

REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: ADM.06001.H.2.B

Product name: Edaptis

Chemical active substances:

Mesosulfuron-methyl, 12 g/L

Pinoxaden, 60 g/L

Safener:

Mefenpyr-diethyl, 35 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Sponsor: ADAMA Agan Ltd.

Applicant: ADAMA Polska Sp. z o.o.

Submission date: June 2021, updated: September 2022

MS Finalisation date: May 2023 (initial Core Assessment)

September 2023, updated December 2023 (final Core Assessment)

Version history

When	What
June 2021	Initial dRR – ADAMA Polska Sp. z o.o
September 2022	Updated GAP – ADAMA Polska Sp. z o.o
May 2023	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 .
September 2023	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded .
December 2023	Final report (Core Assessment updated following the second commenting period) No additional information or assessments after the second commenting period.

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application under article 33 of regulation 1107/2009 submitted by the applicant in June 2021 is for first authorisation of the product ADM.06001.H.2.B (containing 12 g/L mesosulfuron-methyl, 60 g/L pinoxaden and 35 g/L mefenpyr-diethyl (safener) follows the data requirements of

- Regulation (EC) No. 544/2011 for the active substance pinoxaden,
- Regulation (EC) No. 283/2013 for the active substance mesosulfuron-methyl, and
- Regulation (EC) No. 284/2013 for the plant protection product ADM.06001.H.2.B.

Any deviation from this is justified in the relevant parts of the dossier.

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)
Northern zone	No application	-
Central zone	Poland	Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, The Netherlands
Southern zone	Malta	France, Greece, Italy, Spain
Inter-zonal	Not applicable	-
Great Britain	Great Britain	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Mesosulfuron-methyl

Table 0.1-2: Summary of regulatory history of CAS No: 208465-21-8 (mesosulfuron-methyl)

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	<p>Commission Directive 2003/119/EC of 05 December 2003 amending Council Directive 91/414/EEC</p> <p>Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011</p> <p>Commission Implementing Regulation (EU) 823/2012 of 14 September 2012 derogation from Implementing Regulation (EU) No 540/2011 as regards the expiry date of the approval</p> <p>Commission Implementing Regulation (EU) 2016/2016 of 17 November 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods</p> <p>Commission Implementing Regulation (EU) 2017/755 of 28 April 2017 renewing the approval</p>
RMS	France
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.07.2017
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.09.2017 (Art. 43)
Date of final Commission (re-registration) deadline (Step 2)	-
Current expiration of approval	30.06.2032
Low risk substance or Candidate for Substitution?	-

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

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

- the protection of aquatic organisms and non-target terrestrial plants
- the protection of groundwater.

Conditions of use shall include risk mitigation measures, where appropriate.

The Final Renewal Report for mesosulfuron (variant evaluated mesosulfuron-methyl) (SANTE/11827/2016 Rev2 – 23/03/2017) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Conclusion was made available on 20/09/2016 (EFSA Journal (2016);14(10):4584, Peer review of the pesticide risk assessment of the active substance mesosulfuron (variant evaluated mesosulfuron-methyl)).

Table 0.1-3: Information on minimum purity of mesosulfuron-methyl

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
930 g/kg	Equivalence report available: Y for details refer to Part C

0.1.3.2 Pinoxaden

Table 0.1-4: Summary of regulatory history of CAS No: 243973-20-8

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) 2016/370 of 15 March 2016 approving the active substance Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011
RMS	United Kingdom Austria (confirmatory data) Finland (next renewal)
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.07.2016
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.10.2016
Date of final Commission (re-registration) deadline (Step 2)	not relevant
Current expiration of approval	30.06.2026
Low risk substance or Candidate for Substitution?	-

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

In this overall assessment Member shall pay particular attention to

- the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions

The Review Report for pinoxaden (SANCO/11794/2013 rev 3 – 29/01/2016) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Conclusion was made available on 14/06/2013 (EFSA Journal (2013);11(8):3269, Conclusion on the peer review of the pesticide risk assessment of the active substance pinoxaden).

Confirmatory data was submitted to all Member States by Syngenta and the RMS AT launched a public consultation in Q2 2022.

Further data is also evaluated in the Art.12 review (EFSA Journal 2021; 19 (3): 6503).

Table 0.1-5: Information on minimum purity of pinoxaden

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
970 g/kg	Equivalence report available: Y for details refer to Part C

0.1.3.3 Mefenpyr-diethyl

Mefenpyr-diethyl is a safener and data requirements for safeners are not currently defined in Regulation 1107/2009. ADAMA has decided to complete 5B on the safener to address data requirements defined in some countries in and out-side EU.

Table 0.1-6: Summary of regulatory history of CAS No: 135590-91-9

Status	
Approved in EU	N
Mefenpyr-diethyl is a safener used in combination with herbicides and was not reviewed under Regulation 1107/2009. However, a Draft Assessment Report (2011) written by Austria and France is available to all Member States.	

Table 0.1-7: Information on minimum purity of mefenpyr-diethyl

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
940 g/kg	minimum purity of safener: 950 g/kg for details refer to Part C

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

Authorisation of the product ADM.06001.H.2.B is recommended for the control of grass weeds and broad-leaved weeds in winter wheat, winter rye and winter triticale. Authorisation of the product ADM.06001.H.2.B is recommended for the control of grass weeds and broad-leaved weeds in spring wheat in Poland. Authorisation of the product ADM.06001.H.2.B is recommended for the control of grass weeds (LOLMU) in spring wheat in Germany. For spring wheat, other Member States will need to make their own decision based on the available efficacy data and extrapolation possibility according to their national requirements.

Member States will need to consider the acceptance of the results of PEC_{GW} for pinoxaden and make their own conclusion based on simulations at either Tier 1 or Tier 2 performed according to FOCUS recommendations. The detailed discussion on results of Tier 1 and Tier 2 modelling together with zRMS conclusions, explanations of the taken approach and the list of potential mitigation measures depending on the crop, application rate and scenario is provided in the Core Assessment, Part B, Section 8 and is not repeated here.

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

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

All uses/ GAPs are covered by established MRLs.

Appendix 1 ALL intended uses

GAP rev09 10/05/2023

PPP (product name/code): ADM.06001.H.2.B
 Active substance 1: Mesosulfuron-methyl
 Active substance 2: Pinoxaden
 Safener: Mefenpyr-diethyl
 Applicant: ADAMA
 Zone(s): central ^(d)
 Verified by MS: **yes** ~~no~~
 Field of use: herbicide

Formulation type: OD ^(a, b)
 Conc. of as 1: 12 g/L ^(c)
 Conc. of as 2: 60 g/L ^(c)
 Conc. of safener: 35 g/L ^(c)
 Professional use: yes
 Non professional use: no

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 destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)	Overall conclusions						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between n applicat ions (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./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 environment
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	AT, DE, BE, NL, CZ, PL, HU, IE	Winter wheat, rye, triticale	F	ALOMY, APESV, AVESS, BROSS, LOLMU, LOLPE, POAAN, POATR, Broad-leaved weeds	Foliar, sprayin g overall	BBCH 13-20 (spring)	a) 1 b) 1	-	a) 0.75 L/ha b) 0.75 L/ha	a) 9 / 45 g/ha b) 9 / 45 g/ha	80 / 300	n.a. ^g	Mefenpyr-diethyl applied as a safener at 26.3 g/ha In-PL applied also in tank mix with adjuvat Insert: 0,5 + 1,0 + 0,2 l/ha (Insert) And with Camaro 306 SE: 0,5 + 0,5 l/ha (Camaro 306 SE)	-	-	-	-	-	-	-

2	AT, DE, BE, NL, CZ, PL, HU, IE	Winter wheat (TRZAW), winter rye (SECCW), winter triticale (TTLWI)	F	***ALOMY, APESV, AVESV, BROSS, LOLMU, LOLPE, POAAN, POATR, annual broad-leaved weeds	Foliar, sprayin g, overall	BBCH 20-39 (spring)	a) 1 b) 1	-	a) 1 L/ha b) 1 L/ha	a) 12 / 60 g/ha b) 12 / 60 g/ha	80 / 300	n.a.*	Mefenpyr-diethyl applied as a safener at 35.0 g/ha In PL applied also in tank mix with adjuvat Insert : 0,5-1,0 + 0,2 l/ha (Insert) And with Camaro 306 SE: 0,5 + 0,5 l/ha (Camaro 306 SE) Doser range 0.75-1.0 L/ha	A A A A	C	R Aquatics, R3, R4 scenarios	A	A	A
																NTTP	A	APESV, AVESV, CAPBP, DESSO, THLAR (DE)	
																A Remaining species	A	C SECCW (AT)	
3	AT, BE, NL, CZ, PL, HU, IE (DE**)	Spring wheat (TRZAS)	F	***ALOMY, APESV, AVESV, BROSS, LOLMU, LOLPE, POAAN, POATR, annual broad-leaved weeds	Foliar, sprayin g, overall	BBCH 13-39 (spring)	a) 1 b) 1	-	a) 1 L/ha b) 1 L/ha	a) 12 / 60 g/ha b) 12 / 60 g/ha	80 / 300	n.a.*	Mefenpyr-diethyl applied as a safener at 35.0 g/ha In-PL applied also in tank mix with adjuvat Insert : 0,5-1,0 + 0,2 l/ha (Insert) And with Camaro 306 SE: 0,5 + 0,5 l/ha (Camaro 306 SE) Doser range 0.75-1.0 L/ha	A A A A	C	R Aquatics, R3 scenarios	A	A (PL) Application timing: BBCH 20-39	
																A Remaining species	A	C TRZAS and application timing to be confirmed	
3*	AT, BE, NL, CZ, PL, HU, IE (DE**)	Spring wheat (TRZAS)	F	***ALOMY, APESV, AVESV, BROSS, LOLMU, LOLPE, POAAN, POATR,	Foliar, sprayin g, overall	BBCH 13-39 (spring)	a) 1 b) 1	-	a) 0,75 L/ha b) 0,75 L/ha	a) 9 / 45 g/ha b) 9 / 45 g/ha	80 / 300	n.a.*	Mefenpyr-diethyl applied as a safener at 26.3 g/ha	A A A A	C	R Aquatics, R3 scenarios	A	A (PL) Application timing: BBCH 20-39	
																NTTP	A		

				annual broad-leaved weeds														A Remaining species		C TRZAS and application timing to be confirmed	
4	DE	Winter wheat (TRZAW), winter rye (SECCW), winter triticale (TTLW)	F	**** APESV, AVESS, THLAR , annual broad-leaved weeds	Foliar, sprayin g, overall	BBCH 20-39 (spring)	a) 1 b) 1	-	a) 0.75 L/ha b) 0.75 L/ha	a) 9 / 45 g/ha b) 9 / 45 g/ha	80 / 300	n.a.*	Mefenpyr-diethyl applied as a safener at 26.3 g/ha	A	A	A	A	C	R Aquatics, R3, R4 scenarios	A	A
																		NTTP			
																		A Remaining species			
5	DE	Spring wheat (TRZAS)	F	ALOMY, APESV, AVESS, BROSS, POAAN, POATR, annual broad-leaved weeds	Foliar, sprayin g, overall	BBCH 13-20 (spring)	a) 1 b) 1	-	a) 1 L/ha b) 1 L/ha	a) 12 / 60 g/ha b) 12 / 60 g/ha	80 / 300	n.a.*	Mefenpyr-diethyl applied as a safener at 35.0 g/ha	A	A	A	A	C	R Aquatics, R4 scenarios	A	N
																		NTTP			
																		A Remaining species			
6	DE	Spring wheat (TRZAS)	F	***ALOMY, APESV, AVESS, BROSS, POAAN, POATR, annual broad-leaved weeds LOLMU	Foliar, sprayin g, overall	BBCH 20-39 (spring)	a) 1 b) 1	-	a) 1 L/ha b) 1 L/ha	a) 12 / 60 g/ha b) 12 / 60 g/ha	80 / 300	n.a.*	Mefenpyr-diethyl applied as a safener at 35.0 g/ha	A	A	A	A	C	R Aquatics, R4 scenarios	A	A
																		NTTP			
																		A Remaining species			

7	DE	Spring wheat (TRZAS)	F	ALOMY, APESV, AVESS, BROSS, POAAN, POATR, annual broad-leaved weeds	Foliar, sprayin g, overall	BBCH 13-20 (spring)	a) 1 b) 1	-	a) 0.75 L/ha b) 0.75 L/ha	a) 9 / 45 g/ha b) 9 / 45 g/ha	80 / 300	n.a.*	Mefenpyr-diethyl applied as a safener at 26.3 g/ha	A	A	A	A	C	R Aquatics, E4-consulted	A	N
8	DE	Spring wheat (TRZAS)	F	***APESV; AVESS; annual broad-leaved weeds LOLMU	Foliar, sprayin g, overall	BBCH 20-39 (spring)	a) 1 b) 1	-	a) 0.75 L/ha b) 0.75 L/ha	a) 9 / 45 g/ha b) 9 / 45 g/ha	80 / 300	n.a.*	Mefenpyr-diethyl applied as a safener at 26.3 g/ha	A	A	A	A	C	R Aquatics, E4-consulted	A	A

* The PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product and the use of the product (e. g. harvest)

** The German GAP is split in use 5 and 6) i.e. before and after GS 20 due to mitigation required

*** The range of individual weed species accepted by cMss to be confirmed on the national level.

- 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 use 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