

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: ADM.01851.H.1.A

Product name(s): see Part A

Chemical active substances:

Ethofumesate, 500 g/L

Clopyralid, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Country organisation / representative of ADAMA,
as given in Part A

Submission date: July 2024

MS Finalisation date: March 2025 (initial Core Assessment)

June 2025 (final Core Assessment)

Version history

When	What
July 2024	dRR version 1 submitted by applicant
March 2025	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
June 2025	Final report (National Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the CMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.

DATA PROTECTION CLAIM

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for these studies. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A

STATEMENT FOR OWNERSHIP

The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

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Table of Contents

1	Section 1: Identity of the plant protection product	5
1.1	Applicant (KCP 1.1).....	5
1.2	Producer of the plant protection product and of the active substances (KCP 1.2)	5
1.2.1	Producer(s) of the preparation	5
1.2.2	Producer(s) of the active substance(s)	5
1.2.3	Statement of purity (and detailed information on impurities) of the active substance(s)	5
1.2.3.1	Ethofumesate	5
1.2.3.2	Clopyralid	5
1.3	Trade names and producer's development code numbers for the preparation (KCP 1.3).....	5
1.4	Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4).....	6
1.4.1	Composition of the plant protection product (KCP 1.4.1).....	6
1.4.2	Information on the active substance(s) (KCP 1.4.2).....	6
1.4.3	Information on safeners, synergists and co-formulants (KCP 1.4.3).....	6
1.5	Type and code of the plant protection product (KCP 1.5).....	7
1.6	Function (KCP 1.6)	7
2	Section 2: Physical, chemical and technical properties of the plant protection product	8
3	Section 3 is presented as a separate document.....	18
4	Section 4: Further information on the plant protection product	19
4.1	Packaging and Compatibility with the Preparation (KCP 4.4).....	19
4.2	Recommended methods and precautions (KCP 4.2)	23
4.3	Safety intervals and other precautions to protect humans, animals and the environment (KCP 4.1).....	25
4.4	Emergency measures in the case of an accident (KCP 4.3).....	25
4.5	Procedures for destruction or decontamination of the plant protection product and its packaging (KCP 4.5).....	25
Appendix 1	Lists of data considered in support of the evaluation.....	26
Appendix 2	Additional data on the physical, chemical and technical properties of the active substance	30
A 2.1	Ethofumesate	30
A 2.2	Clopyralid	30

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product ADM.01851.H.1.A and the contained technical active substances.

Noticed data gaps are:

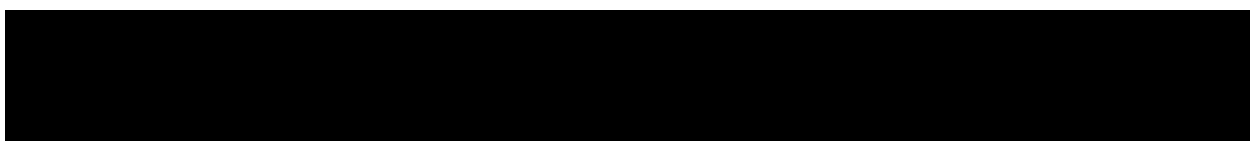
- The 2 years storage stability is still ongoing upon submission of the dossier, which is a formal data GAP. Sufficient data however is available from the accelerated storage testing.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Country organisation/representative as specified in Part A.

Name Country organisation/representative of ADAMA Agan Ltd. as given in Part A



Please refer to Registration Report Part A for national applicant contact details.

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 Ethofumesate

Ethofumesate min. 975 g/kg

According to Commission Implementing Regulation (EU) 2016/1426 of 25 August 2016 the following impurities of toxicological concern have been identified for ethofumesate:

EMS (ethyl methane sulfonate):	max. 0.1 mg/kg
iBMS (iso-butyl methane sulfonate):	max. 0.1 mg/kg

1.2.3.2 Clopyralid

Clopyralid min. 950 g/kg

According to Commission Implementing Regulation (EU) 2021/1191 of 19 July 2021 impurities of toxicologically or ecotoxicologically concern have not been identified for clopyralid.

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 information
Company code number: ADM.01851.H.1.A

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)

ADM.01851.H.1.A is a new product. It was not the representative formulation during evaluation of ethofumesate or clopyralid on EU level.

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/L)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
Ethofumesate	500	500 g/L ± 25 g/L (475 – 525 g/L)	512.8 g/L ± 25 g/L (487.8 – 537.8)	~~43.83~~ 44.40
Clopyralid	75	75 g/L ± 7.5 g/L (67.5 – 82.5 g/L)	78.9 g/L ± 7.5 g/L (71.4 – 86.4)	~~6.74~~ 6.49

* Based on the minimum purity of the active substances:
97.5 % (w/w) for ethofumesate and 95 % (w/w) for clopyralid

** Based on the density of the formulation = ~~1.17 g/mL~~ 1.155 g/cm³

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/kg)
EMS (ethyl methane sulfonate): iBMS (iso-butyl methane sulfonate):	0.1 mg/kg related to active substance content 0.1 mg/kg related to active substance content

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

Table 1.4-3: Information on ethofumesate

Type	Name/Code Number	
ISO common name	ethofumesate	no variant
CAS No.	26225-79-6	-
EC No.	247-525-3	-
CIPAC No.	233	-

Table 1.4-4: Information on clopyralid

Type	Name/Code Number	
ISO common name	clopyralid	no variant
CAS No.	1702-17-6	-
EC No.	216-935-4	-
CIPAC No.	455	-

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

Safeners or synergists are not present in the formulation.

With regard to co-formulants, this is CONFIDENTIAL information and is provided separately (Part C).

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

Type: Suspension concentrate

[Code: SC]

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 an oyster white opaque homogeneous liquid with characteristic odour. It is not explosive, and has no oxidising properties. The product does not flash in the range tested from 10 to 110°C. It has a self-ignition temperature of 485°C. The pH value of the neat formulation is 7.2 and the pH value of a 1% dilution is 7.3 at ambient temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the content of the active ingredients or impurities nor the technical properties were changed. The 2 years shelf-life study is on-going at the time of submission of this dossier. Based on the accelerated storage stability study, the data confirms the formulation meets the regulatory requirements and the shelf life is expected to be at least 2 years when stored at ambient temperature in HDPE/PA commercial containers. Its technical characteristics are acceptable for a SC formulation.

The intended concentration of use is 0.165% to 0.66%.

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 ADM.01851.H.1.A with regard to product classification and labelling:

Studies	Method	Findings	Classification acc. to Regulation (EC) No. 1272/2008
Explosive properties	EC A.14	Not explosive	None
Oxidising properties	EC A.21	Not oxidizing	None
Flammability	--	Not applicable for SC-formulation	--
Flash point	EC A.9	No flash in the range tested from 10 to 110°C	None
Auto-flammability	EC A.15	Self-ignition temperature = 485°C	None
pH	CIPAC MT 75.3	7.2	None
Viscosity	CIPAC MT 192, OECD 114	Shear rate (s⁻¹)	None
		Mean viscosity at 20°C	
		Mean viscosity at 40°C	
		Dynamic viscosity (cP = mPa*s)	
		0.1	
		21695.3	
		10964.7	
		0.2	
		12947.0	
		7148.3	
		0.5	
		6305.7	
		3765.7	
		1.0	
		3632.3	
		2256.7	
		2.0	
		2190.0	
		1400.0	
		4.1	
		1320.0	
		856.5	
		10.2	
		706.5	
		462.6	
		20.4	
		455.4	
		302.1	
		Kinematic viscosity (cSt = mm²/s)	
		0.1	
		18784	
		-	
		0.2	
		11210	
		-	
		0.5	
		5459.5	
		-	
		1.0	
		3144.8	
		-	
		2.0	
		1896.1	
		-	
		4.1	
		1142.9	
		-	
		10.2	
		611.7	
		-	
Surface tension	EEC A.5	42.2 mN/m for 0.84% (v/v) solution of the test item in de-ionized water at 20.0°C	None
Relative density	EEC A.3	1.155 (Batch U3311B)	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 ADM.01851.H.1.A has not 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)	OPPTS 830.6302; 830.6303; 830.6304 Visual examination	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 507.1 g/L Clopyralid: 76.2 g/L Batch No.: U3311B	<u>Before and after storage of 14 days at 54 °C:</u> Oyster white (RAL code 1013) opaque homogeneous liquid with characteristic odour <u>After storage:</u> Oyster white (RAL code 1013) opaque homogeneous liquid with characteristic odour	Y	KCP 2.1/01 Massardi,E. 2024a Doc. no.: 000118842	Accepted.
Explosive properties (KCP 2.2.1)	EC A.14	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 517.4 g/L Clopyralid: 75.6 g/L Batch No.: U3301P1	BAM Fallhammer: Negative Koenen Tube: Negative No explosive properties	Y	KCP 2.2.1 /01 Michnik, I. (2024) Doc. No.: 000116227	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Oxidizing properties (KCP 2.2.2)	EC A.21	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 517.4 g/L Clopyralid: 75.6 g/L Batch No.: U3301P1	Not an Oxidising Liquid	Y	KCP 2.2.1 /01 Michnik, I. (2024) Doc. No.: 000116227	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Flash point (KCP 2.3.1)	EC Reg. 440/2008 A.9 Setaflash Tester	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 507.1 g/L Clopyralid: 76.2 g/L Batch No.: U3311B	No flash in the range tested from 10 to 110°C, therefore the test item is considered to be not flammable	Y	KCP 2.1/01 Massardi,E. 2024a Doc. no.: 000118842	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																											
						manual.																											
Flammability (KCP 2.3.2)	-	-	Not required for SC preparation	-	-	-																											
Self-heating (KCP 2.3.3)	EC A.15	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 517.4 g/L Clopyralid: 75.6 g/L Batch No.: U3301P1	Self-ignition temperature = 485°C	Y	KCP 2.2.1 /01 Michnik, I. (2024) Doc. No.: 000116227	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.																											
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3 OECD 122	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 507.1 g/L Clopyralid: 76.2 g/L Batch No.: U3311B	undiluted product measured at ambient temperature (25 ± 0.5°C): <u>Before storage</u> : pH = 7.2 <u>After storage</u> for 14 days at 54°C: pH = 7.3 Since the pH values were in the range from 4 to 10 the acidity or alkalinity test is not required.	Y	KCP 2.1/01 Massardi,E. 2024a Doc. no.: 000118842	Accepted.																											
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3 OECD 122	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 507.1 g/L Clopyralid: 76.2 g/L Batch No.: U3311B	1% w/w in deionized water measured at ambient temperature (25 ± 0.5°C): <u>Before storage</u> : pH = 7.3 <u>After storage</u> for 14 days at 54°C: pH = 7.4	Y	KCP 2.1/01 Massardi,E. 2024a Doc. no.: 000118842	Accepted.																											
Viscosity (KCP 2.5.1)	CIPAC MT 192 OECD 114 Viscosity by rotational viscometry	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 507.1 g/L Clopyralid: 76.2 g/L Batch No.: U3311B	Viscosity at 20 °C and 40 °C: Non-Newtonian fluid, viscosity decreases as shear rate increases <table><tr><th>Shear rate (s⁻¹)</th><th>Mean viscosity at 20°C</th><th>Mean viscosity at 40°C</th></tr><tr><td colspan="3">Dynamic viscosity (cP = mPa*s)</td></tr><tr><td>0.1</td><td>21695.3</td><td>10964.7</td></tr><tr><td>0.2</td><td>12947.0</td><td>7148.3</td></tr><tr><td>0.5</td><td>6305.7</td><td>3765.7</td></tr><tr><td>1.0</td><td>3632.3</td><td>2256.7</td></tr><tr><td>2.0</td><td>2190.0</td><td>1400.0</td></tr><tr><td>4.1</td><td>1320.0</td><td>856.5</td></tr><tr><td>10.2</td><td>706.5</td><td>462.6</td></tr></table>	Shear rate (s ⁻¹)	Mean viscosity at 20°C	Mean viscosity at 40°C	Dynamic viscosity (cP = mPa*s)			0.1	21695.3	10964.7	0.2	12947.0	7148.3	0.5	6305.7	3765.7	1.0	3632.3	2256.7	2.0	2190.0	1400.0	4.1	1320.0	856.5	10.2	706.5	462.6	Y	KCP 2.1/01 Massardi,E. 2024a Doc. no.: 000118842	Accepted.
Shear rate (s ⁻¹)	Mean viscosity at 20°C	Mean viscosity at 40°C																															
Dynamic viscosity (cP = mPa*s)																																	
0.1	21695.3	10964.7																															
0.2	12947.0	7148.3																															
0.5	6305.7	3765.7																															
1.0	3632.3	2256.7																															
2.0	2190.0	1400.0																															
4.1	1320.0	856.5																															
10.2	706.5	462.6																															

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																											
			<table><tr><td>20.4</td><td>455.4</td><td>302.1</td></tr><tr><td colspan="3">Kinematic viscosity (cSt = mm²/s)</td></tr><tr><td>0.1</td><td>18784</td><td>-</td></tr><tr><td>0.2</td><td>11210</td><td>-</td></tr><tr><td>0.5</td><td>5459.5</td><td>-</td></tr><tr><td>1.0</td><td>3144.8</td><td>-</td></tr><tr><td>2.0</td><td>1896.1</td><td>-</td></tr><tr><td>4.1</td><td>1142.9</td><td>-</td></tr><tr><td>10.2</td><td>611.7</td><td>-</td></tr></table> Mean of 3 measurements Kinematic viscosity = dynamic viscosity / density (1.155)	20.4	455.4	302.1	Kinematic viscosity (cSt = mm ² /s)			0.1	18784	-	0.2	11210	-	0.5	5459.5	-	1.0	3144.8	-	2.0	1896.1	-	4.1	1142.9	-	10.2	611.7	-			
20.4	455.4	302.1																															
Kinematic viscosity (cSt = mm ² /s)																																	
0.1	18784	-																															
0.2	11210	-																															
0.5	5459.5	-																															
1.0	3144.8	-																															
2.0	1896.1	-																															
4.1	1142.9	-																															
10.2	611.7	-																															
Surface tension (KCP 2.5.2)	OECD 115 EC Reg. 440/2008 A.5 Ring Tensiometer	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 507.1 g/L Clopyralid: 76.2 g/L Batch No.: U3311B	Maximum dilution rate of 0.84 %v/v: 42.2 mN/m in de-ionized water at 20.0 °C Surface active formulation	Y	KCP 2.1/01 Massardi,E. 2024a Doc. no.: 000118842	Accepted.																											
Relative density (KCP 2.6.1)	OECD 109 EC Reg. 440/2008 A.3 CIPAC MT 3.3.2 using a density bottle	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 507.1 g/L Clopyralid: 76.2 g/L Batch No.: U3311B	Density at 20°C: 1.155 g/cm ³ Relative density ²⁰ D ₄ = 1.155	Y	KCP 2.1/01 Massardi,E. 2024a Doc. no.: 000118842	Accepted.																											
Bulk density (KCP 2.6.2)	-	-	Not required for SC preparation	-	-	-																											
Storage Stability after 14 days at 54°C (KCP 2.7.1)	CIPAC MT 46.3 The content of a.s´s. and impurities was analysed by HPLC-DAD method (see KCP 5.1.1/01 resp. KCP 5.1.1/02).	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 507.1 g/L Clopyralid: 76.2 g/L Batch No.: U3311B	Results of the analysis before and after storage indicated that ADM.01851.H.1.A is physically and chemically stable when stored for 14 days at 54 °C. The material used was HDPE-PA which stands for high density polyethylene co-extruded with PA (polyamide). Please refer to Table 2.2 for more details.	Y	KCP 2.1/01 Massardi,E. 2024a Doc. no.: 000118842	Accepted. The product showed no significant physical changes after accelerated storage. No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the																											

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						container material. No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (HDPE/PA).
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required as ADM.01851.H.1.A was shown to be stable for 14 days at 54 °C	-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Not required as ADM.01851.H.1.A was shown to be stable for 14 days at 54 °C	-	-	-
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 The content of a.s.'s was analysed by HPLC-DAD method (see KCP 5.1.1/01)	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 507.1 g/L Clopyralid: 76.2 g/L Batch No.: U3311B	Results of the analysis before and after storage indicated that ADM.01851.H.1.A is physically and chemically stable when stored at 0°C for 7 Days. During the low temperature stability, the test item after 24 h and after 7 days at 0°C was homogeneous. The test was therefore concluded at 7 days. Please refer to Table 2.3 for more details.	Y	KCP 2.1/01 Massardi,E. 2024a Doc. no.: 000118842	Accepted.
Ambient temperature shelf life (KCP 2.7.5)	CIPAC MT 75.3 MT 191 MT 47.3 MT 184.1	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 507.1 g/L Clopyralid: 76.2 g/L Batch No.: U3311B	One batch of ADM.01851.H.1.A packed in HDPE-Coex (HDPE/PA) commercial containers were stored at ambient temperature for two years. No interim results are available, as the study is on-going.		KCP 2.7.5/01 Massardi,E. 2024b Doc. no.: 000118841 STUDY PLAN	STUDY ongoing.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																					
	MT 160 MT 185 MT 187 MT 148 OPPTS 830.6320 The content of a.s.'s. and impurities will be analysed by HPLC-DAD method (see KCP 5.1.1/01 resp. KCP 5.1.1/02).		STUDY ongoing																								
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 SC preparation	-	-	-																					
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3 and CIPAC MT 18.1	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 507.1 g/L Clopyralid: 76.2 g/L Batch No.: U3311B	Persistent foaming (ml) at room temperature (25°C ± 5 °C) in standard water D. <table><tr><td>Time</td><td>0.05% v/v product</td><td>0.84% v/v product</td></tr><tr><td colspan="3">Before storage</td></tr><tr><td>After 1 min</td><td>14 mL</td><td>21 mL</td></tr><tr><td>After 12 min</td><td>10 mL</td><td>8 mL</td></tr><tr><td colspan="3">Results after storage at 14 days at 54 °C</td></tr><tr><td>After 1 min</td><td>17 mL</td><td>21 mL</td></tr><tr><td>After 12 min</td><td>11 mL</td><td>4 mL</td></tr></table>	Time	0.05% v/v product	0.84% v/v product	Before storage			After 1 min	14 mL	21 mL	After 12 min	10 mL	8 mL	Results after storage at 14 days at 54 °C			After 1 min	17 mL	21 mL	After 12 min	11 mL	4 mL	Y	KCP 2.1/01 Massardi,E. 2024a Doc. no.: 000118842	Accepted.
Time	0.05% v/v product	0.84% v/v product																									
Before storage																											
After 1 min	14 mL	21 mL																									
After 12 min	10 mL	8 mL																									
Results after storage at 14 days at 54 °C																											
After 1 min	17 mL	21 mL																									
After 12 min	11 mL	4 mL																									
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184 and CIPAC MT 18.1 The content of a.s.'s was analysed by HPLC-DAD method (see KCP	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 507.1 g/L Clopyralid: 76.2 g/L Batch No.: U3311B	Test with standard water D at 25 ± 5°C. <table><tr><td>Test</td><td>0.05% v/v product</td><td>0.84% v/v product</td></tr><tr><td colspan="3">Suspensibility (%)</td></tr><tr><td>Initial results</td><td>EFS: 97.24 % CPY: 100.32%</td><td>EFS: 95.74 % CPY: 100.84%</td></tr><tr><td>Results after storage 14 days at 54°C</td><td>EFS: 96.24 % CPY: 100.30%</td><td>EFS: 90.33 % CPY: 100.53%</td></tr></table>	Test	0.05% v/v product	0.84% v/v product	Suspensibility (%)			Initial results	EFS: 97.24 % CPY: 100.32%	EFS: 95.74 % CPY: 100.84%	Results after storage 14 days at 54°C	EFS: 96.24 % CPY: 100.30%	EFS: 90.33 % CPY: 100.53%	Y	KCP 2.1/01 Massardi,E. 2024a Doc. no.: 000118842	Accepted.									
Test	0.05% v/v product	0.84% v/v product																									
Suspensibility (%)																											
Initial results	EFS: 97.24 % CPY: 100.32%	EFS: 95.74 % CPY: 100.84%																									
Results after storage 14 days at 54°C	EFS: 96.24 % CPY: 100.30%	EFS: 90.33 % CPY: 100.53%																									

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments															
	5.1.1/01)		Results after storage 7 days at 0°C	EFS: 97.71 % CPY: 100.41%	EFS: 95.87 % CPY: 100.75%																		
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160 and CIPAC MT 18.1 The content of a.s. 's was analysed by HPLC-DAD method (see KCP 5.1.1/01)	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 507.1 g/L Clopyralid: 76.2 g/L Batch No.: U3311B	Spontaneity of dispersion 5% v/v measurement of ethofumesate and clopyralid in standard water C. <table><tr><td></td><td>Mean dispersibility*</td></tr><tr><td>Before storage</td><td>EFS: 96.74 % CPY: 97.66%</td></tr><tr><td>After storage</td><td>EFS: 96.59 % CPY: 97.75%</td></tr></table> * Mean of two samples				Mean dispersibility*	Before storage	EFS: 96.74 % CPY: 97.66%	After storage	EFS: 96.59 % CPY: 97.75%	Y	KCP 2.1/01 Massardi,E. 2024a Doc. no.: 000118842	Accepted.									
	Mean dispersibility*																						
Before storage	EFS: 96.74 % CPY: 97.66%																						
After storage	EFS: 96.59 % CPY: 97.75%																						
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for SC preparation			-	-	-															
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required for SC preparation			-	-	-															
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187 Malvern Master-sizer 3000E	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 507.1 g/L Clopyralid: 76.2 g/L Batch No.: U3311B	<table><tr><td>Test</td><td>Initial results</td><td>Results after storage 14 days at 54 °C</td></tr><tr><td colspan="3">Particle size distribution (µm)</td></tr><tr><td>D(0.9)</td><td>9.76</td><td>18.5</td></tr><tr><td>D(0.5)</td><td>3.27</td><td>5.19</td></tr><tr><td>D(0.1)</td><td>0.978</td><td>1.20</td></tr></table>			Test	Initial results	Results after storage 14 days at 54 °C	Particle size distribution (µm)			D(0.9)	9.76	18.5	D(0.5)	3.27	5.19	D(0.1)	0.978	1.20	Y	KCP 2.1/01 Massardi,E. 2024a Doc. no.: 000118842	Accepted.
Test	Initial results	Results after storage 14 days at 54 °C																					
Particle size distribution (µm)																							
D(0.9)	9.76	18.5																					
D(0.5)	3.27	5.19																					
D(0.1)	0.978	1.20																					
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 507.1 g/L Clopyralid: 76.2 g/L Batch No.: U3311B	<table><tr><td colspan="4">Residue on 75µm sieve</td></tr><tr><td>Test</td><td>Initial results</td><td>After storage 14 days at 54°C</td><td>After storage 7 days at 0°C</td></tr><tr><td>Wet sieve test (%)</td><td>0</td><td>0</td><td>0</td></tr></table>			Residue on 75µm sieve				Test	Initial results	After storage 14 days at 54°C	After storage 7 days at 0°C	Wet sieve test (%)	0	0	0	Y	KCP 2.1/01 Massardi,E. 2024a Doc. no.: 000118842	Accepted.			
Residue on 75µm sieve																							
Test	Initial results	After storage 14 days at 54°C	After storage 7 days at 0°C																				
Wet sieve test (%)	0	0	0																				
Dust content (KCP 2.8.5.2.1)	-	-	Not required for SC preparation			-	-	-															
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required for SC preparation			-	-	-															
Attrition (KCP 2.8.5.3)	-	-	Not required for SC preparation			-	-	-															
Hardness and integrity	-	-	Not required for SC preparation			-	-	-															

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments										
(KCP 2.8.5.4)																		
Emulsifiability (KCP 2.8.6.1)	-	-	Not required for SC preparation			-	-	-										
Emulsion stability (KCP 2.8.6.2)	-	-	Not required for SC preparation			-	-	-										
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not required for SC preparation			-	-	-										
Flowability (KCP 2.8.7.1)	-	-	Not required for SC preparation			-	-	-										
Pourability (KCP 2.8.7.2)	CIPAC MT 148	ADM.01851.H.1.A Content of a.s. (analysed): Ethofumesate: 507.1 g/L Clopyralid: 76.2 g/L Batch No.: U3311B	<table><tr><th>Test</th><th>Initial results</th><th>Results after storage 14 days at 54°C</th></tr><tr><td>Pourability (%)</td><td></td><td></td></tr><tr><td>Residue R (%)</td><td>3.34</td><td>3.152.1</td></tr><tr><td>Rinsed residue R' (%)</td><td>0.14</td><td>0.17</td></tr></table>	Test	Initial results	Results after storage 14 days at 54°C	Pourability (%)			Residue R (%)	3.34	3.152.1	Rinsed residue R' (%)	0.14	0.17	Y	KCP 2.1/01 Massardi,E. 2024a Doc. no.: 000118842	Accepted.
Test	Initial results	Results after storage 14 days at 54°C																
Pourability (%)																		
Residue R (%)	3.34	3.152.1																
Rinsed residue R' (%)	0.14	0.17																
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required for SC preparation			-	-	-										
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	The product will not be used in tank mixtures.			-	-	-										
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	The product will not be used in tank mixtures.			-	-	-										
Adhesion to seeds (KCP 2.10.1)	-	-	Not required			-	-	-										
Distribution to seed (KCP 2.10.2)	-	-	Not required			-	-	-										
Other/special studies (KCP 2.11)	-	-	None			-	-	-										

Table 2-2: Test Results of ADM.01851.H.1.A before and after 14 days storage stability at 54°C

Test Method	Results before storage				Results after storage for 14 days at 54°C			
Appearance (physical state and colour)	Oyster white (RAL code 1013) opaque homogeneous liquid with characteristic odour				Oyster white (RAL code 1013) opaque homogeneous liquid with characteristic odour			
Stability of the original test item container (visual) The material used was HDPE-PA which stands for high density polyethylene co-extruded with PA (polyamide).	Before storage the HDPE-Coex bottle (commercial container). No damage to the container shape or size was observed.				After storage of the HDPE-Coex bottle (commercial container) No deformation of packaging on bottom, top and lateral side, panelling and/or ballooning, leakage of sample or evident corrosion phenomena			
Weight change of test item container	-				A minor change in weight was found after storage (-0.02%			
Content of active substances Analytical method validated in the GLP Study CPU-024-23	Ethofumesate active substance content: 507.1 g/L ± 1.9 g/L Clopyralid active substance content: 76.2 g/L ± 0.7 g/L				Ethofumesate active substance content: 504.3 g/L ± 0.5 g/L Clopyralid active substance content: 75.2 g/L ± 0.9 g/L			
Content of impurities	Ethyl methanesulfonate impurity content: < 0.04 mg/L (N.D.)(1) Isobutyl methanesulfonate impurity content: < 0.04 mg/L (N.D.)(1)				Ethyl methanesulfonate impurity content: < 0.04 mg/L (N.D.)(1) Isobutyl methanesulfonate impurity content: < 0.04 mg/L (N.D.)(1)			
pH value of undiluted product (CIPAC MT 75.3) The whole test was carried out at a temperature of 25 ± 0.5°C.	7.2				7.3			
pH value of 1% (w/w) solution (CIPAC MT 75.3) The whole test was carried out at a temperature of 25 ± 0.5°C.	7.3				7.4			
Acidity/ Alkalinity (CIPAC MT 191)	Not determined because the pH of the product was >4 and <10				Not determined because the pH of the product was >4 and<10.			
Persistent Foam (CIPAC MT 47.3) Standard water D	C = 0.05% (v/v)		C = 0.84% (v/v)		C = 0.05% (v/v)		C = 0.84% (v/v)	
	after 1 min	14 mL	after 1 min	21 mL	after 1 min	17 mL	after 1 min	21 mL
	after 12 min	10 mL	after 12 min	8 mL	after 12 min	11 mL	after 12 min	4 mL
Suspensibility of ethofumesate and clopyralid (CIPAC MT 184)	Dose: 0.05 %v/v		Dose: 0.84 %v/v		Dose: 0.05 %v/v		Dose: 0.84 %v/v	
	EFS: 97.24 %		EFS: 95.74 %		EFS: 96.24 %		EFS: 90.33 %	
	CPY: 100.32%		CPY: 100.84%		CPY: 100.30%		CPY: 100.53%	
Spontaneity of dispersion 5% v/v * by ethofumesate (CIPAC MT 160)	96.74 % of ethofumesate 97.66% of clopyralid				96.59 %of ethofumesate 97.75% of clopyralid			
Wet Sieving (CIPAC MT 185)	residue on 75 µm sieve: 0.0%				residue on 75 µm sieve: 0.0%			

Test Method	Results before storage		Results after storage for 14 days at 54°C	
Particle Size Distribution by Malvern Mastersizer 3000 (CIPAC MT 187)	D (0.9): 9.76 µm D (0.5): 3.27 µm D (0.1): 0.978 µm		D (0.9): 18.5 µm D (0.5): 5.19 µm D (0.1): 1.20 µm	
Pourability (CIPAC MT 148)	Residue R (%)	Rinsed residue R' (%)	Residue R	Rinsed residue R'
	3.34	0.14	3.15	0.17

(1) N.D. = Not Detected, impurity content lower than Limit of Detection (LOD = 0.01 mg/L for each impurity in the test item)

Table 2-3: Test Results of ADM.01851.H.1.A before and after 7 days storage stability at 0°C

Test Method	Results before storage		Results after storage at 0 °C for 7 days	
Appearance (physical state and colour)	ADM.01851.H.1.A is a homogeneous liquid		During the low temperature stability, the test item after 24 h and after 7 days at 0°C was homogeneous. The test was therefore concluded at 7 days.	
Wet Sieving (CIPAC MT 185)	residue on 75 µm sieve: 0 %		residue on 75 µm sieve: 0 %	
Suspensibility of ethofumesate and clopyralid (CIPAC MT 184)	Dose: 0.05 %v/v	Dose: 0.84 %v/v	Dose: 0.05 %v/v	Dose: 0.84 %v/v
	EFS: 97.24 % CPY: 100.32%	EFS: 95.74 % CPY: 100.84%	EFS: 97.71 % CPY: 100.41%	EFS: 95.87 % CPY: 100.75%

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)

Comments of zRMS:	The 2 years shelf-life study is on-going. The accelerated data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (HDPE/PA). For aqueous based formulation types e.g. SL, SC, LS, CS or FS, extrapolation between any plastic material types is acceptable. Extrapolation from plastic material to metals is not acceptable.
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The packaging has been designed in accordance with the criteria and guidelines specified in the FAO “Guideline for the Packaging of Pesticides” and has been approved according to criteria of ADR, IATA, IMDG (IMO) regulations.

The formulated product (SC formulation) is intended for containment in 1, 5 and 10 L high density polyethylene (HDPE) bottles/cans and will be distributed in cartons (outer packaging).

Tightness of the intended packaging and compatibility of the packaging material with the preparation have been demonstrated in storage stability tests under accelerated and ambient conditions. For results, please refer to point 2.7.1, 2.7.4 and 2.7.5 above.

Detailed information on the packaging material is summarised below and in ref. KCP 4.4/01-10.

Report:	KCP 4.4/01, Anonymous, 2007
Previous evaluation:	No, not previously submitted
Title:	HDPE - 1 L packaging information (Amraz)
Document No:	Report no. -
Guideline followed in study:	ADR (packaging group II): ADR 6.1.5.3 (drop test), ADR 6.1.5.4 (leakproofness test), ADR 6.1.5.5 (internal pressure hydraulic test), ADR 6.1.5.6 (stacking test);
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/02, Anonymous, 2013
Previous evaluation:	No, not previously submitted
Title:	HDPE (Reyde) 1 L - Packaging information
Document No:	Report no. -
Guideline followed in study:	ADR 6.1.5.3 (drop test), ADR 6.1.5.4 (leakproofness test), ADR 6.1.5.5 (internal pressure hydraulic test), ADR 6.1.5.6 (stacking test); IATA clause 6.3.3 (drop test), IATA clause 6.3.4 (leakproofness test), IATA clause 6.3.5 (pressure test), IATA clause 6.3.6 (stacking test)
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/03, Anonymous, 2020
Previous evaluation:	No, not previously submitted
Title:	HDPE (Reyde) 1 L - Packaging information
Document No:	Report no. -
Guideline followed in study:	ADR 6.1.5.3 (drop test), ADR 6.1.5.4 (leakproofness test), ADR 6.1.5.5 (internal pressure hydraulic test), ADR 6.1.5.6 (stacking test); IATA clause 6.3.3 (drop test), IATA clause 6.3.4 (leakproofness test), IATA clause 6.3.5 (pressure test), IATA clause 6.3.6 (stacking test)
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/04, Anonymous, 2005
Previous evaluation:	No, not previously submitted
Title:	HDPE(AMRAZ) - 4x5 L packaging information
Document No:	Report no. -
Guideline followed in study:	ADR (packaging group II): ADR 6.1.5.3 (drop test), ADR 6.1.5.4 (leakproofness test), ADR 6.1.5.5 (internal pressure hydraulic test), ADR 6.1.5.6 (stacking test); IATA: IATA clause 6.3.3 (drop test), IATA clause 6.3.4 (leakproofness test), IATA clause 6.3.5 (internal pressure hydraulic test), IATA clause 6.3.6 (stacking test)
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/05, Anonymous, 2019
Previous evaluation:	No, not previously submitted
Title:	HDPE (Reyde) 5 L - Packaging information
Document No:	Report no. -
Guideline followed in study:	ADR RID IMDG
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/06, Anonymous, 2018
Previous evaluation:	No, not previously submitted
Title:	HDPE (Mobilak) 5 L - Packaging information
Document No:	Report no. -
Guideline followed in study:	ADR IMDG CODE
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/07, Anonymous, 2017
Previous evaluation:	No, not previously submitted
Title:	HDPE (Pachmas) 5 L - Packaging information
Document No:	Report no. -
Guideline followed in study:	ADR-RID IMO IMDG CODE
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/08, Anonymous, 2020
Previous evaluation:	No, not previously submitted
Title:	HDPE (Mobilak) 10 L - Packaging information
Document No:	Report no. -
Guideline followed in study:	None
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/09, Anonymous, 2019
Previous evaluation:	No, not previously submitted
Title:	HDPE (Reyde) 10 L - Packaging information
Document No:	Report no. -
Guideline followed in study:	None
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/10, Anonymous, 2020
Previous evaluation:	No, not previously submitted
Title:	HDPE (Pachmas) - 10 L packaging information
Document No:	Report no. -
Guideline followed in study:	IMDG code
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Table 4.1-1: Packaging for ADM.01851.H.1.A

1 litre bottle (Amraz)	Material	HDPE
	shape/size	Conical / 240 × 90 mm
	Opening	49.4 mm
	outer package	carton, corrugated single wall cardboard (12 × 1 L)
1 litre bottle (Reyde)	Material	HDPE
	shape/size	Conical / 240 × 88.5 mm
	Opening	42 mm (inner diameter)
	outer package	5 Layers with 176 ((11x8) x2) containers per layer. 5x176= 880 Cont/Pallet 5 Planks. On pallets of 1,2 x 1 x 0,125 m. With film wrapped and rainproof coverage.
1 litre bottle (Reyde)	Material	HDPE
	shape/size	Rectangular / 207.5 x 77.3 x 77.3 mm
	Opening	63 mm
	outer package	5 Layers with 176 ((11x8) x2) containers per layer. 5x176= 880 Cont/Pallet 5 Planks. On pallets of 1,2 x 1 x 0,125 m. With film wrapped and rainproof coverage.
5 litre bottle (Amraz)	Material	HDPE
	shape/size	Square / 192 × 141 × 305 mm
	Opening	63 mm
	Closure	Screw plastic cap
	outer package	carton, corrugated board (4 × 5 L)
5 litre bottle (Reyde)	Material	HDPE
	shape/size	Square / 190 × 148 × 307 mm
	Opening	52.5 mm (inner diameter)
	outer package	4 Layers with 42 (6x7) containers per layer. 4x42= 168 Cont./Pallet CP-1 Heat Treat. With a board in every layer. Film wrapped.
5 litre bottle (Mobilak)	Material	HDPE
	shape/size	Square / 190 × 140 × 307 mm
	Opening	63 mm
5 litre bottle (Pachmas)	Material	HDPE
	shape/size	Square / 190 × 140 × 307 mm
	Opening	63 mm
10 litre container (Pachmas)	Material	HDPE
	shape/size	Square / 227× 157 × 401 mm
	Opening	63 mm
10 litre container (Mobilak)	Material	HDPE
	shape/size	Square / 227× 157 × 402 mm
	Opening	63 mm
10 litre container (Reyde)	Material	HDPE
	shape/size	Square / 227 × 157 × 400 mm
	Opening	63.3 mm
	outer package	3 Layers with 30 (6x5) containers per layer. 3x30 = 90 Cont./Pallet CP-1 Heat Treat. With a board in every layer. Film wrapped.

4.2 Recommended methods and precautions (KCP 4.2)

4.2.1 Procedures for cleaning application equipment and protective clothing (KCP 4.2.1)

Wash all application equipment with water (for cleaning efficiency see chapter 4.2.2 below). Suitable cleaners (commercial detergents) can be used in addition.

Wash protective clothing with washing agents in commercial quality.

4.2.2 Effectiveness of the cleaning procedures (KCP 4.2.2)

Comments of zRMS:	Information on the effectiveness of the cleaning procedure below is sufficient.
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At the time of compilation of this dossier, no specific study had been conducted for the product ADM.01851.H.1.A to investigate the effectiveness of the cleaning procedure described above. Instead, such investigations were replaced by an assessment on a theoretical basis involving a calculation of the predicted residues remaining in the spray tank after cleaning, and subsequently addressing the risk to other crops from these residues applied to the field during another spraying operation.

The efficacy of cleaning the application equipment with regard to impacts on non-target crops was estimated according to the recommendations of the PSD Efficacy Guideline 302 (December, 2001). For the assessment of residues remaining in the spraying equipment after cleaning, a standard sprayer of 2000 litres was considered. Cleaning is performed by a small volume rinse of 200 L of water in the first cleaning step, followed by another two rinses, each with volumes of 400 L corresponding to 20% of the tank volume. A maximum volume of 20 L spray solution was considered to remain in the spray lines and pump after each rinse. Furthermore, the maximum concentration of ADM.01851.H.1.A in the initial spray solution was used as a conservative starting point. In summary, the following prerequisites were considered for a worst-case assessment:

Maximum rate per application:	0.66 L ADM.01851.H.1.A/ha , corresponding to 330 g ethofumesate/ha and 49.5 g clopyralid/ha
Spray volumes:	100 – 400 L/ha
Spray volume used for the assessment of effectiveness:	100 L/ha (lowest spray volume corresponding to the maximum concentration of ADM.01851.H.1.A in diluted spray)
Tank volume:	2000 L
Volume remaining in spray lines and pump after spraying:	20 L

Based on these prerequisites and in consideration of 3 rinses each with 200–400 L of water based on good agricultural cleaning procedures described above, residues remaining in the tank after spraying will be diluted to the following levels:

Cleaning step	Water volume [L]	Concentration of residues		
		Product [mL PPP/ L of water]	Active substance [g a.s./L]	
			ethofumesate	clopyralid
Tank filling: Residues after spraying:	2000 20	6.6	3.3	0.495
1st step: 1/10 dilution of residual spray volume: Residues after spraying:	200 20	0.66	0.33	0.0495
2nd step: 20% of tank volume added: Residues after spraying:	400 20	0.033	0.0165	0.002475

3rd step: 20% of tank volume added: Residues after spraying:	400 20	0.00165	0.000825	0.0001238
Addition of fresh spray solution: Residues in the tank filling:	2000	0.0000165	0.00000825	0.000001238

PPP = ADM.01851.H.1.A

Based on the calculation above, residues remaining in the spraying equipment after the last of three cleaning steps were estimated at 20 L at a concentration of about 1.65 µL ADM.01851.H.1.A per L of water, corresponding to a total of about 33 µL ADM.01851.H.1.A in the tank. Considering these residues to be completely dissolved in the next tank filling, residues of 0.0165 µL ADM.01851.H.1.A per litre of water can be expected after refilling the tank with 2000 L of water for another spraying operation. Assuming a range of spray volumes of 200-600 L/ha to be applied to other crops, **residues of 3.3 – 9.9 µL/ha will be applied to a non-target crop by re-use of the application equipment.**

Data on the biological activity of ADM.01851.H.1.A are available from the two standard test models "seedling emergence" (KCP 10.6.2/01) and "vegetative vigour" (KCP 10.6.2/02), which are considered to be most relevant for the assessment of effects on non-target plants (including non-target crops) after broadcast spraying of ADM.01851.H.1.A and tank residues, respectively. The tests were performed according to OECD 208 (2006) and OECD 227 (2006), respectively, and the test substance ADM.01851.H.1.A was sprayed to the test plants or to the soil after sowing of plants. Each test was performed in 10 representative plant species.

The acceptability of the predicted residue level of ADM.01851.H.1.A was assessed by a comparison of the exposure concentration predicted for the re-use of the application equipment with the effect rates (NOER, ER₅₀) in the most sensitive plant species of the "vegetative vigour" and "seedling emergence" test. Effects on shoot height and plant weight were considered as reliable endpoints for toxic effects and the most sensitive of these toxicity figures was used for the following risk assessment:

Maximum predicted exposure of non-target crops with spray residues:

PER = 0.0099 mL ADM.01851.H.1.A/ha; i.e. 0.0000099 L prod./ha

Risk from spray residues for seedling emergence of non-target plants:

Toxicity endpoints obtained from reference:

KCP 10.6.2/01: Friedemann, A., (2024i): Effects of ADM.01851.H.1.A on seedling emergence and seedling growth of ten non-target terrestrial plant species under greenhouse conditions

Lowest ER ₅₀	0.239 L prod./ha (<i>Avena sativa</i>)
Lowest NOER	0.0176 L prod./ha (<i>Glycine max</i> , <i>Vicia faba</i>)
TER (ER ₅₀ /PER)	24141
NOER/PER	1778

Risk from spray residues for vegetative vigour of non-target plants:

Toxicity endpoints obtained from reference:

KCP 10.6.2/02: Friedemann, A., (2024j): Effects of ADM.01851.H.1.A on vegetative vigour of ten non-target terrestrial plant species under greenhouse conditions

Lowest ER ₅₀	0.0537 L prod./ha (<i>Vicia faba</i>)
Lowest NOER	0.00802 L prod./ha (<i>Glycine max</i>)
TER (ER ₅₀ /PER)	5424
NOER/PER	810

Conclusion: The effectiveness of standard cleaning procedures according to Good Agriculture Practice was assessed for the product ADM.01851.H.1.A on a theoretical basis. Residues of the plant protection product remaining in the tank after 3 rinses with water and the predicted exposure of non-target crops after re-use of the application equipment were calculated for worst case conditions. Compared to the effect levels for non-target plants, which are most likely to be affected by herbicide residues, residue levels are far below concentrations that might pose a risk for the terrestrial flora including non-target crops. Thus, any detrimental effect on plants from tank residues can widely be excluded. The cleaning method is therefore considered to be acceptable, and the performance of any small-scale or a large-scale tests is not considered to be required.

4.3 Safety intervals and other precautions to protect humans, animals and the environment (KCP 4.1)

For the safety intervals and other precautions to protect humans, animals and the environment please refer to the national labels provided in Part A. Further information can be found in the dRR Sections 6, 7, 8, 9, respectively.

4.4 Emergency measures in the case of an accident (KCP 4.3)

Please refer to the MSDS of the product ADM.01851.H.1.A filed under KCP 4.3/01.

4.5 Procedures for destruction or decontamination of the plant protection product and its packaging (KCP 4.5)

The product and its container must be disposed of in a safe way.

Small amounts of the product and unclean empty packaging should be packaged and sealed, labelled and transferred to a suitable incinerator in accordance with the local regulations.

Disposal by incineration in an authorised special waste incineration plant and in compliance with the local legislation. For larger quantities contact the manufacturer of the product.

EU waste keys for the packaging with product: 02 01 08 (Agrochemical waste containing dangerous substances), 20 01 19 (Pesticides).

Where local recycling schemes exist, these should be considered. Empty packaging rinsed with water should be disposed off.

For further information please refer to the MSDS of the product ADM.01851.H.1.A filed under KCP 4.3/01.

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	Massardi, E.	2024a	ADM.01851.H.1.A: physical-chemical characterization, accelerated storage stability at +54 °C for 14 days and low temperature stability at 0 °C for 7 days Report No. CPU-006-24, Sponsor report No. 000118842 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished	N	ADAMA
KCP 2.2.1/01	Michnik, I.	2024	Hazard Properties Testing on a Sample of ADM.01851.H.1.A Report No. GLP3016013507R1/2023, Sponsor report no. 000116227 DEKRA UK Ltd., United Kingdom GLP Unpublished	N	ADAMA
KCP 2.2.2/01	Michnik, I.	2024	Please refer to KCP 2.2.1/01	N	ADAMA
KCP 2.3.1	Massardi, E.	2024a	Please refer to KCP 2.1/01	N	ADAMA
KCP 2.3.3/01	Michnik, I.	2024	Please refer to KCP 2.2.1/01	N	ADAMA
KCP 2.4.1/01	Massardi, E.	2024a	Please refer to KCP 2.1/01	N	ADAMA
KCP 2.4.1/02	Massardi, E.	2024a	Please refer to KCP 2.1/01	N	ADAMA
KCP 2.5.1/01	Massardi, E.	2024a	Please refer to KCP 2.1/01	N	ADAMA
KCP 2.5.2/01	Massardi, E.	2024a	Please refer to KCP 2.1/01	N	ADAMA
KCP 2.6.1/01	Massardi, E.	2024a	Please refer to KCP 2.1/01	N	ADAMA
KCP 2.7.1/01	Massardi, E.	2024a	Please refer to KCP 2.1/01	N	ADAMA
KCP 2.7.4/01	Massardi, E.	2024a	Please refer to KCP 2.1/01	N	ADAMA
KCP 2.7.5/01	Massardi, E.	2024b	STUDY PLAN - ADM.01851.H.1.A: Shelf life at 20 ± 2 °C for 2 years Report No. CPU-007-24, Sponsor report No. 000118841 Research Center BioSphereS by Biotecnologie BT S.r.l. - Società unico socio, Italy GLP Unpublished	N	ADAMA

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 2.8.2/01	Massardi, E.	2024a	Please refer to KCP 2.1/01	N	ADAMA
KCP 2.8.3.1/01	Massardi, E.	2024a	Please refer to KCP 2.1/01	N	ADAMA
KCP 2.8.3.2/01	Massardi, E.	2024a	Please refer to KCP 2.1/01	N	ADAMA
KCP 2.8.5.1.1/01	Massardi, E.	2024a	Please refer to KCP 2.1/01	N	ADAMA
KCP 2.8.5.1.2/01	Massardi, E.	2024a	Please refer to KCP 2.1/01	N	ADAMA
KCP 2.8.7.2/01	Massardi, E.	2024a	Please refer to KCP 2.1/01	N	ADAMA
KCP 4.3/01	Anonymous	2024	Safety Data Sheet – ADM.01851.H.1.A ADAMA Agan Ltd., Ashdod., Israel Report no.: not available No GLP Unpublished	N	ADAMA
KCP 4.4/01	Anonymous	2007	HDPE - 1 L packaging information (Amraz) Amraz Ltd., Israel Report no.: not available No GLP Unpublished	N	Amraz
KCP 4.4/02	Anonymous	2013	HDPE (Reyde) 1 L - Packaging information Reyde, Spain Report no.: not available No GLP Unpublished	N	Reyde
KCP 4.4/03	Anonymous	2020	HDPE (Reyde) 1 L rectangular bottle - Packaging information Reyde, Spain Report no.: not available No GLP Unpublished	N	Reyde
KCP 4.4/04	Anonymous	2005	HDPE - 4x5 L packaging information Amraz Ltd., Israel Report no.: not available No GLP	N	Amraz

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 4.4/05	Anonymous	2019	HDPE (Reyde) 5 L - Packaging information Reyde, Spain Report no.: not available No GLP Unpublished	N	Reyde
KCP 4.4/06	Anonymous	2018	HDPE (Mobilak) 5 L - Packaging information Mobilak Report no.: not available No GLP Unpublished	N	Mobilak
KCP 4.4/07	Anonymous	2017	HDPE (Pachmas) 5 L - Packaging information Pachmas Packaging Ltd Report no.: not available No GLP Unpublished	N	Pachmas
KCP 4.4/08	Anonymous	2020	HDPE (Mobilak) 10 L - Packaging information Mobilak Report no.: not available No GLP Unpublished	N	Mobilak
KCP 4.4/09	Anonymous	2019	HDPE (Reyde) 10 L - Packaging information Reyde, Spain Report no.: not available No GLP Unpublished	N	Reyde
KCP 4.4/10	Anonymous	2020	HDPE (Pachmas) - 10 L packaging information PACHMAS Packaging Ltd., Israel Report no.: not available No GLP Unpublished	N	Pachmas

*The sponsor company ADAMA Agan Ltd. is a member of ADAMA Agricultural Solutions.

Under Article 59, Regulation 1107/2009/EC, the sponsor company claims data protection for these studies. For details on country specific data protection, refer to Part A

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

None.

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Ethofumesate

No additional studies.

A 2.2 Clopyralid

No additional studies.