

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.09050.H.1.A

Product name(s): **STEMPER**

Chemical active substances:

Trinexapac-ethyl, 175 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: **ADAMA**

Submission date: May 2022

Evaluation date: March 2023

Version history

When	What
January 2021	dRR version 1 submitted by applicant
March 2023	Version evaluated by zRMS PL

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

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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product ADM.09050.H.1.A and the contained technical active substance.

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
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Contact:

Name	ADAMA Agan Ltd
Address	PO Box 262 Ashdod 7710201 Israel

Contact Telephone number	XXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXX
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Email	XXXXXXXXXXXXXXXXXXXX
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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 Trinexapac-ethyl

Trinexapac-ethyl: min. 980 g/kg

According to Commission Implementing Regulation (EU) 540/2011 of 25 May 2011 trinexapac-ethyl does not contain any component of toxicological, ecotoxicological or environmental significance.

According to the EFSA Scientific Report from 09/03/2018 (EFSA Journal 2018;16(4):5229) the following relevant impurities have been identified:

toluene: max. 3 g/kg
ethyl (1RS)-ethyl 3-hydroxy-5-oxocyclohex-3-ene-1carboxylate (CGA158377): max. 6 g/kg
Other potentially relevant impurities Open

The ADAMA Agan Ltd. sources of trinexapac-ethyl have been confirmed for being equivalent to the EU reference source. The equivalence reports are published on CIRCA. Details are provided in PART C.

RMS comment:

There are 3 sources of the trinexapac-ethyl used in this PPP. Two sources have minimum purities specified at 98% and the last one at 99%. For full details please refer to Part C. According to reg 540/2011 there are no relevant impurities specified. Renewal process is still pending.

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

Trade name: Stemper

Company code number: ADM.09050.H.1.A, Trinexapac-ethyl 175 EC and AG-T3-175 EC1

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.09050.H.1.A (formerly AG-T3-175 EC1) was not the representative formulation during evaluation of trinexapac-ethyl on EU level. The dossier is for new registration.

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)
Trinexapac-ethyl	175 g/L	164.5 – 185.5 g/L	178.6 g/L (167.89 – 189.32)	17.86

* Based on the minimum purity of the active substances:
Minimum purity of 98.0 % (w/w)

** Based on the density of the formulation 1 g/mL

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

Table 1.4-2: Information on trinexapac-ethyl

Type	Name/Code Number	
ISO common name	Trinexapac	Variant: Trinexapac-ethyl
CAS No.	104273-73-6 (trinexapac keto form) 143294-89-7 (trinexapac, enol form)	95266-40-3
EC No.	Not available	Not available
CIPAC No.	732	732.202

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

There are no safener or synergists that need to be taken into account.

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

Type: Emulsifiable concentrate

[Code: EC]

1.6 Function (KCP 1.6)

Plant growth regulator

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 ADM.09050.H.1.A is that of an amber liquid with an aromatic odor. It is not explosive, has no oxidising properties. The product has a flash point of >150 °C. It has a self ignition temperature of 374°C. The pH value of the formulation (1% w/w) is 3.7 at 25°C. 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 ingredient nor the technical properties were changed. Also the 2 years shelf life study confirms the high quality and stability of ADM.09050.H.1.A when stored at ambient temperature in HDPE/PA or HDPE/EVOH commercial containers. Its technical characteristics are acceptable for an EC formulation.

The product will not be used in tank mixtures.

The intended concentration of use is 0.0625% v/v to 0.6% v/v.

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

Experimental results on the product ADM.09050.H.1.A (Trinexapac-ethyl 175 g/L) 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 EC-formulation	--
Flash point	EEC A.9	> 150°C	None
Auto-flammability	EEC A.15	Self-ignition temperature = 374 ± 5°C	None
pH	CIPAC MT 75.3	3.7	None
Viscosity	ISO 2431:1993(E) and OECD 114	<u>Dynamic viscosity at 20°C</u> 25.9 mPa*s at 61.2 s ⁻¹ 25.9 mPa*s at 73.4 s ⁻¹ and 25.9 mPa*s at 110.0 s ⁻¹ <u>Dynamic viscosity at 40°C</u> 25.9 mPa*s at 61.2 s ⁻¹ 25.9 mPa*s at 73.4 s ⁻¹ and 25.9 mPa*s at 110.0 s ⁻¹ <u>Kinematic Viscosity at 20°C</u> 26.0 mPa*s at 61.2 s ⁻¹ 26.0 mPa*s at 73.4 s ⁻¹ and 26.0 mPa*s at 110.0 s ⁻¹	None
Surface tension	EEC A.5	32.2 mN/m for 0.8% (v/v) solution of the test item in water at 20°C	None
Relative density	EEC A.3	0.997 g/mL	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.09050.H.1.A, Trinexapac-ethyl 175 EC 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)	Visual examination and olfactory	Trinexapac-ethyl 175 g/L test item is ADM.09050.H.1.A Batch: 1601240	Before storage: Amber liquid with aromatic odor After accelerated storage: no change	Y	Edelson, T. (2016)	Accepted
Explosive properties (KCP 2.2.1)	EEC Method A.14, estimation based on chemical structure	Trinexapac-ethyl 175 EC test item is the former composition, see Part C Batch: D-I0703	Predicted negative, the test item is not explosive	N	Atwal, S.S., Tremain, S.P. (2008)	Accepted
Oxidizing properties (KCP 2.2.2)	EEC Method A.21, estimation based on chemical structure	Trinexapac-ethyl 175 EC test item is the former composition, see Part C Batch: D-I0703	Predicted negative, the test item is not oxidizing	N	Atwal, S.S., Tremain, S.P. (2008)	Accepted
Flash point (KCP 2.3.1)	ASTM method D7094 ERA-FLASH tester (in accordance with ISO D93)	Trinexapac-ethyl 175 g/L test item is ADM.09050.H.1.A Batch: I0703	Flash point: > 150°C	Y	Edelson, T. (2016)	Accepted
Flammability (KCP 2.3.2)	-	-	Not required, test substance is a EC formulation (liquid)	-	-	
Self-heating	EEC Method	Trinexapac-ethyl	Auto flammability temperature of 374 ± 5°C	Y	Atwal, S.S.,	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																													
(KCP 2.3.3)	A.15	175 EC test item is the former composition, see Part C Batch: D-I0703			Tremain, S.P. (2008)																														
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 31.2	Trinexapac-ethyl 175 g/L test item is ADM.09050.H.1.A Batch: 1601240	1% w/w of product in de-ionized water Before storage: 4.85%, acidity After storage: 4.70%, acidity	Y	Edelson, T. (2016)	Accepted																													
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3 1% dilution in water	Trinexapac-ethyl 175 g/L test item is ADM.09050.H.1.A Batch: 1601240	Before storage: 3.7 at 24°C After storage: 3.7 at 25°C	Y	Edelson, T. (2016)	Accepted																													
Viscosity (KCP 2.5.1)	ISO 2431:1993(E) and OECD 114 using Apparatus: Brookfield RVDV-II +	Trinexapac-ethyl 175 g/L test item is ADM.09050.H.1.A Batch: 1601240	<table border="1"> <thead> <tr> <th>Shear rate (s⁻¹)</th> <th>Mean viscosity at 20°C</th> <th>Mean viscosity at 40°C</th> </tr> </thead> <tbody> <tr> <td colspan="3">Dynamic viscosity (mPa s)</td> </tr> <tr> <td>61.2</td> <td>25.9</td> <td>15.4</td> </tr> <tr> <td>73.4</td> <td>25.9</td> <td>15.5</td> </tr> <tr> <td>110.0</td> <td>25.9</td> <td>15.6</td> </tr> <tr> <td colspan="3">Kinematic viscosity (cSt = mm²/s) (calculated)</td> </tr> <tr> <td>61.2</td> <td>26.0</td> <td>-</td> </tr> <tr> <td>73.4</td> <td>26.0</td> <td>-</td> </tr> <tr> <td>110.0</td> <td>26.0</td> <td>-</td> </tr> </tbody> </table>			Shear rate (s ⁻¹)	Mean viscosity at 20°C	Mean viscosity at 40°C	Dynamic viscosity (mPa s)			61.2	25.9	15.4	73.4	25.9	15.5	110.0	25.9	15.6	Kinematic viscosity (cSt = mm²/s) (calculated)			61.2	26.0	-	73.4	26.0	-	110.0	26.0	-	Y	Edelson, T. (2016)	Accepted The lowest kinematic viscosity value at 40°C is 15.4 mm ² /s. Yet, there are no coformulants being classified as a Category 1 aspiration hazard.
			Shear rate (s ⁻¹)	Mean viscosity at 20°C	Mean viscosity at 40°C																														
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73.4	26.0	-																																	
110.0	26.0	-																																	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Mean of 2 measurements Kinematic viscosity = dynamic viscosity / density (1.12)			
Surface tension (KCP 2.5.2)	EEC method A5 (DuNouy Tensiometer)	Trinexapac-ethyl 175 g/L test item is ADM.09050.H.1.A Batch: 1601240	0.8% v/v of product in de-ionized water 32.2 mN/m at 20°C	Y	Edelson, T. (2016)	Accepted The product is a surface active.
Relative density (KCP 2.6.1)	CIPAC MT 3.1 and EEC A3	Trinexapac-ethyl 175 g/L test item is ADM.09050.H.1.A Batch: 1601240	0.997 g/mL	Y	Edelson, T. (2016)	Accepted
Bulk density (KCP 2.6.2)	-	-	Not required, test substance is a EC formulation (liquid)	-	-	
Storage Stability after 14 days at 54°C (KCP 2.7.1)	CIPAC MT 46.3 The content of trinexapac-ethyl was analysed using a validated HPLC-UV method (see KCP 5.1.1/01).	Trinexapac-ethyl 175 g/L test item is ADM.09050.H.1.A Batch: 1601240	Results of the analysis before and after storage indicated that ADM.09050.H.1.A is physically and chemically stable when stored for 14 days at 54 °C. Please refer to Table 2.2 and Table 2.3 for more details Note: With respect to the relevant impurities, storage data are strictly 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. 1107/200). As the relevant impurities of trinexapac-ethyl origin from the manufacturing process of the active substance, their investigation during storage are not considered to be required.	Y	Edelson, T. (2016)	Accepted
Stability after storage for other periods and/or temperatures			Not required as ADM.09050.H.1.A was shown to be stable for 14 days at 54 °C			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.7.2)						
Minimum content after heat stability testing (KCP 2.7.3)			Not required as ADM.09050.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 trinexapac-ethyl was analysed using a validated HPLC-UV method (see KCP 5.1.1/01).	Trinexapac-ethyl 175 g/L test item is ADM.09050.H.1.A Batch: 1601240	Results of the analysis before and after storage indicated that ADM.09050.H.1.A is physically and chemically stable when stored at 0°C for 7 Days. Please refer to Table 2.4 for more details	Y	Edelson, T. (2016)	Accepted
Ambient temperature shelf life (KCP 2.7.5)	CIPAC MT 75.3 MT 47.2 MT 36.1.1 The content of trinexapac-ethyl was analysed using a validated HPLC-UV method (see KCP 5.1.1/01).	Trinexapac-ethyl 175 g/L test item is ADM.09050.H.1.A Batch: 1601240	One batch of Trinexapac-ethyl 175 g/L EC (AG-T3-175 EC1) packed in 1 litre HDPE/PA and 1 litre HDPE/EVOH commercial containers, sealed by induction sealing were stored at ambient temperature for two years. None of the properties under evaluation showed any deviation from specified limits when the results after storage were compared to the results before storage. Based on the results of this study the product can be classified as stable when stored in original HDPE commercial containers. Please see Table 2.5 and Table 2.6 below for detailed results of the report.	Y	Edelson, T. (2018)	Accepted
Shelf life in months (if less than 2 years)	-	-	Not required, as accelerated storage study and ambient storage shows stability	-	-	

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, test substance is a EC formulation	-	-										
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	Trinexapac-ethyl 175 g/L test item is ADM.09050.H.1.A Batch: 1601240	Persistent foaming (ml) at 22°C in standard water D <table border="1"> <thead> <tr> <th>Time</th> <th>0.0625% v/v product</th> <th>0.8% v/v product</th> </tr> </thead> <tbody> <tr> <td>After 1 min</td> <td>21 mL</td> <td>55 mL</td> </tr> <tr> <td>After 12 min</td> <td>19 mL</td> <td>5 mL</td> </tr> </tbody> </table>	Time	0.0625% v/v product	0.8% v/v product	After 1 min	21 mL	55 mL	After 12 min	19 mL	5 mL	Y	Edelson, T. (2016)	Accepted
Time	0.0625% v/v product	0.8% v/v product													
After 1 min	21 mL	55 mL													
After 12 min	19 mL	5 mL													
Suspensibility (KCP 2.8.3.1)	-	-	Not required, test substance is a EC formulation	-	-										
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not required, test substance is a EC formulation	-	-										
Dispersion stability (KCP 2.8.3.3)	-	-	Not required, test substance is a EC formulation	-	-										
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required, test substance is a EC formulation	-	-										
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not required, test substance is a EC formulation (liquid)	-	-										
Wet sieve test (KCP 2.8.5.1.2)	-	-	Not required, test substance is a EC formulation (liquid)	-	-										
Dust content (KCP 2.8.5.2.1)	-	-	Not required, test substance is a EC formulation (liquid)	-	-										
Particle size of dust	-	-	Not required, test substance is a EC formulation (liquid)	-	-										

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.5.2.2)						
Attrition (KCP 2.8.5.3)	-	-	Not required, test substance is a EC formulation (liquid)	-	-	
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required, test substance is a EC formulation (liquid)	-	-	
Emulsifiability (KCP 2.8.6.1)			Not required, test substance is a EC formulation (liquid)			
Emulsion stability (KCP 2.8.6.2)	CIPAC MT 36.3	Trinexapac-ethyl 175 g/L test item is ADM.09050.H.1.A Batch: 1601240	Please refer to Point KCP 2.7.1 in Emulsion characteristics (see Table 2-2, Table 2-3, Table 2-5 and Table 2-6.)	Y	Edelson, T. (2016) and (2018)	Accepted
Re-emulsifiability (KCP 2.8.6.3)	-	-	Emulsion stability MT 36.1.1 was performed, please refer to point KCP 2.8.6.2	-	-	
Flowability (KCP 2.8.7.1)	-	-	Not required, test substance is an EC formulation (liquid)	-	-	
Pourability (KCP 2.8.7.2)	-	-	Not required, test substance is an EC formulation (liquid)	-	-	
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required, test substance is an EC formulation (liquid)	-	-	
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not required for ADM.09050.H.1.A	-	-	
Chemical compatibility of tank mixes	-	-	Not required for ADM.09050.H.1.A	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.9.2)						
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 for a Product Packed in HDPE/PA

Test Method	Results before storage	Results after storage for 14 days at 54°C
Appearance (physical state and colour)	ADM.09050.H.1.A was an amber liquid with aromatic odour.	ADM.09050.H.1.A was an amber liquid with aromatic odour. No separation, no sedimentation were observed at the end of the test.
Stability of the original test item container (visual)	No damage to the container shape or size was observed.	No change in the appearance was observed of the product packed in HDPE/PA commercial containers. No significant change in weight nor visible interaction of the formulation with its packaging were observed.
Weight change of test item container	Weight before storage: 1108.9 g	Weight after storage: 1108.8 g
Content of trinexapac ethyl (determined by HPLC-UV method validated in report F16-02/4; see dRR Part B5)	177.47 g/L (17.80% w/w)	177.17 g/L (17.77% w/w)
pH value of undiluted product (CIPAC MT 75.3)	3.7 at 24°C	3.7 at 25°C
Acidity (%) (CIPAC MT 3.2)	4.85%	4.70%

Test Method	Results before storage		Results after storage for 14 days at 54°C	
Emulsion characteristics (mL cream, mL oil) at 25°C ± 2 °C Visual method (CIPAC MT 36.3)	0.1% v/v of product in standard water A and D ^{(1),(3)}		0.1% v/v of product in standard water A and D ^{(1),(3)}	
	- initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min)	Homogeneous 0ml cream; 0ml oil 0ml cream; 0ml oil 0ml cream; 0ml oil Homogeneous 0ml cream; 0ml oil	- initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min)	Homogeneous 0ml cream; 0ml oil 0ml cream; 0ml oil 0ml cream; 0ml oil Homogeneous 0ml cream; 0ml oil
	0.8% v/v of product in standard water A ⁽²⁾ and D ⁽²⁾		0.8% v/v of product in standard water A ⁽²⁾ and D ⁽²⁾	
	- initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min)	Homogeneous 0ml cream; 0ml oil 0ml cream; 0ml oil Trace of cream Homogeneous 0ml cream; 0ml oil	- initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min)	Homogeneous 0ml cream; 0ml oil 0ml cream; 0ml oil Trace of cream Homogeneous 0ml cream; 0ml oil
(1) Minimum concentration of 0.0625% v/v formulation corresponds to minimum application rate of 250 ml/ha in maximum spray volume of 400 l/ha. (2) Maximum concentration of 0.8% v/v formulation corresponds to maximum application rate of 800 ml/ha in minimum spray volume of 100 l/ha. (3) As the lowest concentration is less than 0.1%, the test was carried out at 0.1%.				

Table 2-3: Test Results before and after 14 days storage stability at 54°C for a Product Packed in HDPE/EVOH commercial containers

Test Method	Results before storage	Results after storage for 14 days at 54°C
Appearance (physical state and colour)	ADM.09050.H.1.A was an amber liquid with aromatic odour.	ADM.09050.H.1.A was an amber liquid with aromatic odour. No separation, no sedimentation were observed at the end of the test.
Stability of the original test item container (visual)	No damage to the container shape or size was observed.	No change in the appearance was observed of the product packed in HDPE/EVOH commercial containers. No significant change in weight. No visible interaction of the formulation with its packaging.
Weight change of test item container	Weight before storage: 1110.8 g	Weight after storage: 1110.7 g
Content of trinexapac ethyl (determined by HPLC-UV method validated in report F16-02/4; see dRR Part B5)	177.47 g/L (17.80% w/w)	177.37 g/L (17.79% w/w)

Table 2-4: Test Results before and after low temperature stability test, 7 Days at 0°C

Test Method	Results before storage	Results after storage at 0 °C for 7 days
Appearance (physical state and colour)	ADM.09050.H.1.A was an amber liquid with aromatic odour	Amber liquid, aromatic odour. No separation, no sedimentation were observed at the end of the test.
pH (CIPAC MT 75.3) 1% in deionized water	3.7 (at 24°C)	3.7 (at 25°C)
	0.1% v/v of product in standard water A and D ⁽¹⁾	
	<ul style="list-style-type: none"> - initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min) 	<ul style="list-style-type: none"> Homogeneous 0ml cream; 0ml oil 0ml cream; 0ml oil 0ml cream; 0ml oil Homogeneous 0ml cream; 0ml oil
	0.8% v/v of product in standard water A ⁽²⁾ and D ⁽²⁾	
	<ul style="list-style-type: none"> - initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min) 	<ul style="list-style-type: none"> Homogeneous 0ml cream; 0ml oil 0ml cream; 0ml oil Trace of cream Homogeneous 0ml cream; 0ml oil
	0.1% v/v of product in standard water A and D ⁽¹⁾	
	<ul style="list-style-type: none"> - initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min) 	<ul style="list-style-type: none"> Homogeneous 0ml cream; 0ml oil 0ml cream; 0ml oil 0ml cream; 0ml oil Homogeneous 0ml cream; 0ml oil
	0.8% v/v of product in standard water A ⁽²⁾ and D ⁽²⁾	
	<ul style="list-style-type: none"> - initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min) 	<ul style="list-style-type: none"> Homogeneous 0ml cream; 0ml oil 0ml cream; 0ml oil Trace of cream Homogeneous 0ml cream; 0ml oil
<p>(1) Minimum concentration of 0.0625% v/v formulation corresponds to minimum application rate of 250 ml/ha in maximum spray volume of 400 l/ha. As the lowest concentration is less than 0.1%, the test was carried out at 0.1%.</p> <p>(2) Maximum concentration of 0.8% v/v formulation corresponds to maximum application rate of 800 ml/ha in minimum spray volume of 100 l/ha.</p>		

Table 2-5: Storage stability at ambient temperature for 2 years for a Product Packed in HDPE/PA commercial containers

Test Method	Results before storage	Results after storage for 1 years at room temperature	Results after storage for 2 years at ambient temperature
Appearance (physical state and	ADM.09050.H.1.A was an amber liquid with aromatic odour.	ADM.09050.H.1.A was an amber liquid with aromatic odour. No separation, no sedimentation were observed at the end of the test.	
Stability of the original test item container (visual)	No damage to the container shape or size was observed.	No change in the appearance was observed of the product packed in HDPE/PA commercial containers. No significant change in weight. No visible interaction of the formulation with its packaging.	
Weight change of test item container	Container stored for: 1 Year: 1107.4 g 2 Years: 1108.1 g	Weight after storage: 1107.7 g No significant change in weight.	Weight after storage: 1108.6 No significant change in weight.
Content of trinexapac ethyl (determined by HPLC-UV method validated in report F16-02/4; see dRR Part B5)	177.47 g/L (17.80% w/w)	177.37 g/L (17.79% w/w)	177.17 g/L (17.77% w/w)
pH value of undiluted product (CIPAC MT 75.3)	3.7 at 24°C	3.7 at 25°C	3.7 at 25°C
Acidity (%) (CIPAC MT 3.2)	4.85%	-	4.7

Test Method	Results before storage		Results after storage for 1 years at room temperature		Results after storage for 2 years at ambient temperature	
Emulsion characteristics (mL cream, mL oil) at 25°C ± 2 °C Visual method (CIPAC MT 36.3)	0.1% v/v of product in CIPAC water A and D^D (1),(3)		0.1% v/v of product in standard water A and D (1),(3)		0.1% v/v of product in standard water A and D (1),(3)	
	- initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min)	Homogeneous 0ml cream; 0ml oil 0ml cream; 0ml oil 0ml cream; 0ml oil Homogeneous 0ml cream; 0ml oil	- initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min)	Homogeneous 0ml cream; 0ml oil 0ml cream; 0ml oil 0ml cream; 0ml oil Homogeneous 0ml cream; 0ml oil	- initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min)	Homogeneous 0ml cream; 0ml oil 0ml cream; 0ml oil 0ml cream; 0ml oil Homogeneous 0ml cream; 0ml oil
	0.8% v/v of product in CIPAC water A (2)		0.8% v/v of product in CIPAC water A (2)		0.8% v/v of product in CIPAC water A (2)	
	- initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min)	Homogeneous 0ml cream; 0ml oil 0ml cream; 0ml oil Trace of cream Homogeneous 0ml cream; 0ml oil	- initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min)	Homogeneous 0ml cream; 0ml oil 0ml cream; 0ml oil Trace of cream Homogeneous Trace of cream	- initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min)	Homogeneous 0ml cream; 0ml oil Trace of cream Trace of cream Homogeneous Trace of cream
	0.8% v/v of product in CIPAC water D (2)		0.8% v/v of product in CIPAC water D (2)		0.8% v/v of product in CIPAC water D (2)	
	- initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min)	Homogeneous 0ml cream; 0ml oil 0ml cream; 0ml oil Trace of cream Homogeneous 0ml cream; 0ml oil	- initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min)	Homogeneous 0ml cream; 0ml oil 0ml cream; 0ml oil Trace of cream Homogeneous 0ml cream; 0ml oil	- initially - after 30 minutes - after 2 hours - after 24 hours - after re-emulsification - 30 minutes after re-emulsification (24 hours + 30 min)	Homogeneous 0ml cream; 0ml oil Trace of cream Trace of cream Homogeneous Trace of cream

Test Method	Results before storage	Results after storage for 1 years at room temperature	Results after storage for 2 years at ambient temperature
	(1) Minimum concentration of 0.0625 %v/v formulation corresponds to minimum application rate of 250 mL/ha in maximum spray volume of 400 L/ha. (2) Maximum concentration of 0.8 %v/v formulation corresponds to maximum application rate of 800 mL/ha in minimum spray volume of 100 L/ha. (3) As the lowest concentration is less than 0.1 %, the test was carried out at 0.1		

Table 2-6: Storage stability at ambient temperature for 2 years for a Product Packed in HDPE/EVOH commercial containers

Test Method	Results before storage (see accelerated storage study)	Results after storage for 1 years at room temperature	Results after storage for 2 years at room temperature
Appearance (physical state and	ADM.09050.H.1.A was an amber liquid with aromatic odour.	ADM.09050.H.1.A was an amber liquid with aromatic odour. No separation, no sedimentation was observed at the end of the test.	
Stability of the original test item container (visual)	HDPE/EVOH commercial containers. No damage to the container shape or size was observed.	No change in the appearance was observed of the product packed in HDPE/EVOH commercial containers. No significant change in weight. No visible interaction of the formulation with its packaging.	
Weight change of test item container	Container stored for: 1 Year: 1110.5 g 2 Years: 1108.5	Weight after storage: 1110.7 g No significant change in weight.	Weight after storage: 1108.8 No significant change in weight.
Content of trinexapac ethyl (determined by HPLC-UV method validated in report F16-02/4; see dRR Part B5)	177.47 g/L (17.80% w/w)	177.67 g/L (17.82% w/w)	176.67 g/L (17.67% w/w)

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)

Nature and characteristics of the packaging:

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 (EC formulation) is intended for containment in 5 L and 10 L- COEX containers.

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

The accelerated storage stability of Edelson T. (2016), ref. KCP 2.1/01, has been performed with the intended commercial packaging material (1 L commercial COEX containers (HDPE/PA, HDPE/EVOH)). 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 in the following table and in ref. KCP 4.4/01 to /13.

Table 4.1-1: Packaging information

5 litre container Reyde	Material	COEX
	shape/size	Square / 190 × 140 × 307 mm
	Opening	63 mm
5 litre container Pachmas	Material	COEX
	shape/size	Square / 190 × 140 × 305 mm
	Opening	63 mm
5 litre container Mobilak	Material	COEX
	shape/size	Square / 190 × 140 × 307 mm
	Opening	63 mm
10 litre container Reyde	Material	COEX
	shape/size	Square / 227 × 157 × 400.8 mm
	Opening	63 mm
10 litre container Pachmas	Material	COEX
	shape/size	Square / 227 × 157 × 401 mm
	Opening	63 mm
10 litre container Mobilak	Material	COEX
	shape/size	Square / 227 × 157 × 402 mm
	Opening	63 mm

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)

At the time of compilation of this dossier, no specific study had been conducted for the product ADM.09050.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.09050.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:	1.2 L ADM.09050.H.1.A /ha , corresponding to 210 g Trinexapac-ethyl/ha
Spray volumes:	200 – 400 L/ha
Spray volume used for the assessment of effectiveness:	200 L/ha (lowest spray volume corresponding to the maxi- mum concentration of ADM.09050.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]
			Trinexapac-ethyl
Tank filling: Residues after spraying:	2000 20	6	1.05
1st step: 1/10 dilution of residual spray volume: Residues after spraying:	200 20	1.2	0.105
2nd step: 20% of tank volume added: Residues after spraying:	400 20	0.06	0.00525
3rd step: 20% of tank volume added: Residues after spraying:	400 20	0.003	0.0002625
Addition of fresh spray solution: Residues in the tank filling:	2000	0.00003	0.000002625

PPP = ADM.09050.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 1.5 µL ADM.09050.H.1.A per L of water, corresponding to a total of about 30 µL ADM.09050.H.1.A in the tank. Considering these residues to be completely dissolved in the next tank filling, residues of 0.015 µL ADM.09050.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 –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.09050.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.09050.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.09050.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.09050.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 = 0.009 mL ADM.09050.H.1.A/ha; i.e. **0.000009 L prod./ha**

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

Toxicity endpoints obtained from reference:

KCP 10.6.2/01: Friedrich, S., (2008b): Terrestrial (non-target) plant test with Trinexapac-ethyl 175 EC: Seedling emergence and seedling growth test of non-target terrestrial plants

Lowest ER₅₀ > 0.80 kg a.s./ha, corresponding to > **4.44 L prod./ha**

Lowest NOER > 0.80 kg a.s./ha, corresponding to > **4.44 L prod./ha**

TER (ER₅₀/PER) **493'333**
NOER/PER **493'333**

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

Toxicity endpoints obtained from reference:

KCP 10.6.2/01: Friedrich, S., (2008a): Terrestrial (non-target) plant test with Trinexapac-ethyl 175 EC: Vegetative vigour test of non-target terrestrial plants

Lowest ER₅₀ 0.384 kg a.s./ha (tomato), corresponding to > **2.13 L prod./ha**
Lowest NOER 0.048 kg a.s./ha (tomato), corresponding to > **0.267 L prod./ha**

TER (ER₅₀/PER) **236'667**
NOER/PER **29'667**

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.

Conclusion: The effectiveness of standard cleaning procedures according to Good Agriculture Practice was assessed for the product ADM.09050.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.09050.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.09050.H.1.A filed under KCP 4.3/01.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner*
KCP 2.1/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54°C for 14 Days and at 0°C for 7 Days (including Amendment No 1) AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016 GLP, unpublished	N	ADM
KCP 2.2.1/01	Atwal, S.S. Tremain, S.P.	2008	Determination of Harzadous Physico-Chemical Properties Celsius Property B.V. Safepharm Laboratories Limited, Shardlow, UK SPL Project no. 2584/0003 October 2008 GLP, unpublished	N	ADM
KCP 2.2.2/01	Atwal, S.S. Tremain, S.P.	2008	Determination of Harzadous Physico-Chemical Properties Celsius Property B.V. Safepharm Laboratories Limited, Shardlow, UK SPL Project no. 2584/0003 October 2008 GLP, unpublished Please refer to KCP 2.2.1/01	N	ADM
KCP 2.3.1/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54°C for 14 Days and at 0°C for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016	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*
			GLP, unpublished Please refer to KCP 2.1/01		
KCP 2.3.3/01	Atwal, S.S. Tremain, S.P.	2008	Determination of Harzadous Physico-Chemical Properties Celsius Property B.V. Safepharm Laboratories Limited, Shardlow, UK SPL Project no. 2584/0003 October 2008 GLP, unpublished Please refer to KCP 2.2.1/01	N	ADM
KCP 2.4.1/02	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54°C for 14 Days and at 0°C for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016 GLP, unpublished Please refer to KCP 2.1/01	N	ADM
KCP 2.5.1/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54°C for 14 Days and at 0°C for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016 GLP, unpublished Please refer to KCP 2.1/01	N	ADM
KCP 2.5.2/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54°C for 14 Days and at 0°C for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016 GLP, unpublished Please refer to KCP 2.1/01	N	ADM
KCP 2.6.1/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54°C for 14 Days and at 0°C for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4,	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*
			June 2016 GLP, unpublished Please refer to KCP 2.1/01		
KCP 2.7.1/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54°C for 14 Days and at 0°C for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016 GLP, unpublished Please refer to KCP 2.1/01	N	ADM
KCP 2.7.4/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54°C for 14 Days and at 0°C for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016 GLP, unpublished Please refer to KCP 2.1/01	N	ADM
KCP 2.7.5/01	Edelson, T.	2018	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC1 (Trinexapac-ethyl 175 EC) Stored at Ambient Temperature for Two Years AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/5, June 2018 GLP, unpublished	N	ADM
KCP 2.8.2/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54°C for 14 Days and at 0°C for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016 GLP, unpublished Please refer to KCP 2.1/01	N	ADM
KCP 2.8.6.2/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54°C for 14 Days and at 0°C for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016	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*
			GLP, unpublished Please refer to KCP 2.1/01		
KCP 2.8.6.2/02	Edelson, T.	2018	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC1 (Trinexapac-ethyl 175 EC) Stored at Ambient Temperature for Two Years AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/5, June 2018 GLP, unpublished Please refer to KCP 2.7.5/01	N	ADM
KCP 4.3/01	Anonymous	2020	Safety Data Sheet – ADM.09050.H.1.A ADAMA Agan Ltd., Ashdod., Israel Report no.: Version 4.01 No GLP Unpublished	N	ADM
KCP 4.4/01	Anonymous	2019	COEX_EVOH (Reyde) - 5 L Packaging information Report no. -- Reyde, S.A., Barcelona, Spain No GLP Unpublished	N	Reyde
KCP 4.4/02	Anonymous	2019	COEX_PA (Reyde) - 5 L Packaging information Report no. -- Reyde, S.A., Barcelona, Spain No GLP Unpublished	N	Reyde
KCP 4.4/03	Anonymous	2017	COEX-PA (Pachmas) - 5 L Packaging Information Report no. -- State of Israel, Ministry of Transport The Standards Institution of Israel No GLP Unpublished	N	Pachmas
KCP 4.4/04	Anonymous	2017	HDPE (Pachmas) - 5 L Packaging Information	N	Pachmas

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*
			Report no. -- State of Israel, Ministry of Transport The Standards Institution of Israel No GLP Unpublished		
KCP 4.4/05	Anonymous	2018	COEX-PA (Mobilak) – 5 L Packaging Information Report no. -- The Standards Institution of Israel No GLP Unpublished	N	Mobilak
KCP 4.4/06	Anonymous	2018	Specification 9813205419E (Mobilak) – 5 L Packaging Information Report no. 9813205419 The Standards Institution of Israel No GLP Unpublished	N	Mobilak
KCP 4.4/07	Anonymous	2018	COEX - UN- _2018580 (Mobilak) – 5 L Packaging Information Report no. -- The Standards Institution of Israel No GLP Unpublished	N	Mobilak
KCP 4.4/08	Anonymous	2019	HDPE and COEX – final drawing (Reyde) - 10 L Packaging information Report no. -- Reyde, S.A., Barcelona, Spain No GLP Unpublished	N	Reyde
KCP 4.4/09	Anonymous	2019	COEX_EVOH (Reyde) - 10 L Packaging information Report no. -- Reyde, S.A., Barcelona, Spain No GLP Unpublished	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*
KCP 4.4/10	Anonymous	2019	COEX_PA (Reyde) - 10 L Packaging information Report no. -- Reyde, S.A., Barcelona, Spain No GLP Unpublished	N	Reyde
KCP 4.4/11	Anonymous	2020	COEX-PA (Pachmas) - 10 L Packaging Information Report no. -- State of Israel, Ministry of Transport The Standards Institution of Israel No GLP Unpublished	N	Pachmas
KCP 4.4/12	Anonymous	2020	COEX-PA – pmi 2020003 (Pachmas) - 10 L Packaging Information Report no. 7013201083 State of Israel, Ministry of Transport The Standards Institution of Israel No GLP Unpublished	N	Pachmas
KCP 4.4/13	Anonymous	2020	COEX-PA and COEX-EVOH (Mobilak) – 10 L Packaging Information Report no. -- The Standards Institution of Israel No GLP Unpublished	N	Mobilak

*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

None.

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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