

REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: ADM.3304.H.1.A

Product name(s): Tricera

Chemical active substance(s):

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

Clopyralid, 30 g/L

Fluroxypyr, 75 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: May 2022 (initial Core Assessment)

November 2022, updated March 2023, October 2023

(final Core Assessment)

Version history

When	What
February 2021	Initial dRR Part B0, version reflecting composition change submitted by applicant
May 2022	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency .
November 2022	Final report (Core Assessment updated following the commenting period). No additional information or assessments after the commenting period.
March 2023	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 highlighted in green. Information no longer relevant is struck through and shaded .
October 2023	Auto-correction by zRMS, excluding uses in TTLSO, TTLWI and SECCS, for which the selectivity data package is insufficient (amendments in the GAP table). Additional information included by the zRMS in the report are highlighted in yellow. Information no longer relevant is struck through and shaded.

DATA PROTECTION CLAIM

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

STATEMENT FOR OWNERSHIP

The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it.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authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

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- 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.

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application follows the data requirements for the active substances laid down in Regulation (EC) No. 283/2013 or 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

The reason for application of this dossier is a composition change of the product.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Central zone	Poland, no current authorization	UK, no current authorization

0.1.3 Regulatory history of the active(s)

0.1.3.1 2,4 D / 2,4-D EHE

The product **ADM.3304.H.1.A** ~~AG-CDF1-480-EC~~ is a herbicide containing the active substance 2,4-D as the ester variant 2,4-D EHE.

Table 0.1-2: Summary of regulatory history of CAS No: 1928-43-4

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2001/103/EC
RMS	Greece
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2016
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	01.04.2016
Date of final Commission (re-registration) deadline (Step 2)	-
Current expiration of approval	31.12.2030
Low risk substance or Candidate for Substitution?	No

Issues that need to be considered as part of the EU approval are listed below.

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

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

The SANCO report for 2,4-D (SANCO/11961/2014 Rev 5, 6 October 2017) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available with last update on 21st March 2017. Relevant information for the ester variant 2,4-D EHE can be found in the Bridging report (2018), prepared by RMS Greece.

Table 0.1-3: Information on minimum purity of 2,4-D

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report
≥ 920 g/kg* (2,4-D EHE) ≥ 970 g/kg (2,4-D acid)	≥ 940 g/kg

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

No such table is provided here.

Information on deviating endpoints, where relevant, will be specified in the respective Part B documents.

0.1.3.2 Clopyralid

Table 0.1-4: Summary of regulatory history of CAS No: 1702-17-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2006/64/CE
RMS	Finland
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01-05-2007 01/10/2021
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	-
Date of final Commission (re-registration) deadline (Step 2)	-
Current expiration of approval	30.04.2021 30/09/2036
Low risk substance or Candidate for Substitution?	No

In meantime, 01.10.2021 a.s. clopyralid was re-approved.

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must 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.~~

- the specification of the technical material as commercially manufactured;
- the protection of operators, ensuring that conditions of use for operators include the application of adequate personal protective equipment;
- possible presence of clopyralid residues in rotational crops;
- the possible transfer of clopyralid residues via compost or manure of animals whose feed originates from treated areas, to avoid damage to susceptible crops;
- the protection of groundwater under vulnerable conditions. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water. The applicant shall submit this information within two years after adoption of a guidance document on evaluation of

the effect of water treatment processes on the nature of residues present in surface and groundwater.

The SANCO report for Clopyralid (SANCO/10012/2006—rev. 3, 4 April 2006 SANTE/10206/2021 Rev 1, 20 May 2021) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 23rd January 2006 20 May 2021.

Table 0.1-5: Information on minimum purity of Clopyralid

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report
> 950 mg/kg	> 950 mg/kg

The endpoints used in the evaluation do not deviate from EU endpoints.

0.1.3.3 Fluroxypyr (meptyl)

Table 0.1-6: Summary of regulatory history of CAS No: 81406-37-3

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2000/10/EC
RMS	Ireland
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2012
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	-
Date of final Commission (re-registration) deadline (Step 2)	-
Current expiration of approval	31.12.2024
Low risk substance or Candidate for Substitution?	No

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must 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

The SANCO report for Fluroxypyr SANCO/11019/2011 rev 5, last update 23 March 2017) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 8th March 2011.

Table 0.1-7: Information on minimum purity of Fluroxypyr

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report
> 950 mg/kg (Fluroxypyr meptyl)	> 985 mg/kg

The following table provides the endpoints used in the evaluation in the case that they deviate from EU

endpoints.

No such table is provided here.

Information on deviating endpoints, where relevant, will be specified in the respective Part B documents.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

For the overview of accepted uses see the Complete GAP table in Appendix 1 of this document.
For detailed information see the GAP tables in the individual relevant sections.

Uses to be considered safe on the basis of EU methodology:

See column 15 of the Complete GAP table presented in Appendix 1 of this document.

Uses to be considered non-safe on the basis of EU methodology:

See column 15 of the Complete GAP table presented in Appendix 1 of this document.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

See column 15 of the Complete GAP table presented in Appendix 1 of this document.

All uses/ GAPs are covered by established MRLs.

Appendix 1 ALL intended uses

GAP rev. 2, date: 2022-10

PPP (product name/code): ADM.3304.H.1.A ~~AG-CDF1-480-EC~~
Active substance 1: 2,4-D
Active substance 2: Clopyralid
Active substance 3: Fluroxypyr
Safener: -
Synergist: -
Applicant: ADAMA Registrations B.V.
Zone(s): Central zone
Verified by MS: Yes
Field of use: Herbicide

Formulation type: EC (Emulsifiable Concentrate)
Conc. of as 1: 375 g/L (562.5 g/L as EHE)
Conc. of as 2: 30 g/L
Conc. of as 3: 75 g/L (108 g/L as meptyl)
Conc. of safener: -
Conc. of synergist: -
Professional use: ☒
Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15*							
Use- No. (e)	Member state (s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha (f)	Overall conclusions							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	PL	Established grassland (NNNFW)	F	broadleaved weeds (TTTDD)	foliar spraying, overall	Mar-Aug/ BBCH 24-39	a) 1 (→) b) 1 (→)	--	a) 2 L/ha b) 2 L/ha	a) 750 / 60 / 150 b) 750 / 60 / 150	200- 400	n.a	The BBCH stages were removed since for the established grass the time of the season will be more indicative for application timing than the growth stage Winter cereals considered as surrogate for	A	A	A	A	A	N Mammals N Aquatics (R3) R Aquatics (D3, D4, D5, R1) NTTP A Remaining	A	N

													scenarios R1 and R3						species		
2	PL	Spring wheat (TRZAS), spring barley (HORVS), oats (AVESA), spring triticale (TTLSO), spring rye (SECCS)	F	broadleaved weeds (TTTDD)	foliar spraying, overall	Mar-Jun/ BBCH 21-39	a) 1 (→) b) 1 (→)	--	a) 2 L/ha b) 2 L/ha	a) 750 / 60 / 150 b) 750 / 60 / 150	200- 400	n.a.	n.a.	A	A	A	A	R	N Aquatics (R3)	A	A
																			R Aquatics (D3, D4, D5, R1)		
																			NTTP		
																			A Remaining species		
3	PL	Winter wheat (TRZAW), winter barley (HORVW), winter triticale (TTLW), winter rye (SECCW)	F	broadleaved weeds (TTTDD)	foliar spraying, overall	Mar-May/ BBCH 21-39	a) 1 (-) b) 1 (-)	--	a) 2 L/ha b) 2 L/ha	a) 750 / 60 / 150 b) 750 / 60 / 150	200- 400	n.a.	Winter cereals considered as surrogate for scenarios R1 and R3	A	A	A	A	R	N Aquatics (R3)	A	A
																			R Aquatics (D3, D4, D5, R1)		
																			NTTP		
																			A Remaining species		
A4	UK	Grassland (NNNFW) (permanent grassland, rotational leys, newly-sown spring and autumnal leys)	F	broadleaved weeds (TTTDD)	foliar spraying, overall	Mar— Aug / BBCH 21-39	a) 1 b) 1	--	a) 2.0 L/ha b) 2.0 L/ha	a) 750 / 60 / 150—b) 750 / 60 / 150	200- 400	n.a.	n.a.								
5	UK	Spring wheat (TRZAS); spring barley (HORVS); oats (AVESA); spring triticale	F	broadleaved weeds (TTTDD)	foliar spraying, overall	Mar—Jun /BBCH 21-39	a) 1 b) 1	-	a) 2.0 L/ha b) 2.0 L/ha	a) 750 / 60 / 150—b) 750 / 60 / 150	200- 400	n.a.	n.a.								

		(TTLSQ)																		
6	UK	Winter-wheat (TRZAW); winter-barley (HORVW); winter-triticale (TTLWD); winter-rye (SECCW); winter-oats (AVESW)	F	broadleaved weeds (TTTDD)	foliar spraying; overall	Mar– May/ BBCH 21–39	a) 1 b) 1	-	a) 2.0 L/ha b) 2.0 L/ha	a) 750 / 60 / 150 b) 750 / 60 / 150	200-400	n.a.	n.a.							

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

(d) Select relevant

(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references

2 Use official codes/nomenclatures of EU Member States

3 For crops, the EU and Codex classifications (both) should be used; when relevant, the situation should be described (e.g. fumigation of a structure)

4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.

6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

8 The maximum number of application possible under practical conditions of use must be provided.

9 Minimum interval (in days) between applications of the same product

10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.

11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).

12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.

13 PHI - minimum pre-harvest interval

14 Remarks may include: Extent of use/economic importance/restrictions

15 Overall conclusions - explanation for the column 15 is below *

*** Explanation for column 15 “Overall conclusions”**

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use