

FINAL REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: ~~GLOB289H~~ SAP63H

Product name(s): ~~SAP63H~~ Moxie

Chemical active substances:

Iodosulfuron-methyl sodium, 6 g/kg

Mesosulfuron-methyl, 30 g/kg

Safener: Mefenpyr-diethyl, 90 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Globachem NV / Ascenza Agro S.A.

Submission date: December 2019, 12.2021

MS Finalisation date: 02.2021, 01.2022, 02.2022

Version history

When	What
December 2019	V0 - Original version from applicant for submission to zRMS POLAND in the frame of new PPP registration
02.2021	RMS Assessment
12.2021	V1 – Revised version from applicant, adding 2-year storage stability data. Changes are highlighted in yellow.
01.2022	Final Assessment
02.2022	After commenting period

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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substances.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Globachem NV
Address: Brustem Industriepark, Lichtenberglaan 2019, 3800 Sint-Truiden, Belgium

xxxx

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information, data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information, data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Iodosulfuron-methyl sodium

Iodosulfuron-methyl sodium min. 910 g/kg

There is no relevant impurity
(open point)

as indicated in SANCO/10166/2003-Final and the
EFSA Journal 2016; 14 (4): 4453

~~Information on the impurities: CONFIDENTIAL — data provided separately (Part C)~~

The Renewal Report (SANTE/2016/11167 Rev 3, 7/12/2016) for iodosulfuron-methyl-sodium provides a summary of the relevant scientific information from the EU review.

1.2.3.2 Mesosulfuron-methyl

Mesosulfuron-methyl min. 930 g/kg

There is no relevant impurity

EFSA Journal 2016;14(10):4584

Information on the impurities: ~~CONFIDENTIAL~~ — data provided separately (Part C)

The Renewal Report (SANTE/11827/2016 Rev 2, 23/03/2017) for mesosulfuron-methyl provides a summary of the relevant scientific information from the EU review.

1.2.3.3 **Saefner**: Mefenpyr-diethyl

Mefenpyr-diethyl min. 940 g/kg

There is no relevant impurity

FAO specification min. 940 g/kg
[FAO Specification 651.229/TC (May 2011)]

Information on the impurities: ~~CONFIDENTIAL~~ — data provided separately (Part C)

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Please refer to Registration Report Part A for the relevant country (or)

Company code number: GLOB289H /SAP63H

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

GLOB289H /SAP63H was not the representative formulation during the EU evaluation of iodosulfuron-methyl-sodium or mesosulfuron-methyl.

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/kg)	FAO Limits** (min – max)	Technical content* (g/kg)	Technical content (%w/w)
Iodosulfuron-methyl-sodium	6	4.5 – 7.5	6.6	0.66
Mesosulfuron-methyl	30	27 – 33	32.3	3.23

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

** ± 25% of the declared content for “heterogenous” formulations (WG) up to 25 g/kg; ± 10% of the declared content above 25 g/kg up to 100 g/kg

Table 1.4-2: Safener and synergists

Safener / synergist	Declared content of the safener / synergist (g/L or g/kg)	FAO Limits (min – max) **	Technical content* (g/L or g/kg)	Technical content (%w/w)
Mefenpyr-diethyl	90	81 - 99	95.7	9.6

* Based on the minimum purity of the safener/synergist declared for registration

** ± 10% of the declared content above 25 g/kg up to 100 g/kg

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-3: Information on iodosulfuron

Type	Iodosulfuron-methyl-sodium
ISO common name	Iodosulfuron-methyl-sodium
CAS No.	144550-36-7
EC No.	-
CIPAC No.	634.501

Table 1.4-4: Information on mesosulfuron

Type	Mesosulfuron-methyl
ISO common name	Mesosulfuron-methyl
CAS No.	208465-21-8
EC No.	-
CIPAC No.	663.201

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

Table 1.4-5: Information on mefenpyr-diethyl

Type	mefenpyr-diethyl
Safener /synergist	safener
ISO common name	mefenpyr-diethyl
CAS No.	135590-91-9
EC No.	603-923-2
CIPAC No.	651.229

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Water-dispersible granule

[Code: WG]

1.6 Function (KCP 1.6)

Herbicide

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of light brown coloured granules, which were approximately 1mm to 10mm in size, with a characteristic sweet odour. It is not explosive, has no oxidising properties. The product is not considered highly flammable. In aqueous solution, it has a pH value around 6.7 at 20 °C.

A 2 years and 3 years storage stability study are still ongoing.

However, Based on the accelerated storage study a shelf life of at least 2 years 1 year at ambient temperature is expected when stored in HDPE bottles.

Based on a shelf life storage stability study at least 2 years at ambient temperature is expected when stored in HDPE bottles.

Its technical characteristics are acceptable for a WG formulation.

The intended concentration of use is 0.75 g lowest 0.25 g of product/L to highest 5 g of product/L.

According to the GAP provided, the minimal intended concentration is 0.25 g/L and the maximal is 5 g/L. The differences to the values used in the study (0.75 g lowest and 4 g highest) are slight and it is very low probability that they could influence the final results, so the concentration proposed is accepted.

The product should/can be mixed in the tank together with non-ionic surfactant or vegetal oil adjuvant. Studies regarding the combination with non-ionic surfactant and vegetal oil adjuvant were submitted and the application as tank mixture is acceptable.

The studies are accepted

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Not applicable.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not applicable.

Compliance with FAO specifications:

The product GLOB289H /SAP63H complies with FAO specifications.

Formulation used for tests

The product used in the tests performed has the same composition as the one cited in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual assessment	GLOB289H /SAP63H	The sample consisted of solid, brown granules. The sample had a characteristic odour. The appearance remained unchanged post 8 week storage at 40°C±2°C	Y	Silva S.; 2019 EF/298/19	Accepted
Explosive properties (KCP 2.2.1)	OECD 113	GLOB289H /SAP63H	The test item had no explosive properties and does not have to be classified as an “explosive”, class 1.	Y	Dornhagen J.; 2019 PS20190222-2	Accepted
Oxidizing properties (KCP 2.2.2)	UN test O.1	GLOB289H /SAP63H	The test item had no oxidising properties and does not have to be classified as “oxidising solid”.	Y	Dornhagen J.; 2019 PS20190222-3	Accepted
Flash point (KCP 2.3.1)	-	-	Not required for a WG formulation	-	-	Statement accepted
Flammability (KCP 2.3.2)	UN test N.1	GLOB289H /SAP63H	The test item was not readily combustible solid in the sense of UN Manual of Tests and Criteria, Method N.1. The test item was not flammable solid according to chapter 2.7 of the GHS (CLP) regulations.	Y	Dornhagen J.; 2019 PS20190222-1	Accepted
Self-heating (KCP 2.3.3)	UN test N.4	GLOB289H /SAP63H	An exothermal effect started at 240°C. Based on these results, the material does not have to be classified as a “self-heating substance”.	Y	Dornhagen J.; 2019 PS20190222-4	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)	-	-	Not required as pH is between 6 and 8	-	-	Statement accepted
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	GLOB289H /SAP63H	Initial (before storage): 6.7 at 20°C After 8 weeks at 40°C: 6.5 at 20°C	Y	Silva S.; 2019 EF/298/19	Accepted
Viscosity (KCP 2.5.1)	-	-	Not required for a WG formulation	-	-	Statement accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																											
Surface tension (KCP 2.5.2)	EEC A5	GLOB289H /SAP63H	42.2 mN/m at highest application rate (20°C)	Y	Silva S.; 2019 EF/298/19	Accepted Comments : Surface active product (< 60.0 mN/m)																											
Relative density (KCP 2.6.1)	-	-	Not required for a WG formulation	-		Statement accepted																											
Bulk density (KCP 2.6.2)	CIPAC MT 186	GLOB289H /SAP63H	Pour Density: 0.90 g/mL Tap Density: 0.93 g/mL	Y	Silva S.; 2019 EF/298/19	Accepted																											
Storage Stability after 14 days at 54° C 8 weeks at 40° C variant (KCP 2.7.1)	-	GLOB289H /SAP63H	<table><tr><td></td><td>Before storage</td><td>After storage</td></tr><tr><td>Appearance</td><td colspan="2">The sample consisted of solid, brown granules. The sample had a characteristic odour.</td></tr><tr><td>Iodosulfuron-methyl-sodium content</td><td>0.59% (w/w)</td><td>0.58% (w/w)</td></tr><tr><td>Mesosulfuron-methyl content</td><td>2.99% (w/w)</td><td>2.91% (w/w)</td></tr><tr><td>Mefenpyr-diethyl content</td><td>8.96% (w/w)</td><td>9.03% (w/w)</td></tr><tr><td>pH 1% dilution (CIPAC MT 75)</td><td>6.7</td><td>6.5</td></tr><tr><td>Wet sieve test (CIPAC MT 185)</td><td>0.62%</td><td>0.55%</td></tr><tr><td>Wettability (CIPAC MT 53.3)</td><td>0.0 seconds</td><td>0.0 seconds</td></tr><tr><td>Spontaneity of dispersion CIPAC MT 174</td><td>88%</td><td>85%</td></tr></table>		Before storage	After storage	Appearance	The sample consisted of solid, brown granules. The sample had a characteristic odour.		Iodosulfuron-methyl-sodium content	0.59% (w/w)	0.58% (w/w)	Mesosulfuron-methyl content	2.99% (w/w)	2.91% (w/w)	Mefenpyr-diethyl content	8.96% (w/w)	9.03% (w/w)	pH 1% dilution (CIPAC MT 75)	6.7	6.5	Wet sieve test (CIPAC MT 185)	0.62%	0.55%	Wettability (CIPAC MT 53.3)	0.0 seconds	0.0 seconds	Spontaneity of dispersion CIPAC MT 174	88%	85%	Y	Silva S.; 2019 EF/298/19	Accepted Comments: The product is stable in the accelerated storage stability study (8 weeks at 40°C) . All obtained results are within the limits. The test carried out in HDPE bottles and no change have been noticed. Based on accelerated storage stability study extrapolation for shelf life – 1 year is possible.
	Before storage	After storage																															
Appearance	The sample consisted of solid, brown granules. The sample had a characteristic odour.																																
Iodosulfuron-methyl-sodium content	0.59% (w/w)	0.58% (w/w)																															
Mesosulfuron-methyl content	2.99% (w/w)	2.91% (w/w)																															
Mefenpyr-diethyl content	8.96% (w/w)	9.03% (w/w)																															
pH 1% dilution (CIPAC MT 75)	6.7	6.5																															
Wet sieve test (CIPAC MT 185)	0.62%	0.55%																															
Wettability (CIPAC MT 53.3)	0.0 seconds	0.0 seconds																															
Spontaneity of dispersion CIPAC MT 174	88%	85%																															

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			Suspensibility CIPAC MT 184	Iodosulfuron: 93% Mesosulfuron: 89% Mefenpyr: 89%	Iodosulfuron: 93% Mesosulfuron: 89% Mefenpyr: 89%			
			Dust content (CIPAC MT 171.1)	The sample is considered nearly dust free				
			Attrition (CIPAC MT 178.2)	99.1%	99.2%			
			Package stability	No visual degradation	No visual degradation			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	-			-	-	Statement accepted
Minimum content after heat stability testing (KCP 2.7.3)	House validated methodology	GLOB289H /SAP63H		Before storage	After storage (8w, 40°C ± 2°C)	Y	Silva S.; 2019 EF/298/19	Accepted
			Iodosulfuron-methyl-sodium content	0.59% (w/w)	0.58% (w/w)			
			Mesosulfuron-methyl content	2.99% (w/w)	2.91% (w/w)			
			Mefenpyr-diethyl content	8.96% (w/w)	9.03% (w/w)			
Effect of low temperatures on stability (KCP 2.7.4)	-	-	Not required for a WG formulation			-		Statement accepted
Ambient temperature shelf life	GIFAP monograph 17	GLOB289H /SAP63H	A 2 year and 3 year storage study is underway and will be provided when complete			Y	Silva S.; 2019 EF/298/19	Study on-going Statement accepted

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
(KCP 2.7.5)	GIFAP monograph 17	GLOB289H /SAP63H		Before storage	After 2-years	Y	Silva S.; 2021 EF/298/19	Accepted Comments: All obtained results are within the limits. The test carried out in HDPE bottles and no change have been noticed. Based on a 2 years storage stability study shelf life – 2 years.
			Appearance	The sample consisted of solid, brown granules. The sample had a characteristic odour.				
			Iodosulfuron-methyl-sodium content	0.59% (w/w)	0.62% (w/w)			
			Mesosulfuron-methyl content	2.99% (w/w)	2.93% (w/w)			
			Mefenpyr-diethyl content	8.96% (w/w)	8.98% (w/w)			
			pH 1% dilution (CIPAC MT 75)	6.7	6.8			
			Wet sieve test (CIPAC MT 185)	0.62%	0.51%			
			Wettability (CIPAC MT 53.3)	0.0 seconds	0.0 seconds			
			Spontaneity of dispersion CIPAC MT 174	88%	88%			
			Suspensibility CIPAC MT 184	Iodosulfuron: 93% Mesosulfuron: 89% Mefenpyr: 89%	Iodosulfuron: 88% Mesosulfuron: 88% Mefenpyr: 88%			
			Dust content (CIPAC MT 171.1)	The sample is considered nearly dust free				
			Attrition (CIPAC MT 178.2)	99.1%	99.8%			
			Package stability	No visual degradation	No visual degradation			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not required. A shelf life of 2 years is proposed based on results of accelerated storage testing (point 2.7.1).	-	-	Statement accepted
Wettability (KCP 2.8.1)	CIPAC MT 53.3	GLOB289H /SAP63H	Pre-storage: 0.0 seconds Post-storage (8w, 40°C±2°C): 0.0 seconds	Y	Silva S.; 2019 EF/298/19	Accepted
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	GLOB289H /SAP63H	At the minimum application rate: After 1 minute: 4 mL After 12 minutes: 4 mL At the maximum application rate: After 1 minute: 6 mL After 12 minutes: 4 mL	Y	Silva S.; 2019 EF/298/19	Accepted
Suspensibility Iodosulfuron-methyl-sodium (KCP 2.8.3.1)	CIPAC MT 184 HPLC	GLOB289H /SAP63H	<u>Pre-storage</u> Lowest application concentration: 95 % Highest application concentration: 94% 0.2% application concentration: 93% <u>Post-storage (8w at 40°C)</u> Lowest application concentration: 94% Highest application concentration: 94% 0.2% application concentration: 92%	Y	Silva S.; 2019 EF/298/19	Accepted
Suspensibility Mesosulfuron-methyl (KCP 2.8.3.1)	CIPAC MT 184 HPLC	GLOB289H /SAP63H	<u>Pre-storage</u> Lowest application concentration: 92% Highest application concentration: 91% 0.2% application concentration: 89% <u>Post-storage (8w at 40°C)</u> Lowest application concentration: 91% Highest application concentration: 91% 0.2% application concentration: 89%	Y	Silva S.; 2019 EF/298/19	Accepted
Suspensibility Mefenpyr-diethyl (KCP 2.8.3.1)	CIPAC MT 184 HPLC	GLOB289H /SAP63H	<u>Pre-storage</u> Lowest application concentration: 92% Highest application concentration: 91% 0.2% application concentration: 89%	Y	Silva S.; 2019 EF/298/19	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<u>Post-storage (8w at 40°C)</u> Lowest application concentration: 91% Highest application concentration: 91% 0.2% application concentration: 89%			
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 174	GLOB289H /SAP63H	<u>Pre-storage</u> Determination 1: 88% Determination 2: 88% <u>Post-storage (8w at 40°C)</u> Determination 1: 85% Determination 2: 85%	Y	Silva S.; 2019 EF/298/19	Accepted
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for a WG formulation	-		Statement accepted
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required for a WG formulation	-		Statement accepted
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not required as <1% below 50µm sieve was measured in the dry sieve analysis	-	-	Statement accepted
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	GLOB289H /SAP63H	Pre-storage: 0.62% Post-storage (8w, 40°C±2°C): 0.55%	Y	Silva S.; 2019 EF/298/19	Accepted
Dry sieve test (KCP 2.8.5)	CIPAC MT 170	GLOB289H /SAP63H	Pre-storage: Mean sum of residue ≥90% on the 1000µm sieve Mean sum of residue ≤10% on the 2000µm sieve Post-storage (8w, 40°C±2°C): Mean sum of residue ≥90%	Y	Silva S.; 2019 EF/298/19	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments								
			on the 1000µm sieve Mean sum of residue ≤10% on the 2000µm sieve											
Dust content (KCP 2.8.5.2.1)	CIPAC MT 171.1	GLOB289H /SAP63H	Pre-storage: The sample is considered nearly dust free Post-storage (8w, 40°C±2°C): The sample is considered nearly dust free	Y	Silva S.; 2019 EF/298/19	Accepted								
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required as the dust content is < 1% w/w	-	-	Statement accepted								
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	GLOB289H /SAP63H	Initial (before storage): 99.1% After 8w, 40°C±2°C: 99.2%	Y	Silva S.; 2019 EF/298/19	Accepted								
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for a WG formulation	-		Statement accepted								
Emulsifiability (KCP 2.8.6.1)	-	-	Not required for a WG formulation	-		Statement accepted								
Emulsion stability (KCP 2.8.6.2)	-	-	Not required for a WG formulation	-		Statement accepted								
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not required for a WG formulation	-		Statement accepted								
Flowability (KCP 2.8.7.1)	CIPAC MT 172.2	GLOB289H /SAP63H	The sample did not clump or compact over storage. The sample passed straight through the 5mm sieve.	Y	Silva S.; 2019 EF/298/19	Accepted								
Pourability (KCP 2.8.7.2)	-	-	Not required for a WG formulation	-	-	Statement accepted								
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required for a WG formulation	-	-	Statement accepted								
Physical compatibility of tank mixes – Vegetal oil	ASTM E1518-05	GLOB289H /SAP63H + Actiob	<table><tr><td></td><td>Application concentration</td><td>Test item + Actiob</td><td>Actiob + test item</td></tr><tr><td>Visual</td><td>Low</td><td colspan="2">Well dispersed in water.</td></tr></table>		Application concentration	Test item + Actiob	Actiob + test item	Visual	Low	Well dispersed in water.		Y	Silva S.; 2019 PC/09/2019	Accepted
	Application concentration	Test item + Actiob	Actiob + test item											
Visual	Low	Well dispersed in water.												

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
(KCP 2.9.1)			observation	High	No visual residue observed.				
			Sieve test (% w/w) (>75 µm)	Low	0.00	0.00			
				High	0.00	0.00			
Physical compatibility of tank mixes – non-ionic surfactant (KCP 2.9.1)	ASTM E1518-05	GLOB289H /SAP63H + Pottok		Application concentration	Test item + Pottok	Pottok + test item	Y	Silva S.; 2019 PC/08/2019	Accepted
			Visual observation	Low	Well dispersed in water. No visual residue observed.				
				High					
			Sieve test (% w/w) (>75 µm)	Low	0.00	0.00			
				High	0.00	0.00			
Chemical compatibility of tank mixes – Vegetal oil (KCP 2.9.2)	-	GLOB289H /SAP63H + Actiob		GLOB289H	GLOB289H + Actiob		Y	Silva S.; 2019 EF/298/19; Silva S., 2019 EF/300/19	Accepted
			pH 1% solution	6.7	6.4				Comments : The product with the Vegetal Oil is stable. All obtained results are within the limits. This is surface active product (< 60.0 mN/m) .
			Suspensibility Iodosulfuron-methyl-sodium	Low: 95 % High: 94 %	Low: 87 % High: 90 %				
			Suspensibility Mesosulfuron-methyl content	Low: 92 % High: 91 %	Low: 87 % High: 90 %				
			Suspensibility Mefenpyr-diethyl content	Low: 92 % High: 91 %	Low: 87 % High: 90 %				
			Dispersibility of WDG	1: 88% 2: 88%	1: 83% 2: 80%				
			Wettability (CIPAC MT 53.3)	0.0 seconds	0.0 seconds				
			Surface tension (at highest app rate)	42.2 mN/m	34.3 mN/m				
			Persistence of foaming (CI-PAC MT 47.3)	Minimum app rate					
				1': 4 mL 12': 4 mL	1': 0 mL 12': 0 mL				
				Maximum app rate					

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
				1': 6 mL 12': 4mL	1': 0 mL 12': 0 mL			
Chemical compatibility of tank mixes – non-ionic surfactant (KCP 2.9.2)	-	GLOB289H /SAP63H + Pottok		GLOB289H	GLOB289H + Pottok	-	Silva S.; 2019 EF/298/19; Silva S., 2019 EF/299/19	Accepted Comments : The product with the Pottok is stable. All obtained results are within the limits. This is surface active product (< 60.0 mN/m) .
			pH 1% solution	6.7	6.4			
			Suspensibility Iodosulfuron-methyl-sodium	Low: 95 % High: 94 %	Low: 85 % High: 87 %			
			Suspensibility Mesosulfuron-methyl content	Low: 92 % High: 91 %	Low: 85 % High: 87 %			
			Suspensibility Mefenpyr-diethyl content	Low: 92 % High: 91 %	Low: 85 % High: 87 %			
			Dispersibility of WDG	1: 88 % 2: 88 %	1: 85 % 2: 82 %			
			Wettability (CIPAC MT 53.3)	0.0 seconds	0.0 seconds			
			Surface tension (at highest app rate)	42.2 mN/m	32.5 mN/m			
			Persistence of foaming (CIPAC MT 47.3)	Minimum app rate				
				1': 4 mL 12': 4 mL	1': 34 mL 12': 12 mL			
				Maximum app rate				
	1': 6 mL 12': 4mL	1': 30 mL 12': 2 mL						
Adhesion to seeds (KCP 2.10.1)	-	-	Not applicable as GLOB289H is not used for seed treatment			-	-	Statement accepted
Distribution to seed (KCP 2.10.2)	-	-	Not applicable as GLOB289H is not used for seed treatment			-	-	Statement accepted
Other/special studies (KCP 2.11)	CIPAC MT 30	GLOB289H /SAP63H	Water content Initial (before storage): 1.86 %			Y	Silva S.; 2019 EF/298/19	Accepted

Annex point	Method used / deviations	Test mate- rial	Findings	GLP Y/N	Reference	Acceptability / comments
			After 8w, 40°C±2°C: 1.85 %			

3 **Section 3 is presented as a separate document**

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

The packaging has been designed according to the FAO “Guidelines for the Packaging and Storage of Pesticides”. GLOB289H /SAP63H will be packed in HDPE containers with volumes of 0.1, 0.15, 0.25, 0.5, 1, 2, 5, 10 or 20 L, or in bags of 0.1, 0.25, 0.5, 0.6, 1, 2, 2.5, 3, 4, 5, 10, 20 or 25 kg, laminated Paper or PET (outer layer) / PE or Al (mid layer) / PE (inner layer). The specifications are presented in the tables below.

The dimensions of the bags are not relevant as the product is a solid.

Table 4.1-1: Packaging information for 0.1 litre bottle

Type	Description
Material:	HDPE (High Density PolyEthylene)
Shape/size:	cylindrical / approx. 45 mm diameter x 90 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	Extruded
UN/ADR	Compliant
Content product in the bottle	50 g

Table 4.1-2: Packaging information for 0.15 litre bottle

Type	Description
Material:	HDPE (High Density PolyEthylene)
Shape/size:	cylindrical / approx. 60 mm diameter x 90 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	Extruded
UN/ADR	Compliant
Content product in the bottle	75 g

Table 4.1-3: Packaging information for 0.25 litre bottle

Type	Description
Material:	HDPE (High Density PolyEthylene)
Shape/size:	cylindrical / approx. 60 mm diameter x 125 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal

Type	Description
Manner of construction	Extruded
UN/ADR	Compliant
Content product in the bottle	150 g

Table 4.1-4: Packaging information for 0.5 litre bottle

Type	Description
Material:	HDPE (High Density PolyEthylene)
Shape/size:	cylindrical / approx. 60 mm diameter x 185 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	Extruded
UN/ADR	Compliant
Content product in the bottle	250 or 300 g

Table 4.1-5: Packaging information for 1 litre bottle

Type	Description
Material:	HDPE (High Density PolyEthylene)
Shape/size:	cylindrical / approx. 88.5 mm diameter x 234 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	Extruded
UN/ADR	Compliant
Content product in the bottle	500 g or 600 g

Table 4.1-6: Packaging information for 2 litre bottle

Type	Description
Material:	HDPE (High Density PolyEthylene)
Shape/size:	Height: 189 mm, Width: 106 mm, Length: 155 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	Extruded
UN/ADR	Compliant
Content product in the bottle	1 kg

Table 4.1-7: Packaging information for 5 litre bottle

Type	Description
Material:	HDPE (High Density PolyEthylene)
Shape/size:	Height: 313 mm, Width: 140 mm, Length: 190 mm
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	Extruded
UN/ADR	Compliant
Content product in the bottle	2, 2.5 or 3 kg

Table 4.1-8: Packaging information for 10 litre bottle

Type	Description
Material:	HDPE (High Density PolyEthylene)
Shape/size:	Height: 375 mm, Width: 179 mm, Length: 240 mm
Opening:	63 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	Extruded
UN/ADR	Compliant
Content product in the bottle	4, 5 or 6 kg

Table 4.1-9: Packaging information for 20 litre bottle

Type	Description
Material:	HDPE (High Density PolyEthylene)
Shape/size:	Height: 372 mm, Width: 263 mm, Length: 292 mm
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	Extruded
UN/ADR	Compliant
Content product in the bottle	10 or 12 kg

Table 4.1-10: Packaging information for the bags

Type	Description
Material:	Laminate of Paper or PET (outer layer) / PE or Al (mid layer) / PE (inner layer)
Dimensions (LxWxH, mm)	100 g: 170 x 80 x 50 250 g: 90 x 55 x 130 500 g: 110 x 55 x 180 600 g: 280 x 460 1 kg: 120 x 80 x 318 2, 2.5 and 3 kg: 580 x 750; 400 x 750; 450 x 750; 620 x 750

Type	Description
	4 kg: 500 x 750; 540 x 750 5 kg: 230 x 150 x 370 10 kg: 130 x 400 x 670 20 kg: 170 x 500 x 750 25 kg: 180 x 545 x 810
Seal:	Induction seal
UN/ADR	Compliant

RMS Comments:

Recommended packaging are accepted

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1-2.11	Silva S.	2019	Iodosulfuron-methyl-sodium 0.6% + Mesosulfuron-methyl 3.0% + Mefenpyr-diethyl 9.0% WG (SAP63H) – Physical, chemical and technical properties of the plant protection product EF/298/19 Ascenza Agro S.A. GLP Not published	N	Ascenza Agro S.A. Globachem N.V.
KCP 2.2.1	Dornhagen J.	2019	SAP63H – Explosive properties PS20190222-2 Siemens A.G. GLP Not published	N	Ascenza Agro S.A. Globachem N.V.
KCP 2.2.2	Dornhagen J.	2019	SAP63H – Oxidizing properties of solids O.1 PS20190222-3 Siemens A.G. GLP Not published	N	Ascenza Agro S.A. Globachem N.V.
KCP 2.3.2	Dornhagen J.	2019	SAP63H – Flammability (solids) N.1 PS20190222-1 Siemens A.G. GLP Not published	N	Ascenza Agro S.A. Globachem N.V.
KCP 2.3.3	Dornhagen J.	2019	SAP63H – Relative self-ignition temperature for solids (Grewer-oven) PS20190222-4 Siemens A.G. GLP	N	Ascenza Agro S.A. Globachem N.V.

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
			Not published		
KCP 2.9.1-01	Silva S.	2019	Iodosulfuron-methyl-sodium 0.6% + Mesosulfuron-methyl 3.0% + Mefenpyr-diethyl 9.0% WG (SAP63H) with vegetal oil adjuvant – Evaluation of physical compatibility PC/09/2019 Ascenza Agro S.A. GLP Not published	N	Ascenza Agro S.A. Globachem N.V.
KCP 2.9.1-02	Silva S.	2019	Iodosulfuron-methyl-sodium 0.6% + Mesosulfuron-methyl 3.0% + Mefenpyr-diethyl 9.0% WG (SAP63H) with non-ionic surfactant – Evaluation of physical compatibility PC/08/2019 Ascenza Agro S.A. GLP Not published	N	Ascenza Agro S.A. Globachem N.V.
KCP 2.9.2-01	Silva S.	2019	Iodosulfuron-methyl-sodium 0.6% + Mesosulfuron-methyl 3.0% + Mefenpyr-diethyl 9.0% WG (SAP63H) with vegetal oil adjuvant – Physical, chemical and technical properties of the plant protection product EF/300/19 Ascenza Agro S.A. GLP Not published	N	Ascenza Agro S.A. Globachem N.V.
KCP 2.9.2-02	Silva S.	2019	Iodosulfuron-methyl-sodium 0.6% + Mesosulfuron-methyl 3.0% + Mefenpyr-diethyl 9.0% WG (SAP63H) with non-ionic surfactant – Physical, chemical and technical properties of the plant protection product EF/299/19 Ascenza Agro S.A. GLP Not published	N	Ascenza Agro S.A. Globachem N.V.
KCP 2.7.5	Silva S.	2021	Iodosulfuron-methyl-sodium 0.6% + Mesosulfuron-methyl 3.0% + Mefenpyr-diethyl 9.0% WG (SAP63H) – Physical, chemical and technical properties of the plant protection product EF/298/19	N	Ascenza Agro S.A. Globachem

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
			Ascenza Agro S.A. GLP Not published		N.V.

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

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

