonstrated that they are of **food grade quality**. In that specific case, EFSA is of the opinion that a quantitative consumer dietary risk assessment can be waived. If the technical material does not comply with the food grade specification and raises potential toxicological issues, a data gap might be identified to submit a complete residue data package and to reconsider the consumer risk assessment through dietary intake and drinking water pending the outcome of the outstanding data on the technical specification and on the groundwater exposure assessment”.*

Our technical pelargonic acid does meet criteria to be considered as of food quality (please refer to Part C). As a consequence, no residue data or consumer risk assessment is needed for this submission. The Part B7 has been completed with waivers only.

### 7.1 Summary and zRMS Conclusion

Chapter 7.1 is to be filled in by zRMS only.

#### 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 GLOB2011I are presented in Table 7.1-1. They have been selected from the individual GAPs in the zone for cereals, oilseed rape, potatoes and maize (uses 1 to 13). A list of all intended uses within the zone is given in Part B, Section 0.

Uses 6-10-11-13 are being selected as critical GAPs. Nevertheless, this selection is not deemed necessary as the general conclusion on the entire Part B Section 7 is applicable to any crop. In fact, pelargonic acid is a naturally occurring compound (also approved as a food additive according to Commission Regulation (EU) No 872/2012) for which no residue definition is set/required. Pelargonic acid is temporarily included in Annex IV of Regulation (EC) No 396/2005 and its inclusion is still supported. No MRL, ArfD, ADI were set/required and it was concluded in EFSA Conclusions (2013) that the active substance does not raise toxicological concern for the consumer.

##### Overall conclusion

The data available are considered sufficient for risk assessment. Pelargonic acid is a naturally occurring compound (also approved as a food additive according to Commission Regulation (EU) No 872/2012) for which no residue definition is set/required. Pelargonic acid is temporarily included in Annex IV of Regulation (EC) No 396/2005 and its inclusion is still supported. No MRL, ArfD, ADI were set/required. The chronic and the short-term intakes of pelargonic acid 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(s).

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

**Data gaps**

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

Noticed data gaps are: none

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	Crop and/ or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
<b>6 (covering uses 1-2-3-4-5)</b> 500090 500010 500070	Cereals (winter and spring wheat [TRZAW & TRZAS], winter and spring durum wheat [TRZDW & TRZDS], spelt [TRZSP], winter and spring barley [HORVW & HORVS], winter and spring rye [SECCW & SECCS], winter and spring triticale [TTLWI & TTLSO])	CEU	GLOB2011I	F	Aphids / <i>Rhopalosiphum padi</i> [RHOPPA], <i>Sitobion avenae</i> [MACASV]	EC	650 g/L	downward spraying	BBCH 51-77 (spring: May to beginning of July)	1-2	14 days	0.325-0.65	200-400	1.3	NA	A
<b>10 (covering uses 7-8-9)</b> 401060	Oilseed rape (winter and spring) [BRSNW and	CEU	GLOB2011I	F	Cabbage seed - pod weevil / <i>Ceutorhynchus obstrictus</i>	EC	650 g/L	downward spraying	At first infestation / BBCH 50-65 (spring:	1-2	14 days	0.2438-0.4875	200-400	0.975	NA	A



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	BRSNS]				[CEUTAS]				April to July)							
<b>11</b> 211000	Potato [SOLTU]	CEU	GLOB2011I	F	Colorado beetle / Leptinotarsa decemlineata [LPTNDE]	EC	650 g/L	downward spraying	At first infestation / BBCH 35- 85 (spring- summer: May to August)	1-2	14 days	0.2438- 0.4875	200-400	0.975	NA	A
<b>13</b> (covering use 12) 500030	Maize [ZEAMX]	CEU	GLOB2011I	F	Corn borer / Ostrinia nubilalis [PYRUNU]	EC	650 g/L	downward spraying	At first infestation / BBCH 51- 71 (summer: June to July)	1-2	14 days	0.325- 0.975	200-600	1.95	NA	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

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## 7.1.2 Summary of the evaluation

The preparation GLOB2011I is composed of pelargonic acid.

**Table 7.1-2: Toxicological reference values for the dietary risk assessment of pelargonic acid**

Reference value	Source	Year	Value	Study relied upon	Safety factor
Pelargonic acid					
ADI	EFSA	2013	Not required	-	-
ARfD	EFSA	2013	Not required	-	-

Not set due to food grade quality

### 7.1.2.1 Summary for pelargonic acid

**Table 7.1-3: Summary for pelargonic acid**

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 to 6	Cereals	NR**	NR**	NR**	NR**	NR**	No	No
7 to 10	Oilseed rape	NR**	NR**	NR**	NR**	NR**		No
11	Potatoes	NR**	NR**	NR**	NR**	NR**		No
12-13	Maize	NR**	NR**	NR**	NR**	NR**		No

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

\*\* Not required. Metabolism studies in plant and animal were not necessary for pelargonic acid which is a naturally occurring compound of food grade quality and does not raise toxicological concern for consumer. It is also approved as a food additive according to Commission Regulation (EU) No 872/2012.

Pelargonic acid is temporarily included in Annex IV of Regulation (EC) No 396/2005 and its inclusion is still supported. No MRL, ADI, ARfD have been set and no consumer risk assessment is necessary.

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### 7.1.2.2 Summary for GLOB2011I

**Table 7.1-4: Information on GLOB2011I (KCA 6.8)**

Crop	PHI for GLOB2011I proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for GLOB2011I proposed by zRMS	zRMS Comments (if different PHI proposed)
		Pelargonic acid		
Cereals	Not applicable	NR		-
Oilseed rape	Not applicable	NR		-
Potatoes	Not applicable	NR		-
Maize	Not applicable	NR		-

NR: not relevant

\* Purpose of withholding period to be specified

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

Fatty acids naturally occur in plants therefore residues on/in plants would be indistinguishable from fatty acids from other sources. Moreover, pelargonic acid is considered not to be of toxicological relevance. Thus, supervised residue trials are not required as well as data on the stability of residues during the storage of samples or in sample extracts.

**Table 7.1-5: Waiting periods before planting succeeding crops**

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for GLOB2011I
Crop group	Led by pelargonic acid	
Cereals	NR	-
Oilseed rape	NR	-
Potatoes	NR	-
Maize	NR	-

NR: not relevant

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## 7.2 Pelargonic acid

General data on pelargonic acid are summarized in the table below (last updated 2021/07/28)

**Table 7.2-1: General information on pelargonic acid**

Active substance (ISO Common Name)	Pelargonic acid
IUPAC	Nonanoic acid

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Chemical structure	
Molecular formula	C <sub>18</sub> H <sub>36</sub> O <sub>2</sub>
Molar mass	158.24 g/mol
Chemical group	Fatty acid
Mode of action (if available)	-
Systemic	No
Company (ies)	<u>Original inclusion:</u> W. Neudorff GmbH KG; The Fatty acid Task Force & Oleon n.v.* <u>Actually:</u> Globachem N.V.; Syngenta Crop Protection AG; SBM Développement SAS; Seipasa, S.A.; Novamont SpA; W. Neudorff GmbH KG; Bayer AG; Belchim Crop Protection NV/SA; INDUSTRIAS AFRASA, S.A.; Grupo Agrotecnologia S.L.; Alpha BioPesticides Ltd; COMPO GmbH; Emery Oleochemicals LLC; Evergreen Garden Care France S.A.S.*
Rapporteur Member State (RMS)	Greece
Approval status	Approved Date of (01/09/2009) and reference to decision ( <a href="#">COMMISSION DIRECTIVE 2008/127/EC</a> (old legislation)- <a href="#">REGULATION (EU) No 2021/745</a> (actual legislation)- COMMISSION IMPLEMENTING REGULATION (EU) 2023/1446 (current legislation) <del>Re-approval on going</del>
Restriction	Only uses as insecticide, acaricide, and herbicide and plant growth regulator may be authorised.
Review Report	SANCO/2611/08 – rev. 1, 1 August 2008 Update: SANCO/2611/08 – rev. 2, 16 July 2013
Current MRL regulation	Regulation (EC) No 839/2008
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	No, not required***.
EFSA Journal: Conclusion on the peer review	Yes**
EFSA Journal: conclusion on article 12	No, not required***.
Current MRL applications on intended uses	No, not required***.

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

\*\* If yes: EFSA 2013 - see list of references

\*\*\* Pelargonic acid is temporarily included in Annex IV of Regulation (EC) No 396/2005 (EFSA 2013).

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## 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>			
NR*	NR*	NR*	EFSA 2013
<b>Animal Products</b>			
NR*	NR*	NR*	EFSA 2013
<b>New data</b>			
<b>Plant products</b>			
-	-	-	-
<b>Animal Products</b>			
-	-	-	-

\*NR: Not required

#### Conclusion on stability of residues during storage

No data is required (as concluded in EFSA 2013).

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

#### Available data

No data is required (as concluded in EFSA 2013).

#### Conclusion on stability of residues in sample extracts

No data is required (as concluded in EFSA 2013).

Fatty acids naturally occur in plants therefore residues on/in plants would be indistinguishable from fatty acids from other sources. Moreover, pelargonic acid is considered not to be of toxicological relevance. Thus, supervised residue trials are not required as well as data on the stability of residues during the storage of samples or in sample extracts.

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## 7.2.2 Nature of residues in plants, livestock and processed commodities

### 7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

#### Available data

No new data submitted in the framework of this application.

**Table 7.2-3: Summary of plant metabolism studies**

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	-	-	-	-	-	-	NR*	EFSA 2013
Leafy vegetables	-	-	-	-	-	-	NR*	EFSA 2013
Root and tuber vegetables	-	-	-	-	-	-	NR*	EFSA 2013
Pulses and oilseeds	-	-	-	-	-	-	NR*	EFSA 2013
Cereals	-	-	-	-	-	-	NR*	EFSA 2013
New data								
Fruits and fruiting vegetable	-	-	-	-	-	-	-	-
Leafy vegetables	-	-	-	-	-	-	-	-
Root and tuber vegetables	-	-	-	-	-	-	-	-
Pulses and oilseeds	-	-	-	-	-	-	-	-
Cereals	-	-	-	-	-	-	-	-

\*NR: Not required

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

No data is required (as concluded in EFSA 2013).

#### Summary of new plant metabolism studies

No new study required.

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### Conclusion on metabolism in primary crops

No data is required (as concluded in EFSA 2013).

### 7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

#### Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	-	-	-	-	-	-	NR**	EFSA 2013
Leafy vegetables	-	-	-	-	-	-	NR**	EFSA 2013
Root and tuber vegetables	-	-	-	-	-	-	NR**	EFSA 2013
Pulses and oilseeds	-	-	-	-	-	-	NR**	EFSA 2013
Cereals	-	-	-	-	-	-	NR**	EFSA 2013
New data								
Fruits and fruiting vegetable	-	-	-	-	-	-	-	-
Leafy vegetables	-	-	-	-	-	-	-	-
Root and tuber vegetables	-	-	-	-	-	-	-	-
Pulses and oilseeds	-	-	-	-	-	-	-	-
Cereals	-	-	-	-	-	-	-	-

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

\*\* NR: Not required

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

No data is required (as concluded in EFSA 2013).

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### Summary of new plant metabolism studies

No new study required.

### Conclusion on metabolism in rotational crops

No data is required (as concluded in EFSA 2013).

According to EFSA Peer review of the pesticide risk assessment of the active substance pelargonic acid (nonanoic acid) (2021): “Metabolism studies in plants and animals were not necessary for pelargonic acid (nonanoic acid) which is a naturally occurring compound, of food grade quality and it does not raise toxicological concern for the consumer. A study on the natural presence of pelargonic acid was conducted in samples of lettuce, potatoes, oilseed rape, wheat and plums to investigate pelargonic acid levels in these commodities. Significant levels were only determined in oilseed rape (0.104 mg/kg in whole plant, 0.35 mg/kg in straw and 0.45 mg/kg in seed) and wheat (1.22 mg/kg in whole plant, 2.21 mg/kg in straw and 0.135 mg/kg in grain), while in the other crops investigated the levels were below the limit of quantification. Pelargonic acid is also approved as a food additive according to Commission Regulation (EU) No 872/2012. The proposal to maintain pelargonic acid in Annex IV of Regulation (EC) No 396/2005 is supported.”

Fatty acids are components of every cell and they are essential for metabolism. Therefore, residues in soil are indistinguishable from naturally occurring compounds. Fatty acids are biodegradable, thus, there are no expected residues that could be found in succeeding crops.

The above citation is included for information.

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

#### Available data

No new data submitted in the framework of this application.

**Table 7.2-5: Nature of the residues in processed commodities**

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
<b>EU data</b>		
<b>Pasteurisation</b> (20 minutes, 90°C, pH 4)	NR**	EFSA 2013
<b>Baking, boiling, brewing</b> (60 minutes, 100°C, pH 5)	NR**	EFSA 2013
<b>Sterilisation</b> (20 minutes, 120°C, pH 6)	NR**	EFSA 2013
<b>Other conditions</b>	<b>Identified compound(s) (%)</b>	
<b>Winemaking ...</b>	Not applicable	-
<b>New data</b>		
<b>Pasteurisation</b> (20 minutes, 90°C, pH 4)	-	-
<b>Baking, boiling, brewing</b> (60 minutes, 100°C, pH 5)	-	-
<b>Sterilisation</b> (20 minutes, 120°C, pH 6)	-	-



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Conditions (Duration, Temperature, pH)		Identified compound(s) (%)	Reference
Other conditions	Identified compound(s) (%)		
Winemaking ...	-		-

\*NR: Not required

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

No data is required (as concluded in EFSA 2013).

Fatty acids naturally occur in humans, animals and plants and are essential components in animal and human diet. Thus, no residues in food commodities derived from the application of Pelargonic acid are expected.

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

**Table 7.2-6: Summary of the nature of residues in commodities of plant origin**

Endpoints	
Plant groups covered	No data required.
Rotational crops covered	No data required
Metabolism in rotational crops similar to metabolism in primary crops?	No data required.
Processed commodities	No data required.
Residue pattern in processed commodities similar to pattern in raw commodities?	No data required.
Plant residue definition for monitoring	No residue definition set (EFSA 2013).
Plant residue definition for risk assessment	No residue definition set (EFSA 2013).
Conversion factor from enforcement to RA	No data required (EFSA 2013)

#### 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.

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**Table 7.2-7: Summary of animal metabolism studies**

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	NR*	NR*	NR*	NR*	NR*	NR*	NR*	EFSA 2013
						NR*	NR*	
						NR*	NR*	
Laying poultry	NR*	NR*	NR*	NR*	NR*	NR*	NR*	EFSA 2013
						NR*	NR*	
						NR*	NR*	
New data								
Lactating ruminants	-	-	-	-	-	-	-	-
						-	-	
						-	-	
Laying poultry	-					-	-	-
						-	-	
						-	-	

\*NR: Not required

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

No data is required (as concluded in EFSA 2013).

#### Summary of new animal metabolism studies

No new study required.

#### Conclusion on metabolism in livestock

No data is required (as concluded in EFSA 2013).

Pelargonic acid is a natural substance used as a feed additive that will be metabolized in the same way as endogenous fatty acids, thus a metabolism study with pelargonic acid is not necessary.

#### 7.2.2.6 Conclusion on the nature of residues in commodities of animal origin

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**(KCA 6.7.1)**

**Table 7.2-8: Summary on the nature of residues in commodities of animal origin**

	Endpoints
Animals covered	No data required.
	No data required.
Time needed to reach a plateau concentration	No data required.
	No data required.
Animal residue definition for monitoring	No residue definition set (EFSA 2013).
Animal residue definition for risk assessment	No residue definition set (EFSA 2013).
Conversion factor	- (EFSA 2013)
Metabolism in rat and ruminant similar	-
Fat soluble residue	-

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### 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 7.2-9: Summary of EU reported and new data supporting the intended uses of GLOB2011I 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
All	EFSA 2013	All	Not data required	-	-	-	Not required**	Not applicable

\* Source of EU MRL: Regulation (EC) No 839/2008

\*\* Substances temporarily included in Annex IV, pending finalisation of their evaluation under Directive. 91/414/EEC and pending submission of EFSA's reasoned opinion in accordance with Article 12(1).'

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

No data is required (as concluded in EFSA 2013).

Fatty acids C<sub>7</sub> to C<sub>20</sub> are included in Annex IV of Regulation (EC) No 396/2005 containing a list of active substances for which MRLs are not required. Therefore an exceedance of the MRL for fatty acids C<sub>7</sub> to C<sub>20</sub> as laid down in Reg. (EU) 396/2005 is not expected.

### 7.2.4 Magnitude of residues in livestock

#### 7.2.4.1 Dietary burden calculation

Not data required (EFSA 2013).

**Table 7.2-10: Input values for the dietary burden calculation (considering the uses authorized within the zone and the uses under consideration)**

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition 1 (if applicable)				
-	-	-	-	-

**Table 7.2-11: Results of the dietary burden calculation**

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition 1 (if applicable)					
Beef cattle*	-	-	-	-	-
Dairy cattle*	-	-	-	-	-
Ram/ewe	-	-	-	-	-
Lamb	-	-	-	-	-
Breeding swine	-	-	-	-	-
Finishing swine*	-	-	-	-	-
Broiler poultry	-	-	-	-	-
Layer poultry*	-	-	-	-	-
Turkey	-	-	-	-	-

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

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No MRL has been established, therefore it is not considered necessary to perform the calculation of the dietary burden.

#### **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.

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	Calculated MRL (mg/kg)	CF for RA <sup>(d)</sup>
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) <sup>(a)</sup>	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (EFSA 2013)												
Enforcement residue definition 1												
Pig meat	Not data required.											
Pig fat												
Pig liver												
Pig kidney												
Ruminant meat												
Ruminant fat												
Ruminant liver												
Ruminant kidney												
Poultry meat												
Poultry fat												
Poultry liver												
Milk												
Eggs												

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<b>New data (Author, year, report No)</b>	
Enforcement residue definition 1	
<b>Pig meat</b>	Not required.
<b>Pig fat</b>	
<b>Pig liver</b>	
<b>Pig kidney</b>	
<b>New data (Author, year, report No)</b>	
<b>Ruminant meat</b>	Not required.
<b>Ruminant fat</b>	
<b>Ruminant liver</b>	
<b>Ruminant kidney</b>	
<b>New data (Author, year, report No)</b>	
<b>Poultry meat</b>	Not required.
<b>Poultry fat</b>	
<b>Poultry liver</b>	
<b>Milk</b>	
<b>Eggs</b>	

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.

n.r.: Not reported

(\*): Indicates that the MRL is set at the limit of analytical quantification.

(F): MRL is expressed as mg/kg of fat contained in the whole product.

(a): Based on a xx kg animal consuming xx kg feed DM/day.

(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).



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- (d): The median conversion factor for enforcement to risk assessment.
- (e): Mean residue level from day X until day XX (X cows, Y sampling days).

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### Conclusion on feeding studies

Not data required (EFSA 2013).

Pelargonic acid is a natural substance of food grade quality used as a feed). Therefore, livestock feeding studies are not required. No risk to ~~animals~~ ~~humans~~ is expected as no MRL had to be established.

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

### 7.2.5.1 Available data for all crops under consideration

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

**Table 7.2-13: Overview of the available processing studies**

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
<b>EU data</b>					
Enforcement residue definition 1					
-	-	-	-	NR***	EFSA 2013
<b>New data</b>					
Enforcement residue definition 1					
commodity, peeled	-	-	-	-	-

\* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

\*\* The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

\*\*\* Not required

### 7.2.5.2 Conclusion on processing studies

Not data required (EFSA 2013).

Fatty acids naturally occur in humans, animals and plants and are essential components in animal and human diet. No residues in food commodities derived from the application of pelargonic acid are expected.

## 7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

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

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

#### Available data

No new data submitted in the framework of this application.

**Table 7.2-14: 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
EU data					
Not required	-	-	-	-	EFSA 2013
New data					
-	-	-	-	-	-

#### Conclusion on rotational crops studies

Not data required (EFSA 2013).

Fatty acids are components of every cell and they are essential for metabolism. Therefore, residues in soil are indistinguishable from naturally occurring compounds. Fatty acids are biodegradable, thus, there are no expected residues that could be found in rotational crops.

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of GLOB2011I. Therefore, other special studies are not needed.

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

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

As ARfD was not deemed necessary, acute risk assessment is not relevant.

#### 7.2.8.1 Input values for the consumer risk assessment

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**Table 7.2-15: Input values for the consumer risk assessment**

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition 1				
-	-	Not required (EFSA 2013)		Not required (EFSA 2013)

### 7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

**Table 7.2-16: Consumer risk assessment**

TMDI (% ADI) according to EFSA PRIMo	Not required
IEDI (% ADI) according to EFSA PRIMo	Not required
IESTI (% ARfD) according to EFSA PRIMo*	Not required
NTMDI (% ADI) **	Not required
NEDI (% ADI)**	Not required
NESTI (% ARfD) **	Not required

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

\*\* if national model is available

The proposed uses of pelargonic acid in the formulation GLOB2011I do not represent unacceptable acute and chronic risks for the consumer.

A quantitative consumer risk assessment is not necessary since pelargonic acid is a naturally occurring compound for which toxicological reference values were not needed.

## 7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

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## **7.4               References**

EFSA (European Food Safety Authority), 2013. Peer review of the pesticide risk assessment of the active substance fatty acids C7 to C18; EFSA Journal 2013;11(1):3023; 2013.

EFSA (European Food Safety Authority), 2021 (Peer review of the pesticide risk assessment of the active substance pelargonic acid (nonanoic acid); EFSA Journal 2021;19(8):6813.

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

Tables considered not relevant can be deleted as appropriate.

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

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

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

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

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

The following tables are to be completed by MS.

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

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

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

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

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

Not applicable, no new study submitted.

## **Appendix 3 Pesticide Residue Intake Model (PRIMo)**

Not required. A quantitative consumer risk assessment is not necessary since pelargonic acid is a naturally occurring compound for which toxicological reference values were not needed. Pelargonic acid is temporarily included in Annex IV of Regulation (EC) No 396/2005 and its inclusion is still supported.

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

No additional information provided.