

# 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.3304.H.1.A

Product name: Tricera

Chemical active substance(s):

2,4-D, 375 g/L (562.5 g/L as 2,4-D EHE)

Clopyralid, 30 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

(composition change)

Sponsor: ADAMA Agan Ltd.

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

Submission date: February 2021

MS Finalisation date: September 2021 (initial Core Assessment)

November 2022, updated December 2022 (final Core Assessment)

### Version history

When	What
January 2021	dRR Part B – Section 1, 2 and 4; Version 1 submitted by applicant
September 2021	Initial ZRMS assessment  The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and <b>highlighted in grey</b> . Not agreed or not relevant information are <del>struck through and shaded for transparency</del> .
November 2022	Final report (Core Assessment updated following the commenting period).  No additional information or assessments after the commenting period.
December 2022	Final report (Core Assessment updated following the Applicant's comments).  Additional information/assessments included by the zRMS in the report in response to comments received from the Applicant are <b>highlighted in green</b> . Information no longer relevant <del>is struck through and shaded</del> .

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The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it.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authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

- from the owner of the data, or
- from a second party that has obtained permission from the owner of the data for this purpose or,
- following expiry of any period of exclusive use, by offering – in certain jurisdictions – mandatory compensation, unless the period of protection of the proprietary data concerned has expired.

## Introduction

### General remark:

The product ADM.3304.H.1.A is a herbicide containing the active substance 2,4-D (as the ester variant 2,4-D EHE).

In the dossier below information is presented for the acid form –that will be referred as “2,4-D”- as well as for the ester form (that will be referred as “2,4-D EHE”).

This document reviews the information related to the identity, the physical and chemical properties, further information for the plant protection product ADM.3304.H.1.A containing the active substances 2,4-D, Clopyralid and Fluroxypyr.

**2,4-D** was reviewed as part of the renewal of approval procedure by the Member States and the Commission and the Commission review <sup>report</sup> finalised on 13.11.2015 approved 2,4-D in accordance with Regulation (EC) No. 1107/2009 (Regulation 2015/2033).

**Clopyralid** was included into Annex I of Directive 91/414/EEC according to Commission Regulation (EC) No 451/2000 (renewal of inclusion of the second and third group of active substances in Annex I, see Commission Directive 2006/64/EC of 18 July 2006, Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 that replaced the Directive 2006/64/EC after the application of Regulation 1107/2009, and ~~Commission Implementing Regulation (EU) 2020/421 of 18 March 2020 that fixes the new expiry date of approval to 30/04/2021~~ **Commission Implementing Regulation (EU) 2021/1191 of 19 July 2021 with new date of expiration of approval to 30 September 2036.**

**Fluroxypyr** was included into Annex I of Directive 91/414/EEC according to Commission Regulation (EC) No 736/2011 (renewal of inclusion of the first group of active substances in Annex I).

However, all the relevant information about this last approval are indicated in Review report for active substance Fluroxypyr (SANCO/111019/201, 17 June 2011), as was evaluated within the assessment of active substance Fluroxypyr.

Where appropriate this document refers to the conclusions of the EU review or the Draft Assessment Report (DAR) of the active substances. This will be where:

- the active substance data is relied upon in the risk assessment of the formulation; *or when*
- the EU review or DAR concluded that additional data/information should be considered at national re-registration.

Note: this Part B document only reviews data (Annex II or Annex III) (Chemical Active or Chemical Product) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision. New annex II (Chemical active) data have only be included if they were considered essential for the evaluation and in this case a full study summary was be provided. In the case where the formulation has been previously evaluated, at European level, detailed summaries have not been provided.

This product was not the representative formulation. The product has not been previously evaluated according to Uniform Principles.

The EFSA Report of 2,4-D (EFSA Journal 2014;12(9):3812) that was updated on 21<sup>st</sup> March 2017, the EFSA report of Clopyralid (EFSA Scientific Report (2005) 50, 1–65, EFSA Journal 2018;16(8):5389, 21 pp.) and the EFSA Report of Fluroxypyr (EFSA Journal 2011;9(3):2091) are considered to provide the relevant review information or a reference to where such information can be found.

For the information on 2,4-D EHE, please refer to the Bridging dossier (2018) prepared by the RMS for the a.i. (Greece).

The following table provided the EU endpoint to be used in the evaluation.

#### Agreed EU Endpoints

Endpoint	2,4-D		Clopyralid		Fluroxypyr*	
	EU agreed endpoint	Endpoint used*	EU agreed endpoint (EFSA Scientific Report (2005) 50, 1–65, EFSA Journal 2018;16(8):5389, 21 pp.)	Endpoint used	EU agreed endpoint (EFSA Journal 2011;9(3):2091)	Endpoint used*
Purity of active substance	≥ 920 g/kg* (2,4-D EHE)  ≥ 970 g/kg (2,4-D Acid)	≥ 940 g/kg	≥ 950 g/kg	≥ 950g/kg	≥ 950 g/kg	≥ 985 g/kg

\*ADAMA Agan Ltd. have their own sources of 2,4-D EHE and Fluroxypyr-meptyl which have been judged as being equivalent to the respective notified reference sources.

\*\* Based on FAO specification of 2,4-D EHE

The Annex I Inclusion Directives for the active substances **2,4-D** (Commission Directive 2001/103/EC) gives specific provisions under Part B which need to be considered by the applicant in the preparation of their submission prior to granting an authorisation.

For the implementation of the uniform principles of Regulation (EC) 546/2011, the conclusions of the review report on **2,4-D**, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28. May 2015 shall be taken into account. In this overall assessment:

Member States must pay particular attention to the:

- *Risk to aquatic organisms, terrestrial organisms and consumers in cases of uses above 750 g/ha.*

The Annex I Inclusion Directives for the active substances **Clopyralid** (Commission Directive 2006/64/CE) gives specific provisions under Part B which need to be considered by the applicant in the preparation of their submission prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the active substance Clopyralid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 04. April 2006 shall be taken into account. In this overall assessment member states should pay particular attention to:

- The protection of non-target plants and groundwater under vulnerable conditions. Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify potential groundwater contamination in vulnerable zones, where appropriate.

**Fluroxypyr** (Commission Implementing Regulation (EU) No 736/2011) gives specific provisions under Part B which need to be considered by the applicant in the preparation of their submission prior to granting an authorisation.

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on **Fluroxypyr**, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.

- Only uses as herbicides may be authorised.

In this overall assessment Member States shall pay particular attention to:

- The potential contamination of groundwater by metabolite Fluroxypyr Pyridinol, when the active substance is applied in regions with alkaline or vulnerable soil and/or with vulnerable climatic conditions.
- The risk to aquatic organisms.

These concerns have, where relevant, been addressed within the current submission in the respective sections.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation (only new data).

Appendix 2 of this document contains the new data of the active substances present in ADM.3304.H.1.A in this section.

Information on the detailed composition of ADM.3304.H.1.A can be found in the confidential dossier of this submission (Registration Report - Part C).

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Comments of zRMS:	<p>This document has been prepared by the applicant in the context of confirming the properties of the product after the composition change proposed in document C.</p> <p>In order to confirm that the available data package is still suitable for the registration of the product after proposed changes in the composition, the applicant has completed the required data in the registration report for the product, and the data provided below are considered sufficient for the registration of the product after the composition change.</p>
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## 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
------	---

#### Contact:

Name	ADAMA Polska Sp. z o.o.
Address	ul. Sienna 39, 00-121 Warszawa
Phone	...
E-mail	...
Contact	...

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

#### 1.2.1 Producer(s) of the preparation

CONFIDENTIAL information - data provided separately (Part C).

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

CONFIDENTIAL information - data provided separately (Part C).

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

#### 1.2.3.1 2,4-D 2-EHE

2,4-D 2-EHE min.  $\geq 940$  g/kg

Impurities of toxicologically or ecotoxicologically concern are

Free phenols (expressed as 2,4 DCP): not more than 3 g/kg

TCDD toxic equivalents (TEQ): not more than 10  $\mu\text{g/kg}$  (all the companies of the "EU 2,4-D Task Force 2012" comply with this limit)

(please refer to Review Report (SANCO/11961/2014 rev 5 final 6 October 2017)).

#### 1.2.3.2 Clopyralid

Clopyralid: min.  $\geq 950$  g/kg

Impurities of toxicologically or ecotoxicologically concern have not been identified for this active

(please refer to [SANTE/10206/2021 Rev 1 20 May 2021 and Commission Implementing Regulation \(EU\)](#))



2021/1191 of 19 July 2021 Review Report (SANCO/10012/2006—rev. 3-4 April 2006)).

### 1.2.3.3 Fluroxypyr-meptyl

Fluroxypyr-meptyl: min.  $\geq 985$  g/kg

The following manufacturing impurity is of toxicological concern and must not exceed a certain amount in the technical material:

N-methyl-2-pyrrolidone (NMP):  $< 3$  g/kg.

(please refer to Review Report (SANCO/11019/2011 rev 5, 17 June 2011, 23 March 2017)).

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

Manufacturer's code for the formulation: ADM.3304.H.1.A, ADM.03304.H.1.A

Trade name: Tricera (for further tradenames please refer to Registration Report Part A for the relevant country)

For the Safety Data Sheet (SDS) of the plant protection product, please refer to document KCP 1.3/01.

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

#### 1.4.1 Composition of the plant protection product (KCP 1.4.1)

The information of the composition of ADM.3304.H.1.A is confidential and is provided separately in Part C. ADM.3304.H.1.A is a new formulated product. It was not the representative formulation during evaluation of 2,4-D, Clopyralid or Fluroxypyr on EU level.

**Table 1.4.1-1: 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]	FAO Limits (min – max)
2,4-D as 2-EHE	565	$565 \pm 25$ g/L	601.06	$601.06 \pm 25$ g/L
Clopyralid	30	$30 \pm 3$ g/L	31.58	$31.58 \pm 3.16$ g/L
Fluroxypyr-meptyl	108	$108 \pm 6.48$ g/L	109.64	$109.64 \pm 6.58$ g/L

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

at a minimum purity of the technical active substance 1 of 94 % as 2,4-D 2-EHE

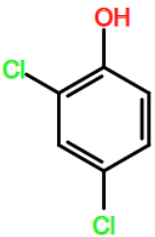
at a minimum purity of the technical active substance 2 of 95 % w/w

at a minimum purity of the technical active substance of 98.5 % w/w as Fluroxypyr-meptyl

According to COMMISSION IMPLEMENTING REGULATION (EU) 2015/2033 of 13 November 2015, the following relevant impurity was listed for 2,4-D TGAI.

**Table 1.4.1-2: Information on relevant impurities**

Name	Free phenols (expressed as 2,4-DCP)
ISO common name	2,4-dichlorophenol
CAS No.	120-83-2

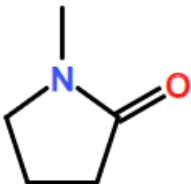
<b>EC No.</b>	204-429-6
<b>Molecular formula</b>	C <sub>6</sub> H <sub>4</sub> Cl <sub>2</sub> O
<b>Molecular weight</b>	163.0 g/mol
<b>Structural formula</b>	
<b>Max. content</b>	3.0 g/kg a.i.

**Table 1.4.1-3: Information on relevant impurities**

<b>Name</b>	Sum of dioxins and furans (WHO-TCDD TEQ) <sup>1</sup>
<b>ISO common name</b>	-
<b>CAS No.</b>	-
<b>EC No.</b>	-
<b>Molecular formula</b>	-
<b>Structural formula</b>	-
<b>Max. content</b>	0.01 mg/ kg a.i.

<sup>1</sup> Dioxins (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs), expressed as World Health Organisation (WHO) toxic equivalent (TEQ) using the WHO-toxic equivalency factors (WHO-TEFs).

**Table 1.4.1-4: Information on relevant impurities**

<b>Name</b>	N-methylpyrrolidinone (NMP)
<b>ISO common name</b>	1-methyl-2-pyrrolidinone
<b>CAS No.</b>	872-50-4
<b>EC No.</b>	212-828-1
<b>Molecular formula</b>	C <sub>5</sub> H <sub>9</sub> NO
<b>Structural formula</b>	
<b>Max. content</b>	3 mg/ kg a.i.

## Formulants

CONFIDENTIAL information - data provided separately (Part C).

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

**Table 1.4.2-1: Information on 2,4-D**

Type	Name/Code Number	
ISO common name	2,4-D	Variant: 2,4-D 2-EHE

Type	Name/Code Number	
IUPAC name	(2,4-dichlorophenoxy)acetic acid	Variant: (2,4-dichlorophenoxy) acetic acid, 2-ethylhexyl ester
CAS No.	94-75-7	1928-43-4
EC No.	202-361-7	217-673-3
CIPAC No.	1	1.3

**Table 1.4.2-2: Information on Clopyralid**

Type	Name/Code Number	
ISO common name	Clopyralid	Variant
IUPAC name	3,6-dichloropyridine-2-carboxylic acid	-
CAS No.	1702-17-6	-
EC No.	216-935-4	-
CIPAC No.	455	-

**Table 1.4.2-3: Information on Fluroxypyr acid**

Type	Name/Code Number	
ISO common name	Fluroxypyr acid	Variant: Fluroxypyr-meptyl
IUPAC name	4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyacetic acid	(RS)-1-methylheptyl 4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyacetate
CAS No.	69377-81-7	81406-37-3
EC No.	614-957-2	279-752-9
CIPAC No.	431	431.214

For the Safety Data Sheets (SDS) of the active substances, please refer to the documents KCP 1.4.2/01 to KCP 1.4.2/03 provided separately in Part C.

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

The information of co-formulants present in the formulation is confidential and is provided separately in Part C.

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

Type: Emulsifiable Concentrate [Code: EC]

No change compared to the old formulation

### 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 ADM.3304.H.1.A is a brown-orange homogeneous liquid. It is not explosive and it has no oxidising properties. Its flash point is determined to be ~~111.2 °C~~ **100 °C** and the auto-flammability is determined at 265 °C. In aqueous solution, it has a pH value around ~~2.8~~ **3.4** at 25 °C. There is no effect at high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed when the product is stored at 0°C. The 2 years shelf life study is on-going. Based on the accelerated storage stability 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 COEX commercial packaging. Its technical characteristics are acceptable for an *emulsifiable concentrate* formulation and indicate that no particular problems are to be expected, when it is used as recommended.

Thus, the old and the new composition are comparable with respect to phys-chem. properties of the product.

The intended concentration of use is 0.5% to 1.0%.

The product will not be mixed in the tank together with other plant protection products.

Only new documents are submitted (please refer to Appendix 1)

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

Classification according to	DPD (Directive 67/845/EEC)	CLP (Regulation (EC) No. 1272/2008)
	Hazard symbol(s)	Pictograms
	None	None
	Indications of danger	Signal word
	None	None
		Hazard class and hazard category
		None

### Notifier Proposals for Risk and Safety Phrases (KCP 12)

With respect to physical/chemical data	Risk phrases:	Hazard statements:
	None	None
	Safety phrases:	Precautionary statements
	None	None

No change is needed compared to the old formulation.

### Compliance with FAO specifications:

The product ADM.3304.H.1.A complies with FAO specifications.

### Formulation used for tests

For data on the composition of the test products used, please refer to 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.3304.H.1.A Batch n°: N6002P2/1	Brown-orange homogeneous liquid.	Y	Tsesin, N. (2020) Sponsor n°: 000106540 (KCP 2.1/01)	Accepted.									
Explosive properties (KCP 2.2.1)	EC A.14	AG-CDF1-480 EC Batch n°: N6504	The test item has no explosive properties.	Y	Krack, M. (2015a) Report n°: 20150202.01 (KCP 2.2.1/01)	Accepted.									
Oxidizing properties (KCP 2.2.2)	EC A.21	AG-CDF1-480 EC Batch n°: N6504	The test item has no oxidizing properties.	Y	Krack, M. (2015b) Report n°: 20150202.02 (KCP 2.2.2/01)	Accepted.									
Flash point (KCP 2.3.1)	EC A.9	ADM.3304.H.1.A Batch n°: N6002P2/1	The flash point was determined to be > 100 °C.  The formulation is non-flammable	Y	Tsesin, N. (2020) Sponsor n°: 000106540 <b>(Submitted in KCP 2.1/01)</b>	Accepted.									
Flammability (KCP 2.3.2)	-	-	Not relevant, since the preparation is a liquid.	-	-	-									
Self-heating (KCP 2.3.3)	EC A.15	AG-CDF1-480 EC Batch n°: N6504	The self-ignition temperature of the test item is 265 °C.	Y	Nau, M. (2015) Report n°: 20150436.01 (KCP 2.3.3/01)	Accepted.									
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	ADM.3304.H.1.A Batch n°: N6002P2/1	Acidity in H <sub>2</sub> SO <sub>4</sub> (% , w/w) 1% in deionized water: 0.43 %	Y	Tsesin, N. (2020) Sponsor n°: 000106540 <b>(Submitted in KCP 2.1/01)</b>	Accepted.									
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	ADM.3304.H.1.A Batch n°: N6002P2/1	pH at 25 °C, 1% w/w in deionized water: 3.4  No test is available to show that the product is not corrosive to metals. But since the acidity value of the product is so low (0.43 %), no corrosiveness to metals is expected.	Y	Tsesin, N. (2020) Sponsor n°: 000106540 <b>(Submitted in KCP 2.1/01)</b>	Accepted.									
Viscosity (KCP 2.5.1)	OECD 114 and ISO 2431:1993 (E)	ADM.3304.H.1.A Batch n°: N6002P2/1	Dynamic Viscosity: <table><tr><th>Temperature [°C]</th><th>At 18 s<sup>-1</sup> [mPa· s]</th><th>At 105 s<sup>-1</sup> [mPa· s]</th></tr><tr><td>20</td><td>76.0</td><td>75.5</td></tr><tr><td>40</td><td>24.5</td><td>25.4</td></tr></table>  Kinematic Viscosity*:	Temperature [°C]	At 18 s <sup>-1</sup> [mPa· s]	At 105 s <sup>-1</sup> [mPa· s]	20	76.0	75.5	40	24.5	25.4	Y	Tsesin, N. (2020) Sponsor n°: 000106540 <b>(Submitted in KCP 2.1/01)</b>	Accepted.
Temperature [°C]	At 18 s <sup>-1</sup> [mPa· s]	At 105 s <sup>-1</sup> [mPa· s]													
20	76.0	75.5													
40	24.5	25.4													

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments											
			<table><tr><th>Temperature [°C]</th><th>At 5 s<sup>-1</sup> [mm²/s]</th><th>At 100 s<sup>-1</sup> [mm²/s]</th></tr><tr><td>20</td><td>70.0</td><td>69.6</td></tr><tr><td>40</td><td>22.6</td><td>23.4</td></tr></table> <p>* calculation using density of 1.086 g/mL</p> <p>The test item is considered to be a Newtonian liquid.</p>	Temperature [°C]	At 5 s <sup>-1</sup> [mm²/s]	At 100 s <sup>-1</sup> [mm²/s]	20	70.0	69.6	40	22.6	23.4							
Temperature [°C]	At 5 s <sup>-1</sup> [mm²/s]	At 100 s <sup>-1</sup> [mm²/s]																	
20	70.0	69.6																	
40	22.6	23.4																	
Surface tension (KCP 2.5.2)	EC A.5	ADM.3304.H.1.A Batch n°: N6002P2/1	At 22 °C: 31.1 mN/m (neat) At 22 °C: 27.7 mN/m (2 %, v/v dilution)  Since the surface tension is below 60 mN/m the test item is considered as surface-active formulation.			Y	Tsesin, N. (2020) Sponsor n°: 000106540 <b>(Submitted in KCP 2.1/01)</b>	Accepted.											
Relative density (KCP 2.6.1)	EC A.3	ADM.3304.H.1.A Batch n°: N6002P2/1	At 20 °C: 1.09 g/mL			Y	Tsesin, N. (2020) Sponsor n°: 000106540 <b>(Submitted in KCP 2.1/01)</b>	Accepted.											
Bulk density (KCP 2.6.2)	-	-	Not relevant, since the preparation is a liquid.			-	-	-											
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3 Appearance & content CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 47.2 CIPAC MT 36.3	ADM.3304.H.1.A Batch n°: N6002P2/1	<p>After storage for 14 days at 54 °C ± 2 °C in HDPE/PA COEX commercial packaging.</p> <p><u>Appearance:</u> Before: Brown-orange homogeneous liquid. After: Uniform brown-orange homogeneous liquid. No precipitation was detected</p> <p><u>Packaging:</u> No changes in the packaging after storage. No significant change in the weight</p> <p><u>A.I. content g/L (% w/w):</u></p> <table><tr><th rowspan="2"></th><th colspan="2">Content [g/L] (% w/w)</th></tr><tr><th>Before</th><th>After</th></tr><tr><td>2,4-D 2-EHE</td><td>566.9 (52.2)</td><td>551.6 (50.8)</td></tr><tr><td>2,4-D acid</td><td>374.2 (34.5)</td><td>364.1 (33.5)</td></tr></table>				Content [g/L] (% w/w)		Before	After	2,4-D 2-EHE	566.9 (52.2)	551.6 (50.8)	2,4-D acid	374.2 (34.5)	364.1 (33.5)	Y	Tsesin, N. (2020) Sponsor n°: 000106540 <b>(Submitted in KCP 2.1/01)</b>	Accepted. The product showed no significant physical changes after accelerated storage and all performance properties were within acceptable limits.
	Content [g/L] (% w/w)																		
	Before	After																	
2,4-D 2-EHE	566.9 (52.2)	551.6 (50.8)																	
2,4-D acid	374.2 (34.5)	364.1 (33.5)																	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																																															
			<table><tr><td>Clopyralid</td><td>29.7 (2.73)</td><td>29.3 (2.70)</td></tr><tr><td>Fluroxypyr-meptyl</td><td>106.6 (9.81)</td><td>105.9 (9.75)</td></tr><tr><td>Fluroxypyr acid</td><td>73.6 (6.77)</td><td>73.1 (6.73)</td></tr></table> <p>pH (1% w/w): Before: 3.4 After: 3.3</p> <p>Acidity/alkalinity: Before: 0.43% (w/w) in H<sub>2</sub>SO<sub>4</sub> After: 0.51% (w/w) in H<sub>2</sub>SO<sub>4</sub></p> <p>Persistent foam:</p> <table><tr><td></td><td>0.25 % dilution</td><td>1.0 % dilution</td><td>1.5 % dilution</td><td>2.0 % dilution</td></tr><tr><td colspan="5">Initial results [mL of foam]</td></tr><tr><td>Directly after mixing</td><td>32 mL</td><td>62 mL</td><td>72 mL</td><td>65 mL</td></tr><tr><td>1 min</td><td>30 mL</td><td>53 mL</td><td>64 mL</td><td>65 mL</td></tr><tr><td>12 min</td><td>25 mL</td><td>45 mL</td><td>53 mL</td><td>65 mL</td></tr><tr><td colspan="5">Results after storage 2 weeks at 54 °C [mL of foam]</td></tr><tr><td>Directly after mixing</td><td>55 mL</td><td>77 mL</td><td>78 mL</td><td>70 mL</td></tr><tr><td>1 min</td><td>50 mL</td><td>71 mL</td><td>66 mL</td><td>70 mL</td></tr><tr><td>12 min</td><td>33 mL</td><td>60 mL</td><td>59 mL</td><td>70 mL</td></tr></table> <p>Emulstion characteristics:</p> <p>Before storage</p> <table><tr><td></td><td colspan="2">0.25 % v/v</td><td colspan="2">2.0 % v/v</td></tr><tr><td></td><td>Water A</td><td>Water D</td><td>Water A</td><td>Water D</td></tr><tr><td>Initially</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td></tr><tr><td>After 30'</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td></tr><tr><td>After 2 h</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid + Thin layer</td><td>Uniform liquid + Thin layer</td></tr></table>	Clopyralid	29.7 (2.73)	29.3 (2.70)	Fluroxypyr-meptyl	106.6 (9.81)	105.9 (9.75)	Fluroxypyr acid	73.6 (6.77)	73.1 (6.73)		0.25 % dilution	1.0 % dilution	1.5 % dilution	2.0 % dilution	Initial results [mL of foam]					Directly after mixing	32 mL	62 mL	72 mL	65 mL	1 min	30 mL	53 mL	64 mL	65 mL	12 min	25 mL	45 mL	53 mL	65 mL	Results after storage 2 weeks at 54 °C [mL of foam]					Directly after mixing	55 mL	77 mL	78 mL	70 mL	1 min	50 mL	71 mL	66 mL	70 mL	12 min	33 mL	60 mL	59 mL	70 mL		0.25 % v/v		2.0 % v/v			Water A	Water D	Water A	Water D	Initially	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid	After 30'	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid	After 2 h	Uniform liquid	Uniform liquid	Uniform liquid + Thin layer	Uniform liquid + Thin layer			
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Annex point	Method used / deviations	Test material	Findings					GLP Y/N	Reference	Acceptability / comments
			After 24 h	Uniform liquid	Uniform liquid	Uniform liquid + Thin layer	Uniform liquid + Thin layer			
			After re-emulsification	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid			
			30' after re-emulsification (24 h + 30')	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid			
			After storage							
				0.25 % v/v		2.0 % v/v				
				Water A	Water D	Water A	Water D			
			Initially	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid			
			After 30'	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid			
			After 2 h	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid			
			After 24 h	Uniform liquid	Uniform liquid	Uniform liquid + Thin layer	Uniform liquid + Thin layer			
			After re-emulsification	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid			
			30' after re-emulsification (24 h + 30')	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid			
			Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	-				
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Not required, because the content of the active substance in the preparation ADM.3304.H.1.A did not decrease by more than 5% in heat stability testing. Please refer to Point KCP 2.7.1					-	-	-
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 Appearance & content CIPAC MT 75.3	ADM.3304.H.1.A Batch n°: N6002P2/1	After storage for 7 days at 0 °C in HDPE/PA COEX commercial packaging  <u>Appearance:</u>					Y	Tsesin, N. (2020) Sponsor n°: 000106540 <b>(Submitted in KCP 2.1/01)</b>	Accepted.



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																								
	CIPAC MT 36.3		<p>Brown-orange homogeneous liquid. No separation or sedimentation was detected. No cristallization.</p> <p>Emulstion characteristics:</p> <table><tr><td></td><td colspan="2">0.25 % v/v</td><td colspan="2">2.0 % v/v</td></tr><tr><td></td><td>Water A</td><td>Water D</td><td>Water A</td><td>Water D</td></tr><tr><td>Initially</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td></tr><tr><td>After 30'</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td></tr><tr><td>After 2 h</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid + Thin layer</td><td>Uniform liquid + Thin layer</td></tr><tr><td>After 24 h</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid + Thin layer</td><td>Uniform liquid + Thin layer</td></tr><tr><td>After re-emulsification</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td></tr><tr><td>30' after re-emulsification (24 h + 30')</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td></tr></table>		0.25 % v/v		2.0 % v/v			Water A	Water D	Water A	Water D	Initially	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid	After 30'	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid	After 2 h	Uniform liquid	Uniform liquid	Uniform liquid + Thin layer	Uniform liquid + Thin layer	After 24 h	Uniform liquid	Uniform liquid	Uniform liquid + Thin layer	Uniform liquid + Thin layer	After re-emulsification	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid	30' after re-emulsification (24 h + 30')	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid			
	0.25 % v/v		2.0 % v/v																																											
	Water A	Water D	Water A	Water D																																										
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After 24 h	Uniform liquid	Uniform liquid	Uniform liquid + Thin layer	Uniform liquid + Thin layer																																										
After re-emulsification	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid																																										
30' after re-emulsification (24 h + 30')	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid																																										
Ambient temperature shelf life (KCP 2.7.5)	-	-	<p><u>Study on-going</u></p> <p><i>The results from the 2-year storage will be submitted as soon as available.</i></p>	-	-	The ambient temperature study is currently ongoing, and should be provided upon completion.																																								
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	-	-	-	-																																								
Wettability (KCP 2.8.1)	-	-	Not required for EC formulation	-	-	-																																								
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	ADM.3304.H.1.A Batch n°: N6002P2/1	<p>Persistent foaming in standard water D:</p> <table><tr><td></td><td>0.25 % dilution</td><td>1.0 % dilution</td><td>1.5 % dilution</td><td>2.0 % dilution</td></tr><tr><td colspan="5">Initial results [mL of foam]</td></tr></table>		0.25 % dilution	1.0 % dilution	1.5 % dilution	2.0 % dilution	Initial results [mL of foam]					Y	Tsesin, N. (2020) Sponsor n°: 000106540 (Submitted in KCP 2.1/01)	The results show that the foam volume exceeds the allowable limit of 60 ml for 1.5% and 2% dilutions. However,																														
	0.25 % dilution	1.0 % dilution	1.5 % dilution	2.0 % dilution																																										
Initial results [mL of foam]																																														

Annex point	Method used / deviations	Test material	Findings					GLP Y/N	Reference	Acceptability / comments
			Directly after mixing	32 mL	62 mL	72 mL	65 mL			the highest proposed use does not exceed 1% and the results can therefore be considered sufficient to accept the proposed uses.
			1 min	30 mL	53 mL	64 mL	65 mL			
			12 min	25 mL	45 mL	53 mL	65 mL			
Suspensibility (KCP 2.8.3.1)	-	-	Not required for EC formulation					-	-	-
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not required for EC formulation					-	-	-
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for EC formulation					-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required for EC formulation					-	-	-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not required for EC formulation					-	-	-
Wet sieve test (KCP 2.8.5.1.2)	-	-	Not required for EC formulation					-	-	-
Dust content (KCP 2.8.5.2.1)	-	-	Not required for EC formulation					-	-	-
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required for EC formulation					-	-	-
Attrition (KCP 2.8.5.3)	-	-	Not required for EC formulation					-	-	-
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for EC formulation					-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																								
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3	ADM.3304.H.1.A Batch n°: N6002P2/1	<table><tr><td></td><td colspan="2">0.25 % v/v</td><td colspan="2">2.0 % v/v</td></tr><tr><td></td><td>Water A</td><td>Water D</td><td>Water A</td><td>Water D</td></tr><tr><td>Initially</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td></tr><tr><td>After 30'</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td></tr><tr><td>After 2 h</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid + Thin layer</td><td>Uniform liquid + Thin layer</td></tr><tr><td>After 24 h</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid + Thin layer</td><td>Uniform liquid + Thin layer</td></tr><tr><td>After re-emulsification</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td></tr><tr><td>30' after re-emulsification (24 h + 30')</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td></tr></table>		0.25 % v/v		2.0 % v/v			Water A	Water D	Water A	Water D	Initially	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid	After 30'	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid	After 2 h	Uniform liquid	Uniform liquid	Uniform liquid + Thin layer	Uniform liquid + Thin layer	After 24 h	Uniform liquid	Uniform liquid	Uniform liquid + Thin layer	Uniform liquid + Thin layer	After re-emulsification	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid	30' after re-emulsification (24 h + 30')	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid	Y	Tsesin, N. (2020) Sponsor n°: 000106540 <b>(Submitted in KCP 2.1/01)</b>	Accepted.
	0.25 % v/v		2.0 % v/v																																											
	Water A	Water D	Water A	Water D																																										
Initially	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid																																										
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After 24 h	Uniform liquid	Uniform liquid	Uniform liquid + Thin layer	Uniform liquid + Thin layer																																										
After re-emulsification	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid																																										
30' after re-emulsification (24 h + 30')	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid																																										
Emulsion stability (KCP 2.8.6.2)	CIPAC MT 36.3	ADM.3304.H.1.A Batch n°: N6002P2/1	<table><tr><td>After 30'</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td></tr><tr><td>After 2 h</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid + Thin layer</td><td>Uniform liquid + Thin layer</td></tr><tr><td>After 24 h</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid + Thin layer</td><td>Uniform liquid + Thin layer</td></tr><tr><td>After re-emulsification</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td></tr><tr><td>30' after re-emulsification (24 h + 30')</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td></tr></table>	After 30'	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid	After 2 h	Uniform liquid	Uniform liquid	Uniform liquid + Thin layer	Uniform liquid + Thin layer	After 24 h	Uniform liquid	Uniform liquid	Uniform liquid + Thin layer	Uniform liquid + Thin layer	After re-emulsification	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid	30' after re-emulsification (24 h + 30')	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid			Accepted.															
After 30'	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid																																										
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After re-emulsification	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid																																										
30' after re-emulsification (24 h + 30')	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid																																										
Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3	ADM.3304.H.1.A Batch n°: N6002P2/1	<table><tr><td>After re-emulsification</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td></tr><tr><td>30' after re-emulsification (24 h + 30')</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td><td>Uniform liquid</td></tr></table>	After re-emulsification	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid	30' after re-emulsification (24 h + 30')	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid			Accepted.																														
After re-emulsification	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid																																										
30' after re-emulsification (24 h + 30')	Uniform liquid	Uniform liquid	Uniform liquid	Uniform liquid																																										
Flowability (KCP 2.8.7.1)	-	-	Not required for EC formulation	-	-	-																																								
Pourability (KCP 2.8.7.2)	-	-	Not required for EC formulation	-	-	-																																								
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required for EC formulation	-	-	-																																								
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not required, since the formulation is not intended to be used as tank mixture.	-	-	-																																								
Chemical compatibility of tank	-	-	Not required, since the formulation is not intended to be used as tank mixture.	-	-	-																																								

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
mixes (KCP 2.9.2)						
Adhesion to seeds (KCP 2.10.1)	-	-	Not required, since the product is not for seed treatment.	-	-	-
Distribution to seed (KCP 2.10.2)	-	-	Not required, since the product is not for seed treatment.	-	-	-
Other/special studies (KCP 2.11)	-	-	Not required.	-	-	-

The references in *italics* are part of the original dossier and are not re-submitted. Only new information is listed in the reference list in Appendix 1.

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

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

There is no impact which requires the submission of a new master label.

## 4 Section 4: Further information on the plant protection product

### 4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

Comments of zRMS:	The ambient temperature study is currently ongoing, and should be provided upon completion. Based on the accelerated storage stability 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 COEX commercial packaging. For the EC formulation, the results of HDPE/PA packaging stability study can be extrapolated to HDPE/EVOH packaging.
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There is new packaging information available for the containment of the product ADM.3304.H.1.A in 5 and 10 L containers compared to the previous submission. The specifications for 1 L and 20 L packaging remains the same and is not included in this dossier for composition change again.

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 1, 5, 10 and 20 L HDPE bottles and containers, respectively.

There are four suppliers of bottles/containers: (1) Reyde, (2) Mobilak, (3) Pachmas and (4) Amraz.

The accelerated storage stability of Tsesin N. (2020), ref. KCP 2.1/01, has been performed with the intended commercial packaging material (1 L commercial HDPE/PA COEX 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 in the following table. For information on the new packaging containers (5 and 10 L) please refer to KCP 4.4/01 to 4.4/11.

**Table 4.1-1: Packaging information**

	<i>1 L bottle</i>	<b>5 L Jerry can</b>	<b>10 L Jerry can</b>	<i>20 L Jerry can</i>
<b>Size</b>	<i>1 L</i>	5 L	10 L	<i>20 L</i>
<b>Material</b>	<i>CoEx HDPE/EVOH or HDPE/PA</i>	CoEx HDPE/PA	CoEx HDPE/PA	<i>CoEx HDPE/PA</i>
<b>Shape</b>	<i>Round</i> <i>240 mm (high) × 90 mm</i>	Rectangular 307 mm (high) × 190 mm × 140 mm	Rectangular 401 mm (high) × 227mm × 157 mm	<i>Rectangular</i> <i>398 mm (high) × 297 mm × 246 mm</i>
<b>Weight (g)</b>	<i>100 - 120</i>	270	450 - 470	<i>1300</i>
<b>Opening</b>	<i>38 mm (inner diameter)</i> <i>48.4 mm (outer diameter)</i>	63mm (inner diameter)	63 mm (outer diameter)	<i>48 mm (inner diameter)</i> <i>61 mm(outer diameter)</i>
<b>Closure</b>	<i>Screwed on</i>	Screwed on	Screwed on	<i>Screwed on</i>

In *Italic*: no new information compared to the original dossier. The respective K-documents are not submitted again.

### 4.2 Recommended methods and precautions (KCP 4.2)

No changes are expected compared to the old composition

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

No changes are expected compared to the old composition.

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

No changes are expected compared to the old composition.

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

No changes are expected compared to the old composition.

## 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 1.3/01	Anonymous	2021	SAFETY DATA SHEET – ADM.03304.H.1.A ADAMA Agan Ltd., Ashdod., Israel Report no.: not available (version 1) GLP: no Published: no	N	ADM
KCP 2.1/01	Tsesin, N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Tricera (ADM.03304.H.1.A) Stored at 54 °C for 14 Days and at 0 °C for 7 Days Adama Agan Ltd., Israel Report No.: 000106540.072FL Sponsor No.: 000106540 GLP: yes Published: no	N	ADM
KCP 2.3.1/01	Tsesin, N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Tricera (ADM.03304.H.1.A) Stored at 54 °C for 14 Days and at 0 °C for 7 Days Adama Agan Ltd., Israel Report No.: 000106540.072FL Sponsor No.: 000106540 GLP: yes Published: no <b>Submitted in KCP 2.1/01</b>	N	ADM
KCP 2.4.1/01	Tsesin, N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Tricera (ADM.03304.H.1.A) Stored at 54 °C for 14 Days and at 0 °C for 7 Days Adama Agan Ltd., Israel Report No.: 000106540.072FL Sponsor No.: 000106540 GLP: yes Published: no <b>Submitted in KCP 2.1/01</b>	N	ADM



<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner*</b>
KCP 2.4.2/01	Tsesin, N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Tricera (ADM.03304.H.1.A) Stored at 54 °C for 14 Days and at 0 °C for 7 Days Adama Agan Ltd., Israel Report No.: 000106540.072FL Sponsor No.: 000106540 GLP: yes Published: no <b>Submitted in KCP 2.1/01</b>	N	ADM
KCP 2.5.1/01	Tsesin, N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Tricera (ADM.03304.H.1.A) Stored at 54 °C for 14 Days and at 0 °C for 7 Days Adama Agan Ltd., Israel Report No.: 000106540.072FL Sponsor No.: 000106540 GLP: yes Published: no <b>Submitted in KCP 2.1/01</b>	N	ADM
KCP 2.5.2/01	Tsesin, N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Tricera (ADM.03304.H.1.A) Stored at 54 °C for 14 Days and at 0 °C for 7 Days Adama Agan Ltd., Israel Report No.: 000106540.072FL Sponsor No.: 000106540 GLP: yes Published: no <b>Submitted in KCP 2.1/01</b>	N	ADM
KCP 2.6.1/01	Tsesin, N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Tricera (ADM.03304.H.1.A) Stored at 54 °C for 14 Days and at 0 °C for 7 Days Adama Agan Ltd., Israel Report No.: 000106540.072FL Sponsor No.: 000106540 GLP: yes Published: no <b>Submitted in KCP 2.1/01</b>	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 2.7.1/01	Tsesin, N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Tricera (ADM.03304.H.1.A) Stored at 54 °C for 14 Days and at 0 °C for 7 Days Adama Agan Ltd., Israel Report No.: 000106540.072FL Sponsor No.: 000106540 GLP: yes Published: no <b>Submitted in KCP 2.1/01</b>	N	ADM
KCP 2.7.4/01	Tsesin, N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Tricera (ADM.03304.H.1.A) Stored at 54 °C for 14 Days and at 0 °C for 7 Days Adama Agan Ltd., Israel Report No.: 000106540.072FL Sponsor No.: 000106540 GLP: yes Published: no <b>Submitted in KCP 2.1/01</b>	N	ADM
KCP 2.8.2/01	Tsesin, N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Tricera (ADM.03304.H.1.A) Stored at 54 °C for 14 Days and at 0 °C for 7 Days Adama Agan Ltd., Israel Report No.: 000106540.072FL Sponsor No.: 000106540 GLP: yes Published: no <b>Submitted in KCP 2.1/01</b>	N	ADM
KCP 2.8.7/01	Tsesin, N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Tricera (ADM.03304.H.1.A) Stored at 54 °C for 14 Days and at 0 °C for 7 Days Adama Agan Ltd., Israel Report No.: 000106540.072FL Sponsor No.: 000106540 GLP: yes Published: no <b>Submitted in KCP 2.1/01</b>	N	ADM

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner*</b>
KCP 2.8.7/02	Tsesin, N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Tricera (ADM.03304.H.1.A) Stored at 54 °C for 14 Days and at 0 °C for 7 Days Adama Agan Ltd., Israel Report No.: 000106540.072FL Sponsor No.: 000106540 GLP: yes Published: no <b>Submitted in KCP 2.1/01</b>	N	ADM
KCP 2.8.7/03	Tsesin, N.	2020	Determination of Storage Stability and Physical-Chemical Properties of Tricera (ADM.3304.H.1.A) Stored at 54 °C for 14 Days and at 0 °C for 7 Days Adama Agan Ltd., Israel Report No.: 000106540.072FL Sponsor No.: 000106540 GLP: yes Published: no <b>Submitted in KCP 2.1/01</b>	N	ADM
KCP 4.4/01	Anonymous	2019	COEX_PA (Reyde) - 5 L Packaging information Report no. -- Reyde, S.A., Barcelona, Spain No GLP Published: no	N	Reyde
KCP 4.4/02	Anonymous	2017	COEX-PA (Pachmas) - 5 L Packaging Information Report no. -- State of Israel, Ministry of Transport The Standards Institution of Israel No GLP Published: no	N	Pachmas
KCP 4.4/03	Anonymous	2017	HDPE (Pachmas) - 5 L Packaging Information Report no. -- State of Israel, Ministry of Transport The Standards Institution of Israel No GLP Published: no	N	Pachmas

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner*</b>
KCP 4.4/04	Anonymous	2018	COEX-PA (Mobilak) – 5 L Packaging Information Report no. -- The Standards Institution of Israel No GLP Published: no	N	Mobilak
KCP 4.4/05	Anonymous	2018	Specification 9813205419E (Mobilak) – 5 L Packaging Information Report no. 9813205419 The Standards Institution of Israel No GLP Published: no	N	Mobilak
KCP 4.4/06	Anonymous	2018	COEX - UN- _2018580 (Mobilak) – 5 L Packaging Information Report no. -- The Standards Institution of Israel No GLP Published: no	N	Mobilak
KCP 4.4/07	Anonymous	2019	HDPE and COEX – final drawing (Reyde) - 10 L Packaging information Report no. -- Reyde, S.A., Barcelona, Spain No GLP Published: no	N	Reyde
KCP 4.4/08	Anonymous	2019	COEX_PA (Reyde) - 10 L Packaging information Report no. -- Reyde, S.A., Barcelona, Spain No GLP Published: no	N	Reyde
KCP 4.4/09	Anonymous	2020	COEX-PA (Pachmas) - 10 L Packaging Information Report no. -- State of Israel, Ministry of Transport The Standards Institution of Israel No GLP Published: no	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*
KCP 4.4/10	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 Published: no	N	Pachmas
KCP 4.4/11	Anonymous	2020	COEX-PA and COEX-EVOH (Mobilak) – 10 L Packaging Information Report no. -- The Standards Institution of Israel No GLP Published: no	N	Mobilak

\* ADM: ADAMA Agan Ltd.

**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**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
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## **Appendix 2     Additional data on the physical, chemical and technical properties of the active substance**

### **A 2.1                    2,4-D**

No new data.

### **A 2.2                    Clopyralid**

No new data.

### **A 2.3                    Fluroxypyr**

No new data.