

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: SAE053H/01

Product name(s): KAGURA/GENKI

Chemical active substances:

Mesotrione, 80 g/L

Nicosulfuron, 30 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Document number – SAEDoc-00014 CEU

(authorization)

Applicant: Sumi Agro Europe Limited

Submission date: June 2020, July 2021

MS Finalisation date: 18/02/2022

Version history

When	What
June 2020	Version 0, dRR Part B1, 2 & 4 submitted by applicant
August 2020	Dossier sent for evaluation to Merit Mark (PL)
July 2021	Version 1, dRR Part B1, 2 & 4 submitted by applicant Data from 2 year storage stability study report is now available and has been added. Pack material description amended to be clearer (<i>but is not changed</i>).
October 2021	zRMS finalised evaluation
January 2022	Final version prepared by zRMS after Commenting period
February 2022	Final version prepared by zRMS after Commenting period

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zRMS comments:

The text highlighted in grey was provided by the evaluator.

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

Noticed data gaps are:

- none

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Sumi Agro Europe Limited

Address: Vintners' Place
68 Upper Thames Street
London EC4V 3BJ

Contact: xxxxx

Phone: xxxxxx

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 or data are provided separately (Part C).

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

Confidential information or 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 Mesotrione

Mesotrione min. 980 g/kg

Impurity 1: R287431 min. 2 mg/kg

Impurity 2: R287432 min. 2 g/kg

Impurity 3: 1,2-dichloroethane min. 1 g/kg

Impurity 1: 6-(methylsulfonyl)-7-nitro-9-oxo-9H-xanthene-1-carbonitrile

Impurity 2: 6-(methylsulfonyl)-9-oxo-9H-xanthene-1-carbonitrile

1.2.3.2 Nicosulfuron

Nicosulfuron min. 930 910 g/kg

Impurities of toxicologically or ecotoxicologically concern have not been identified for Nicosulfuron (please refer to Review Report for Nicosulfuron (SANCO/3780/07 – 22/01/2008)).

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

Company code number: SAE053H/01

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)

Sumi Agro Europe Limited has developed SAE053H/01 plant protection product. It was not the representative formulation during evaluation of Mesotrione or Nicosulfuron on EU level.

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

Active substance	Declared content of the pure active substance / variant [g/L]	FAO Limits (min – max)	Technical content* [g/L]	Technical content** [% w/w]
Mesotrione	80	72 – 88 g/L	81.6	8.33
Nicosulfuron	30	27 – 33 g/L	32.3	3.29

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

** Based on the density of the formulation = 0.980 g/mL

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content
R287431	2 mg/kg (mesotrione); 0.16 mg/L (PPP)
R287432	2 g/kg (mesotrione); 0.16 g/L (PPP)
1,2-dichloroethane	1 g/kg (mesotrione); 0.08 g/L (PPP)

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

Table 1.4-3: Information on Mesotrione

Type	Name/Code Number	
ISO common name	Mesotrione	-
CAS No.	104206-82-8	-
EC No.	609-064-00	-
CIPAC No.	625	-

Table 1.4-3: Information on Nicosulfuron

Type	Name/Code Number	
ISO common name	Nicosulfuron	-
CAS No.	111991-09-4	-
EC No.	601-148-4	-
CIPAC No.	709	-

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

No safener and no synergist are used in SAE053H/01.

CONFIDENTIAL information is provided separately (Part C).

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

Type: Oil Dispersion

[Code: OD]

1.6 Function (KCP 1.6)

SAE053H/01 is an herbicide applied in maize.

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 an Off-white opaque free-flowing liquid of medium viscosity with no foreign matter present. It is not explosive, has no oxidising properties. The product has no flash point below 100 °C. It has a self-ignition temperature of 335 °C. The pH value of the neat formulation is 3.3 at 23.4 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 12 weeks at 35 °C, neither the content of the two active ingredients, the amount of impurities nor the technical properties were changed. The 2 years shelf life study confirms the high quality of the formulation and it is stable for 2 years when stored at ambient temperature in PE/PA commercial containers. Its technical characteristics are acceptable for an OD formulation.

The intended concentration of use is 0.3% to 0.6%.

The product will not be used in tank mixtures.

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

Experimental results on the product SAE053H/01 with regard to product classification and labelling:

Studies	Method	Findings	Classification acc. to Regulation (EC) No. 1272/2008
Explosive properties	Calculation	Not explosive	None
Oxidising properties	Calculation	Not oxidizing	None
Flammability	--	Not applicable for OD-formulation	--
Flash point	ASTM D93	> 100 °C	None
Auto-flammability	EEC A.15	Self-ignition temperature = 335 °C	None
pH	CIPAC MT 75.3	3.3	None
Acidity	CIPAC MT 191	1.69 % m/m H ₂ SO ₄	None
Viscosity	CIPAC MT 192	Kinematic viscosity > 20.5 mm ² /s at 40 °C	None
Surface tension	EEC A.5	32.5 mN/m for neat formulation 30.8 mN/m for 0.75 % in water	None
Relative density	EEC A.3	0.980 (neat formulation)	None

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No precautionary statements according to Regulation (EC) No. 1272/2008 are needed with regard to the physical/chemical data of the product.

Compliance with FAO specifications:

The product SAE053H/01 complies with FAO specifications.

Formulation used for tests

The test item used in the tests 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 inspection	SAE053H/01 Content of a.s. (analysed): 79.6 g/L Mesotrione 29.8 g/L Nicosulfuron Batch No.: 55110-103	Off-white opaque free-flowing liquid of medium viscosity with no foreign matter present. <u>After storage of 12 weeks at 35 °C:</u> Off-white opaque free-flowing liquid of medium viscosity with no foreign matter present. 24 % clear brown supernatant, which required 8 inverts to fully re-homogenise. No sediment. <u>After storage of 7 days at 0 °C:</u> After 7 days at 0 °C, the sample was an opaque off-white free-flowing liquid of medium viscosity, and there was a pale yellow clear layer of 3 mL at the surface. After returning to room temperature for 24 hours, the tube was inverted once, but a clear layer of 2 mL returned to the surface. This was successfully re-homogenised with 5 inverts.	Y	KCP 2.1/01 Bance, G. (2018a) Report no.: JP/18/002/1	Accepted
Explosive properties (KCP 2.2.1)	EC A.14	SAE053H/01 Batch No.: 55110-103	BAM Fallhammer test: negative Koenen Tube test: negative	Y	KCP 2.2.1/01 Younis, S. (2018) GLP3016003919R1V1/ 2018	Accepted
Oxidizing properties (KCP 2.2.2)	EC A.21	SAE053H/01 Batch No.: 55110-103	Not an oxidising liquid	Y	KCP 2.2.1/01 Younis, S. (2018) GLP3016003919R1V1/ 2018	Accepted
Flash point (KCP 2.3.1)	EC A9 1.6.3.2 (ASTM D93B)	SAE053H/01 Content of a.s. (analysed): 79.6 g/L Mesotrione 29.8 g/L Nicosulfuron Batch No.:	Flash Point: > 100 °C	Y	KCP 2.1/01 Bance, G. (2018a) Report no.: JP/18/002/1	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		55110-103				
Flammability (KCP 2.3.2)			Not required for OD preparation			
Self-heating (KCP 2.3.3)	EC A.15	SAE053H/01 Batch No.: 55110-103	Auto-ignition temperature 335 °C	Y	KCP 2.2.1/01 Younis, S. (2018) GLP3016003919R1V1/ 2018	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	SAE053H/01 Content of a.s. (analysed): 79.6 g/L Mesotrione 29.8 g/L Nicosulfuron Batch No.: 55110-103	Acidity (%m/m H ₂ SO ₄) Initial: 1.69 12W@35 °C 1.81	Y	KCP 2.1/01 Bance, G. (2018a) Report no.: JP/18/002/1	Accepted
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	SAE053H/01 Content of a.s. (analysed): 79.6 g/L Mesotrione 29.8 g/L Nicosulfuron Batch No.: 55110-103	Diluted product: 1% in deionised water measured to be: Before storage: pH = 3.3 at 23.4 °C After storage at 35 °C for 12 weeks: pH = 3.4 at 23.2 °C	Y	KCP 2.1/01 Bance, G. (2018a) Report no.: JP/18/002/1	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments												
Viscosity (KCP 2.5.1)	CIPAC MT 192 (OECD 114), using Anton Paar MCR302 and MCR 92	SAE053H/01 Content of a.s. (analysed): 79.6 g/L Mesotrione 29.8 g/L Nicosulfuron Batch No.: 55110-103	Dynamic Viscosity:	Y	KCP 2.1/01 Bance, G. (2018a) Report no.: JP/18/002/1	Accepted												
			<table><tr><th>At 10s⁻¹ [mPa·s]</th><th>At 100s⁻¹ [mPa·s]</th><th>Flow behaviour</th><th>Temp [°C]</th></tr><tr><td>259</td><td>178</td><td>Non Newtonian thixotropic flow behaviour</td><td>20</td></tr><tr><td>186</td><td>94</td><td>Non Newtonian thixotropic flow behaviour</td><td>40</td></tr></table>				At 10s ⁻¹ [mPa·s]	At 100s ⁻¹ [mPa·s]	Flow behaviour	Temp [°C]	259	178	Non Newtonian thixotropic flow behaviour	20	186	94	Non Newtonian thixotropic flow behaviour	40
			At 10s ⁻¹ [mPa·s]				At 100s ⁻¹ [mPa·s]	Flow behaviour	Temp [°C]									
			259				178	Non Newtonian thixotropic flow behaviour	20									
			186				94	Non Newtonian thixotropic flow behaviour	40									
			Dynamic Viscosity after 12 weeks storage at 35 °C:															
			<table><tr><th>At 10s⁻¹ [mPa·s]</th><th>At 100s⁻¹ [mPa·s]</th><th>Flow behaviour</th><th>Temp [°C]</th></tr><tr><td>225</td><td>118</td><td>Non Newtonian thixotropic flow behaviour</td><td>20</td></tr><tr><td>134</td><td>88</td><td>Non Newtonian thixotropic flow behaviour</td><td>40</td></tr></table>				At 10s ⁻¹ [mPa·s]	At 100s ⁻¹ [mPa·s]	Flow behaviour	Temp [°C]	225	118	Non Newtonian thixotropic flow behaviour	20	134	88	Non Newtonian thixotropic flow behaviour	40
			At 10s ⁻¹ [mPa·s]				At 100s ⁻¹ [mPa·s]	Flow behaviour	Temp [°C]									
			225				118	Non Newtonian thixotropic flow behaviour	20									
			134				88	Non Newtonian thixotropic flow behaviour	40									
Kinematic Viscosity:																		
<table><tr><th>At 10s⁻¹ [mm²/s]</th><th>At 100s⁻¹ [mm²/s]</th><th>Flow behaviour</th><th>Temp [°C]</th></tr><tr><td>230</td><td>120</td><td>Non Newtonian thixotropic</td><td>20</td></tr><tr><td>137</td><td>90</td><td>Non Newtonian thixotropic</td><td>40</td></tr></table>	At 10s ⁻¹ [mm ² /s]	At 100s ⁻¹ [mm ² /s]	Flow behaviour	Temp [°C]	230	120	Non Newtonian thixotropic	20	137	90	Non Newtonian thixotropic	40						
At 10s ⁻¹ [mm ² /s]	At 100s ⁻¹ [mm ² /s]	Flow behaviour	Temp [°C]															
230	120	Non Newtonian thixotropic	20															
137	90	Non Newtonian thixotropic	40															
Calculation using relative density of 0.980																		
Surface tension (KCP 2.5.2)	EC A.5 Wilhelmy Plate Method	SAE053H/01 Content of a.s. (analysed): 79.6 g/L Mesotrione	Neat formulation at 25 °C: 32.5 mN/m 0.75 % in deionized water at 25 °C: 30.8 mN/m Surface active formulation	Y	KCP 2.1/01 Bance, G. (2018a) Report no.: JP/18/002/1	Accepted												

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments		
		29.8 g/L Nicosulfuron Batch No.: 55110-103						
Relative density (KCP 2.6.1)	EC A.3 OECD 109	SAE053H/01 Content of a.s. (analysed): 79.6 g/L Mesotrione 29.8 g/L Nicosulfuron Batch No.: 55110-103	Measured at 20 °C	Y	KCP 2.1/01 Bance, G. (2018a) Report no.: JP/18/002/1	Accepted		
			Storage period				Density [g/mL]	Relative density D ²⁰ ₄
			Initial				0.9797	0.980
			12 weeks at 35 °C				0.9822	0.982
Bulk density (KCP 2.6.2)			Not required for liquid preparation					
Storage Stability after 14 days at 54° C (KCP 2.7.1)			Please refer to study/information provided under point 2.7.2.					
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	Content of Mesotrione and Nicosulfuron by HPLC following method JP16001-1. The mesotrione im- purities R1, R2 and DCE were determined fol- lowing methods JP16001-5 and JP16001-6	SAE053H/01 Content of a.s. (analysed): 79.6 g/L Mesotrione 29.8 g/L Nicosulfuron Batch No.: 55110-103	Results of the analysis before and after storage indicated that SAE053H/01 is physically and chemically stable when stored at 35 °C for 12 weeks.	Y	KCP 2.1/01 Bance, G. (2018a) Report no.: JP/18/002/1	Accepted		
			Test				Initial results	Results after storage 12 weeks at 35 °C
			Appearance				Off-white opaque free- flowing liquid of medi- um viscosity with no foreign matter present	Off-white opaque free- flowing liquid of medi- um viscosity with no foreign matter present. 24 % clear brown su- pernatant, which re- quired 8 inverts to fully re-homogenise. No sediment

Annex point	Method used / deviations	Test material	Findings					GLP Y/N	Reference	Acceptability / comments	
	pH – CIPAC MT 75.3 Acidity – CIPAC 191 Dispersion stability – CIPAC MT 180 Persistent foaming CIPAC MT 47.3 Pourability CIPAC MT 148.1 Particle size distribution – CIPAC MT 187 Wet sieve test CIPAC MT 185		Packaging	White opaque cylindrical one litre PE/PA Coextruded bottle, fitted with 50mm white screw cap and foil induction seal. All in good condition.		White opaque cylindrical one litre PE/PA Coextruded bottle, fitted with 50mm white screw cap and foil induction seal. All in good condition.					
			A.I. content								
			Mesotrione Method: JP16001-1	79.6 g/L		80.1 g/L					
			Nicosulfuron Method: JP16001-1	29.8 g/L		29.1 g/L					
			Dichloroethane Method: JP16001-6	< LOQ (< 0.05 %)		<LOQ (< 0.05 %)					
			R1Method: JP16001-5	Pass (< 1µg/g)		Pass (< 1µg/g)					
			R2 Method: JP16001-5	None detected		<LOQ					
			pH 1% diluted	At 23.4 °C 3.3		At 23.2 °C 3.4					
			Acidity (% m/m H ₂ SO ₄)	1.69		1.81					
			Persistence foaming (%) in CIPAC water D Volume of foam [mL]								
				After 1 min	After 12min	After 1 min	After 12 min				
			0.25 % dilution	14	14	16	16				
			0.75 % dilution	24	16	26	22				
			Dispersion stability in standard water D at room temperature								

Annex point	Method used / deviations	Test material	Findings					GLP Y/N	Reference	Acceptability / comments	
					Volume of cream, oil, or sediment mL]						
					0.25 %	0.75 %	0.25 %	0.75 %			
			Initial Dispersibility	Nil separation	Nil separation	Nil separation	Nil separation	Nil separation			
			Separation after 30 minutes	Nil sediment 0.05ml top cream	Nil sediment 0.15ml top cream	Nil sediment Nil cream	Nil sediment Nil cream				
			Re-dispersibility after 24 hrs	Nil sediment	Nil sediment	Nil separation	Trace separation				
			Separation after 24 hours + 30 minutes	Nil sediment 0.05ml top cream	Nil sediment 0.15ml top cream	Nil sediment Nil cream	<0.05ml sediment Nil cream				
			Pourability [%]								
			Poured Residue [%]	1.08 %		1.05 %					
			The pourability is acceptable before and after storage. The rinse residue test was not carried out, as the pourability was < 5 %.								
			Particle size distribution [µm] (dispersed in rapeseed oil)								
			D(10)	1.2		1.3					
			D(50)	4.6		5.1					
			D(90)	8.7		10.3					
			Wet sieve test [%]	0.00		0.00					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments															
Minimum content after heat stability testing (KCP 2.7.3)			Please refer to study/information provided under point 2.7.2.																		
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 CIPAC MT 185	SAE053H/01 Content of a.s. (analysed): 79.6 g/L Mesotrione 29.8 g/L Nicosulfuron Batch No.: 55110-103	After 7 days at 0 °C, the sample was an opaque off-white free-flowing liquid of medium viscosity, and there was a pale yellow clear layer of 3 mL at the surface. After returning to room temperature for 24 hours, the tube was inverted once, but a clear layer of 2 mL returned to the surface. This was successfully re-homogenised with 5 inverts. A wet sieve test (CIPAC MT 185) was carried out. Residue on a 75 µm sieve: 0.00 %	Y	KCP 2.1/01 Bance, G. (2018a) Report no.: JP/18/002/1	Accepted															
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 CIPAC MT 180	SAE053H/01 Content of a.s. (analysed): 79.6 g/L Mesotrione 29.8 g/L Nicosulfuron Batch No.: 55110-103	<div>The product showed good physical and chemical stability after storage for 7 days at 0 °C.</div> <div>Dispersion Stability:</div> <table><thead><tr><th></th><th>0.25 % w/v CIPAC water D</th><th>0.75 % w/v CIPAC water D</th></tr></thead><tbody><tr><td>Initial dispersibility</td><td>Nil separation</td><td>Nil separation</td></tr><tr><td>Separation after 30 minutes</td><td>Nil sediment Nil top cream</td><td>Nil sediment Nil top cream</td></tr><tr><td>Separation after 24 hours + re-dispersion</td><td>Nil sediment</td><td>Nil sediment</td></tr><tr><td>Separation after 24 hours + 30 minutes</td><td>Nil sediment Nil top cream</td><td>Nil sediment Nil top cream</td></tr></tbody></table>		0.25 % w/v CIPAC water D	0.75 % w/v CIPAC water D	Initial dispersibility	Nil separation	Nil separation	Separation after 30 minutes	Nil sediment Nil top cream	Nil sediment Nil top cream	Separation after 24 hours + re-dispersion	Nil sediment	Nil sediment	Separation after 24 hours + 30 minutes	Nil sediment Nil top cream	Nil sediment Nil top cream	Y	KCP 2.7.4/01 Bance, G. (2018b) Report no.: JP/18/002/3	Accepted
	0.25 % w/v CIPAC water D	0.75 % w/v CIPAC water D																			
Initial dispersibility	Nil separation	Nil separation																			
Separation after 30 minutes	Nil sediment Nil top cream	Nil sediment Nil top cream																			
Separation after 24 hours + re-dispersion	Nil sediment	Nil sediment																			
Separation after 24 hours + 30 minutes	Nil sediment Nil top cream	Nil sediment Nil top cream																			
Ambient temperature shelf life (KCP 2.7.5)		SAE053H/01 Content of a.s. (analysed):	Results of the analysis before and after storage indicated that SAE053H/01 is physically and chemically stable when stored at 20 °C for 104 weeks.	Y	KCP 2.7.5/02 Bance, G. (2020) Report no.: JP/18/002/2	Accepted Coextruded PE/PA															

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
		79.6 g/L Mesotrione 29.8 g/L Nicosulfuron Batch No.: 55110-103	Test	Initial results	Results after storage 104 weeks at 20 °C			pack remained intact after storage.
			Appearance	Off-white opaque free-flowing liquid of medium viscosity with no foreign matter present	Off-white opaque free-flowing liquid of medium viscosity with no foreign matter present. There was 60 % dark brown clear supernatant and no sediment. The samples was fully re-homogenised with 12 inverts.			Summarizing, the two-year shelf life can be granted for the PPP.
			Packaging	White opaque cylindrical one litre PE/PA Coextruded bottle, fitted with 50mm white screw cap and foil induction seal. All in good condition.	White opaque round-profile one litre PE/PA bottle, fitted with 50mm screw cap. Ratchet and foil induction seal intact. Pack in good conditions. No weight change is observed			
			A.I. content					
			Mesotrione Method: JP16001-1	79.6 g/L	80.6 g/L			
			Nicosulfuron Method: JP16001-1	29.8 g/L	29.5 g/L			
			Dichloroethane Method: JP16001-6	< LOQ (< 0.05 %)	<LOQ (< 0.05 %)			
			R1Method: JP16001-5	Pass (< 1µg/g)	Pass (< 1µg/g)			
			R2 Method: JP16001-5	None detected	None detected			

Annex point	Method used / deviations	Test material	Findings					GLP Y/N	Reference	Acceptability / comments
			pH 1% diluted	At 23.4 °C 3.3	At 21.8 °C 3.4					
			Acidity (% m/m H ₂ SO ₄)	1.69	1.76					
			Persistence foaming (%) in CIPAC water D							
			Volume of foam [mL]							
				After 1 min	After 12min	After 1 min	After 12 min			
			0.25 % dilution	14	14	10	10			
			0.75 % dilution	16	16	22	10			
			Dispersion stability in standard water D at room temperature							
				Volume of cream, oil, or sediment mL]						
				0.25 %	0.75 %	0.25 %	0.75 %			
			Initial Dispersibility	Nil separation	Nil separation	Nil separation	Nil separation			
			Separation after 30 minutes	Nil sediment 0.05mL top cream	Nil sediment 0.15mL top cream	Nil separation	Nil separation			
			Re-dispersibility after 24 hrs	Nil sediment	Nil sediment	Nil sediment	< 1 mL sediment			
			Separation after 24 hours + 30 minutes	Nil sediment 0.05mL top cream	Nil sediment 0.15mL top cream	Nil separation	< 0.05mL sediment			
			Pourability [%]							
			Poured Residue [%]	1.08 %		1.07 %				
			The pourability is acceptable before and after storage. The rinse residue test was not carried out, as the pourability was < 5 %.							

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																									
			<table><tr><td colspan="5">Particle size distribution [µm] (dispersed in rapeseed oil)</td></tr><tr><td>D(10)</td><td colspan="2">1.2</td><td colspan="2">1.3</td></tr><tr><td>D(50)</td><td colspan="2">4.6</td><td colspan="2">5.2</td></tr><tr><td>D(90)</td><td colspan="2">8.7</td><td colspan="2">10.5</td></tr><tr><td>Wet sieve test [%]</td><td colspan="2">0.00</td><td colspan="2">0.01</td></tr></table>	Particle size distribution [µm] (dispersed in rapeseed oil)					D(10)	1.2		1.3		D(50)	4.6		5.2		D(90)	8.7		10.5		Wet sieve test [%]	0.00		0.01				
Particle size distribution [µm] (dispersed in rapeseed oil)																															
D(10)	1.2		1.3																												
D(50)	4.6		5.2																												
D(90)	8.7		10.5																												
Wet sieve test [%]	0.00		0.01																												
Shelf life in months (if less than 2 years) (KCP 2.7.6)			Not required formulation is expected to be stable for at least 2 years at shelf life conditions																												
Wettability (KCP 2.8.1)			Not required for OD preparation																												
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	SAE053H/01 Content of a.s. (analysed): 79.6 g/L Meso-trione 29.8 g/L Nico-sulfuron Batch No.: 55110-103	<table><tr><td>Test</td><td colspan="2">Initial results</td><td colspan="2">Results after storage 12 weeks at 35 °C</td></tr><tr><td colspan="5">Persistence foaming [%] in CIPAC water D</td></tr><tr><td></td><td>After 1 min</td><td>After 12min</td><td>After 1 min</td><td>After 12 min</td></tr><tr><td>0.25 % dilution</td><td>14</td><td>14</td><td>16</td><td>16</td></tr><tr><td>0.75 % dilution</td><td>24</td><td>16</td><td>26</td><td>22</td></tr></table>	Test	Initial results		Results after storage 12 weeks at 35 °C		Persistence foaming [%] in CIPAC water D						After 1 min	After 12min	After 1 min	After 12 min	0.25 % dilution	14	14	16	16	0.75 % dilution	24	16	26	22	Y	KCP 2.1/01 Bance, G. (2018a) Report no.: JP/18/002/1	Accepted
Test	Initial results		Results after storage 12 weeks at 35 °C																												
Persistence foaming [%] in CIPAC water D																															
	After 1 min	After 12min	After 1 min	After 12 min																											
0.25 % dilution	14	14	16	16																											
0.75 % dilution	24	16	26	22																											
Suspensibility (KCP 2.8.3.1)			Not required for OD preparation																												
Spontaneity of dispersion (KCP 2.8.3.2)			Not required for OD preparation																												

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments				
Dispersion stability (KCP 2.8.3.3)	CIPAC MT 180	SAE053H/01 Content of a.s. (analysed): 79.6 g/L Meso- trione 29.8 g/L Nico- sulfuron Batch No.: 55110-103					Y	KCP 2.1/01 Bance, G. (2018a) Report no.: JP/18/002/1	Accepted	
			Test	Initial results		Results after storage 12 weeks at 35 °C				
			Dispersion stability of product in standard water D							
				Volume of cream, oil, or sediment [mL]						
				0.25 %	0.75 %	0.25 %				0.75 %
			Initial Dispersibility	Nil separation	Nil separation	Nil separation				Nil separation
			Separation after 30 minutes	Nil sediment 0.05ml top cream	Nil sediment 0.15ml top cream	Nil sediment Nil cream				Nil sediment Nil cream
			Re-dispersibility after 24 hrs	Nil sediment	Nil sediment	Nil separation				Trace separation
Degree of dissolution and dilution stability (KCP 2.8.4)			Not required for OD preparation							
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	SAE053H/01 Content of a.s. (analysed): 79.6 g/L Mesotrione 29.8 g/L Nicosulfuron Batch No.: 55110-103					Y	KCP 2.1/01 Bance, G. (2018a) Report no.: JP/18/002/1	Accepted	
			Test	Initial results		Results after storage 12 weeks at 35 °C				
			Particle size distribution [µm+ (dispersed in rapeseed oil)]							
			D(10)	1.2		1.3				
			D(50)	4.6		5.1				

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	SAE053H/01 Content of a.s. (analysed): 79.6 g/L Mesotrione 29.8 g/L Nicosulfuron Batch No.: 55110-103	Test	Initial results	Results after storage 12 weeks at 35 °C	Y	KCP 2.1/01 Bance, G. (2018a) Report no.: JP/18/002/1	Accepted
			Wet sieve test [%]	0.00	0.00			
Dust content (KCP 2.8.5.2.1)			Not required for OD preparation					
Particle size of dust (KCP 2.8.5.2.2)			Not required for OD preparation					
Attrition (KCP 2.8.5.3)			Not required for OD preparation					
Hardness and integrity (KCP 2.8.5.4)			Not required for OD preparation					
Emulsifiability (KCP 2.8.6.1)			Not required for OD preparation					
Emulsion stability (KCP 2.8.6.2)			Not required for OD preparation					
Re-emulsifiability (KCP 2.8.6.3)			Not required for OD preparation					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments									
Flowability (KCP 2.8.7.1)			Not required for OD preparation												
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	SAE053H/01 Content of a.s. (analysed): 79.6 g/L Mesotrione 29.8 g/L Nicosulfuron Batch No.: 55110-103	<table><tr><th>Test</th><th>Initial results</th><th>Results after storage 12 weeks at 35 °C</th></tr><tr><td colspan="3">Pourability [%]</td></tr><tr><td>Poured Residue [%]</td><td>1.08</td><td>1.05</td></tr></table>	Test	Initial results	Results after storage 12 weeks at 35 °C	Pourability [%]			Poured Residue [%]	1.08	1.05	Y	KCP 2.1/01 Bance, G. (2018a) Report no.: JP/18/002/1	Accepted
Test	Initial results	Results after storage 12 weeks at 35 °C													
Pourability [%]															
Poured Residue [%]	1.08	1.05													
Dustability following accelerated storage (KCP 2.8.7.3)			Not required for OD preparation												
Physical compatibility of tank mixes (KCP 2.9.1)			SAE053H/01will not be used in tank mixtures												
Chemical compatibility of tank mixes (KCP 2.9.2)			Not required for OD preparation												
Adhesion to seeds (KCP 2.10.1)			Not required for OD preparation												

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
Distribution to seed (KCP 2.10.2)			Not required for OD preparation					
Other/special studies (KCP 2.11)	PSD Efficacy guideline 305 Analytical method JP16001-1.	SAE053H/01 Content of a.s. (analysed): 79.6 g/L Mesotrione 29.8 g/L Nicosulfuron Batch No.: 55110-103	Tank cleaning effectiveness test:			Y	KCP 2.1/01 Bance, G. (2018a) Report no.: JP/18/002/1	Accepted
			Dilution rate	Mean % removed Mesotrione	Mean % removed Nicosulfuron			
			0.25 %	99.97	99.89			
			0.75 %	99.96	99.91			

3 Section 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 formulated product is intended for containment in 1, 5 and 10 L bottles.

Detailed information on the packaging material is summarised below and in ref. KCP 4.4/01 to KCP 4.4/09.

Table 4.1-1: Packaging information for 1L bottle

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	cylindrical / approx.88.5 mm diameter × 234 mm high
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Heat Foil liner
Tare mass	110g
Capacity	1.1 L
Manner of construction	extruded
UN/ADR	Compliant: 1H1/Y1.3/150/.../D/BAM 12761 K WA

Table 4.1-2: Packaging information for 5L bottle

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	Plastic jerricans non-removable head Length 190 mm, width 140 mm, Height 313 mm
Opening:	54.5 mm inner diameter
Closure:	container without closure
Seal:	Heat Foil Liner
Tare mass	220g
Capacity	5.71 L
Manner of construction	extruded
UN/ADR	Compliant: 3H1/Y1.3/150/...../D/BAM 12932-KWA

Table 4.1-3: Packaging information for 10L bottle

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	Plastics Jerrican non-removable head Length 230 mm, Width 165 mm, Height 375 mm
Opening:	54.5 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Heat Foil Liner
Tare mass	400g
Capacity	10.78 L

Type	Description
Manner of construction	extruded
UN/ADR	Compliant: 3H1/Y1.3/150/./D/BAM 12903-KWA

RMS comment:

Based on the two-year storage stability study at ambient temperature all mentioned above packs are accepted for this PPP

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 2.1/01	Bance, G.	2018a	Physical and Chemical Properties of SAE053H/01: Storage Stability for up to 12 weeks at 35 °C stored in a 1 litre PE/PA coextruded bottle. BATTELLE Report No.: JP/18/002/1 Battelle UK Ltd. GLP Unpublished	N	Sumi Agro Europe Ltd
KCP 2.2.1/01	Younis, S.	2018	Phys/Chem Testing on a Sample of SAE053H/01. Report No.: GLP3016003919R1V1/2018 Chilworth Technology Ltd GLP Unpublished	N	Sumi Agro Europe Ltd
KCP 2.2.2/02 = KCP 2.2.1/01	Younis, S.	2018	See KCP 2.2.1/01	N	Sumi Agro Europe Ltd
KCP 2.3.1/01 = KCP 2.1/01	Bance, G.	2018a	See KCP 2.1/01	N	Sumi Agro Europe Ltd
KCP 2.3.3/01 = KCP 2.2.1/01	Younis, S.	2018	See KCP 2.2.1/01	N	Sumi Agro Europe Ltd
KCP 2.4.1/01 = KCP 2.1/01	Bance, G.	2018a	See KCP 2.1/01	N	Sumi Agro Europe Ltd
KCP 2.4.2/01 = KCP 2.1/01	Bance, G.	2018a	See KCP 2.1/01	N	Sumi Agro Europe Ltd
KCP 2.5.1/01 = KCP 2.1/01	Bance, G.	2018a	See KCP 2.1/01	N	Sumi Agro Europe Ltd

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.5.2/01 = KCP 2.1/01	Bance, G.	2018a	See KCP 2.1/01	N	Sumi Agro Europe Ltd
KCP 2.6.1/01 = KCP 2.1/01	Bance, G.	2018a	See KCP 2.1/01	N	Sumi Agro Europe Ltd
KCP 2.7.2/01 = KCP 2.1/01	Bance, G.	2018a	See KCP 2.1/01	N	Sumi Agro Europe Ltd
KCP 2.7.4/01 = KCP 2.1/01	Bance, G.	2018a	See KCP 2.1/01	N	Sumi Agro Europe Ltd
KCP 2.7.4/02	Bance, G.	2018b	Physical and Chemical Properties of SAE053H/01: Storage Stability for 7 days at 0 °C. BATTELLE Report No.: JP/18/002/3 Battelle UK Ltd. GLP Unpublished	N	Sumi Agro Europe Ltd
KCP 2.7.5/01	Bance, G.	2018c	Study Plan - Physical and Chemical Properties of SAE053H/01: Storage Stability for 104 weeks at 35 °C stored in a 1 litre PE/PA coextruded bottle. BATTELLE Report No.: JP/18/002/2 Battelle UK Ltd. GLP Unpublished	N	Sumi Agro Europe Ltd
KCP 2.7.5/02	Bance, G.	2020	Final Report - Physical and Chemical Properties of SAE053H/01: Storage Stability for 104 weeks at 20 °C stored in a 1 litre PE/PA coextruded bottle. BATTELLE Report No.: JP/18/002/2 Battelle UK Ltd. GLP Unpublished	N	Sumi Agro Europe Ltd
KCP 2.8.2/01 = KCP 2.1/01	Bance, G.	2018a	See KCP 2.1/01	N	Sumi Agro Europe Ltd

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.8.3.3/01 = KCP 2.1/01	Bance, G.	2018a	See KCP 2.1/01	N	Sumi Agro Europe Ltd
KCP 2.8.5.1.1/01 = KCP 2.1/01	Bance, G.	2018a	See KCP 2.1/01	N	Sumi Agro Europe Ltd
KCP 2.8.5.1.2/01 = KCP 2.1/01	Bance, G.	2018a	See KCP 2.1/01	N	Sumi Agro Europe Ltd
KCP 2.8.7.2/01 = KCP 2.1/01	Bance, G.	2018a	See KCP 2.1/01	N	Sumi Agro Europe Ltd
KCP 2.11/01 = KCP 2.1/01	Bance, G.	2018a	See KCP 2.1/01	N	Sumi Agro Europe Ltd
KCP 4.4/01	Anonymous	n.r.	Product Information – AgroPack Dual 1000 mL PE-PA UN Report No: n.a. Kautex Textron GmbH&Co.Kg. Non-GLP Published	N	Not relevant
KCP 4.4/02	Vadala, B.	2008	Rundflasche 1000 mL TB 50 Report No: Drawing number 321 217 C Kautex Textron GmbH&Co.Kg. Non-GLP Published	N	Not relevant
KCP 4.4/03	Wienecke, B.-U.	2010	Zulassungsschein / Certificate of Approval Nr. D/BAM 12760/1H1 BAM Non-GLP Published	N	Not relevant

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 4.4/04	Anonymous	n.r.	Product Information – AgroPack Dual 5 L PE-PA C95 UN Report No: n.a. Kautex Textron GmbH&Co.Kg. Non-GLP Published	N	Not relevant
KCP 4.4/05	Meyer	2010	5L Pflanzenschutzkanister C95 Report No: Drawing number 1/225/112 Bl.2 Kautex Textron GmbH&Co.Kg. Non-GLP Published	N	Not relevant
KCP 4.4/06	Wienecke, B.-U.	2012	Zulassungsschein / Certificate of Approval Nr. D/BAM 12932/3H1 BAM Non-GLP Published	N	Not relevant
KCP 4.4/07	Anonymous	n.r.	Product Information – AgroPack Dual 10 L PE-PA N Report No: n.a. Kautex Textron GmbH&Co.Kg. Non-GLP Published	N	Not relevant
KCP 4.4/08	Meyer	2010	10 L Kanister Pool Coex Report No: Drawing number 0-225-85 Bl.2 Kautex Textron GmbH&Co.Kg. Non-GLP Published	N	Not relevant
KCP 4.4/09	Wienecke, B.-U.	2015	Zulassungsschein / Certificate of Approval Nr. D/BAM 12903/3H1 BAM Non-GLP Published	N	Not relevant

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

None.