

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.06001.H.2.B

Product name(s): EDAPTIS

Chemical active substances:

Mesosulfuron-methyl, 12 g/L

Pinoxaden, 60 g/L

Safener:

Mefenpyr-diethyl, 35 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Sponsor: ADAMA Agan Ltd.

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

Submission date: June 2021 (updated July 2022)

MS Finalisation date: December 2022 (initial Core Assessment)

September 2023, December 2023 (final Core Assessment)

Version history

When	What
June 2021	Applicant submission
July 2022	Applicant updated with information from shelf life storage stability study and tank mix study.
December 2022	<p>Initial assessment by the zRMS</p> <p>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.</p> <p>Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.</p>
September 2023	<p>Final report (Core Assessment updated following the commenting period)</p> <p>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. Information no longer relevant is struck through and shaded.</p>
December 2023	<p>Final report (Core Assessment updated following the second commenting period)</p> <p>No additional information or assessments after the second commenting period.</p>

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The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it.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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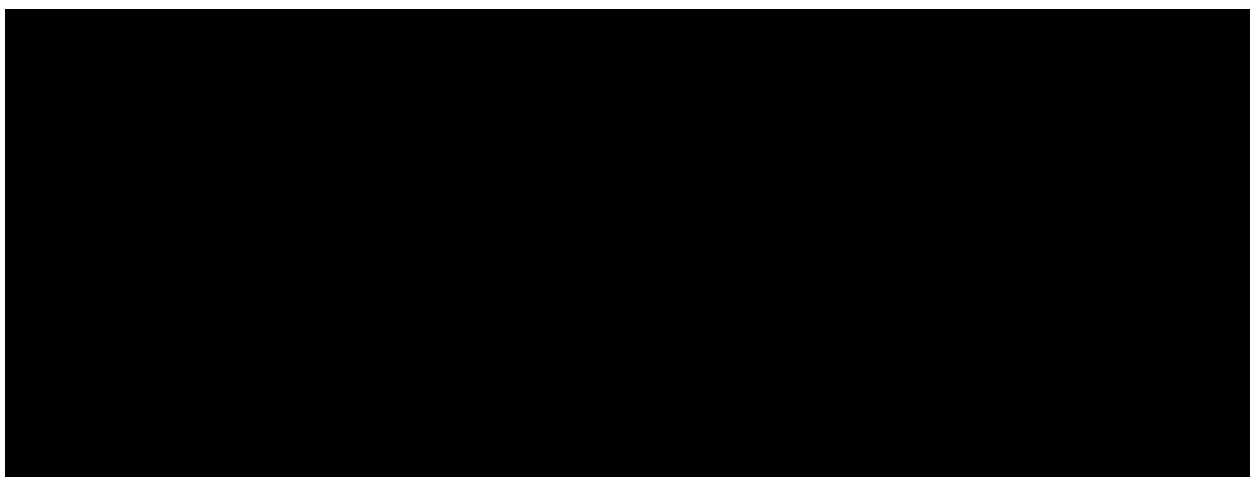
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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product ADM.06001.H.2.B and the contained technical active substances.

Noticed data gaps are: none.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)



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 Mesosulfuron-methyl

Mesosulfuron-methyl min. 930g/kg

Impurities of toxicologically or ecotoxicologically concern have not been identified for mesosulfuron-methyl. Please refer to Renewal Report for mesosulfuron (SANTE/11872/2016 Rev 2 – 23/03/2017).

For details on ADAMA Agan Ltd. source of mesosulfuron-methyl please refer to Part C.

1.2.3.2 Pinoxaden

Pinoxaden min. 970 g/kg

According to Commission Implementing Regulation (EU) 2016/370 of 15 March 2016 the following impurities of toxicologically concern have been identified for pinoxaden:

Toluene: max. 1 g/kg

For details on ADAMA Agan Ltd. source of pinoxaden please refer to Part C.

1.2.3.3 Mefenpyr-diethyl (safener)

Mefenpyr-diethyl min. 940 g/kg

Mefenpyr-diethyl is a safener used in combination with herbicides and was not reviewed under Regulation (EU) 1107/2009. However, a Draft Assessment Report (2011) written by Austria and France is available. According to the List of Endpoints of October 2011 the decision on the identity of relevant impurities is open.

For details on ADAMA Agan Ltd. source of mefenpyr-diethyl please refer to Part C.

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

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

Company code number: ADM.06001.H.2.B

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.06001.H.2.B is a new product. It was not the representative formulation during evaluation of mesosulfuron and pinoxaden on EU level.

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

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)
Mesosulfuron-methyl	12	12 g/L ± 15 % (10.2 – 13.8 g/L)	12.9 ± 15 % (10.97 – 14.84)	1.33
Pinoxaden	60	60 g/L ± 10 % (54 – 66 g/L)	61.9 ± 10 % (55.71 – 68.09)	6.38
Mefenpyr-diethyl (safener)	35	35 g/L ± 10 % (31.5 – 38.5 g/L)	37.2 g/L ± 10 % (33.48 – 40.92 g/L)	3.83

* Based on the minimum purity of the active substances and safener:

93 % (w/w) for mesosulfuron-methyl, 97.0 % (w/w) for pinoxaden and 94% (w/w) for mefenpyr-diethyl

** Based on the density of the formulation = 0.970 g/mL (0.95-0.99 g/mL) at 20°C

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/kg)
Toluene	1 mg/kg related to active substance content of pinoxaden; The nominal content of 60 g/L pinoxaden would correspond to 60 mg/L toluene or 61.9 mg/kg ADM.06001.H.2.B (0.00619%).

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

Table 1.4-3: Information on mesosulfuron-methyl

Type	Name/Code Number	
ISO common name	Mesosulfuron	Variant: Mesosulfuron-methyl
CAS No.	400852-66-6	208465-21-8
EC No.	Not available	Not available

Type	Name/Code Number	
CIPAC No.	663	663.201

Table 1.4-4: Information on pinoxaden

Type	Name/Code Number	
ISO common name	Pinoxaden	no variant
CAS No.	243973-20-8	-
EC No.	Not available	-
CIPAC No.	776	-

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

Table 1.4-5: Information on mefenpyr-diethyl

Type	Name/Code Number
ISO common name	Mefenpyr-diethyl
Function	Safener
CAS No.	135590-91-9
EC No.	603-923-2
CIPAC No.	651.229

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

Type: Oil Dispersion

[Code: OD]

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 off-white slightly viscous suspension. It is not explosive, has no oxidising properties. The product has a flash point of $> 95^{\circ}\text{C}$. It has a self-ignition temperature of 416°C . The pH value of a 1% v/v solution is 5.2 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 two active ingredients and the safener nor the technical properties were changed. The 2 years shelf life study confirms information from the accelerated storage stability study. Based on the accelerated storage stability study and the shelf life study, the data confirms the high quality of the formulation 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 an OD formulation. The intended concentration of use is 0.25% to 1.25%.

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

Experimental results on the product ADM.06001.H.2.B with regard to product classification and labelling:

Studies	Method	Findings	Classification acc. to Regulation (EC) No. 1272/2008
Explosive properties	Expert statement	Not explosive	None
Oxidising properties	Expert statement	Not oxidizing	None
Flammability	--	Not applicable for OD-formulation	--
Flash point	EEC A.9	not flammable (no flash point up to 96°C)	None
Auto-flammability	EEC A.15	Self-ignition temperature = $416^{\circ}\text{C} \pm 3^{\circ}\text{C}$	None
pH	CIPAC MT 75.3	pH = 5.2	None
Viscosity	OECD 114	Dynamic viscosity at 20°C 490 mPa*s at 18 s^{-1} and 267 mPa*s at 105 s^{-1} Dynamic viscosity at 40°C 301 mPa*s at 18 s^{-1} and 145 mPa*s at 105 s^{-1}	None
Surface tension	EEC A.5	Surface active material 31.2 mN/m (neat formulation) at $21.5^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ 31.1 mN/m (1.25% v/v) at $20.8^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$	None
Relative density	EEC A.3	0.97	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.06001.H.2.B 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 examination	ADM.06001.H.2.B Batch no. A8001	<p><u>Before storage:</u> Off-white slightly viscous suspension.</p> <p><u>After accelerated storage at 54°C for 14 days:</u> Bleeding about 5% v/v. Uniform after four inversions of the bottle. No precipitation. No colour changes.</p> <p><u>After storage of 7 days at 0 °C:</u> No precipitation or phase separation was detected. Several spots of oil were detected on a wall. Peripheral oil on the top. Homogeneous after 3 inversions. No colour change was detected.</p>	Y	KCP 2.1/01 Tsesin N. (2020) Study no: 000105084	Accepted.
Explosive properties (KCP 2.2.1)	Theoretical assessment (according to CLP criteria, as outlined in regulation (EC) No 1272/2008, Appendix 6 of UN Recommendations on the Transport of Dangerous Goods – Manual of tests and criteria (5 th revision, 2009) and REACH Annex VII, No. 7.11, 7.12 and 7.13, column 2.)	ADM.06001.H.2.B Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr diethyl 35 g/L OD	No explosive properties	N	KCP 2.2.1/01 Tzur L. (2020) Study no: 000105606	Accepted.
Oxidizing properties (KCP 2.2.2)		ADM.06001.H.2.B Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr diethyl 35 g/L OD	No oxidising properties	N	KCP 2.2.2/01 Tzur L. (2020) Study no: 000105606	Accepted.
Flash point (KCP 2.3.1)	EEC A.9 Cup closed non-equilibrium method (ASTM D 93)	ADM.06001.H.2.B Batch no. A8001	No flash point up to 95°C therefore the test item is considered to be not flammable	Y	KCP 2.1/01 Tsesin N. (2020) Study no: 000105084	Accepted.
Flammability (KCP 2.3.2)	-	-	Not required for OD preparation	-	-	-
Self-heating (KCP 2.3.3)	EEC A.15, F T 20-037 (1985)	ADM.06001.H.2.B Batch no. A8001	Self-ignition temperature = 416°C ± 3°C	Y	KCP 2.3.3/01 Halbwachs P. (2020) Study no: 000105481	Accepted.
Acidity or alkalinity and pH (KCP 2.4.1)			Acidity or alkalinity not required because pH >4 and <10			-
pH of a 1% aqueous dilution, emulsion or dispersion	Based on CIPAC MT 75.3	ADM.06001.H.2.B Batch no. A8001	<p><u>1% v/v solution at ambient temperature:</u></p> <p><u>Before storage:</u> pH = 5.2</p>	Y	KCP 2.1/01 Tsesin N. (2020) Study no: 000105084	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments									
(KCP 2.4.2)			After storage at 54°C for 14 days: pH = 4.7												
Viscosity (KCP 2.5.1)	ISO 2431:1993(E) According to OECD 114 Using rotational viscosimeter RheolabQC	ADM.06001.H.2.B Batch no. A8001	<div>Dynamic viscosity (total mean of 2 measurements):<table><tr><th>Shear rate (s⁻¹)</th><th>Mean viscosity at 20°C (mPa·s)</th><th>Mean viscosity at 40°C (mPa·s)</th></tr><tr><td>18</td><td>490</td><td>301</td></tr><tr><td>105</td><td>267</td><td>145</td></tr></table></div> <div>The viscosity depends on shear rate, therefore the test item is a non-Newtonian fluid.</div>	Shear rate (s ⁻¹)	Mean viscosity at 20°C (mPa·s)	Mean viscosity at 40°C (mPa·s)	18	490	301	105	267	145	Y	KCP 2.1/01 Tsesin N. (2020) Study no: 000105084	Accepted.
Shear rate (s ⁻¹)	Mean viscosity at 20°C (mPa·s)	Mean viscosity at 40°C (mPa·s)													
18	490	301													
105	267	145													
Surface tension (KCP 2.5.2)	EEC A.5 using Krüss Force tensiometer K20	ADM.06001.H.2.B Batch no. A8001	Neat and diluted in deionized water (1.25% v/v) preparations were examined. 31.2 mN/m (neat formulation) at 21.5°C ± 0.5°C 31.1 mN/m (1.25% v/v) at 20.8°C ± 0.5°C Surface active formulation	Y	KCP 2.1/01 Tsesin N. (2020) Study no: 000105084	Accepted.									
Relative density (KCP 2.6.1)	OECD 109 using Density Meter DMA 501	ADM.06001.H.2.B Batch no. A8001	Relative density at 20°C 0.973	Y	KCP 2.1/01 Tsesin N. (2020) Study no: 000105084	Accepted.									
Bulk density (KCP 2.6.2)	-	-	Not required for OD preparation	-	-	-									
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3 Analysis using validated method 000105084.069FL (see KCP 5.1.1/01). The content of Mesosulfuron-methyl, Pinoxaden and Mefenpyr diethyl was analysed by a validated HPLC-DAD method with external standard technique	ADM.06001.H.2.B Batch no. A8001	Results of the analysis before and after storage indicated that ADM.06001.H.2.B is physically and chemically stable when stored at 54°C for 14 days. Please refer to table 2.2 for more details Note: With respect to the relevant impurities, storage data are only required where the relevant impurities may form upon storage of the product or during manufacture of the formulation (guidance document for the generation of data on physical, chemical and technical properties of plant protection product under regulation (EC) no. 1107/2009). For those impurities that are formed during manufacture of the active substance, levels prior and following storage do not need to be determined. As the relevant impurity of pinoxaden origin from the manufacturing process of the active substance and it will not be formed during storage, the investigation during storage is not considered to be required.	Y	KCP 2.1/01 Tsesin N. (2020) Study no: 000105084 KCP 2.7.1/02 Ricau H. (2021) Study no: 000106368	The product showed no significant physical changes after accelerated storage. No significant changes were observed in the, HDPE/PA packaging and therefore it can be concluded that the test item was not corrosive to the 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									

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						HDPE/PA.
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	-	-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	-	-	-	-	-	-
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	ADM.06001.H.2.B Batch no. A8001	Results of the analysis before and after storage indicated that ADM.06001.H.2.B is physically and chemically stable when stored at 0°C for 7 Days. Please refer to table 2.3 for more details	Y	KCP 2.1/01 Tsesin N. (2020) Study no: 000105084	Accepted.
Ambient temperature shelf life (KCP 2.7.5)	CIPAC MT 75.3 MT 180 MT 148 MT 185 MT 47.3 Analysis using validated method 000105084.069FL (see KCP 5.1.1/01). The content of Mesosulfuron-methyl, Pinoxaden and Mefenpyr diethyl was analysed by a validated HPLC-DAD method with external standard technique.	ADM.06001.H.2.B Batch no. A8001	One batch of ADM.06001.H.2.B packed in HDPE/PA commercial containers were stored at ambient temperature for two years. None of the properties under evaluation showed any relevant deviation from specified limits when the results after two-year storage were compared to the results before storage. Based on the results of this interim data, the product is expected to be stable when stored in original HDPE/PA commercial containers. Please see Table 2.4 below for detailed results of the report <u>Note:</u> With respect to the relevant impurities, storage data are only re-quired where the relevant impurities may form upon storage of the product or during manufacture of the formulation (guidance document for the generation of data on physical, chemical and technical properties of plant protection product under regulation (EC) no. 1107/2009). For those impurities that are formed during manufacture of the active substance, levels prior and following storage do not need to be determined. As the relevant impurity of pinoxaden origin from the manufacturing process of the active substance and it will not be formed during storage, the investigation during storage is not considered to be required.	Y	KCP 2.7.5/01 Tsesin N. (2021) Study no: 000105085 KCP 2.7.5/01 Tsesin N. (2022) Study no: 000105085	The product showed no significant physical changes after 2-years of storage and all performance properties were within acceptable limits. No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage, evaluation of this parameter after storage is not necessary. Based on the results obtained (the oil/cream layer was observed before and after storage), “it is recommended to mix/agitate the product during use”. Stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/PA.
Shelf life in months (if less than 2 years)	-	-	Not required formulation is expected to be stable for at least 2 years at shelf life conditions	-		-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																
(KCP 2.7.6)																																																						
Wettability (KCP 2.8.1)	-	-	Not required for OD preparation	-	-	-																																																
Persistence of foaming (KCP 2.8.2)	SOP based on CIPAC MT 47.3	ADM.06001.H.2.B Batch no. A8001	<div>Persistent foaming, (ml) at 20 - 21°C in standard water D</div> <div>Before storage:</div> <table><tr><td>Time</td><td>0.19% v/v of product</td><td>1.25% v/v of product</td></tr><tr><td>Immediately</td><td>0 mL</td><td>2 mL</td></tr><tr><td>After 1 minute</td><td>0 mL</td><td>2 mL</td></tr><tr><td>After 12 minutes</td><td>0 mL</td><td>2 mL</td></tr></table> <div>After accelerated storage at 54°C for 14 days:</div> <table><tr><td>Time</td><td>0.19% v/v of product</td><td>1.25% v/v of product</td></tr><tr><td>Immediately</td><td>0 mL</td><td>2 mL</td></tr><tr><td>After 1 minute</td><td>0 mL</td><td>2 mL</td></tr><tr><td>After 12 minutes</td><td>0 mL</td><td>2 mL</td></tr></table> <div>After 1 year shelf life storage at ambient temperatures:</div> <table><tr><td>Time</td><td>0.19% v/v of product</td><td>1.25% v/v of product</td></tr><tr><td>Immediately</td><td>0 mL</td><td>2 mL</td></tr><tr><td>After 1 minute</td><td>0 mL</td><td>2 mL</td></tr><tr><td>After 12 minutes</td><td>0 mL</td><td>2 mL</td></tr></table> <div>After 2 year shelf life storage at ambient temperatures:</div> <table><tr><td>Time</td><td>0.19% v/v of product</td><td>1.25% v/v of product</td></tr><tr><td>Immediately</td><td>0 mL</td><td>3 mL</td></tr><tr><td>After 1 minute</td><td>0 mL</td><td>0 mL</td></tr><tr><td>After 12 minutes</td><td>0 mL</td><td>0 mL</td></tr></table>	Time	0.19% v/v of product	1.25% v/v of product	Immediately	0 mL	2 mL	After 1 minute	0 mL	2 mL	After 12 minutes	0 mL	2 mL	Time	0.19% v/v of product	1.25% v/v of product	Immediately	0 mL	2 mL	After 1 minute	0 mL	2 mL	After 12 minutes	0 mL	2 mL	Time	0.19% v/v of product	1.25% v/v of product	Immediately	0 mL	2 mL	After 1 minute	0 mL	2 mL	After 12 minutes	0 mL	2 mL	Time	0.19% v/v of product	1.25% v/v of product	Immediately	0 mL	3 mL	After 1 minute	0 mL	0 mL	After 12 minutes	0 mL	0 mL	Y	KCP 2.1/01 Tsesin N. (2020) Study no: 000105084 KCP 2.7.5/01 Tsesin N. (2021) Study no: 000105085 KCP 2.7.5/01 Tsesin N. (2022) Study no: 000105085	Accepted.
Time	0.19% v/v of product	1.25% v/v of product																																																				
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After 1 minute	0 mL	0 mL																																																				
After 12 minutes	0 mL	0 mL																																																				
Suspensibility (KCP 2.8.3.1)	-	-	Not required for OD preparation	-	-	-																																																
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not required for OD preparation	-	-	-																																																
Dispersion stability (KCP 2.8.3.3)	CIPAC MT 180	ADM.06001.H.2.B Batch no. A8001	<div>Dispersion Stability of a 0.19 % and 1.25 % (v/v) aqueous oil dispersion in waters A and D (CIPAC MT 18.1)</div> <table><tr><td>Test</td><td>Initial Result</td></tr><tr><td colspan="2">a) 0.19% v/v, water A</td></tr><tr><td>Cylinder visual description</td><td>U¹, T²</td></tr></table>	Test	Initial Result	a) 0.19% v/v, water A		Cylinder visual description	U ¹ , T ²	Y	KCP 2.1/01 Tsesin N. (2020) Study no: 000105084	Accepted. Based on the results obtained (the oil/cream layer was observed before and after storage), “it is recommended to																																										
Test	Initial Result																																																					
a) 0.19% v/v, water A																																																						
Cylinder visual description	U ¹ , T ²																																																					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																				
			<table><tr><td>Sediment volume</td><td>0</td></tr><tr><td>Oil/ cream corr. Volume</td><td>0</td></tr><tr><td>Hours (Re-dispersion): Cylinder visual description</td><td>U, TCL³</td></tr><tr><td>Sediment volume</td><td>0</td></tr><tr><td>Oil/ cream corr. Volume</td><td>0</td></tr><tr><td colspan="2">b) 1.25% v/v, water A</td></tr><tr><td>Cylinder visual description</td><td>U</td></tr><tr><td>Sediment volume</td><td>0</td></tr><tr><td>Oil/ cream corr. Volume</td><td><0.04</td></tr><tr><td>Hours (Re-dispersion): Cylinder visual description</td><td>C4 (~2 ml), U, TL⁵</td></tr><tr><td>Sediment volume</td><td>0</td></tr><tr><td>Oil/ cream corr. Volume</td><td>0.04</td></tr><tr><td colspan="2">c) 0.19% v/v, water D</td></tr><tr><td>Cylinder visual description</td><td>U, T</td></tr><tr><td>Sediment volume</td><td>0</td></tr><tr><td>Oil/ cream corr. Volume</td><td>0</td></tr><tr><td>Hours (Re-dispersion): Cylinder visual description</td><td>U, TCL</td></tr><tr><td>Sediment volume</td><td>0</td></tr><tr><td>Oil/ cream corr. Volume</td><td>0</td></tr><tr><td colspan="2">d) 1.25% v/v, water D</td></tr><tr><td>Cylinder visual description</td><td>U</td></tr><tr><td>Sediment volume</td><td>0</td></tr><tr><td>Oil/ cream corr. volume</td><td>0.04</td></tr><tr><td>Hours (Re-dispersion): Cylinder visual description</td><td>C (~2 ml), U, TL</td></tr><tr><td>Sediment volume</td><td>0</td></tr><tr><td>Oil/ cream corr. volume</td><td><0.04</td></tr></table> <p>Legend: ¹ Uniform liquid (U), ² Turbid (T), ³ Thin cream layer on a surface (TCL), not detectable volume, ⁴ Cream on a surface (C), ⁵ Thin layer at the bottom (TL), not detectable volume, ⁶ Accumulation of a cream along the wall side.</p> <p>For the sake of clarity, the data from the stability studies are shown below. See Table 2-2, Table 2-3 and Table 2-4.</p>	Sediment volume	0	Oil/ cream corr. Volume	0	Hours (Re-dispersion): Cylinder visual description	U, TCL ³	Sediment volume	0	Oil/ cream corr. Volume	0	b) 1.25% v/v, water A		Cylinder visual description	U	Sediment volume	0	Oil/ cream corr. Volume	<0.04	Hours (Re-dispersion): Cylinder visual description	C4 (~2 ml), U, TL ⁵	Sediment volume	0	Oil/ cream corr. Volume	0.04	c) 0.19% v/v, water D		Cylinder visual description	U, T	Sediment volume	0	Oil/ cream corr. Volume	0	Hours (Re-dispersion): Cylinder visual description	U, TCL	Sediment volume	0	Oil/ cream corr. Volume	0	d) 1.25% v/v, water D		Cylinder visual description	U	Sediment volume	0	Oil/ cream corr. volume	0.04	Hours (Re-dispersion): Cylinder visual description	C (~2 ml), U, TL	Sediment volume	0	Oil/ cream corr. volume	<0.04			mix/agitate the product during use”.
Sediment volume	0																																																									
Oil/ cream corr. Volume	0																																																									
Hours (Re-dispersion): Cylinder visual description	U, TCL ³																																																									
Sediment volume	0																																																									
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Sediment volume	0																																																									
Oil/ cream corr. volume	<0.04																																																									
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not required for OD preparation	-	-	-																																																				

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	ADM.06001.H.2.B Batch no. A8001	Residue on 75µm sieve	Y	KCP 2.1/01 Tsesin N. (2020) Study no: 000105084 KCP 2.7.5/01 Tsesin N. (2021) Study no: 000105085 KCP 2.7.5/01 Tsesin N. (2022) Study no: 000105085	Accepted.		
			Test				Initial results	Results after storage 14 days at 54°C
			Wet sieve test (%)				0.0	0.0
			Test				Initial results	Results after storge 7 days at 0°C
			Wet sieve test (%)				0.0	0.0
			Test				Initial results	Results after 1 year shelf life storage
			Wet sieve test (%)				0.0	0.0
			Test				Initial results	Results after 2 year shelf life storage
			Wet sieve test (%)				0.0	0.0
			Dust content (KCP 2.8.5.2.1)				-	-
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	-	-	-		
Flowability (KCP 2.8.7.1)	-	-	Not required for OD preparation	-	-	-		

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments									
Pourability (KCP 2.8.7.2)	CIPAC 148	-	<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>4.2</td><td>4.3</td></tr><tr><td>Rinsed (%)</td><td>0.52</td><td>0.49</td></tr></table>	Test	Initial results	Results after storage 14 days at 54°C	Pourability (%)	4.2	4.3	Rinsed (%)	0.52	0.49	Y	KCP 2.1/01 Tsesin N. (2020) Study no: 000105084 KCP 2.7.5/01 Tsesin N. (2021) Study no: 000105085 KCP 2.7.5/01 Tsesin N. (2022) Study no: 000105085	Accepted. Triple rinse is recommended. Triple rinsing is based on good agricultural cleaning procedures. The procedure is described in section 4.2.2.
			Test	Initial results	Results after storage 14 days at 54°C										
			Pourability (%)	4.2	4.3										
			Rinsed (%)	0.52	0.49										
			<table><tr><th>Test</th><th>Initial results</th><th>Results after 1 year shelf life storage</th></tr><tr><td>Pourability (%)</td><td>4.2</td><td>3.8</td></tr><tr><td>Rinsed (%)</td><td>0.52</td><td>0.48</td></tr></table>	Test	Initial results	Results after 1 year shelf life storage	Pourability (%)	4.2	3.8	Rinsed (%)	0.52	0.48			
			Test	Initial results	Results after 1 year shelf life storage										
			Pourability (%)	4.2	3.8										
			Rinsed (%)	0.52	0.48										
			<table><tr><th>Test</th><th>Initial results</th><th>Results after 2 year shelf life storage</th></tr><tr><td>Pourability (%)</td><td>4.2</td><td>3.9</td></tr><tr><td>Rinsed (%)</td><td>0.52</td><td>0.39</td></tr></table>	Test	Initial results	Results after 2 year shelf life storage	Pourability (%)	4.2	3.9	Rinsed (%)	0.52	0.39			
			Test	Initial results	Results after 2 year shelf life storage										
Pourability (%)	4.2	3.9													
Rinsed (%)	0.52	0.39													
Not required for OD preparation															
-	-	-													
Physical compatibility of tank mixes (KCP 2.9.1)	ASTM E1518-05	ADM.06001.H.2.B Pinoxaden + mesosulfuron-methyl + mefenpyr-diethyl 60 + 12 + 35 g/L Batch No.: B2012P1	Data on compatibility is not relevant / national supplements where relevant. An evaluation of the physical compatibility and stability of pesticide tank mixtures diluted for aqueous application was performed. The pesticides were diluted in water and tank mixed at specific application rates. Evaluations were conducted under dynamic conditions. Pesticides were mixed and kept under agitation by a mechanical shaker. Evaluations were conducted at chosen water hardnesses and temperatures. Compatibility was measured in terms of the dispersion stability and screen residue. Pesticides that were examined for mixing compatibility were evaluated individually as controls. Order of Addition: Pesticides were tank mixed as recommended on the product label. If the order of the addition was not specified, the following order was used: (1) water soluble concentrates, (2) water dispersible granules (dry flowables), (3) wettable powders, (4) liquid flowables, and (5) emulsifiable concentrates. For a full results please refer the Table 2-5: Evaluation of the Physical and Chemical Compatibility of Tank Mixtures of ADM-06001.H.2.B. The mixtures shown in the study as “compatible” are physically compatible under dynamic conditions in the laboratory according to this study. All mixtures reported as “compatible” gave well-dispersed mixtures in water. No	Y	KCP 2.9.1/01 Thomas R. (2021) Study no: UK21HONOPLA044A	All mixtures reported as “compatible” gave well-dispersed mixtures in water. No separation, flocculation, coagulation, gel or curd were noticed. There were no residues on the wall of the flasks and no residues remaining on a sieve. With the exception of Columbus, Trimmer SX, Pixxaro and Zypar, the mixtures with ADM-06001.H.2.B are chemically compatible. This does not mean mixtures with Columbus, Pixxaro and Zypar are incompatible, just that there is not enough data to confirm this beyond doubt. Mixtures with Trimmer SX should be used with caution and very soon									

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			separation, flocculation, coagulation, gel or curd were noticed. There were no residues on the wall of the flasks and no residues remaining on a sieve.			after preparation. Compatibility is complex and can be affected by other variables such as order of addition, pH of the dilution water, pumping shear, etc. Under the parameters of this study, the results define whether the pesticide mixture is or is not compatible in the laboratory. Compatibility or incompatibility should be confirmed under field spray conditions. In any case the spraying mixtures should be used shortly after preparation.
Chemical compatibility of tank mixes (KCP 2.9.2)	ASTM E1518-05	ADM.06001.H.2.B Pinoxaden + mesosulfuron-methyl + mefenpyr-diethyl 60 + 12 + 35 g/L Batch No.: B2012P1	The mixtures tested in the study are chemically compatible. The results are inconclusive for the mixtures with Columbus, Trimmer SX, Pixxaro and Zypar, There is not enough data to confirm the stability at low pH. Mixtures with Trimmer SX should be used with caution and very soon after preparation.	Y	KCP 2.9.2/01 Thomas R. (2021) Study no: UK21HONOPLA044A	No chemical reactions were observed in the tested mixtures. From the chemical data of the active substances (see appendix) the following conclusions can be drawn: - All mixtures are acidic, most of the mixtures showing a pH <5. - Most of the active substances are stable at pH 5 – 7, for some substances no stability data are known below pH5 (2,4-D, Florasulam, Mesosulfuron-methyl). Even though, for most of the mixtures hydrolytic stability for spray application, i.e. for max. 24 hours can be assumed, with these exceptions: o Tribenuron-methyl (Trimmer SX) has a very

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>low stability at acidic pH (0.1 d at pH 4)</p> <ul style="list-style-type: none"> o no sufficient data for Halauxifen-methyl (Pixxaro, Zypar) are available. o The mixture with Columbus has an extremely low pH (2.5) – an influence on the stability of the active substances in ADM-06001.H.2.B can't be excluded. <p>Based on the individual chemistries of the active substances, tank mixing of ADM-06001.H.2.B with all products should be possible. In the case of Columbus, Trimmer SX, Pixxaro and Zypar losses of biological efficacy can't be excluded.</p>
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 before and after 14 days storage stability at 54°C (CIPAC 46.3)

Test Method	Results before storage		Results after storage for 14 days at 54 °C	
Appearance (physical state and colour)	Off-white slightly viscous suspension.		Bleeding about 5% v/v. Uniform after four inversions of the bottle. No precipitation. No colour change	
Stability of the original test item container (visual)	Packaging: HDPE/PA containers		Packaging: HDPE/PA containers. No change in packaging size. No visible interaction of the formulation with its packaging.	
Weight change of test item container	-		No significant change in weight	
Content of Mesosulfuron-methyl g/L (% , w/w)	12.1 (1.24)		12.2 (1.25)	
Content of Pinoxaden g/L, (% , w/w)	61.6 (6.33)		61.9 (6.37)	
Content of Mefenpyr-diethyl g/L, (% , w/w)	36.6 (3.77)		37.1 (3.82)	
Content of Toluene %, w/w	0.000620		Not determined, as toluene will not be formed during storage.	
pH value (CIPAC MT 75.3)	pH = 5.2 (1% v/v)		pH = 4.7 (1% v/v)	
Pourability (%) (CIPAC 148)	4.2		4.3	
Rinsed (%)	0.52		0.49	
Wet Sieving (CIPAC MT 185)	residue on 75 µm sieve: 0 %		residue on 75 µm sieve: 0 %	
Persistent foaming (CIPAC 47.3)	Test	Persistent foaming	Test	Persistent foaming
	Results at 0.19 % v/v in standard water D at 23 °C		Results at 0.19 % v/v in standard water D at 23 °C	
	After 10 s	0	After 10 s	0
	After 1 min	0	After 1 min	0
	After 12 min	0	After 12 min	0
	Results at 1.25 % v/v in standard water D at 23 °C		Results at 1.25 % v/v in standard water D at 23 °C	
	After 10 s	2	After 10 s	2
	After 1 min	2	After 1 min	2
	After 12 min	2	After 12 min	2

Dispersion Stability (CIPAC 180)	Test	Initial Result	Test	After 14 days at 54°C
	a) 0.19% v/v, water A		a) 0.19% v/v, water A	
Legend: 1 Uniform liquid (U) 2 Turbid (T) 3 Thin cream layer on a surface, not detectable volume (TLC), 4 Cream on a surface (C), 5 Thin layer at the bottom, not detectable volume (TL), 6 Accumulation of a cream along the wall side	Cylinder visual description	U ¹ , T ²	Cylinder visual description	U, T
	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. Volume	0	Oil/ cream corr. Volume	0
	Hours (Re-dispersion):	U, TCL ³	Hours (Re-dispersion):	U, TCL
	Cylinder visual description		Cylinder visual description	
	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. Volume	0	Oil/ cream corr. Volume	0
	b) 1.25% v/v, water A		b) 1.25% v/v, water A	
	Cylinder visual description	U	Cylinder visual description	U
	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. Volume	<0.04	Oil/ cream corr. Volume	0.13
	Hours (Re-dispersion):	C ⁴ (~2 ml), U, TL ⁵	Hours (Re-dispersion):	C ⁴ (~2 ml), U, TL ⁵
	Cylinder visual description		Cylinder visual description	
	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. Volume	0.04	Oil/ cream corr. Volume	0.04
	c) 0.19% v/v, water D		c) 0.19% v/v, water D	
	Cylinder visual description	U, T	Cylinder visual description	U, T
	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. Volume	0	Oil/ cream corr. Volume	0
	Hours (Re-dispersion):	U, TCL	Hours (Re-dispersion):	U, TCL
	Cylinder visual description		Cylinder visual description	
	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. Volume	0	Oil/ cream corr. Volume	0
	d) 1.25% v/v, water D		d) 1.25% v/v, water D	
	Cylinder visual description	U	Cylinder visual description	U
	Sediment volume	0	Sediment volume	<0.05
	Oil/ cream corr. volume	0.04	Oil/ cream corr. volume	0.06
	Hours (Re-dispersion):	C (~2 ml), U, TL	Hours (Re-dispersion):	C (~2 ml), U, TL
	Cylinder visual description		Cylinder visual description	
	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. volume	<0.04	Oil/ cream corr. volume	0.04

Table 2-3: Test results before and after 7 days storage stability at 0°C (CIPAC 39.3)

Test Method	Results before storage		Results after storage for 7 days at 0°C	
Appearance (physical state and colour) (visual observation)	Off-white slightly viscous suspension.		No precipitation or phase separation was detected. Several spots of oil were detected on a wall. Peripheral oil on the top. Homogeneous after 3 inversions. No colour change was detected.	
Wet Sieving (CIPAC MT 185)	residue on 75 µm sieve: 0 %		residue on 75 µm sieve: 0 %	
Dispersion Stability (CIPAC 180) Legend: 1 Uniform liquid (U) 2 Turbid (T) 3 Thin cream layer on a surface, not detectable volume (TLC), 4 Cream on a surface (C), 5 Thin layer at the bottom, not detectable volume (TL), 6 Accumulation of a cream along the wall side	Test	Initial Result	Test	After 7 days at 0°C
	a) 0.19% v/v, water A		a) 0.19% v/v, water A	
	Cylinder visual description	U ¹ , T ²	Cylinder visual description	U, T
	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. Volume	0	Oil/ cream corr. Volume	0
	Hours (Re-dispersion):	U, TCL ³	Hours (Re-dispersion):	U, TCL
	Cylinder visual description		Cylinder visual description	
	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. Volume	0	Oil/ cream corr. Volume	0
	b) 1.25% v/v, water A		b) 1.25% v/v, water A	
	Cylinder visual description	U	Cylinder visual description	U
	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. Volume	<0.04	Oil/ cream corr. Volume	<0.04
	Hours (Re-dispersion):	C ⁴ (~2 ml), U, TL ⁵	Hours (Re-dispersion):	C (2 ml), U, TL
	Cylinder visual description		Cylinder visual description	
	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. Volume	0.04	Oil/ cream corr. Volume	0.09
	c) 0.19% v/v, water D		c) 0.19% v/v, water D	
	Cylinder visual description	U, T	Cylinder visual description	U, T
	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. Volume	0	Oil/ cream corr. Volume	0
	Hours (Re-dispersion):	U, TCL	Hours (Re-dispersion):	U, TCL
	Cylinder visual description		Cylinder visual description	
	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. Volume	0	Oil/ cream corr. Volume	0
	d) 1.25% v/v, water D		d) 1.25% v/v, water D	
	Cylinder visual description	U	Cylinder visual description	U
	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. volume	0.04	Oil/ cream corr. volume	<0.04
	Hours (Re-dispersion):	C (~2 ml), U, TL	Hours (Re-dispersion):	C (~2 ml), U, TL
	Cylinder visual description		Cylinder visual description	
	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. volume	<0.04	Oil/ cream corr. volume	0.04

Table 2-4: Storage stability at ambient temperature for 2 years for a product packed in HDPE/PE commercial containers (1 year interim results and 2 year results)

Test Method	Results before storage		Results after storage for 1 year at ambient temperature		Results after storage for 2 year at ambient temperature	
Appearance (physical state and colour)	Off-white slightly viscous suspension.		Off-white slightly viscous suspension. Bleeding about 20-25% v/v. Uniform after four inversions of the bottle. No precipitation. No color changes.		Off-white slightly viscous suspension. Bleeding about 20-25% v/v. Uniform after four inversions of the bottle. No precipitation. No color changes.	
Stability of the original test item container (visual)	Packaging: HDPE/PA containers		Packaging: HDPE/PA containers. No change in packaging size. No visible interaction of the formulation with its packaging.		Packaging: HDPE/PA containers. No change in packaging size. No visible interaction of the formulation with its packaging.	
Weight change of test item container	-		No significant change in weight		No significant change in weight	
Content of Mesosulfuron-methyl g/L (% , w/w)	12.1 (1.24)		12.1 (1.24)		11.9 (1.22)	
Content of Pinoxaden g/L, (% , w/w)	61.6 (6.33)		61.7 (6.34)		60.9 (6.26)	
Content of Mefenpyr-diethyl g/L, (% , w/w)	36.6 (3.77)		35.8 (3.68)		35.4 (3.64)	
pH value (CIPAC MT 75.3)	pH = 5.2 (1% v/v)		pH = 5.1 (1% v/v)		pH = 5.3 (1% v/v)	
Pourability (%) (CIPAC 148)	4.2		3.8		3.9	
Rinsed (%)	0.52		0.48		0.39	
Wet Sieving (CIPAC MT 185)	residue on 75 µm sieve: 0 %		residue on 75 µm sieve: 0 %		residue on 75 µm sieve: 0 %	
Persistent foaming (CIPAC 47.3)	Test	Persistent foaming	Test	Persistent foaming	Test	Persistent foaming
	Results at 0.19 % v/v in standard water D at 23 °C		Results at 0.19 % v/v in standard water D at 23 °C		Results at 0.19 % v/v in standard water D at 23 °C	
	After 10 s	0	After 10 s	0	After 10 s	0
	After 1 min	0	After 1 min	0	After 1 min	0
	After 12 min	0	After 12 min	0	After 12 min	0
	Results at 1.25 % v/v in standard water D at 23 °C		Results at 1.25 % v/v in standard water D at 23 °C		Results at 1.25 % v/v in standard water D at 23 °C	
	After 10 s	2	After 10 s	5	After 10 s	3
	After 1 min	2	After 1 min	0	After 1 min	0
	After 12 min	2	After 12 min	0	After 12 min	0
Dispersion Stability (CIPAC 180) Legend: 1 Uniform liquid (U) 2 Turbid (T) 3 Thin cream layer on a surface, not detectable volume (TLC), 4 Cream on a surface (C), 5 Thin layer at the bottom, not detectable volume (TL), 6 Accumulation of a cream along	Test	Initial Result	Test	After 1year at ambient temperature	Test	After 2year
	a) 0.19% v/v, water A		a) 0.19% v/v, water A		a) 0.19% v/v, water A	
	Cylinder visual description	U ¹ , T ²	Cylinder visual description	U ¹ , T ²	Cylinder visual description	U ¹
	Sediment volume	0	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. Volume	0	Oil/ cream corr. Volume	0	Oil/ cream corr. Volume	0
	Hours (Re-dispersion): Cylinder visual description	U, TCL ³	Hours (Re-dispersion): Cylinder visual description	U, TCL	Hours (Re-dispersion): Cylinder visual description	U, TCL
	Sediment volume	0	Sediment volume	0	Sediment volume	0
	Oil/ cream corr. Vol-	0	Oil/ cream corr. Volume	0		
			b) 1.25% v/v, water A			

Test Method	Results before storage		Results after storage for 1 year at ambient temperature		Results after storage for 2 year at ambient temperature	
the wall side	ume		Cylinder visual description	U	Oil/ cream corr. Volume	<0.5ml
	b) 1.25% v/v, water A		Sediment volume	0	b) 1.25% v/v, water A	
	Cylinder visual description	U	Oil/ cream corr. Volume	0.04	Cylinder visual description	U
	Sediment volume	0	Hours (Re-dispersion): Cylinder visual description	C ⁴ (~4 ml), U	Sediment volume	0
	Oil/ cream corr. Volume	<0.04	Sediment volume	0	Oil/ cream corr. Volume	<0.05 ml
	Hours (Re-dispersion): Cylinder visual description	C ⁴ (~2 ml), U, TL ⁵	Oil/ cream corr. Volume	0.04	Hours (Re-dispersion): Cylinder visual description	C ⁴ (~4 ml), U
	Sediment volume	0	c) 0.19% v/v, water D		Sediment volume	0
	Oil/ cream corr. Volume	0.04	Cylinder visual description	U, T	Oil/ cream corr. Volume	0.04
	c) 0.19% v/v, water D		Sediment volume	0	c) 0.19% v/v, water D	
	Cylinder visual description	U, T	Oil/ cream corr. Volume	<0.04	Cylinder visual description	U
	Sediment volume	0	Hours (Re-dispersion): Cylinder visual description	U, TCL	Sediment volume	0
	Oil/ cream corr. Volume	0	Sediment volume	0	Oil/ cream corr. Volume	0
	Hours (Re-dispersion): Cylinder visual description	U, TCL	Oil/ cream corr. Volume	0	Hours (Re-dispersion): Cylinder visual description	C (~20 ml), U
	Sediment volume	0	d) 1.25% v/v, water D		Sediment volume	0
	Oil/ cream corr. Volume	0	Cylinder visual description	U	Oil/ cream corr. Volume	<0.05 ml
	d) 1.25% v/v, water D		Sediment volume	0	d) 1.25% v/v, water D	
	Cylinder visual description	U	Oil/ cream corr. volume	<0.04	Cylinder visual description	U
	Sediment volume	0			Sediment volume	0
	Oil/ cream corr. volume	0.04			Oil/ cream corr. volume	0.15 ml
	Hours (Re-dispersion): Cylinder visual description	C (~2 ml), U, TL			Hours (Re-dispersion): Cylinder visual description	C (~4 ml), U
	Sediment volume	0			Sediment volume	0
	Oil/ cream corr. volume	<0.04			Oil/ cream corr. volume	0.2 ml

Table 2-5: Evaluation of the Physical and Chemical Compatibility of Tank Mixtures of ADM-06001.H.2.B

No.	Product	Application rate	Water	Test application per 100 mL water	Dispersion stability	Nonrinsable residue on flask walls	Residue on sieve	Result: compatible?	pH
M1	ADM-06001.H.2.B Columbus	1.00 L/ha 1.50 L/ha	100 L/ha	1.00 mL 1.50 mL	yes	no	no	yes	2.49
M2	ADM-06001.H.2.B Zenith Gold	1.00 L/ha 0.15 L/ha	100 L/ha	1.00 mL 0.150 mL	yes	no	no	yes	4.30
M3	ADM-06001.H.2.B Ariane II	1.00 L/ha 4.00 L/ha	200 L/ha	0.50 mL 2.00 mL	yes	no	no	yes	6.27
M4	ADM-06001.H.2.B Saracen	1.00 L/ha 0.125 L/ha	200 L/ha	0.50 mL 0.063 mL	yes	no	no	yes	4.54
M5	ADM-06001.H.2.B Trimmer SX	1.00 L/ha 30 g/ha	200 L/ha	0.50 mL 15 mg	yes	no	no	yes	4.48
M6	ADM-06001.H.2.B Elegant 2 FD	1.00 L/ha 0.75 L/ha	200 L/ha	0.50 mL 0.375 mL	yes	no	no	yes	4.30
M7	ADM-06001.H.2.B Zypar	1.00 L/ha 1.00 L/ha	100 L/ha	1.00 mL 1.00 mL	yes	no	no	yes	4.34
M8	ADM-06001.H.2.B Pixaro	1.00 L/ha 0.50 L/ha	100 L/ha	1.00 mL 0.50 mL	yes	no	no	yes	4.66
M9	ADM-06001.H.2.B Cleave (Tomigan Forte)	1.00 L/ha 1.50 L/ha	200 L/ha	0.50 mL 0.75 mL	yes	no	no	yes	4.59
M10	ADM-06001.H.2.B Topik 240 EC	1.00 L/ha 0.25 L/ha	100 L/ha	1.00 mL 0.25 mL	yes	no	no*	yes	4.47
M11	ADM-06001.H.2.B Tomigan (Tomahawk)	1.00 L/ha 1.00 L/ha	200 L/ha	0.50 mL 0.50 mL	yes	no	no	yes	4.67
M12	ADM-06001.H.2.B Antarktis	1.00 L/ha 1.00 L/ha	100 L/ha	1.00 mL 1.00 mL	yes	no	no	yes	5.52
M13	ADM-06001.H.2.B Adigor	1.00 L/ha 1.00 L/ha	100 L/ha	1.00 mL 1.00 mL	yes	no	no	yes	4.61

* very small amount of an oily film observed, rated as compatible

No.	Product	Application rate	Water	Test application per 100 mL water	Dispersion stability	Nonrinsable residue on flask walls	Residue on sieve	Result: compatible?	pH
M14	ADM-06001.H.2.B BioPower	1.00 L/ha 1.00 L/ha	100 L/ha	1.00 mL 1.00 mL	yes	no	no	yes	4.43
M15	ADM-06001.H.2.B Kantor	1.00 L/ha 0.15 L/ha	100 L/ha	1.00 mL 0.15 mL	yes	no	no	yes	3.98
M16	ADM-06001.H.2.B Activator 90	1.00 L/ha 0.10 L/ha	100 L/ha	1.00 mL 0.10 mL	yes	no	no	yes	4.60
M17	ADM-06001.H.2.B Insert	1.00 L/ha 0.20 L/ha	200 L/ha	0.50 mL 0.10 mL	yes	no	no	yes	4.74
M18	ADM-06001.H.2.B Gold 450 EC	1.00 L/ha 1.25 L/ha	200 L/ha	0.50 mL 0.625 mL	yes	no	no	yes	4.29

Test temperature: 26.5 °C

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:	Two years of storage at ambient temperature stability report is available. None of the properties examined showed any deviation beyond the specified limits. No significant interaction between the package material and the product which may affect the stability of both HDPE/PA packaging material was noticed after the storage period. The properties, examined before and after storage demonstrated that the product was stable during the storage period when kept in original commercial containers. The accelerated stability data and two years of storage at ambient temperature stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/PA.
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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 (OD formulation) is intended for containment in 1 to 20 L bottles and containers, respectively.

There are three suppliers of bottles/containers: (1) Mobilak, (2) Pachmas and (3) Reyde

The accelerated storage stability of Tsesin, N. (2020), ref. KCP 2.7.2/01, and the shelf life study Tsesin, N. (2022), ref. KCP 2.7.2/01, have been performed with the intended commercial packaging material (1 L HDPE/PA containers). Tightness of the intended packaging and compatibility of the packaging material with the preparation have been demonstrated in this study.

Detailed information on the packaging material is summarised below and in ref. KCP 4.4/01-12.

Normal cap can be used on all cans in addition CTS cap (ref. KCP 4.4/13) for 1 L rectangular, 5 L, 10 L, 15 L and 20 L.

Table 4.1-1: Packaging information for 1 L bottle

Type	1L		
Manufacturer:	MOBILAK (KCP 4.4/01)	PACHMAS (KCP 4.4/02)	REYDE (KCP 4.4/03)
Material:	HDPE/PA	HDPE/PA	HDPE/PA
Shape/size:	Ø 90 mm, h:240 mm	Ø 90 mm, h:239 mm	Ø 88.5 mm, h:240 mm
Opening:	48.4 ± 0.5 mm (outer Ø), 38 mm (inner Ø)	50 ± 0.3 mm (outer Ø), 38 mm (inner Ø)	42 mm (inner Ø)
Closure:	K50 (49 – 38), screw cap	K50 (50 – 38), screw cap	K50, screw cap
Seal:	IHS / PE-PET gasket + security ring	IHS / PE-PET gasket + security ring	PE-PET gasket
UN/ADR	UN approved 1H1/Y1.4/150/XX/IL/ML/2014149	UN approved 3H1/Y1.5/150/XX/IL/PMI/0933	UN approved 1H1/Y1,3/150/E/XX/02 B737- 11AA3

Table 4.1-2: Packaging information for 1 L rectangular

Type	1L
Manufacturer:	REYDE (KCP 4.4/04)
Material:	HDPE/PA
Shape/size:	207.5 x 77.3 x 94.3 mm (h/w/d)
Opening:	63.3 ± 0.3 mm (outer Ø), 52.5 ± 0.5 mm (inner Ø)
Closure:	K63, screw cap

Type	1L
Seal:	not specified
UN/ADR	not specified

Table 4.1-3: Packaging information for 5 L container

Type	5L		
Manufacturer:	MOBILAK (KCP 4.4/05)	PACHMAS (KCP 4.4/06)	REYDE (KCP 4.4/07)
Material:	HDPE/PA	HDPE/PA	HDPE/PA
Shape/size:	307 x 190 x 140 mm (h/w/d)	307 x 190 x 140 mm (h/w/d)	307 x 190 x 140 mm (h/w/d)
Opening:	63.3 ± 0.3 mm (outer Ø)	63.4 mm (outer Ø)	52.5 ± 0.5 mm (inner Ø)
Closure:	K63, screw cap	K63, screw cap	Proslit 63
Seal:	IHS (Induction Heat Seal)	IHS (Induction Heat Seal)	PE-PET gasket
UN/ADR	UN approved 3H1/Y1.5/150/XX/IL/ML/201858 0	UN approved 3H1/Y1.5/150/**/IL/ PMI2017441	UN approved 3H1/Y1,5/150/XX E/J-3034/AA3

Table 4.1-4: Packaging information for 10 L container

Type	10L		
Manufacturer:	MOBILAK (KCP 4.4/08)	PACHMAS (KCP 4.4/09)	REYDE (KCP 4.4/10 and KCP 4.4/11)
Material:	HDPE/PA	HDPE/PA	HDPE/PA
Shape/size:	402 x 227 x 157 mm (h/w/d)	401 x 227 x 157 mm (h/w/d)	400 x 227 x 157 mm (h/w/d)
Opening:	63.3 ± 0.3 mm (outer Ø)	64 mm (outer Ø)	63.3 mm (outer Ø)
Closure:	K63, screw cap	K63, screw cap	Proslit 63
Seal:	not specified	PE gasket + security ring	not specified
UN/ADR	UN approved 3H1/Y1.4/150/XX/2020057	UN approved 3H1/Y1.3/130/**/IL/ PMI2020003	not specified

Table 4.1-5: Packaging information for 20 L container

Type	20L
Manufacturer:	PACHMAS (KCP 4.4/12)
Material:	HDPE/PA
Shape/size:	398 x 246 x 297 mm (h/w/d)
Opening:	48 mm (inner Ø)
Closure:	K61, screw cap
Seal:	PE Gasket + security ring
UN/ADR	UN approved 3H1/Y1.9/200/xx/IL/PMI 0911

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:	The proposed cleaning procedure is considered sufficient. Triple rinse is recommended.
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At the time of compilation of this dossier, no specific study had been conducted for the product ADM.06001.H.2.B 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.06001.H.2.B 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:	1 L ADM.06001.H.2.B , corresponding to 12 g mesosulfuron-methyl/ha and 60 g pinoxaden/ha
Spray volumes:	80 – 300 L/ha
Spray volume used for the assessment of effectiveness:	80 L/ha (lowest spray volume corresponding to the maximum concentration of ADM.06001.H.2.B 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]	
			mesosulfuron-methyl	pinoxaden
Tank filling: Residues after spraying:	2000 20	12.5	0.15	0.75
1st step: 1/10 dilution of residual spray volume: Residues after spraying:	200 20	1.25	0.015	0.075
2nd step: 20% of tank volume added: Residues after spraying:	400 20	0.0625	0.00075	0.00375
3rd step: 20% of tank volume added: Residues after spraying:	400 20	0.003125	0.0000375	0.0001875
Addition of fresh spray solution: Residues in the tank filling:	2000	0.00003125	0.000000375	0.000001875

PPP = ADM.06001.H.2.B

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 3.125 µL ADM.06001.H.2.B per L of water, corresponding to a total of about 62.5 µL ADM.06001.H.2.B in the tank. Considering these residues to be completely dissolved in the next tank filling, residues of 0.03125 µL ADM.06001.H.2.B 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 6.25 – 18.75 µL/ha will be applied to a non-target crop by re-use of the application equipment.**

Data on the biological activity of ADM.06001.H.2.B 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.06001.H.2.B and tank residues, respectively. The tests were performed according to OECD 208 (2006) and OECD 227 (2006), respectively, and the test substance ADM.06001.H.2.B 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.06001.H.2.B 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 = 0.01875 mL ADM.06001.H.2.B /ha; i.e. 0.00001875 L prod./ha

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

Toxicity endpoints obtained from reference:

KCP 10.6.2/01: Spatz, B. and Kowalczyk, F., (2021a), 000105379: ADM.06001.H.2.B: Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test

Lowest ER ₅₀	0.351 L prod./ha (<i>Raphanus sativus</i>) for plant dry weight > 1 L prod./ha (all species tested) for plant height
Lowest NOER	0.0123 L prod./ha (<i>Raphanus sativus</i>) for plant dry weight < 0.001370 L prod./ha (<i>Helianthus annuus</i>) for plant height, EC10 not determined
Lowest EC ₁₀	0.0172 L prod./ha (<i>Raphanus sativus</i>) for plant dry weight 0.0261 L prod./ha (<i>Raphanus sativus</i>) for plant height
TER (ER ₅₀ /PER)	18720 for plant dry weight > 53333 for plant height
NOER/PER	656 for plant dry weight < 73 for plant height
TER (EC ₁₀ /PER)	917 for plant dry weight 1392 for plant dry weight

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

Toxicity endpoints obtained from reference:

KCP 10.6.2/02: Spatz, B. and Kowalczyk, F., (2021b), 000105380: ADM.06001.H.2.B: Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test

Lowest ER ₅₀	0.133 L prod./ha (<i>Brassica napus</i>) for plant dry weight
Lowest NOER	0.0123 L prod./ha (<i>Raphanus sativus</i>) for plant dry weight and plant height, 0.0123

L prod./ha (*Allium cepa*) for plant height

TER (ER₅₀/PER) 7093

NOER/PER 656

According to the PSD efficacy guideline 302, a cleaning method can be considered to be acceptable, if the predicted exposure rate of the plant protection product (when the application equipment is re-used after cleaning) is at least an order of magnitude less than the no observable effect level or ED₁₀ value for the most sensitive crop species.

Since no NOER value (plant height) is available from seedling emergence testing by Spatz, B. and Kowalczyk, F., (2021a), the assessment is based on worst-case median effective rates and Toxicity/Exposure Ratios are compared to the standard trigger of 5 for acceptability of risk for terrestrial non-target plants as in accordance with the guidance document SANCO/10329/2002 rev.2 final (October 17, 2002)¹. The ER₅₀ based TER value of 18720 for the most sensitive plant species of the seedling emergence test is greater than 5² by more than 2 orders of magnitude. Therefore, the potential risk for non-target terrestrial plants from product residues remaining in tanks following cleaning is considered to be acceptable.

Conclusion: The effectiveness of standard cleaning procedures according to Good Agriculture Practice was assessed for the product ADM.06001.H.2.B 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 SDS of the product ADM.06001.H.2.B 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 SDS of the product ADM.06001.H.2.B filed under KCP 4.3/01.

¹ Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC

² A trigger of 5 can be applied, if at least 6 plant species have been tested

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	Tsesin N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/l OD (ADM.06001.H.2.B) Stored at 54°C for 14 Days and at 0°C for 7 Days, including 1 st and 2 nd Amendment to report, 2021 Study no. 000 1 05084.069FL, Sponsor Reference No. 000105084 Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished	N	ADM
KCP 2.2.1/01	Tzur L.	2020	Theoretical Assessment of Explosive and Oxidizing properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr diethyl 35 g/L OD (ADM.06001.H.2.B) Sponsor Reference No. 000105606 ADAMA Agricultural Solutions Ltd., Israel Not-GLP, unpublished	N	ADM
KCP 2.2.2/01	Tzur L.	2020	Theoretical Assessment of Explosive and Oxidizing properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr diethyl 35 g/L OD (ADM.06001.H.2.B) Sponsor Reference No. 000105606 ADAMA Agricultural Solutions Ltd., Israel Not-GLP, unpublished Please refer to KCP 2.2.1/01	N	ADM
KCP 2.3.1	Tsesin N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/l OD (ADM.06001.H.2.B) Stored at 54°C for 14 Days and at 0°C for 7 Days Study no. 000 1 05084.069FL, Sponsor Reference No. 000105084 Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished Please refer to KCP 2.1/01	N	ADM
KCP 2.3.3/01	Halbwachs P.	2020	Auto-ignition temperature of liquids on PINOXADEN 60 + MESOSULFURON-M 12 + MEFENPYR DIETHYL 35 G/L OD (ADM.06001.H.2.B) Report No. 20-901066-009, Sponsor Reference No. 000105481 ANADIAG Group, DEFITRACES, FRANCE GLP, unpublished	N	ADM
KCP 2.4.2/01	Tsesin N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/l OD (ADM.06001.H.2.B) Stored at 54°C for 14 Days and at 0°C for 7 Days Study no. 000 1 05084.069FL, Sponsor Reference No. 000105084	N	ADM

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*
			Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished Please refer to KCP 2.1/01		
KCP 2.5.1/01	Tsesin N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/l OD (ADM.06001.H.2.B) Stored at 54°C for 14 Days and at 0°C for 7 Days Study no. 000 1 05084.069FL, Sponsor Reference No. 000105084 Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished Please refer to KCP 2.1/01	N	ADM
KCP 2.5.2/01	Tsesin N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/l OD (ADM.06001.H.2.B) Stored at 54°C for 14 Days and at 0°C for 7 Days Study no. 000 1 05084.069FL, Sponsor Reference No. 000105084 Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished Please refer to KCP 2.1/01	N	ADM
KCP 2.6.1/01	Tsesin N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/l OD (ADM.06001.H.2.B) Stored at 54°C for 14 Days and at 0°C for 7 Days Study no. 000 1 05084.069FL, Sponsor Reference No. 000105084 Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished Please refer to KCP 2.1/01	N	ADM
KCP 2.7.1/01	Tsesin N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/l OD (ADM.06001.H.2.B) Stored at 54°C for 14 Days and at 0°C for 7 Days Study no. 000 1 05084.069FL, Sponsor Reference No. 000105084 Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished Please refer to KCP 2.1/01	N	ADM
KCP 2.7.1/02	Ricau H.	2021	Quantitative determination of toluene in MESOSULFURON-METHYL 12 G/L + PINOXADEN 60 G/L + MEFENPYR-DIETHYL 35 G/L OD (ADM.06001.H.2.B) Report no. 20-901066-036, Sponsor reference no. 000106368 ANADIAG, DEFITRACES, France GLP, unpublished	N	ADM
KCP 2.7.4/01	Tsesin N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/l OD (ADM.06001.H.2.B) Stored at 54°C for 14 Days and at 0°C for 7 Days	N	ADM

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*
			Study no. 000105084.069FL, Sponsor Reference No. 000105084 Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished Please refer to KCP 2.1/01		
KCP 2.7.5/01	Tsesin N.	2021 2022	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/L OD (ADM.06001.H.2.B) Stored at Ambient Temperature for Two Years Including 1 st amendment Study no. 000105085.070FL, Sponsor Reference No. 000105085 Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished	N	ADM
KCP 2.8.2/01	Tsesin N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/L OD (ADM.06001.H.2.B) Stored at 54°C for 14 Days and at 0°C for 7 Days Study no. 000 1 05084.069FL, Sponsor Reference No. 000105084 Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished Please refer to KCP 2.1/01	N	ADM
KCP 2.8.2/02	Tsesin N.	2021	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/L OD (ADM.06001.H.2.B) Stored at Ambient Temperature for Two Years Study no. 000105085.070FL, Sponsor Reference No. 000105085 Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished Please refer to KCP 2.7.5/01	N	ADM
KCP 2.8.3.3/01	Tsesin N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/L OD (ADM.06001.H.2.B) Stored at 54°C for 14 Days and at 0°C for 7 Days Study no. 000 1 05084.069FL, Sponsor Reference No. 000105084 Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished Please refer to KCP 2.1/01	N	ADM
KCP 2.8.3.3/02	Tsesin N.	2021	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/L OD (ADM.06001.H.2.B) Stored at Ambient Temperature for Two Years Study no. 000105085.070FL, Sponsor Reference No. 000105085 Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished Please refer to KCP 2.7.5/01	N	ADM

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 2.8.5.1.2/01	Tsesin N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/l OD (ADM.06001.H.2.B) Stored at 54°C for 14 Days and at 0°C for 7 Days Study no. 000 1 05084.069FL, Sponsor Reference No. 000105084 Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished Please refer to KCP 2.1/01	N	ADM
KCP 2.8.5.1.2/02	Tsesin N.	2021	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/L OD (ADM.06001.H.2.B) Stored at Ambient Temperature for Two Years Study no. 000105085.070FL, Sponsor Reference No. 000105085 Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished Please refer to KCP 2.7.5/01	N	ADM
KCP 2.8.7.2/01	Tsesin N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/l OD (ADM.06001.H.2.B) Stored at 54°C for 14 Days and at 0°C for 7 Days Study no. 000 1 05084.069FL, Sponsor Reference No. 000105084 Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished Please refer to KCP 2.1/01	N	ADM
KCP 2.8.7.2/02	Tsesin N.	2021	Determination of Storage Stability and Physical-Chemical Properties of Mesosulfuron-methyl 12 g/L + Pinoxaden 60 g/L + Mefenpyr-diethyl 35 g/L OD (ADM.06001.H.2.B) Stored at Ambient Temperature for Two Years Study no. 000105085.070FL, Sponsor Reference No. 000105085 Registration Laboratory Research and Development Division, ADAMA Makhteshim Ltd., Israel GLP, unpublished Please refer to KCP 2.7.5/01	N	ADM
KCP 2.9.1/01	Thomas R.	2021	Evaluation of the Physical and Chemical Compatibility of Tank Mixtures of ADM-06001.H.2.B Study no.UK21HONOPLA044A BioChem agrar Labor für biologische und chemische Analytik GmbH Kupferstraße 6 04827 Machern OT Gerichshain, Germany GLP, unpublished	N	ADM
KCP 4.3/01	Anonymous	2021	Safety Data Sheet – ADM.06001.H.2.B ADAMA Agan Ltd., Ashdod., Israel Report no.: not available No GLP Unpublished	N	ADM

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 4.4/01	Anonymous	2020	COEX (MOBILAK) - 1 litre bottle MOBILAK Ltd., Israel Report no.: not available No GLP Unpublished	N	Mobilak
KCP 4.4/02	Anonymous	2013	COEX (PACHMAS) - 1 litre bottle PACHMAS Packaging Ltd., Israel Report no.: not available No GLP Unpublished	N	Pachmas
KCP 4.4/03	Anonymous	2019	COEX (REYDE) - 1 litre bottle Reyde, Spain Report no.: not available No GLP Unpublished	N	REYDE
KCP 4.4/04	Anonymous	2020	COEX (REYDE) - 1 litre container (rectangular) Reyde, Spain Report no.: not available No GLP Unpublished	N	REYDE
KCP 4.4/05	Anonymous	2018	COEX (MOBILAK) - 5 litre container MOBILAK Ltd., Israel Report no.: not available No GLP Unpublished	N	Mobilak
KCP 4.4/06	Anonymous	2017	COEX (PACHMAS) - 5 litre container PACHMAS Packaging Ltd., Israel Report no.: not available No GLP Unpublished	N	Pachmas
KCP 4.4/07	Anonymous	2019	COEX (Reyde) - 5 litre container Reyde, Spain Report no.: not available No GLP	N	Reyde

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 4.4/08	Anonymous	2020	COEX (MOBILAK) - 10 litre container MOBILAK Ltd., Israel Report no.: not available No GLP Unpublished	N	Mobilak
KCP 4.4/09	Anonymous	2020	COEX (PACHMAS) - 10 litre container PACHMAS Packaging Ltd., Israel Report no.: not available No GLP Unpublished	N	Pachmas
KCP 4.4/10	Anonymous	2019	COEX (Reyde) - 10 litre container Reyde, Spain Report no.: not available No GLP Unpublished	N	Reyde
KCP 4.4/11	Anonymous	2019	COEX (Reyde) - 10 litre container - Drawing Reyde, Spain Report no.: not available No GLP Unpublished	N	Reyde
KCP 4.4/12	Anonymous	2014	COEX (PACHMAS) - 20 litre container PACHMAS Packaging Ltd., Israel Report no.: not available No GLP Unpublished	N	Pachmas
KCP 4.4/13	Anonymous	Not reported	Easyconnect Cap - Drawing Not reported Report no.: not available No GLP Unpublished	N	Not reported

*The sponsor company ADAMA Agan Ltd. (ADM) 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

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 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 Mesosulfuron-methyl

No additional studies.

A 2.2 Pinoxaden

No additional studies.