

REGISTRATION REPORT

Part A

Risk Management

Product code: ADM.03503.F.1.A

Product name(s): Avastel 225 EC

Chemical active substances:

Fluxapyroxad, 75 g/L

Prothioconazole, 150 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

Applicant: ADAMA Polska Sp. z o.o.

Submission date: April 2022

MS Finalization date: August 2023 (initial National Assessment)

December 2023 (final National Assessment)

Version history

When	What
April 2022	Version 1 Applicant
August 2023	<p>Initial zRMS assessment</p> <p>In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and in the product label (Appendix 2) and Lists of data considered for national authorization (Appendix 4) are highlighted in grey, while not agreed use pattern is struck through and shaded.</p>
December 2023	<p>Final report (National Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded.</p>
December 2023	<p>Final report (National Assessment updated after the correction of Appendix 4 prepared by the Applicant)</p> <p>In order to facilitate tracking of changes in the Lists of data considered for national authorization (Appendix 4), amendments are highlighted in turquoise.</p>

DATA PROTECTION CLAIM

In order to present a dossier fully compliant with today's requirements (Reg. 284/2013), studies have been performed on ADM.03503.F.1.A. Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for the studies conducted with ADM.03503.F.1.A. 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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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application is for authorisation of ADM.03503.F.1.A, a new product containing fluxapyroxad and prothioconazole. The intended uses are set out at Section 2.6.

1.2 Letters of Access

The Letters of Access are confidential and are provided separate to this submission.

1.3 Justification for submission of tests and studies

The test and study reports provided are to meet the plant protection product data requirements set out in Commission Regulation (EU) No 284/2013, necessary for the first authorisation of a plant protection product.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4. This list includes only data submitted with this application.

2 Details of the authorization decision

2.1 Product identity

Product code	ADM.03503.F.1.A
Product name in MS	Avastel 225 EC
Authorization number	n.a.
Function	Fungicide
Applicant	ADAMA Polska Sp. z o.o.
Active substance(s) (incl. content)	Fluxapyroxad , 75 g/L Prothioconazole, 150 g/L
Formulation type	Emulsifiable Concentrate [Code: EC]
Packaging	0.5 to 20L COEX HDPE/PA plastic bottle or canister, professional user
Coformulants of concern for national authorizations	None
Restrictions related to identity	None
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for Avastel resulted in the decision to grant the authorization (see column 15 of the GAP table presented in the point 2.6 of this document and to the point 5).

2.3 Substances of concern for national monitoring

None.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Acute Tox. 4, Skin Corr. 1B Eye Dam. 1 H318 , Lact. H362, Aquatic chronic 2 H 411
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GHS05 , GHS07 , GHS09
Signal word:	Danger
Hazard statement(s):	H302: Harmful if swallowed H314: Causes severe skin burns and eye damage H318: Causes serious eye damage H362: May cause harm to breast-fed children H411 Toxic to aquatic life with long lasting effects
Precautionary statement(s):	P102: Keep out of reach of children P201: Obtain special instructions before use P263: Avoid contact during pregnancy/while nursing. P260: Do not breathe dust/mist P280: Wear protective gloves/protective clothing/eye protection/face protection. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P303 + P361 + P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P501: Dispose of contents/ container in accordance with local/ regional/ national/international regulation

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

See Part B6 and Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic organisms respect a vegetated buffer zone of 10m to surface water bodies.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
respective code if available	Wear eye protection (as a result of Skin Corr. 1B, H314 classification) Wear protective gloves/clothing (as a result of Skin Corr. 1B, H314 classification)
Environmental protection	
respective code if available	To protect aquatic organisms respect a vegetated buffer zone of 10 m to surface water bodies.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
	None	
Environmental protection:		Relevant for use no.
	None	

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): ADM.03503.F.1.A
Active substance 1: Fluxapyroxad
Active substance 2: Prothioconazole
Applicant: Country organisation/representative of ADAMA as given in Part A
Zone(s): Central
Verified by MS: yes
Field of use: Fungicide

Formulation type: EC ^(a, b)
Conc. of as 1: 75 g/L ^(c)
Conc. of as 2: 150 g/L ^(c)
Professional use: ☒
Non professional use: ☐

GAP rev. 1, date: December 2023 ~~August 2023~~

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/syn ergist 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 applicati ons (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	Efficacy	
Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	Poland	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis</i> f. sp. <i>tritici</i> , <i>Fusarium</i> + <i>microdochium</i>	foliar, spraying, overall	-/ BBCH 30-69 spring <i>Fusarium</i> - BBCH 61-69	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0- 1.25L	A	A	R	A	A	A	A	A
2	Poland	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> in HORVW only, <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis</i> f. sp. <i>hordei</i>	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0- 1.25L	A	A	R	A	A	A	A	A
3	Poland	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0- 1.25L	A	A	R	A	A	A	A	N
4	Poland	Triticale	F	<i>Zymoseptoria tritici</i>	foliar,	-/ BBCH	a) 1 (-)		a) 1.25 L/ha	a) 93.75 / 187.5	125-400		Range of	A	A	R	A	A	A	A	A

Remarks table heading:	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d) Select relevant
	(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c) g/kg or g/l	(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	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
	2 Use official codes/nomenclatures of EU Member States	8 The maximum number of application possible under practical conditions of use must be provided.
	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)	9 Minimum interval (in days) between applications of the same product
	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	10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPQ-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	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.	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 *

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

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a light yellow to light brown, clear, homogeneous liquid. It is neither explosive nor oxidising. The product has a flash point of 92.5°C and an auto-ignition temperature of 420°C. In aqueous solution, it has a pH value of 3.67 at 20.7 °C and neat it has a pH value of 2.67 at 20.4 °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 active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging material (HDPE/PA). Its technical characteristics are acceptable for an emulsifiable concentrate type formulation. The intended concentration of use is 0.31% to 1.00%. (concentration of use included in the studies: 0.19% to 1.6%). The product is not intended for tank mixing. No classification or label phrases are required.

3.2 Efficacy (Part B, Section 3)

This draft Registration Report summary supports an Article 33 submission for the authorisation of a new fungicide, ADM.03503.F.1.A. This product contains the active substances fluxapyroxad (75 g/L) and prothioconazole (150 g/L), formulated an Emulsifiable Concentrate (EC). Its intended use as a fungicide for the control of foliar and ear diseases of cereals within the Central registration zone.

The maximum proposed rate for all cereals is 1.25 L/ha.

3.2.1 Efficacy data

To study the interest of the association fluxapyroxad and prothioconazole, a total of 99 valid efficacy trials were carried out to demonstrate the interest of the association fluxapyroxad + prothioconazole formulated in ADM.03503.F.1.A. By and large, in these trials performed from 2019 to 2021 in the Maritime, the Northeast and the Southeast EPPO climatic zones.

In all trials, ADM.03503.F.1.A applied at 1.25 L/ha (93.75 g a.s./ha fluxapyroxad+187.5 g a.s./ha prothioconazole) was compared to IMTrex at 1.5 L/ha 93.75 g a.s./ha fluxapyroxad) and PROLINE at 0.75 L/ha (187.5 g a.s./ha prothioconazole).

The association fluxapyroxad + prothioconazole formulated in ADM.03503.F.1.A allowed increasing the control of the disease complex of wheat (SEPTTR, Puccrt, Puccst, PYRNTR, ERYSGT), barley (RHYNSE, PYRNTE, PUCCHD, ERYSGH and RAMUCC) and rye (RHYNSE, PUCCRE) compared to the same rate of fluxapyroxad or prothioconazole applied straight.

Based on the benefits with respect to resistance prevention, the knowledge of each active substances, and technical possibilities on formulation, the combination of the active substances fluxapyroxad + prothioconazole in ADM.03503.F.1.A and their rate ratio are clearly justified on cereals.

In 10 trials, several tank-mixes IMTrex/PROLINE were tested to justify the ratio between both active substances contained in ADM.03503.F.1.A.

Even if few data are available, the rates fluxapyroxad (93.75 g a.s./ha) and prothioconazole (187.5 g a.s./ha) bringing by ADM.03503.F.1.A at 1.25 L/ha against the wheat disease complex (SEPTTR, Puccrt, Puccst) and against the barley disease complex (RHYNSE, PYRNTE, PUCCHD) can be considered as justified.

The confirmation of required doses of ADM.03503.F.1.A was supported by the data from 263 valid efficacy trials carried out between 2019 and 2021 in the Maritime (2 trials in Austria, 2 trials in Belgium, 11 trials in Czech Republic, 53 trials in Germany, 7 trials in Ireland and 2 trials in The Netherlands, 26 trials in the United Kingdom and 41 trials in France), the Northeast (42 trials in Poland) and the Southeast (15 trials in Hungary, 37 trials in Romania and 25 trials in Slovakia) EPPO climatic zones.

ADM.03503.F.1.A was tested at 0.70-0.75, 1.00 and 1.25 L/ha and. These rates reflect 56-60%, 80% and 100% (1.25 L/ha, the maximum recommended dose of ADM.03503.F.1.A) in accordance with the EPPO guideline PP 1/225(1) “Minimum effective rate”.

A total of 143 valid efficacy trials were carried out in wheat against SEPTTR (63 trials), PUCCRT (33 trials), PUCST (28 trials), PYRNTR (15 trials), ERYSGT (19 trials), FUSASS (22 trials), or MONGNI (2 trials).

A total of 99 valid efficacy trials were carried out in barley against RHYNSE (31 trials), PYRNTE (35 trials), PUCCHD (27 trials), RAMUCC (20 trials), or ERYSGH (26 trials).

A total of 8 valid efficacy trials were carried out in rye against RHYNSE (7 trials) and PUCCRE (3 trials). Moreover, to complete the data package, 2 efficacy trials performed from 2020 to 2021 in the Northeast EPPO climatic zone in Latvia and Lithuania are also provided as supportive data.

A total of 13 valid efficacy trials were carried out in triticale to against SEPTTR (1 trial), PUCCRE (8 trials), PUCST (1 trial), PYRNTR (6 trials), or ERYSGR (5 trials). Moreover, to complete the data package, 6 efficacy trials performed from 2020 to 2021 in the Maritime and the Northeast EPPO climatic zone in Denmark (1 trial), Sweden (2 trials) and Latvia (3 trials) are also provided as supportive data.

By and large, the mean efficacy increases in function of the dose rate of ADM.03503.F.1.A. ADM.03503.F.1.A at 1.25 L/ha reached a good efficacy to control the disease complex on cereals confirming the selection of 1.25 L/ha as maximum registered dose.

However, even if the efficacy was overall inferior to ADM.03503.F.1.A at 1.25 L/ha, the efficacy of ADM.03503.F.1.A at 1.00 L/ha was also acceptable to control cereals diseases according to the disease pressure.

Data to confirm efficacy claims for applications of ADM.03503.F.1.A were taken from a set of 231 efficacy trials carried out from 2019 to 2021 in Austria (2 trials), Belgium (2 trials), Czech Republic (12 trials), Germany (55 trials), The Netherlands (2 trials), Ireland (10 trials), Poland (46 trials), Hungary (37 trials), Romania (39 trials) and Slovakia (26 trials) on cereals.

In addition, to complete the data package on wheat and barley, 79 efficacy trials performed from 2019 to 2021 in the Maritime EPPO climatic zone (as defined by EPPO standard PP 1/241(2)) from France (47 trials) and the United Kingdom (32 trials) are also provided.

Moreover, to complete the data package on rye and triticale, 8 efficacy trials performed from 2020 to 2021 in the Maritime and the Northeast EPPO climatic zones (as defined by EPPO standard PP 1/241(2)) from Denmark (1 trial), Sweden (2 trials), Latvia (4 trials) and Lithuania (1 trial) are also provided.

According to the efficacy results, ADM.03503.F.1.A at 1.25 L/ha controlled all diseases of cereals with a level of efficacy similar or even superior to the reference standard LIBRAX.

Therefore, provided data are sufficient to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha to control cereals disease complex.

3.2.2 Information on the occurrence or possible occurrence of the development of resistance

A resistance risk analysis has been conducted in accordance with EPPO guideline PP1/213(3) ‘*Resistance risk analysis*’. The combined risk is low to medium. The resistance risk is therefore acceptable.

Although the risk evaluation is acceptable, additional recommendations can be proposed.

First, agronomical means as the use of tolerant cultivars, crop rotation to break the disease cycle or cultivation in order to reduce the inoculum in the soil must be applied.

Then as described above, application of ADM.03503.F.1.A must be carried out according to the infection level or modelling that forecast the disease pressure and the date of application based on the weather conditions and also according to preliminary assessments in field and other parameters.

Even if only one application is requested, ADM.03503.F.1.A will be applied within fungicide programme in alternation with other mode of action (QoI's, multisite moA ...). Alternation programmes can also include mixtures.

ADAMA will continue to be active members of the FRAC and FRAG networks.

3.2.3 Adverse effects on treated crops

The crop sensitivity of ADM.03503.F.1.A was studied from a set of 300 efficacy trials carried out from 2019 to 2021 in wheat (159 trials), barley (118 trials), rye (9 trials), and triticale (14 trials).

Overall, no phytotoxicity symptoms caused by ADM.03503.F.1.A at the proposed dose of 1.25 L/ha were recorded. Therefore, no effect is expected in requested crops if ADM.03503.F.1.A is applied at the maximum requested rate of 1.25 L/ha according to the Good Agricultural Practices and label recommendations.

No adverse effect on the yield and on the quality of requested crops is expected if ADM.03503.F.1.A is applied at the maximum requested rate of 1.25 L/ha according to the Good Agricultural Practices and label recommendations.

The possible effect of ADM.03503.F.1.A on the transformation processes was studied from a set of 9 confirmatory processing trials implemented in 2020 and 2021 in France in the Maritime EPPO climatic zone.

The potential unintentional effects of ADM.03503.F.1.A at 1.25 L/ha in spring and winter barley on beer and malt quality and malting and brewing processes has been assessed in 6 processing trials and ADM.03503.F.1.A applied at 1.25 L/ha did not lead to negative significant changes to barley, fermentation, taste and smell criteria, in comparison with the PROLINE at 0.8 L/ha.

The potential unintentional effects of ADM.03503.F.1.A at 1.25 L/ha in winter wheat on flour and bread quality and breadmaking process has been assessed in 3 processing trials and ADM.03503.F.1.A applied at 1.25 L/ha did not lead to any significant modifications in comparison with the LIBRAX at 2.0 L/ha.

Therefore, no adverse influence on the transformation processes is expected if ADM.03503.F.1.A is used in accordance with good agricultural practices, including label instructions.

Any potential impact of ADM.03503.F.1.A on seeds would principally be related to the active substances. Fluxapyroxad and prothioconazole are used in Europe for many years and no effect on treated plants or plant products to be used for propagation is known in Europe. Moreover, no problem with respect to propagation has been encountered during the experimental testing of ADM.03503.F.1.A which has been used to treat plants with no negative impact. Based on this, further investigation of the effects of treatments with ADM.03503.F.1.A was considered unnecessary. Therefore, no effect on parts of plant used for propagating purposes is expected if ADM.03503.F.1.A is applied in accordance with the Good Agricultural Practices and label recommendations.

3.2.4 Observations on other undesirable or unintended side-effects

Fungicides usually do not exhibit herbicidal activity. Phytotoxicity was considered as acceptable on cereals (wheat, barley, rye and triticale) in any of the 300 efficacy trials where ADM.03503.F.1.A was applied as a straight product up to 1.25 L/ha. In addition, any potential impact of ADM.03503.F.1.A on succeeding and adjacent crops would principally be related to the active substances. Fluxapyroxad and prothioconazole are used in Europe for many years and no effect on succeeding crops is known in Europe. Therefore, no undesirable or unintended side - effects is expected on succeeding crops if ADM.03503.F.1.A is used according to the Good Agricultural Practices and label recommendations.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods based on UPLC-DAD (fluxapyroxad and prothioconazole), GC-MS (relevant impurity toluene) and UPLC-MS/MS (relevant impurity desthio-prothioconazole) and validated in terms of specificity, linearity, accuracy, precision and LOQ in accordance with the requirements of SANCO/3030/99 rev. 5 22/03/2019 are available for ADM.03503.F.1.A

3.3.2 Analytical methods for residues

Suitably validated analytical methods have been submitted for the data submitted with this application.

Prothioconazole

According to the EFSA Journal 2014;12(5):3689:

Methods for enforcement of residues in food of plant origin

During the peer review under Directive 91/414/EEC, an analytical method using GC-MS and its ILV were evaluated and validated for the determination of prothioconazole-desthio in plant matrices with an LOQ of 0.02 mg/kg in high water content (tomato), high oil content (rape seed), acidic (orange), dry (wheat grain) commodities and an LOQ of 0.05 mg/kg in straw. This method can be confirmed by an independent analytical method using HPLC-MS/MS fully validated for the determination of prothioconazole-desthio in high water content commodities and in straw with an LOQ of 0.05 mg/kg and in high oil content and in dry commodities with an LOQ of 0.01 mg/kg (United Kingdom, 2004). The analytical methods are not enantioselective, hence the sum of isomers will be analyzed.

The multi-residue QuEChERS method in combination with HPLC-MS/MS, as described by CEN (2008), is also available to analyse the prothioconazole-desthio in plant commodities. Nevertheless, the validation data reported are too limited to conclude on the validity of this analytical method (EURL, 2013).

Hence it is concluded that prothioconazole-desthio can be enforced in food of plant origin with an LOQ of 0.02 mg/kg in high oil content and dry commodities and an LOQ of 0.05 mg/kg in high water content commodities and in straw taking into account the highest LOQ of both methods.

Methods for enforcement of residues in food of animal origin

During the peer review under Directive 91/414/EEC, an analytical method using HPLC-MS/MS and its ILV were evaluated and validated for the determination of prothioconazole-desthio only in food of animal origin with an LOQ of 0.004 mg/kg in milk and an LOQ of 0.01 mg/kg in muscle, fat, liver and kidney (United Kingdom, 2004; EFSA, 2007b). Hence it is concluded that prothioconazole-desthio can be enforced in food of animal origin with an LOQ of 0.004 mg/kg in milk and an LOQ of 0.01 mg/kg in muscle, fat, liver and kidney. Nevertheless, prothioconazole-desthio cannot be enforced in eggs. Therefore, a fully validated analytical method for the determination of prothioconazole-desthio in eggs is required.

The available analytical method is not enantioselective, hence the sum of isomers will be analyzed.

The Applicant submitted a number of methods for analysis of residues of prothioconazole for the generation of pre-authorization data and methods for post-authorization control and monitoring purposes. Since many MRLs have been lowered to 0.01 mg/kg, the validated LOQ of the EU agreed methods by Weeren and Pelz (2000) and Class (2001) is not sufficient to monitor these lowered MRLs for food of plant origin. To cover the current residue definition and MRL limits, at the request of the evaluator, the applicant provided a suitable monitoring method, including confirmation and ILV for all major matrix groups with a LOQ of 0.01 mg/kg for the determination of prothioconazole in plant commodities (Lefresne, S., 2020 and Watson, G., 2022a). The studies of Lefresne, S., 2020 and Watson, G., 2022a were evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL

Note:

- The analytical method for the residues of prothioconazole in body fluids and tissues is required.

A body fluids method for the determination of residues of prothioconazole-desthio in blood has been submitted by Applicant. The limit of quantification was established at 0.01 mg/L.

- According to the conclusions presented in EFSA Journal 2014;12(5):3689, a fully validated analytical method for the determination of prothioconazole-desthio in eggs is required.

Applicant submitted the analytical method for the determination of prothioconazole-desthio in egg with LOQ 0.01 mg/kg. The analytical method of Watson, G., 2022 (Report No.: RES-00394) has been independently validated (Lindner, M., Büdel, A., 2022).

- Applicant submitted the analytical method of Lefresne, S., 2021 (Report No.: B21S-A4-P-04) for the determination of prothioconazole-desthio in honey with LOQ 0.01 mg/kg. The analytical method was independently validated (ILV; Lindner, M., 2022 Report No.: S21-06313).

- Applicant submitted the ILV (HPLC-MS/MS analytical method) of the analytical method for determination of prothioconazole and prothioconazole-desthio in surface water. The method is also applicable for drinking water.

The details of the evaluation of new and additional studies are referred in Appendix 2 of Part B5.

No additional data are required to support the intended uses for ADM.03503.F.1.A.

Fluxapyroxad

In the EFSA Journal 2012;10(1):2522 – “Peer Review of the pesticide risk assessment of the active substance fluxapyroxad (BAS 700 F) it is stated that *Appropriate analytical methods are available for the post-registration monitoring of fluxapyroxad (BAS 700 F) in food and feed of plant origin with a LOQ of 0.01 mg/kg (dry, high water, high fat and high acid commodities). Residues of fluxapyroxad (BAS 700 F) in food and feed of animal origin can be monitored with a LOQ of 0.01 mg/kg, and with a LOQ of 0.001 mg/kg in milk, skimmed milk, cream and eggs. Residues of fluxapyroxad (BAS 700 F) (as well as its metabolites M700F001 and M700F002) in soil can be analysed by HPLC-MS/MS and UPLC-MS/MS with a LOQ of 0.001 mg/kg. Residues of fluxapyroxad (BAS 700 F) (as well as its metabolites M700F001, M700F002 and M700F007) in drinking water and surface water can be monitored by HPLC-MS/MS with a LOQ of 0.03 µg/L. Fluxapyroxad (BAS 700 F) residues in air can be determined by HPLC-MS/MS or UPLCMS/ MS with a LOQ of 0.06 µg/m³. A method for residues in body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.*

- A validation of the primary monitoring method in an independent laboratory (ILV) is required for the determination of residues in drinking water. The ILV shall confirm the LOQ of the primary method, or at least cover the lowest MRL.
- Analytical methods for monitoring residues in body fluids and tissues are required for detection of active substances and/or metabolites in humans and animals after possible intoxications or for biomonitoring purposes, regardless of their toxicological classification.

Therefore, an analytical methods for the residues of fluxapyroxad in body fluids and tissues and ILV for drinking water are required.

The Applicant submitted information that the required studies report were included in BASF Chemical Active dossier (CA) for Fluxapyroxad active substance renewal and were submitted in May 2022 (for drinking water - Lee, M., 2021, KCP 5.2/07; for body fluids and tissues - Richter, S., Djedovic, S., 2016; KCP 5.2/08).

It should be noted that the documentation: BASF Chemical Active dossier (CA) for Fluxapyroxad active substance renewal on the DMS cannot be located at this moment and therefore the above-mentioned studies have been evaluated in this registration report by zRMS-PL (see Appendix 2 of Part B5).

The details of the evaluation of new and additional studies are referred in Appendix 2 of Part B5.

No additional data are required to support the intended uses for ADM.03503.F.1.A.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

A summary of the toxicological evaluation for ADM.03503.F.1.A is given in the following tables. To support the evaluation in the EU, the Acute Toxicity Estimate was calculated based on the acute toxicity profile of the ingredients in the formulation. In addition, to satisfy regulatory requirements of countries outside of the EU, *in vitro* and *in vivo* acute toxicity studies were conducted with this formulation. The results of all available data are presented in the table below. For those instances where the results of the studies with the mixture show a different result to the ATE based on the ingredients, the experimental results of the formulation will be used in accordance with Regulation (EC) No 1272/2008, para. 3.1.3.4.1.

Acute toxicity endpoint	Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)
Acute oral toxicity	Calculation method	ATE _{mix} =978	Yes Not considered for hazard assessment**	Acute Tox. 4 H302
	LD ₅₀ oral, rat (OECD 423)	> 2000 mg/kg bw	Supplementary Yes	None
Acute dermal toxicity	Calculation method	> 2000 mg/kg bw	Yes Not considered for hazard assessment**	None
	LD ₅₀ dermal, rat (OECD 402, waiver report)	> 2000 mg/kg bw	Supplementary Yes	None
Acute inhalation toxicity	Calculation method	> 2000 mg/kg bw	Yes Not considered for hazard assessment**	None
	LC ₅₀ inhalation, rat (OECD 436)	> 5.28 mg/L air	Supplementary Yes	None
Skin irritation	Calculation method	Corrosive	Yes Not considered for hazard assessment**	Skin Corr. 1B H314
	Skin corrosion, RhE (OECD 431)	Non-corrosive	No	None
	Skin irritation, RhE (OECD 439)	Irritant	No	Skin Irrit. 2 H315 Not possible to classify***
	Skin irritation, rabbit (OECD 404)	Non-irritant	Supplementary Yes	None
Eye irritation	Calculation method	Irritant	Yes Not considered for hazard assessment**	Eye Dam. 1 H318
	Eye irritation, BCOP (OECD 437)	Inconclusive	No	Inconclusive
	Eye irritation, rabbit (OECD 405)	Irritant	Supplementary Yes	Eye Dam. 1 H318
Skin sensitisation	Calculation method	Non-sensitising	Yes Not considered for hazard assessment**	None

	Skin sensitisation, DPRA (OECD 442C)	Inconclusive	No	Not possible to classify using 2 out of 3 defined approach
	Skin sensitisation, KeratinoSens (OECD 442D)	Positive	No	Not possible to classify using 2 out of 3 defined approach
	Skin sensitisation, mouse (OECD 429, LLNA)	Non-sensitising	Supplementary Yes	None
	Supplementary studies for combinations of plant protection products	No data – not required	--	

* These *in vivo* studies were not performed with intention for use within the EU, but to satisfy the regulatory requirements of countries outside of the EU. The results do not indicate that a more severe classification is required than has been determined based on the ingredients of ADM.03503.F.1.A. However, they are submitted with this application as relevant information.

****Hazard assessment has been revised taking into account outcome of the *in vivo* tests (recommendation provided in Regulation (EC) No. 1272/2008 to give animal data preference)**

- Considering that the Acute Oral Toxicity Study “██████████, 2021” is valid from a scientific point of view, study resulted in no classification in line with Regulation (EC) No 1272/2008
- Considering that the Acute Dermal Toxicity Study “██████████, 2021” is valid from a scientific point of view, study resulted in no classification in line with Regulation (EC) No 1272/2008
- Considering that the Acute Inhalation Toxicity Study “██████████, 2021” is valid from a scientific point of view, study resulted in no classification in line with Regulation (EC) No 1272/2008
- Considering that the Skin Irritation Study “██████████, 2021” is valid from a scientific point of view, study resulted in no classification in line with Regulation (EC) No 1272/2008
- Considering that the Eye Irritation Study “██████████, 2021” is valid from a scientific point of view, **study resulted in H318 classification** in line with Regulation (EC) No 1272/2008
- Considering that the Skin Sensitization Study “██████████, 2021” is valid from a scientific point of view, study resulted in no classification in line with Regulation (EC) No 1272/2008

*****Conclusion is only possible if the study data is used in combination with the data from the other *in vitro* study**

3.4.2 Operator exposure

ADM.03503.F.1.A is a fungicide applied as spray in cereals. All applications are done via tractor-mounted downward spraying. The highest application rate is 1.25 L product/ha.

~~According to the DAR (2005)¹, diluted prothioconazole can degrade to the metabolite prothioconazole-desthio:~~

~~“It has been found that JAU 6476 desthio (SXX 0665) may be formed in diluted prothioconazole formulations. This may happen on clothing, skin or certain plant surfaces during the drying process. The degradation product, JAU 6476 desthio, is known to have an embryotoxic potential in experimental animals.”~~

~~According to the EFSA conclusion of prothioconazole², the degradation product prothioconazole-desthio is more toxic than the parent compound and is therefore considered in the risk assessments of all relevant population groups. The content of prothioconazole-desthio in the concentrate is however assumed to be very low. This assumption is based on the Commission Implementing Regulation (EU) No 540/2011 (amending Regulation (EU) No 1107/2009), in which it is declared that the amount of prothioconazole-~~

¹ DAR (2005), B.6.15.1 Operator exposure (III 7.2.1), p. 327

² Conclusion regarding the peer review of the pesticide risk assessment of the active substance prothioconazole. EFSA Journal 2007; 5(8): RN-106, 1-98. doi:10.2903/j.efsa.2007.106r

~~desthio may not exceed 0.5 g/kg, i.e. 0.05 % (w/w) in the technical material.³ To reflect this non-availability of prothioconazole-desthio when handling the concentrate, i.e. during mixing and loading, the value for the dermal absorption of prothioconazole-desthio in the concentrate was set to 0 %.~~

~~In a conservative approach, two exposure assessments are conducted for each relevant exposure group. One assessment reflects exposure to 100 % prothioconazole when handling the concentrate, the dilution or the dried formulation, while the other assessment reflects exposure to 100 % prothioconazole-desthio when handling the dilution or the dried formulation.~~

~~The product is applied in a water volume of 125 L/ha to 400 L/ha in cereals. . For completeness the assessment for residents considers applications made using both the minimum and maximum water volumes.~~

According to the DAR (2005)⁴, diluted prothioconazole can degrade to the metabolite prothioconazole-desthio:

"It has been found that JAU 6476-desthio (SXX 0665) may be formed in diluted prothioconazole formulations. This may happen on clothing, skin or certain plant surfaces during the drying process. The degradation product, JAU 6476-desthio, is known to have an embryotoxic potential in experimental animals."

According to the EFSA conclusion of prothioconazole⁵, the degradation product prothioconazole-desthio is more toxic than the parent compound and is therefore considered in the risk assessments of all relevant population groups. The content of prothioconazole-desthio in the concentrate is however assumed to be very low. This assumption is based on the Commission Implementing Regulation (EU) No 540/2011 (amending Regulation (EU) No 1107/2009), in which it is declared that the amount of prothioconazole-desthio may not exceed 0.5 g/kg, i.e. 0.05 % (w/w) in the technical material.⁶

However, as a highly conservative approach exposure to prothioconazole-desthio has been considered during mixing and loading the concentrated product since a very low level of conversion may take place when the concentrate is exposed to humid air or sweat on the skin of the operator. Since storage stability data have shown that ADM.03503.F.1.A is stable as a concentrate 100% conversion upon exposure to low levels of moisture is not considered realistic and therefore represents a theoretical worst case.

In a conservative approach, three exposure assessments are conducted for each relevant exposure group. One assessment reflects exposure to 100 % prothioconazole. A further scenario has also been considered in which both substances are present at 50%. It is considered that for mixing and loading even 50% conversion is an over estimation and provides a highly conservative exposure estimate for prothioconazole-desthio.

As default dermal absorption values are used for prothioconazole, the exposure assessment considers applications are made in the minimum water volume, as this provides a worst-case risk assessment for bystanders and residents exposure from spray drift.

Exposure was assessed according to the EFSA published exposure model: Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874, calculator version: 30/03/2015.

The estimated operator exposure for an operator wearing normal work clothing but no gloves, considering both conversion factors of 100% and 50% were below the established AOELs. Thus, it is concluded that the use of ADM.03503.F.1.A. is at an acceptable risk for the operator.

Additional RMM: regarding proposed product hazard classification Operators must wear protective gloves/protective clothing/eye protection/face protection

³ dRR Part B Section 1: Identity, Section 2: Physical and chemical properties, Section 4: Further information, 2020

⁴ DAR (2005), B.6.15.1 Operator exposure (III 7.2.1), p. 327

⁵ Conclusion regarding the peer review of the pesticide risk assessment of the active substance prothioconazole. EFSA Journal 2007; 5(8): RN-106, 1-98. doi:10.2903/j.efsa.2007.106r

⁶ dRR Part B Section 1: Identity, Section 2: Physical and chemical properties, Section 4: Further information, 2020

3.4.3 Worker exposure

Exposure was assessed according to the EFSA published exposure model: Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874, calculator version: 30/03/2015.

Additional estimation of worker exposure taking into account a conversion factor of 50% of prothioconazole to prothioconazole -desthio has been done.

The estimated exposure of a worker dressed in work wear (arms, body and legs covered, no gloves) considering both conversion factors of 100% and 50% was below the established AOELs. Thus, it is concluded that the use of ADM.03503.F.1.A. is at an acceptable risk for the worker.

As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

3.4.4 Bystander and resident exposure

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

Exposure was assessed according to the EFSA published exposure model: Guidance on the assessment of exposure of operators, workers, residents, and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874, calculator version: 30/03/2015.

The calculated total systemic exposure for residents, considering both conversion factors of 100% and 50%, were below the established AOELs for the child and adult scenario. Thus, it is concluded that the use of ADM.03503.F.1.A. is at an acceptable risk for the residents and no mitigation measures are required.

With respect to combined exposure the Hazard Index is < 1 for all scenarios. Thus, combined exposure to all active substances in ADM.03503.F.1.A is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

3.5 Residues and consumer exposure (Part B, Section 7)

3.5.1 Residues

Prothioconazole

Wheat, rye, triticale

Wheat and rye are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on wheat can be used for extrapolation to rye and triticale before and after forming of the edible part.

Sufficient trials on wheat were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 175-200 g a.s. /ha, application at BBCH 69, outdoor. The trials are supported by valid storage stability data (for TDMs, not all submitted trials were covered by the storage stability data for the metabolites – see boxes with zRMS comments in Appendix 2) and validated analytical methods.

Residues of prothioconazole-desthio (RD-Mo) in wheat grain at harvest were < 0.01 mg/kg except for one trial for which residues equal 0.013 mg/kg.

Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were < 0.06 mg/kg.

Available results show that the in force MRL of prothioconazole on wheat of 0.1 mg/kg and on rye of 0.05 (Reg. (EU) 2019/552) will not be exceeded. According to Commission Regulation (EU) No 752/2014 replacing Annex I to Regulation (EC) No 396/2005, MRLs for wheat (code number: 0500090) are also applicable to triticale (code number: 0500090-006).

The current EU MRLs for prothioconazole are sufficient to support the proposed uses.

Residues of 1,2,4-T were <LOQ.

Residues of TLA in grain were <0.01 mg/kg.

Residues of TA in grain were between 0.26 and 0.61 mg/kg.

Residues of TAA in grain were between 0.06 and 0.39 mg/kg.

More details of the residue studies on wheat are provided in Appendix 2 of B7.

The proposed uses on wheat, triticale and rye are considered acceptable.

Barley

Barley is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.

Sufficient trials on barley were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 175-200 g a.s. /ha, application at BBCH 65-69, outdoor. The trials are supported by valid storage stability data (for TDMs, not all submitted trials were covered by the storage stability data for the metabolites – see boxes with zRMS comments in Appendix 2) and validated analytical methods.

Residues of prothioconazole-desthio (RD-Mo) in barley grain at harvest were between <0.01 mg/kg and 0.061 mg/kg.

Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were between <0.06 mg/kg and 0.095 mg/kg.

Available results show that the in force MRL of prothioconazole on barley of 0.2 mg/kg (Reg. (EU) 2019/552) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed use.

Residues of 1,2,4-T in grain were <LOQ.

Residues of TLA in grain were between <LOQ and 0.02 mg/kg.

Residues of TA in grain were between 0.04 and 0.29 mg/kg.

Residues of TAA in grain were between 0.02 and 0.13 mg/kg.

More details of the residue studies on barley are provided in Appendix 2 of B7.

The proposed use on barley is considered acceptable.

Fluxapyroxad

Wheat, rye, triticale

Wheat and rye are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on wheat can be used for extrapolation to rye and triticale before and after forming of the edible part.

Sufficient residue trial data is presented in EFSA Journal 2011;9(6):2196 68 and in EFSA Journal 2012;10(1):2522.

In addition to this new four GAP compliant residue trials on wheat in Northern Europe have been submitted by the Applicant. These trials were conducted within an application rate of 93.75 g/ha of Fluxapyroxad at BBCH 69.

The trials are supported by valid storage stability data and validated analytical method.

In seed specimens taken at normal commercial harvest residues of fluxapyroxad were between 0.026 and 0.049 mg/kg.

Available results show that the in force MRL of fluxapyroxad on wheat and rye of 0.4 mg/kg (Reg. (EU) 2022/1324) will not be exceeded. According to Commission Regulation (EU) No 752/2014 replacing Annex I to Regulation (EC) No 396/2005, MRLs for wheat (code number: 0500090) are also applicable to triticale (code number: 0500090-006).

The current EU MRLs for fluxapyroxad are sufficient to support the proposed uses.

More details of the residue study on wheat are provided in Appendix 2.

The proposed uses on wheat, triticale and rye are considered acceptable.

Barley

Barley is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.

Sufficient residue trial data is presented in EFSA Journal 2011;9(6):2196 68 and in EFSA Journal 2012;10(1):2522.

In addition to this new four GAP compliant residue trials on barley in Northern Europe have been submitted by the Applicant. These trials were conducted within an application rate of 93.75 g/ha of Fluxapyroxad at BBCH 69.

The trials are supported by valid storage stability data and validated analytical method.

In seed specimens taken at normal commercial harvest residues of fluxapyroxad were between 0.11 and 0.38 mg/kg.

Available results show that the in force MRL of fluxapyroxad on barley of 3 mg/kg (Reg. (EU) 2022/1324) will not be exceeded. The current EU MRLs for fluxapyroxad are sufficient to support the proposed uses.

More details of the residue study on barley are provided in Appendix 2.

The proposed use on barley is considered acceptable.

3.5.2 Consumer exposure

Prothioconazole except TDMs

TMDI (% ADI*) according to EFSA PRIMo 3.1	43% (based on NL toddler; main contributor: Milk:cattle)
IEDI (% ADI*) according to EFSA PRIMo 3.1	Normal mode: 15% (based on NL toddler; main contributor: milk: cattle); Refined calculation mode: 6% (based on DK child; main contributor: rye)
IESTI (% ARfD**) according to EFSA PRIMo 3.1	Wheat: 9% (based on unprocessed commodities, children) Wheat: 5% (based on unprocessed commodities, adults) Wheat (milling flour): 7% (based on processed commodities, children) Barley / beer: 5% (based on processed commodities, adults)

* ADI of prothioconazole-desthio

** ARfD of prothioconazole-desthio

TDMs:

1,2,4-triazole

TMDI (% ADI) according to EFSA PRIMo 3.1	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo 3.1	Normal mode: 51% (based on NL toddler; main contributor: milk: cattle); Refined mode*: 44% (NL toddler; main contributor: milk: cattle)

IENTI (% ARfD) according to EFSA PRIMo 3.1	Milk: cattle: 20% (based on unprocessed commodities, children) Milk: cattle: 6% (based on unprocessed commodities, adults) Wheat (milling flour): 0.6% (based on processed commodities, children) Barley / beer: 0.4% (based on processed commodities, adults)
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*Refined mode includes GAPs under assessment as well as livestock matrices/products.

TA

TMDI (% ADI) according to EFSA PRIMo 3.1	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo 3.1	Normal mode: 5% (based on NL toddler; main contributor: maize/corn); Refined mode*: 2% (DK child; main contributor: rye)
IENTI (% ARfD) according to EFSA PRIMo 3.1	Wheat: 3% (based on unprocessed commodities, children) Wheat: 2% (based on unprocessed commodities, adults) Wheat (milling flour): 3% (based on processed commodities, children) Barley / beer: 1% (based on processed commodities, adults)

*Refined mode includes GAPs under assessment as well as livestock matrices/products.

TLA

TMDI (% ADI) according to EFSA PRIMo 3.1	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo 3.1	Normal mode: 1% (based on NL toddler; main contributor: milk: cattle); Refined mode*: 0.7% (based on NL toddler; main contributor: milk: cattle)
IENTI (% ARfD) according to EFSA PRIMo 3.1	Milk: cattle: 1% (based on unprocessed commodities, children) Milk: cattle: 0.4% (based on unprocessed commodities, adults) Wheat (milling flour): 0.1% (based on processed commodities, children) Barley / beer: 0.1% (based on processed commodities, adults)

*Refined mode includes GAPs under assessment as well as livestock matrices/products.

TAA

TMDI (% ADI) according to EFSA PRIMo 3.1	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo 3.1	Normal mode: 1% (based on NL toddler; main contributor: maize/corn); Refined mode*: 0.9% (DK child; main contributor: rye)
IENTI (% ARfD) according to EFSA PRIMo 3.1	Wheat: 1% (based on unprocessed commodities, children) Wheat: 0.7% (based on unprocessed commodities, adults) Wheat (milling flour): 1% (based on processed commodities, children) Barley / beer: 0.6% (based on processed commodities, adults)

*Refined mode includes GAPs under assessment as well as livestock matrices/products.

TA and TLA can be assigned to a common assessment group. Therefore a combined risk assessment for these TDM can be performed by simple addition of NEDIs and NESTIs of both metabolites.

The combined EU IEDIs are less than the ADI of 0.3 mg/kg bw/day.

The combined EU IESTIs are less than the ARfD of 0.3 mg/kg bw/day.

The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of prothioconazole residues and TDMs are unlikely to present a public health concern.

Fluxapyroxad

TMDI (% ADI) according to EFSA PRIMo	Not assessed
IEDI (% ADI) according to EFSA PRIMo 3.1	Normal mode: 48% (based on NL toddler; main contributor: Apples) Refined calculation mode: 7% (based on DK child; main

	contributor: Rye)
IESTI (% ARfD) according to EFSA PRIMo 3.1	Barley: 1% (based on unprocessed commodities for children and adults) Barley cooked: 0.8% (based on processed commodities children) Barley/beer: 2% (based on processed commodities for adults)

The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of fluxapyroxad residues are unlikely to present a public health concern.

The proposed uses of fluxapyroxad and prothioconazole in the formulation ADM.03503.F.1.A do not represent unacceptable acute and chronic risks for the consumer. The intended uses of ADM.03503.F.1.A are accepted.

3.6 Environmental fate and behaviour (Part B, Section 8)

3.6.1 Predicted environmental concentrations in soil (PEC_{soil})

Soil exposure for fluxapyroxad and prothioconazole and its soil metabolites M700F001, M700F002, JAU-S-methyl and JAU-desthio was calculated using approach described in respective FOCUS guidance for the intended uses of ADM.03503.F.1.A. For all compounds, EU agreed data were taken into account. Soil exposure for the formulated product was also calculated. The results for PEC_{soil} for the active substances and their metabolites were used for the ecotoxicological risk assessment.

3.6.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The leaching behaviour of fluxapyroxad and prothioconazole and its soil metabolites M700F001, M700F002, JAU-S-methyl and JAU-desthio was assessed using FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4 on the basis of the EU agreed input parameters and intended use pattern of ADM.03503.F.1.A.

Performed calculations resulted with PEC_{GW} values <0.1 µg/L in all relevant Polish scenarios for fluxapyroxad and metabolite M700F001. PEC_{GW} for toxicologically non-relevant metabolite M700F002 were above the threshold concentration of 0.75 µg/L but <10.0 µg/L following application to winter and spring cereals. The consumer risk assessment has been performed in the Core Assessment, Part B, Section 10 indicating acceptable risk for this metabolite.

Performed calculations resulted with PEC_{GW} values <0.1 µg/L in all relevant Polish scenarios for prothioconazole and its metabolites JAU-S-methyl and JAU-desthio.

Based on the performed assessment no unacceptable leaching of fluxapyroxad and prothioconazole and its metabolites is expected when ADM.03503.F.1.A. is used according to recommendations.

3.6.3 Predicted environmental concentrations in surface water (PEC_{sw})

The surface water modelling was performed for the intended use pattern of ADM.03503.F.1.A in line with recommendations of respective FOCUS guidance documents using most up-to-date versions of the models. Obtained PEC_{SW/SED} values were used in the risk assessment for aquatic organisms.

3.6.4 Predicted environmental concentrations in air (PEC_{air})

The vapour pressure at 20 °C of the active substance fluxapyroxad is < 10⁻⁵ Pa. Hence the active substance fluxapyroxad is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance fluxapyroxad due to volatilization with subsequent deposition are not considered.

The vapour pressure at 20 °C of the active substance prothioconazole is < 10⁻⁵ Pa. Hence prothioconazole is regarded as non-volatile. Therefore, an assessment of the exposure of adjacent surface waters and terrestrial ecosystems by the active substance prothioconazole due to volatilisation with subsequent

deposition is not triggered and not performed.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

The risk assessment for birds and mammals was carried out according to the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

Birds

The acute and reproductive (long-term) risk for birds from dietary exposure to fluxapyroxad, prothioconazole and the desethio-prothioconazole transformation product is indicated to be acceptable based on Screening Step and/or Tier 1 assessments, including considerations of combined exposure.

Likewise, acceptable risk is indicated for the exposure via drinking water and the indirect exposure via secondary poisoning for earthworm- and fish-eating birds.

Overall, the risk for birds exposed following the intended uses of ADM.03503.F.1.A is acceptable.

Terrestrial vertebrates other than birds

The acute and reproductive (long-term) risk for terrestrial vertebrates other than birds from dietary exposure to fluxapyroxad, prothioconazole and the desethio-prothioconazole transformation product is indicated to be acceptable based on Screening Step and/or Tier 1 assessments, including considerations of combined exposure. For the small herbivorous scenario, an acceptable risk is presented based on higher tier assessments accounting for revised crop interception.

Likewise, acceptable risk is indicated for the exposure via drinking water and the indirect exposure via secondary poisoning for earthworm- and fish-eating mammals.

Overall, the risk for terrestrial vertebrates other than birds exposed following the intended uses of ADM.03503.F.1.A is acceptable.

3.7.2 Effects on aquatic species

The risk assessment for aquatic organisms was carried out according to the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EF-SA Journal 2013;11(7):3290).

Based on the available data and risk assessment for aquatic organisms including considerations on potential mixture toxicity, acceptable risk is indicated if a 10 m vegetated buffer distance is taken into account for both uses, i.e. winter and spring cereals.

3.7.3 Effects on bees

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

An acceptable acute risk is indicated for exposure of bees towards the formulated product as well as the individual active substances for the intended worst-case use of ADM.03503.F.1.A. The chronic studies for bees according to requirement EU Reg. 284/2013 were submitted by the Applicant and the risk assessment (according EFSA 2013 GD not implemented at EU level yet) based on those studies indicating acceptable risk.

3.7.4 Effects on other arthropod species other than bees

The risk assessment was conducted according to the ESCORT 2 Guidance Document (2000) and the Guidance Document on Terrestrial Ecotoxicology (2002).

An acceptable in-field and off-field risk is indicated for exposure of terrestrial non-target arthropods other than bees towards the formulated product for the intended worst-case use of ADM.03503.F.1.A without the necessity to account for risk mitigations.

3.7.5 Effects on soil organisms

The risk assessment was conducted according to the Guidance Document on Terrestrial Ecotoxicology (2002).

Meso- and macrofauna

An acceptable risk is indicated for soil macro- and meso-fauna for the intended worst-case use of ADM.03503.F.1.A in cereals with Toxicity Exposure Ratios greater than five for the active substances, relevant transformation products as well as formulated product, respectively.

Soil microbial functions

An acceptable risk is indicated for soil microflora for the intended worst-case use of ADM.03503.F.1.A in cereals with NOAECs (i.e. the maximum tested concentration with effects < 25% at ≤ 100 days) greater than the maximum predicted environmental concentrations of the active substances, relevant transformation products as well as formulated product, respectively.

3.7.6 Effects on non-target terrestrial plants

The risk assessment was conducted according to the Guidance Document on Terrestrial Ecotoxicology (2002).

An acceptable off-field risk is indicated for exposure of terrestrial non-target plants towards the formulated product for the intended worst-case use of ADM.03503.F.1.A without the necessity to account for risk mitigations.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

No further relevant data available nor considered necessary.

3.8 Relevance of metabolites (Part B, Section 10)

As evaluated in model calculations prothioconazole metabolites prothioconazole-desthio and prothioconazole-S-methyl did not exceed the groundwater threshold value of 0.1 µg/L

The relevance of the fluxapyroxad groundwater metabolite M700F001 has already been assessed and the assessment agreed at EU level and is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR between 0.1 and 0.75 µg/L). M700F001 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.

The relevance of the fluxapyroxad groundwater metabolite M700F002 has already been assessed and the assessment agreed at EU level and is applicable for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are

valid with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). M700F002 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Neither fluxapyroxad or prothioconazole are candidates for substitution and therefore a comparative assessment is not required.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

~~None.~~

Section 2: Physical and chemical properties:

- pH < 4, the applicant was requested to provide information on the effects on metals. The study for corrosion to metals has been planned and will be provided once available.

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Komentarz oceniających:

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, pozostałości, toksykologii i istotności toksykologicznej metabolitów, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym podświetleniem tekstu (fragmenty dodane) lub przekreśleniem i jasno-szarym cieniem (fragmenty usunięte).

Zakres zmian jest następujący:

Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodne z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008 r. nie jest wymagane.
2. Okres ważności: 2 lata na podstawie zaakceptowanego 2-letniego badania stabilności środka ochrony roślin przechowywanego w opakowaniu wykonanym z HDPE/PA. W związku z powyższym, wszystkie opakowania wymienione, w punktach 2.1 dokumentu A i 4.1 Sekcji 1,2,4 można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin.
3. Brak uwag do punktów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin i opakowania oraz sporządzania cieczy użytkowej.
4. Brak uwag do zapisu grup chemicznych do których przyporządkowano substancje czynne. Dodano zawartości substancji czynnych (gęstość względna zgodnie z punktem 2.6.1 Sekcji 1,2,4 wynosi 1,08).
5. Zgodnie z informacjami zawartymi w punktach IIIA 2.9.1 i IIIA 2.9.2 Sekcji 1,2,4 Raportu Rejestracyjnego środek nie jest dedykowany do łącznego stosowania.

Sekcja skuteczność:

1. Zastosowanie w pszenicy ograniczono do formy ozimej, zgodnie z GAP. Uzasadnienie: nie przedłożono ani jednego badania w pszenicy jarej, uniemożliwiającej ekstrapolację
2. Skorygowano okno zabiegowe dla zwalczania fuzariozy kłosów z BBCH 59-69 na BBCH 61-69. Uzasadnienie: Wnioskodawca w pierwotnej postaci tabeli GAP nie wyróżnia odrębnego terminu dla zabiegu przeciwko *Fusarium*, dlatego został on przyjęty zgodnie z dominującymi zaleceniami w uprawie pszenicy w Polsce, gdzie wprowadzie termin począwszy od BBCH 59 także jest stosowany, lecz zalecany jest stosunkowo rzadziej niż termin BBCH 61-69. Co więcej, sam wnioskodawca, odpowiadając w procesie komentowania na zapytanie jednego z cMS (NL) podaje także okno BBCH 61-69. Przyjęto zatem, że taki jest zamiar wnioskodawcy.
3. Wykreślono ramulariozę spośród zastosowań w jęczmieniu, zgodnie z GAP. Uzasadnienie: zbyt niska liczba badań. Przedłożono tylko jedno badanie z Polski, a ADM.03503.F.1.A jest nowym środkiem.
4. Wykreślono zastosowania w uprawie żyta ozimego. Uzasadnienie: Przedłożono tylko 2 badania z Polski dotyczące rynchosporiozy, które są nieporównywalne pod względem skuteczności z dwoma innymi badaniami z Litwy i Łotwy, przedłożonymi jako wspierające. Ekstrapolacja z jęczmienia nie została uznana za uprawnioną, ponieważ dostępne są tylko 4 badania z Polski tym patogenem w jęczmieniu. W jednym i w drugim przypadku jest to zbyt ograniczony zestaw danych dla nowego środka. Nie przedłożono również żadnych badań z Polski nad rdzą brunatną w życie, jedynie pojedyncze badanie z Łotwy. Ewentualna ekstrapolacja musiałaby zatem opierać się na tych samych czterech badaniach w pszenicy z tym patogenem. Zostało to ocenione jako niewystarczające, podobnie jak w przypadku rynchosporiozy. Rdza żółta nie wystąpiła w żadnym z badań na życie.
5. Usunięto rdzę żółtą z zastosowań w pszenicy ozimym, zgodnie z GAP. Uzasadnienie: patogen występował tylko w 3 badaniach z Niemiec, Danii i Szwecji.
6. Dodano zastosowanie do zwalczania mączniaka prawdziwego zbóż i traw, zgodnie z wnioskowanym GAP, i zgodnie z wynikiem oceny, ponieważ nie znalazło się w projekcie etykiety.
7. Dodano nagłówek akapitu STRATEGIA ANTYODPORNOŚCIOWA, oraz zmodyfikowano brzmienie akapitu.

Sekcja metody analityczne:

1. Brak uwag.

Sekcja toksykologia i istotność toksykologiczna metabolitów:

1. W części dotyczącej klasyfikacji zagrożeń wprowadzono zwroty określające zagrożenie: H302 i H314. Ze względu na wprowadzenie H314 wykreślono znak H318 (redundantny). Zmodyfikowano zwroty wskazujące środki ostrożności: P280 oraz wprowadzono zwrot P260 i P303+P361+P353.
2. Biorąc pod uwagę komentarze cMS dotyczące klasyfikacji zagrożeń zgodnie z GHS/CLP, zRMS zweryfikował zaproponowane podejście do ww. klasyfikacji i podjął decyzję aby środek ochrony roślin został sklasyfikowany na podstawie wyników badań *in vivo*. W części dotyczącej klasyfikacji wykreślono zwroty H302, H314 i

P303+P361+P353 oraz przywrócono zwrot H318. Wykreślono piktogram GHS07. Zmodyfikowano zwrot wskazujące środki ostrożności: P280.

3. W części dotyczącej środków ostrożności dla osób stosujących środek, został wprowadzony odpowiedni zapis zgodnie z wymaganiami harmonizacyjnymi.

Sekcja pozostałości

1. Wprowadzono zapis do etykiety dotyczący roślin następnych: „*Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie: nie ma ograniczeń co do okresu od ostatniego zastosowania środka do dnia, w którym można siać lub sadzić rośliny uprawiane następnie.*”

Sekcja los i zachowanie w środowisku:

1. Brak uwag

Sekcja ekotoksykologia:

1. Wprowadzono zwrot P501.

Załącznik do zezwolenia MRiRW nr R - .../2023 z dnia2023 r.

- Posiadacz zezwolenia:
ADAMA Polska Sp. z o.o. ul. Sienna 39, 00 - 121 Warszawa, tel. 22 395 66 60, infolinia: 22 395 66 66, e-mail: biuro@adama.com, www.adama.com
- Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:
.....

AVASTEL 225 EC


Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zezwolenie MRiRW nr R -/2023 z dnia2023 r.

Zawartość substancji czynnej:

fluksapyroksad - związek z grupy karboksamidów - 75 g/l (6,94%)

protriokonazol - związek z grupy triazoli - 150 g/l (13,9%)

	
Niebezpieczeństwo	
H302 H314 H318 H362 H411	Działa szkodliwie po połknięciu. Powoduje poważne oparzenia skóry i uszkodzenia oczu. Powoduje poważne uszkodzenie oczu. Może działać szkodliwie na dzieci karmione piersią. Działa toksycznie na organizmy wodne, powodując długotrwałe skutki
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia
P201 P260 P263 P280	Przed użyciem zapoznać się ze specjalnymi środkami ostrożności. Nie wdychać pyłu/mgły. Unikać kontaktu w czasie ciąży i podczas karmienia piersią. Stosować ochronę oczu/ochronę twarzy. Stosować rękawice ochronne/odzież ochronną / ochronę oczu / ochronę twarzy.
P305+P351+P338 P303+P361+P353	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. W PRZYPADKU DOSTANIA SIĘ NA SKÓRĘ (lub włosy): Natychmiast usunąć/zdjąć całą zanieczyszczoną odzież. Spłukać skórę pod strumieniem wody [lub prysznicem].
P410 P501	Chronić przed światłem słonecznym. Zawartość / pojemnik usuwać do recyklingu bądź składowania na składowiskach odpowiednich dla pestycydów lub spalania w odpowiednich instalacjach.

OPIS DZIAŁANIA

FUNGICYD w formie rozpuszczalnego koncentratu (EC) do sporządzania roztworu wodnego o działaniu układowym do stosowania zapobiegawczego, interwencyjnego oraz wyniszczającego.

Zgodnie z klasyfikacją FRAC substancja czynna protriokonazol zaliczana jest do grupy 3 (fungicydy DMI), a substancja czynna fluksapyroksad do grupy 7 (fungicydy SDHI).

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

Pszenica ozima, ~~pszenica jara~~

septorioza paskowana liści pszenicy, brunatna plamistość liści, rdza żółta zbóż i traw, rdza brunatna pszenicy, mączniak prawdziwy zbóż i traw

Zalecana dawka dla jednorazowego zastosowania: 1 – 1,25 l/ha.

Maksymalna dawka dla jednorazowego zastosowania: 1,25 l/ha

Termin stosowania:

Środek stosować zapobiegawczo lub bezpośrednio po zauważeniu pierwszych objawów chorób, od początku fazy strzelania w źdźbło do końca fazy kwitnienia (BBCH 30-69).

fuzarioza kłosów

Zalecana dawka dla jednorazowego zastosowania: 1 – 1,25 l/ha.

Maksymalna dawka dla jednorazowego zastosowania: 1,25 l/ha

Termin stosowania:

Środek stosować po wykłoszeniu, gdy kłos jest całkowicie widoczny do końca fazy kwitnienia (~~BBCH 59-69~~) (BBCH 61-69).

Zalecana ilość wody: 125-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Jęczmień ozimy, ~~jęczmień jary~~

Rynchosporioza zbóż, plamistość siatkowa jęczmienia, ~~ramularia jęczmienia~~, rdza jęczmienia, mączniak prawdziwy zbóż i traw

Zalecana dawka dla jednorazowego zastosowania: 1 – 1,25 l/ha.

Maksymalna dawka dla jednorazowego zastosowania: 1,25 l/ha

Termin stosowania:

Środek stosować zapobiegawczo lub bezpośrednio po zauważeniu pierwszych objawów chorób, od początku fazy strzelania w źdźbło do pełni fazy kwitnienia (BBCH 30-65).

Zalecana ilość wody: 125-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Jęczmień jary

Plamistość siatkowa jęczmienia, rdza jęczmienia, mączniak prawdziwy zbóż i traw

Zalecana dawka dla jednorazowego zastosowania: 1 – 1,25 l/ha.

Maksymalna dawka dla jednorazowego zastosowania: 1,25 l/ha

Termin stosowania:

Środek stosować zapobiegawczo lub bezpośrednio po zauważeniu pierwszych objawów chorób, od początku fazy strzelania w źdźbło do pełni fazy kwitnienia (BBCH 30-65).

Zalecana ilość wody: 125-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Żyto ozime

Rynchosporioza zbóż, rdza brunatna żyta, rdza żółta

Zalecana dawka dla jednorazowego zastosowania: 1 – 1,25 l/ha.

Maksymalna dawka dla jednorazowego zastosowania: 1,25 l/ha

Termin stosowania:

~~Środek stosować zapobiegawczo lub bezpośrednio po zauważeniu pierwszych objawów chorób, od początku fazy strzelania w źdźbło do końca fazy kwitnienia (BBCH 30-69).~~

~~Zalecana ilość wody: 125-400 l/ha.~~

~~Zalecane opryskiwanie: drobnokropliste.~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.~~

Pszenżyto ozime

Septorioza paskowana liści pszenicy, rdza żółta zbóż i traw, rdza brunatna, brunatna plamistość liści, mączniak prawdziwy zbóż i traw

Zalecana dawka dla jednorazowego zastosowania: 1 – 1,25 l/ha.

Maksymalna dawka dla jednorazowego zastosowania: 1,25 l/ha

Termin stosowania:

Środek stosować zapobiegawczo lub bezpośrednio po zauważeniu pierwszych objawów chorób, od początku fazy strzelania w źdźbło do końca fazy kwitnienia (BBCH 30-69).

Zalecana ilość wody: 125-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Nie dotyczy

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie: nie ma ograniczeń co do okresu od ostatniego zastosowania środka do dnia, w którym można siać lub sadzić rośliny uprawiane następnie.

Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie uprawy,
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

Środek zawiera substancję czynną protiokonazol z grupy triazoli (fungicydy inhibitory biosyntezy steroli - inhibitory demetylacji, SBI- DMI, wg FRAC grupa 3) oraz substancję czynną fluksapyroksad z grupy karboksamidów (fungicydy inhibitory dehydrogenazy bursztynianowej - SDHI - grupa FRAC 7).

STRATEGIA ANTYODPORNOŚCIOWA

W ramach strategii antyodpornościowej zaleca się m. in.:

- przestrzeganie zalecanej maksymalnej liczby zabiegów w sezonie wegetacyjnym: jeden zabieg,
- stosowanie środka głównie do zabiegów zapobiegawczych,
- ~~niestosowanie środka w dawkach innych niż jest zalecana,~~
- stosowanie środka wyłącznie w dawkach zalecanych przez producenta, z uwzględnieniem zależności dawki od nasilenia infekcji: niższą dawkę należy stosować **wyłącznie** w warunkach słabego porażenia roślin,
- włączenie do przyjętego programu ochrony środków grzybobójczych, zawierających substancje czynne z innych grup, o odmiennych mechanizmach działania (stosowanie przemienne lub w mieszaninie zbiornikowej).
- Powszechnie uznane środki agrotechniczne ograniczające poziom infekcji, takie jak odpowiedni płodozmian, stosowanie odpornych odmian i nieuproszczona uprawa gleby, powinny być stosowane równolegle z ochroną chemiczną.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Zawartością opakowania przed użyciem wstrząsnąć. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem) i uzupełnić wodą do potrzebnej ilości. Opryskiwać z włączonym mieszadłem. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne ciecz mechanicznie wymieszać. Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wody użytej do mycia aparatury należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

~~Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież ochronną zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.~~

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież roboczą (kombinezon), w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 10 m od zbiorników i cieków wodnych

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,

- w oryginalnych, szczelnie zamkniętych opakowaniach, w chłodnym, dobrze wentylowanym miejscu,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0°C-30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

The Letters of Access are confidential and are provided separate to this submission.

Appendix 4 Lists of data considered for national authorization

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1/01	Riedl, S.	2021a	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Accelerated Storage Procedure at 54 °C for 2 Weeks Noack Laboratorien GmbH, Germany, Report No. SO20253 / CPL19043 ADAMA Reference No. 000105596 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 2.1/02 (filed in KCP 2.1/01)	Riedl, S.	2021a	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Accelerated Storage Procedure at 54 °C for 2 Weeks Noack Laboratorien GmbH, Germany, Report No. SO20253 / CPL19043 ADAMA Reference No. 000105596 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 2.2.1	Bender, D.	2020a	ADM.03503.F.1.A Determination of physico-chemical properties Screening Explosive Substances (UN Class 1) Consilab Gesellschaft für Anlagensicherheit mbH, Germany, Report No. CSL-20-0595.02 ADAMA Reference No. 000105599 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 2.2.2	Bender, D.	2020b	ADM.03503.F.1.A Determination of physico-chemical properties Oxidizing properties of liquids (UN Class 5, Division 5.1 Test O.2) Consilab Gesellschaft für Anlagensicherheit mbH, Germany, Report No. CSL-20-0595.04 ADAMA Reference No. 000105600 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.3.1	Bender, D.	2020c	ADM.03503.F.1.A Determination of physico-chemical properties Flash Point (EC A.9.) Consilab Gesellschaft für Anlagensicherheit mbH, Germany, Report No. CSL-20-0595.01 ADAMA Reference No. 000106480 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 2.3.3	Bender, D.	2020d	ADM.03503.F.1.A Determination of physico-chemical properties Auto-Ignition Temperature (Liquids and Gases) (EC A.15) Consilab Gesellschaft für Anlagensicherheit mbH, Germany, Report No. CSL-20-0595.03 ADAMA Reference No. 000106481 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 2.4.1/01 (filed in KCP 2.1/01)	Riedl, S.	2021a	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Accelerated Storage Procedure at 54 °C for 2 Weeks Noack Laboratorien GmbH, Germany, Report No. SO20253 / CPL19043 ADAMA Reference No. 000105596 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 2.4.1/02 (filed in KCP 2.1/01)	Riedl, S.	2021a	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Accelerated Storage Procedure at 54 °C for 2 Weeks Noack Laboratorien GmbH, Germany, Report No. SO20253 / CPL19043 ADAMA Reference No. 000105596 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 2.4.2 (filed in KCP 2.1/01)	Riedl, S.	2021a	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Accelerated Storage Procedure at 54 °C for 2 Weeks Noack Laboratorien GmbH, Germany, Report No. SO20253 / CPL19043 ADAMA Reference No. 000105596 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.5.1	Tsesin, N.	2020	Determination of Viscosity Properties of Fluxapyroxad 75 g/L + Prothioconazole 150 g/L EC (ADM.03503.F.1.A) Registration Laboratory, Research and Development Division, ADAMA Makhteshim Ltd., Israel, Report No. 000106627.075FL ADAMA Reference No. 000106627 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 2.5.2	Riedl, S.	2020b	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Determination of Surface Tension Noack Laboratorien GmbH, Germany, Report No. SO20258 / CPT19043 ADAMA Reference No. 000106704 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 2.6.1/01 (filed in KCP 2.5.1/01)	Tsesin, N.	2020	Determination of Viscosity Properties of Fluxapyroxad 75 g/L + Prothioconazole 150 g/L EC (ADM.03503.F.1.A) Registration Laboratory, Research and Development Division, ADAMA Makhteshim Ltd., Israel, Report No. 000106627.075FL ADAMA Reference No. 000106627 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 2.6.1/02	Riedl, S.	2021b	Determination of the Content of the Active Substances and Impurities including Analytical Method Validation and Determination of Density Study SO20252/CGB19043, Report 000106478 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 2.7.1/01 (filed in KCP 2.6.1/02)	Riedl, S.	2021b	Determination of the Content of the Active Substances and Impurities including Analytical Method Validation and Determination of Density Noack Laboratorien GmbH, Germany, Report No. SO20252 / CGB19043 ADAMA Reference No. 000106478 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.7.1/02 (filed in KCP 2.1/01)	Riedl, S.	2021a	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Accelerated Storage Procedure at 54 °C for 2 Weeks Noack Laboratorien GmbH, Germany, Report No. SO20253 / CPL19043 ADAMA Reference No. 000105596 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 2.7.4	Riedl, S.	2020c	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Low Temperature Stability of Liquid Formulations Noack Laboratorien GmbH, Germany, Report No. SO20256 / CLN19043 ADAMA Reference No. 000106479 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 2.7.5	Riedl S.	2022	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): 2-Year Storage Stability Test Noack Laboratorien GmbH, Germany, Report No. SO20254 / CLR19043 ADAMA Reference No. 000105597 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 2.8.2 (filed in KCP 2.1/01)	Riedl, S.	2021a	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Accelerated Storage Procedure at 54 °C for 2 Weeks Noack Laboratorien GmbH, Germany, Report No. SO20253 / CPL19043 ADAMA Reference No. 000105596 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 2.8.6.1 (filed in KCP 2.1/01)	Riedl, S.	2021a	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Accelerated Storage Procedure at 54 °C for 2 Weeks Noack Laboratorien GmbH, Germany, Report No. SO20253 / CPL19043 ADAMA Reference No. 000105596 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1/01 (filed in KCP 2.6.1/02)	Riedl, S.	2021	Determination of the Content of the Active Substances and Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A) - Impurities including Analytical Method Validation and Determination of Density Study SO20252/CGB19043, Report 000106478 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 5.1.1/02 (filed in KCP 2.6.1/02)	Riedl, S.	2021	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A) - Determination of the Content of the Active Substances and Impurities including Analytical Method Validation and Determination of Density Study SO20252/CGB19043, Report 000106478 Noack Laboratorien GmbH, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 5.1.2/01 (filed in KCP 8/ KCA 6.3.2/06)	Huaultmé, J.-M.	2022a	Residue study of fluxapyroxad and prothioconazole and their metabolites in barley raw agricultural commodities after application of ADM.03503.F.1.A under field conditions - Northern Europe - 2021 Study no.: BPL21/962/GC, sponsor no.: 000107616 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 (for a.s. prothioconazole) Data protection has not expired	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/02 (filed in KCP 8/ KCA 6.3.1/03)	Le Mineur, A.	2022	Residue study of Prothioconazole and Fluxapyroxad and their respective metabolites in wheat Raw Agricultural Commodities after foliar application of ADM.03503.F.1.A under field conditions –Northern Europe - 2021 BIOTEK Agriculture, France, Study No.: BPL21/954/GC, EFSA ref. EFSA-2021-00000513, spnosor no.: 000107608 GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Sorate! 250 EC, Reg. no. 156/2023 dated 18.09.23 (for a.s. prothioconazole) Data protection has not expired	ADM
KCP 5.1.2/03 (filed in KCP 10.2.1/01)		2021a	Acute ADM.03503.F.1.A to <i>Oncorhynchus mykiss</i> in a 96-hour semi-static test GLP Unpublished	Y	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 5.1.2/04 (filed in KCP 10.2.1/02)	Juckeland, D.	2021b	Acute toxicity of ADM.03503.F.1.A to <i>Daphnia magna</i> in a 48-hour static test BioChem agrar GmbH, Germany, Study No.: 20 48 ADL 0005, ADAMA Ref No.: 000105070 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 5.1.2/05 (filed in KCP 10.2.1/03)	Juckeland, D.	2021c	Effects of ADM.03503.F.1.A on <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test BioChem agrar GmbH, Germany, Study No.: 20 48 AAL 0007, ADAMA Ref No.: 000105071 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 5.1.2/06 (filed in KCP 10.3.1.2/01)	Dreßler, K.	2021	Chronic toxicity of ADM.03503.F.1.A to the honey bee <i>Apis mellifera</i> L. under laboratory conditions BioChem agrar GmbH, Germany, Study No.: 20 48 BAC 0010, ADAMA Ref No.: 000105073 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/07 (filed in KCP 10.3.1.3/0 1)	Hänsel, M.	2021	ADM.03503.F.1.A – Repeated exposure of honey bee larvae (<i>Apis mellifera</i> L.) under laboratory conditions BioChem agrar GmbH, Germany, Study No.: 20 48 BLC 0012, ADAMA Ref No.: 000105074 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 5.1.2/08	Lindner, M. & Grewe, D.	2021	Validation of an Analytical Method for Determination of Fluxapyroxad in Flowers, Nectar and Pollen Eurofins Agrosience Services Chem GmbH, Germany Study No.: S21-00223, ADAMA Ref No.: 000107307 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 5.1.2/09 (filed in KCP 10.6.2/01)	Friedemann, A.	2021a	Effects of ADM.03503.F.1.A on seedling emergence and seedling growth of six non-target terrestrial plant species under greenhouse conditions BioChem agrar GmbH, Germany, Study No.: 20 46 PSE 0004, ADAMA Ref No.: 000105081 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 5.1.2/10 (filed in KCP 10.6.2/02)	Friedemann, A.	2021b	Effects of ADM.03503.F.1.A on vegetative vigour of six non-target terrestrial plant species under greenhouse conditions BioChem agrar GmbH, Germany, Study No.: 20 46 PVV 0006, ADAMA Ref No.: 000105082 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 5.1.2/11 (filed in KCP 8/ KCA 6.1/01)	Klimmek, S. and Gizler, A.	2017	Freezing storage stability & validation of residues of 1,2,4-Triazole, Triazole Alanine, Triazole Acetic Acid and Triazole Lactic Acid in water, acid and dry matrix: cucumber, grapes and dry bean at 0, 3, 6, 12, 18, 24 and 36 months. Report No.: S12-00072, sponsor no.: 000074067 (R30330) Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B, Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 ADM.03502.F.1.A, ADM.03509.F.1.A and ADM.03501.F.1.A. Data protection has not expired	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/12 (filed in KCP 8/ KCA 6.1/02)	Lefresne, S.	2020	Freezing storage stability of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio in plant matrices at/below -18°C during 24 months (0, 1, 3, 12, 18 and 24 months): Wheat whole plant (high water content), wheat grain (high starch content), wheat straw (difficult commodity), oilseed rape grain (high oil content), strawberry (high acid content) and dry bean (high protein content). Report no. B18S-A4-P-02, Sponsor no. 000107139 (R-39653) POLLENIZ / GIRPA, Beaucouze Cedex, France GLP / GEP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B, Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 ADM.03502.F.1.A, ADM.03509.F.1.A and ADM.03501.F.1.A. Data protection has not expired	ADM
KCP 5.1.2/13 (filed in KCP 8/ KCA 6.3.1/01)	Amic, S.	2020b	Residue study of prothioconazole and its metabolites in wheat whole plant and Raw Agricultural Commodity after one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) - 2 harvest and 2 decline trials – Northern Europe (France, Hungary and Poland) – 2019 Report no. BPL19/762/GC, Sponsor no. 000102751 BIOTEK Agriculture, Saint-Pouange, France GLP / GEP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B, Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	ADM
KCP 5.1.2/14	Gustloff, C.; Wallbaum, P.	2021	Validation of an analytical method for the determination of triazole metabolites (TDMs) in crop matrices of season 2021 Report no. S21-02262, MAC-2135V, Sponsor no. 000107909 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B, Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/15	Lefresne, S.	2021	Validation of an analytical method for the determination of prothioconazole residues in cereals, honey, oilseed rape and sugar beet. Report no. B21S-A4-P-01, EFSA-2021-00003265, Sponsor no. 000108024 GIRPA, Beaucauzé Cedex, France GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	ADM
KCP 5.1.2/16 (filed in KCP 8/ KCA 6.3.2/01)	Amic, S.	2020d	Residue study of prothioconazole and its metabolites in barley whole plant and Raw Agricultural Commodity after one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) - 2 harvest and 2 decline trials – Northern Europe (France, Hungary and Poland) - 2019 Report no. BPL19/764/GC, Sponsor no. 000102753 BIOTEK Agriculture, Saint-Pouange, France GLP / GEP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 and ADM.03509.F.1.A Data protection has not expired	ADM
KCP 5.1.2/17 (filed in KCP 8/ KCA 6.3.2/03)	Huaultmé, J.-M.	2021a	Residue study of prothioconazole and its metabolites, and fenpropidin in barley whole plant and raw agricultural commodity after one foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) - 2 harvest and 2 decline trials – Northern Europe (France, Poland and Hungary) - 2020. Report no.: BPL20/844/GC, sponsor no.: 000105350 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 and ADM.03502.F.1.A Data protection has not expired	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/18 (filed in KCA 6.6.2/01)	Semrau, J.,	2021	Determination of Residues of Prothioconazole and its Metabolites after One Application of MCW-2073 on Bare Soil in Rotational Crops (Radish, Leaf lettuce and Barley) at 2 Sites in Northern Europe and 2 Sites in Southern Europe 2018/2019 Report no. S18-02513, Sponsor no.: 000109154 (R-39638) Eurofins Agrosience Services GmbH, Stade, Germany GLP, Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	ADM
KCP 5.1.2/19	Lindner, M.; Grewe, D.	2020	Validation of an analytical method for the determination of prothioconazole, prothioconazole-desthio and azoxystrobin in nectar, pollen, flower and honey report no.: S19-20860 (MAC-1940V), sponsor no.: 000104134 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP, Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B, Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 ADM.03509.F.1.A and ADM.03501.F.1.A. Data protection has not expired	ADM
KCP 5.2/01	Lefresne, S.	2020	Validation of an analytical method for the determination of prothioconazole residues in honey report no.: B21S-A4-P-04 (MAC-1940V), EFSA-2021-00004881, sponsor no.: 000108774GIRPA, Beaucouzé Cedex, France GLP, Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/02	Lindner, M.	2021	Independent Laboratory Validation of an Analytical method for determination of Prothioconazole residues in honey. Report no. S21-06313 (MAC-2144V), EFSA-2021-00006378, Sponsor no. 000108775 Eurofins Agroscience Services Chem GmbH, GermanyGLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	ADM
KCP 5.2/03	Thies, S.	2015	Independent laboratory validation of the BCS analytical method 01387/M002 for the determination of various pesticides in surface water by HPLC-MS/MS Currenta GmbH & Co. OHG Analytik 51368 Leverkusen Germany, Report no.: 2015/0034/01, Adama reference no. 000110077 GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	ADM
KCP 5.2/04	Brown, S.	2022	Development and Validation of an Analytical Method for Determination of Residues of Prothioconazole-desthio in Body Fluids (Blood) by LC-MS/MS Report no.: RES-00373, EFSA-2021-00006377, Sponsor no.: 000109608 ResChem Analytical Limited, Derby, UK GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/05	Watson, G.	2022	Validation of an analytical method for the determination of residues of prothioconazole-desthio in egg by LC-MS/MS Report no.: RES-00394, Sponsor no.: 000110773 ResChem Analytical Limited, Derby, UK GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B; Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	
KCP 5.2/06	Lindner, M., Büdel, A.	2022	Independent Laboratory Validation of an Analytical Method for the Determination of Residues of Prothioconazole-desthio in Egg by LC-MS/MS Report no.: S22-04421 (MAC-2219V), Sponsor no.: 000111069 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B; Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	
KCP 6.0-1	Adama	2022	DRAFT REGISTRATION REPORT - Part B - Section 3 - Efficacy Data and Information - Detailed summary - Product code: ADM.03503.F.1.A- CORE ASSESSMENT (authorization) ADAMA Makhteshim Ltd Not GEP Unpublished	N	N		ADM
KCP 6.1-001	Voisin, J.F.	2019	An evaluation of different ratios of fluxapyroxad +prothioconazole for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in France, 2019 Agrotest, France, Report No. E-1939 ADAMA Makhteshim Ltd, Report No. FR19FETRZAX112A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-002	Voisin, J.F.	2019	An evaluation of different ratios of fluxapyroxad +prothioconazole for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in France, 2019 Agrotest, France, Report No. E-1940 ADAMA Makhteshim Ltd, Report No. FR19FETRZAX112B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-003	Pierucci, S.	2019	Evaluation of different ratios of fluxapyroxad + prothioconazole for the control of rust (PUCCSP) on Winter wheat in France in 2019 Antedis, France, Report No. ADA-FE19BT-03110-AC ADAMA Makhteshim Ltd, Report No. FR19FETRZAX113A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-004	Hetterich, A.	2019	An evaluation of different ratios of fluxapyroxad + prothioconazole for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in (Germany), 2019 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE19FETRZAW911A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-005	Martin, T.	2019	An evaluation of different ratios of fluxapyroxad + prothioconazole for the control rusts (PUCCSP) on winter wheat in (Germany), 2019 Martin Feldversuchswesen, Germany ADAMA Makhteshim Ltd, Report No. DE19FETRZAW912A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-006	Kay, C.	2019	An evaluation of different ratios of fluxapyroxad + prothioconazole for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in the UK, 2019 OAT, United Kingdom, Report No. 19-1037A-ADA ADAMA Makhteshim Ltd, Report No. UK19FETRZAW350A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-007	Makó, I.	2019	An evaluation of different ratios of fluxapyroxad + prothioconazole for the control rusts (PUCCSP) on winter wheat in Hungary, 2019 SynTech Research, Hungary, Report No. SRHU19-026-135FE ADAMA Makhteshim Ltd, Report No. HU19FETRZAW299A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-008	Tvaruzek, L.	2019	An evaluation of different ratios of fluxapyroxad + prothioconazole for the control of Pyrenophora teres (PYRNTE) on barley in the Czech Republic, 2019 Agricultural Research , Czech Republic ADAMA Makhteshim Ltd, Report No. CZ19FEHORVW353A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-009	Rivet, J.	2019	An evaluation of different ratios of fluxapyroxad + prothioconazole for the control of Rhynchosporium (RHYNSE) on barley, in France 2019 Essais +, France, Report No. 19 38 F 02 ADAMA Makhteshim Ltd, Report No. FR19FEHORVX109B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-010	Kay, C.	2019	An evaluation of different ratios of fluxapyroxad + prothioconazole for the control of Rhynchosporium (RHYNSE) on barley in the UK, 2019 OAT, United Kingdom, Report No. 19-1038A-ADA ADAMA Makhteshim Ltd, Report No. UK19FEHORVX352A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-011	Hrabovsky, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in the Czech Republic, 2020 ZZS Kujavy, Czech Republic, Report No. 20H25 ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW301A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-012	Čáp, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in the Czech Republic in 2021 ZS Nechanice, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FETRZAW300A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-013	Gouille, L.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Puccinia striiformis (PuccST) on winter wheat in France, 2019 Biotek Agriculture, France, Report No. BPE19/286/FGC01 ADAMA Makhteshim Ltd, Report No. FR19FETRZAW110A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-014	Varret, F.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Zymoseptoria tritici (SEPTTR) on winter wheat, in France 2019. Staphyt, France, Report No. FVT 19 40058 FR01 ADAMA Makhteshim Ltd, Report No. FR19FETRZAX108A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-015	Varret, F.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Zymoseptoria tritici (SEPTTR) on winter wheat, in France 2019 Staphyt, France, Report No. FVT 19 40058 FR02 ADAMA Makhteshim Ltd, Report No. FR19FETRZAX108B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-016	Boeuf, V.	2019	Efficacy comparison of ADM.3503.F.1.A with its equivalent tank mix for the control of Brown rust (PUCCRE) on winter wheat in France in 2019 Antedis, France, Report No. ADA FE19BT 03107 AR ADAMA Makhteshim Ltd, Report No. FR19FETRZAX109A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-017	Deberny, E.	2019	Efficacy comparison of ADM.3503.F.1.A with its equivalent tank mix for the control of Brown rust (PUCCRE) on winter wheat in France in 2019 Antedis, France, Report No. ADA FE19BT 03108 CA ADAMA Makhteshim Ltd, Report No. FR19FETRZAX109B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-018	Ternois, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in FRANCE, 2020 Ephydia, France, Report No. FRM 20 F13 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW500A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-019	Flahaut, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in FRANCE, 2020 Staphyt, France, Report No. JFT 20 45675 FR01 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW500B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-020	Lombart, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in France in 2021 Ephydia, France, Report No. FRM 21 F20 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW551A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-021	Flahaut, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in France in 2021 Staphyt, France, Report No. JFT 21 50445 FR01 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW551C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-022	Labusch, U.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in (Germany), 2019 BioChem Agrar, Germany, Report No. 19 1069 5062 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW905A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.1-023	Rohr, J.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in (Germany), 2019 Trial-Tec, Germany, Report No. 19-ADA-HE-WW-071 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW905B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-024	Hetterich, A.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Brown rust (Puccinia) on winter wheat in (Germany), 2019 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE19FETRZAW906A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-025	Wolf, P.	2019	Efficacy of ADM.3503.F.1.A in comparison to the equivalent tank mix vs. Yellow Rust (Puccinia) in Winter Wheat Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE19FETRZAW907A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-026	Perner, J.	2019	Efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Pyrenophora (Drechslera) tritici-repentis (PYRNTR) on winter wheat in Germany, 2019 U.A.S., Germany, Report No. 170_19_Z ADAMA Makhteshim Ltd, Report No. DE19FETRZAW908A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-027	Rohr, J.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Pyrenophora (Drechslera) tritici-repentis (PYRNTR) on winter wheat in (Germany), 2019 Trial-Tec, Germany, Report No. 19-ADA-HE-WW-072 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW908B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-028	Rohr, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in Germany in 2021 Trial-Tec, Germany, Report No. 21-ADA-SH-WW-222 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW500A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-029	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in Ireland, 2020 Eurofins, Ireland, Report No. S20-02701-01 ADAMA Makhteshim Ltd, Report No. IE20FETRZAW301A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-030	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in Ireland in 2021 Eurofins, Ireland, Report No. S21-03031-02 ADAMA Makhteshim Ltd, Report No. IE21FETRZAW322B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-031	Van Tilburg, F.W.G.	2020	Control of Zymoseptoria tritici in winter wheat in the Netherlands, 2020 Eurofins, Netherlands, Report No. S20-02814-01 ADAMA Makhteshim Ltd, Report No. NL20FETRZAW010A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-032	Kay, C.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in the UK, 2019 OAT, United Kingdom, Report No. 19-1034A-ADA ADAMA Makhteshim Ltd, Report No. UK19FETRZAW344A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-033	Kay, C.	2019	An efficacy comparison of ADM.03503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in the UK, 2019 OAT, United Kingdom, Report No. 19-1034B-ADA ADAMA Makhteshim Ltd, Report No. UK19FETRZAW344B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-034	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1022-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW300A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-035	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in the UK in 2021 OAT, United Kingdom, Report No. 21-1074-ADA ADAMA Makhteshim Ltd, Report No. UK21FETRZAW300A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-036	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Poland, 2020 Staphyt, Poland, Report No. APK-20-44718-PL01 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW060A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-037	Rusek, K.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Poland 2020 Fertico, Poland, Report No. 57_01_F20_77 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW060B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.1-038	Rusek, K	2021	Efficacy evaluation of ADM.03503.F.1.A against Zymoseptoria tritici (SEPTTR) on winter wheat in Poland, 2021 Fertico, Poland, Report No. 71_01_F21_178 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW023B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-039	Tuna, V.	2019	Determination of Efficacy of ADM.3503.F.1.A compared to the equivalent tank mix, applied post-emergence against Zymoseptoria tritici (SEPTTR) in Winter Wheat, outdoor 2019 Eurofins, Romania, Report No. S19-03922-01 ADAMA Makhteshim Ltd, Report No. RO19FETRZAW169A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-040	Tuna, V.	2019	Determination of Efficacy of ADM.3503.F.1.A compared to the equivalent tank mix, applied post-emergence against Yellow rust (PUCCST) in Winter Wheat, outdoor 2019 Eurofins, Romania, Report No. S19-03923-01 ADAMA Makhteshim Ltd, Report No. RO19FETRZAW170A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-041	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW248A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-042	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW248B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.1-043	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02892-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW215A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-044	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02892-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW215B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-045	Hudec, K.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Brown rust (Puccinia) on winter wheat in Slovakia, 2019 Blumeria Consulting, Slovakia ADAMA Makhteshim Ltd, Report No. SK19FETRZAW345A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-046	Ondisová, M.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in Slovakia, 2020 UKSUP, Slovakia, Report No. KE-F-04-2020 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW301A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-047	Hudec, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in Slovakia, 2020 Blumeria Consulting, Slovakia, Report No. ADA-301B-O ADAMA Makhteshim Ltd, Report No. SK20FETRZAW301B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.1-048	Forgáčová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in (Slovakia) in 2021 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW300A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-049	Bataille, C.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against net blotch on winter barley CRA W, Belgium, Report No. MAL HORVW 21 E 19 ADAMA Makhteshim Ltd, Report No. BE21FEHORVW035A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-050	Čáp, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in the Czech Republic, 2020 ZS Nechanice, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ20FEHORVS315A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-051	Negrini, P.	2019	Efficacy comparison of ADM.3503.F.1.A to the equivalent tank mix for the control of RAMUCC and PYRNTE on Barley in France in 2019 Antedis, France, Report No. ADA FE19OH 03109 CA ADAMA Makhteshim Ltd, Report No. FR19FEHORVX107A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-052	Flahaut, J.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Pyrenophora teres (PYRNTE) and Rhynchosporium secalis (RHYNSE) on barley in France, 2019 Staphyt, France, Report No. JFT 19 40084 FR01 ADAMA Makhteshim Ltd, Report No. FR19FEHORVX108A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-053	Voisin, J.F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on barley in FRANCE, 2020 Agrotest, France, Report No. E-2018 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW512C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-054	Wallart, F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Leaf Blotch) on barley in France, 2020 Ephydia, France, Report No. FRM-20-F19 ADAMA Makhteshim Ltd, Report No. FR20FEHORVX514A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-055	Biaunier, M.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in FRANCE, 2020 Qualiphyt, France, Report No. QUALI20100F25 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW514C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-056	Rouane, W.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on barley in France, 2020 Anadiag, France, Report No. FR203031PS303 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW517B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-057	Wallart, F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on barley in France, 2020 Ephydia, France, Report No. FRM-20-F18 ADAMA Makhteshim Ltd, Report No. FR20FEHORVX512A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-058	Negrini, P	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC on Barley in France in 2020 Antedis, France, Report No. ADA-FE20OH-05273-PR ADAMA Makhteshim Ltd, Report No. FR20FEHORVX517A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-059	Wallart, F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in France in 2021 Ephydia, France, Report No. FRM-21-F19 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW558B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-060	Biaunier, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in FRANCE in 2021 Qualiphyt, France, Report No. QUALI21107D07 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW559A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-061	Biaunier, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in FRANCE in 2021 Qualiphyt, France, Report No. QUALI21107F15 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW559B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-062	Hetterich, A.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Rhynchosporium (RHYNSE) on barley (Germany), 2019 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW909A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-063	Thomas Martin	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Rhynchosporium (RHYNSE) on barley (Germany), 2019 Martin Feldversuchswesen, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW909B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-064	Peter Wolf	2019	Efficacy of ADM.3503.F.1.A compared to the equivalent active ingredients in tank mix for the control of Pyrenophora teres (PYRNTE) in Barley Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW910B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-065	Magyaróvári, V.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on barley in Germany, 2020 Agrartest, Germany, Report No. S20-03247 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW228A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-066	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-HE-WG-147 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW229A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-067	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (Ramularia collo-cygni) on barley in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWG 20 ADA 231A ADAMA Makhteshim Ltd, Report No. DE20FEHORVW231A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-068	Peter Wolf	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (Ramularia collo-cygni) on Barley Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE20FEHORVW231B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-069	Martin, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (Ramularia collo-cygni) on barley in Germany in 2021 Martin Feldversuchswesen, Germany, Report No. FWG 21 ADA 507A ADAMA Makhteshim Ltd, Report No. DE21FEHORVX507A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-070	Perner, J.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in Germany in 2021 U.A.S., Germany, Report No. 148_21_Z ADAMA Makhteshim Ltd, Report No. DE21FEHORVX508A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-071	Ommen, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (Ramularia) on barley in Germany in 2021 Plantus, Germany, Report No. 21F-2-PLA-017 ADAMA Makhteshim Ltd, Report No. DE21FEHORVX510A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-072	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RAMUCC (Ramularia collo-cygni) on barley in Ireland, 2020 Eurofins, Ireland, Report No. S20-02702-01 ADAMA Makhteshim Ltd, Report No. IE20FEHORVX318A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP.6.1-073	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03032-01 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX323A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP.6.1-074	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03032-02 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX323B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP.6.1-075	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (Ramularia) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03303-01 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX325A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP.6.1-076	Joynt, R.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Rhynchosporium (RHYNSE) on barley in the UK, 2019 ADAS, Ireland, Report No. WA19-WB-Adama-9T (348) ADAMA Makhteshim Ltd, Report No. UK19FEHORVX348A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP.6.1-077	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1028A-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX314A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-078	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (Ramularia collo-eygmi) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1030-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX317A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-079	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in the UK in 2021 OAT, United Kingdom, Report No. 21-1079B-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX308B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-080	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in the UK in 2021 Eurofins, Derby, United Kingdom, Report No. S21-03034-01 ADAMA Makhteshim Ltd, Report No. UK21FEHORVX308C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-081	Sawinska, Z.	2020	The evaluation of efficacy ADM.03503.F.1.A and ADM.01352.F.3.A in fungal diseases control in winter barley cultivation, Poland 2020 Poznań University, Poland, Report No. AF/20/JO/19/Pr/067A ADAMA Makhteshim Ltd, Report No. PL20FEHORVW067A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-082	Kukuła, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on barley in Poland, 2020 Agreco, Poland, Report No. 20ADA0677-1 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW067B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-083	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Poland, 2020 Fertico, Poland, Report No. 61_01_F20_81 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW068A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-084	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Poland, 2020 Staphyt, Poland, Report No. APK-20-44722-PL01 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW068B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-085	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against Rhynchosporium secalis (RHYNSE) on winter barley in Poland, 2021 Fertico, Poland, Report No. 75_01_F21_182 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW030A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-086	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter barley cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/JO/9/ZI/030B ADAMA Makhteshim Ltd, Report No. PL21FEHORVW030B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-087	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against Pyrenophora teres (PYRNTE) on winter barley in Poland, 2021 Fertico, Poland, Report No. 76_01_F21_183 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW031A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-088	Tuna, V.	2019	Determination of Efficacy of ADM.3503.F.1.A compared to the equivalent tank mix, applied post emergence against Pyrenophora teres (PYRNTE) in barley, outdoor 2019 Eurofins, Romania, Report No. S19-03924-01 ADAMA Makhteshim Ltd, Report No. RO19FEHORVW171A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-088	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (Rhynchosporium secalis) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW246B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-090	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW247A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-091	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW247B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-092	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02898-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW211A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-093	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02898-02 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW211B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-094	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02899-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW212A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-095	Holcikova, D.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Rhynchosporium (RHYNSE) on barley Slovakia, 2019 FYSE,Slovakia, Report No. FYSE-103201915 ADAMA Makhteshim Ltd, Report No. SK19FEHORVW348A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-096	Kovacova Holcikova, D.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (Rhynchosporium secalis) on barley in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE103202015 ADAMA Makhteshim Ltd, Report No. SK20FEHORVW313A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-097	Tóth, F.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (Rhynchosporium secalis) on barley in Slovakia, 2020 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW313B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-098	Forgáčová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in Slovakia, 2020 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW315A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-099	Kováčová Holčíková, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in (Slovakia) in 2021 Berberis, Slovakia, Report No. SK21FEHORVW307A - ZV04 ADAMA Makhteshim Ltd, Report No. SK21FEHORVW307A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-100	Kováčová Holčíková, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in (Slovakia) in 2021 Berberis, Slovakia, Report No. SK21FEHORVW308A- ZV03 ADAMA Makhteshim Ltd, Report No. SK21FEHORVW308A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-101	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on rye in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WR-148 ADAMA Makhteshim Ltd, Report No. DE20FESECSS232A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-102	Magyaróvári, V.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on rye in Germany, 2020 Agrartest, Germany, Report No. S20-03246-01 ADAMA Makhteshim Ltd, Report No. DE20FESECSS232B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-103	Wied, H.M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRE (Puccinia recondita) on rye in Germany in 2021 Staphyt, Germany, Report No. HWD-21-50086-DE01 ADAMA Makhteshim Ltd, Report No. DE21FESECSS511A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-104	Zöllner, H.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on rye in Germany in 2021 Field Research Support, Germany, Report No. FRS105/21 ADAMA Makhteshim Ltd, Report No. DE21FESECSS511B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-105	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A and ADM.01352.F.3.A in fungal diseases control in winter rye , Poland, 2020 Poznań University, Germany, Report No. AF/20/ŻO/19/BR/070A ADAMA Makhteshim Ltd, Report No. PL20FESECSS070A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-106	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter rye cultivation, Poland, 2021 Poznań University, Germany, Report No. AF/21/ŻO/9/Br/033A ADAMA Makhteshim Ltd, Report No. PL21FESECSS033A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-107	Maesim, C.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on rye in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02902-01 ADAMA Makhteshim Ltd, Report No. RO21FESECSS214A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.1-108	Maesim, C.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on rye in ROMANIA in 2021 Eurofins, Romania, Report No. S21-04520-01 ADAMA Makhteshim Ltd, Report No. RO21FESECSS250A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-001	Herzmaier, C.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of <i>Puccinia triticina</i> (brown rust) on winter wheat, GEP Trial, AUSTRIA, 2020 Staphyt, Austria, Report No. HWD-20-45585-AT01 ADAMA Makhteshim Ltd, Report No. AT20FETRZAW221A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-002	Kempernek, H.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (DTR) on winter wheat, GEP Trial, AUSTRIA, 2020 Staphyt, Austria, Report No. HWD-20-45586-AT01 ADAMA Makhteshim Ltd, Report No. AT20FETRZAW224A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-003	Bataille, C.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against brown rust on winter wheat CRA W, Belgium, Report No. MAL2021-04 ADAMA Makhteshim Ltd, Report No. BE21FETRZAW034A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-004 Submitted under KCP 6.1-011	Hrabovsky, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in the Czech Republic, 2020 ZZS Kujavy, Czech Republic, Report No. 20H25 ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW301A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-005	Bezdičková, B.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT (brown rust) on winter wheat in the Czech Republic, 2020 Ditana, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW303A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-006	Bauer, T.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (Pyrenophora tritici-repentis) on winter wheat in the Czech Republic, 2020 InTec Agro Trials, Czech Republic, Report No. F-20-G-574-01 ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW308A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-007	Bezdičková, A.	2020	An efficacy evaluation of ADM.03503.F.1.A against Fusarium and Microdochium at T3 on winter wheat in the Czech Republic, 2020 Ditana, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW309A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-008 Submitted under KCP 6.1-012	Čáp, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in the Czech Republic in 2021 ZS Nechanice, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FETRZAW300A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-009	Bezdičková, A.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium and Microdochium in winter wheat at T3 in the Czech Republic in 2021 Ditana, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FETRZAW305A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-010 Submitted under KCP 6.1-013	Gouille, L.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Puccinia striiformis (PUCCST) on winter wheat in France, 2019 Biotek Agriculture, France, Report No. BPE19/286/FGC01 ADAMA Makhteshim Ltd, Report No. FR19FETRZAW110A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-011 Submitted under KCP 6.1-014	Varret, F.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat, in France 2019. Staphyt, France, Report No. FVT 19 40058 FR01 ADAMA Makhteshim Ltd, Report No. FR19FETRZAX108A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-012 Submitted under KCP 6.1-015	Varret, F.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat, in France 2019. Staphyt, France, Report No. FVT 19 40058 FR02 ADAMA Makhteshim Ltd, Report No. FR19FETRZAX108B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-013 Submitted under KCP 6.1-016	Boeuf, V.	2019	Efficacy comparison of ADM.3503.F.1.A with its equivalent tank mix for the control of Brown rust (PUCCRE) on winter wheat in France in 2019 Antedis, France, Report No. ADA FE19BT 03107 AR ADAMA Makhteshim Ltd, Report No. FR19FETRZAX109A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-014 Submitted under KCP 6.1-017	Deberny, E.	2019	Efficacy comparison of ADM.3503.F.1.A with its equivalent tank mix for the control of Brown rust (PUCCRE) on winter wheat in France in 2019 Antedis, France, Report No. ADA FE19BT 03108 CA ADAMA Makhteshim Ltd, Report No. FR19FETRZAX109B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-015 Submitted under KCP 6.1-018	Ternois, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in FRANCE, 2020 Ephydia, France, Report No. FRM 20 F13 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW500A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-016 Submitted under KCP 6.1-019	Flahaut, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in FRANCE, 2020 Staphyt, France, Report No. JFT-20-45675-FR01 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW500B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-017	Biaunier, M.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in FRANCE, 2020 Qualiphyt, France, Report No. QUALI20098A21 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW502A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-018	Crepin, D.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A against brown rust on winter wheat, in France in 2020 Essais +, France, Report No. 20-38-F-13 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW502B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-019	Lombart, L.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PuccSI (yellow rust) on winter wheat in France, 2020 Ephydia, France, Report No. FRM-20-F14 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW504A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-020	Maitte, B.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PuccSI (yellow rust) on winter wheat in FRANCE, 2020 Promo Vert, France, Report No. 20F-FCEADA-FR15 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW504C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-021	Lombart, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in France, 2020 Ephydia, France, Report No. FRM-20-F15 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW506A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-022	Jondot, A.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT on Winter Wheat in France in 2020 Antedis, France, Report No. ADA-FE20BT-05271-SV ADAMA Makhteshim Ltd, Report No. FR20FETRZAW506B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-023	Ballan, J.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT, SEPTTR and PUCCSI on Winter Wheat in France in 2020 Antedis, France, Report No. ADA-FE20BT-05272-JA ADAMA Makhteshim Ltd, Report No. FR20FETRZAW506C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-024	Lombart, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in France, 2020 Ephydia, France, Report No. FRM-20-F16 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW509A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-025	Biaunier, M.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in FRANCE, 2020 Qualiphyt, France, Report No. QUALI20099H07 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW509C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2-026 Submitted under KCP 6.1-020	Lombart, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in France in 2021 Ephydia, France, Report No. FRM 21 F20 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW551A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-027 Submitted under KCP 6.1-021	Flahaut, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in France in 2021 Staphyt, France, Report No. JFT 21 50445 FR01 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW551C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-028	Crepin, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in FRANCE in 2021 Essais r, France, Report No. 21 38 F 27 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW552A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-029	Voisin, J.F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in FRANCE in 2021 Agrotest, France, Report No. E 2154 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW552C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-030	Gouaille, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCSI (Puccinia striiformis tritici) on winter wheat in France in 2021 Biotek Agriculture, France, Report No. BPE21/205/FGC01 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW553B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2-031	Lombart, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) and SEPTTR (Septoria) on winter wheat in France in 2021 Ephydia, France, Report No. FRM 21 F21 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW554A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-032	Biaunier, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium (FUSACU in artificial contamination) in winter wheat at T3 in FRANCE in 2021 Qualiphyt, France, Report No. QUALI21106E23 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW556B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-033 Submitted under KCP 6.1-022	Labusch, U.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in (Germany), 2019 BioChem Agrar, Germany, Report No. 19 1069 5062 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW905A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-034 Submitted under KCP 6.1-023	Rohr, J.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in (Germany), 2019 Trial-Tec, Germany, Report No. 19-ADA-HE-WW-071 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW905B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-035 Submitted under KCP 6.1-024	Hetterich, A.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Brown rust (PUCCRT) on winter wheat in (Germany), 2019 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE19FETRZAW906A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-036 Submitted under KCP 6.1-025	Wolf, P.	2019	Efficacy of ADM.3503.F.1.A in comparison to the equivalent tank mix vs. Yellow Rust (PUCCSI) in Winter Wheat Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE19FETRZAW907A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-037 Submitted under KCP 6.1-026	Perner, J.	2019	Efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Pyrenophora (Drechslera) tritici-repentis (PYRNTR) on winter wheat in Germany, 2019 U.A.S., Germany, Report No. 170_19_Z ADAMA Makhteshim Ltd, Report No. DE19FETRZAW908A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-038 Submitted under KCP 6.1-027	Rohr, J.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Pyrenophora (Drechslera) tritici-repentis (PYRNTR) on winter wheat in (Germany), 2019 Trial-Tec, Germany, Report No. 19-ADA-HE-WW-072 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW908B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-039	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of Puccinia (brown rust) on winter wheat in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWW 20 ADA 221A ADAMA Makhteshim Ltd, Report No. DE20FETRZAW221A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-040	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of Puccinia (brown rust) on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WW-141 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW221B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-041	Magyaróvári, V.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of Puccinia (yellow rust) on winter wheat in Germany, 2020 Agrartest, Germany, Report No. S20-03244-01 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW222A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-042	Lamers, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of Puccinia (yellow rust) on winter wheat in Germany, 2020 BioChem Agrar, Germany, Report No. 20 1069 5128 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW222B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-043	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Erysiphe (powdery mildew) on winter wheat in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWW 20 ADA 223A ADAMA Makhteshim Ltd, Report No. DE20FETRZAW223A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-044	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Erysiphe (powdery mildew) on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WW-142 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW223B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-045	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (Pyrenophora tritici-repentis) on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WW-143 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW224A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-046	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (Pyrenophora tritici-repentis) on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-HE-WW-144 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW224B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-047	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (Pyrenophora tritici-repentis) on winter wheat in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWW 20 ADA 224C ADAMA Makhteshim Ltd, Report No. DE20FETRZAW224C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-048	Lamers, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in Germany, 2020 BioChem Agrar, Germany, Report No. 20 1069 5129 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW225A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-049	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-HE-WW-145 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW225B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-050 Submitted under KCP 6.1-028	Rohr, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in Germany in 2021 Trial-Tec, Germany, Report No. 21-ADA-SH-WW-222 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW500A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-051	Hapke, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in Germany in 2021 Acceres, Germany, Report No. F21NMW35 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW501A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-052	Endres, U.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in Germany in 2021 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE21FETRZAW501B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-053	Torkler, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in Germany in 2021 Quintus, Germany, Report No. K-136-QUI-21-235 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW502A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-054	Wolf, P.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Zymoseptoria tritici (SEPTTR) on winter wheat in Germany in 2021 Agricola, Germany, ADAMA Makhteshim Ltd, Report No. DE21FETRZAW503A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-055	Perner, J.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in Germany in 2021 U.A.S., Germany, Report No. 147_21_Z ADAMA Makhteshim Ltd, Report No. DE21FETRZAW503B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-056	Rohr, H.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTR (DTR) on winter wheat in Germany in 2021 Trial-Tec, Germany, Report No. 21-ADA-SH-WW-223 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW504A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-057	Maleck, A.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR on winter wheat in Germany in 2021 Agro-check, Germany, Report No. AC/21/050 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW504B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-058	Zickart, U.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR on winter wheat in Germany in 2021 BioChem Agrar, Germany, Report No. 21 1064 1192 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW504C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-059	Rohr, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium and Microdochium in winter wheat at T3 in Germany in 2021 Trial-Tec, Germany, Report No. 21-ADA-HE-WW-224 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW505A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-060	Endres, U.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium and Microdochium in winter wheat at T3 in Germany in 2021 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE21FETRZAW505B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-061 Submitted under KCP 6.1-029	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in Ireland, 2020 Eurofins, Ireland, Report No. S20-02701-01 ADAMA Makhteshim Ltd, Report No. IE20FETRZAW301A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-062 Submitted under KCP 6.1-030	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in Ireland in 2021 Eurofins, Ireland, Report No. S21-03031-02 ADAMA Makhteshim Ltd, Report No. IE21FETRZAW322B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-063 Submitted under KCP 6.1-031	Van Tilburg, F.W.G.	2020	Control of Zymoseptoria tritici in winter wheat in the Netherlands, 2020 Eurofins, Netherlands, Report No. S20-02814-01 ADAMA Makhteshim Ltd, Report No. NL20FETRZAW010A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-064	Van Tilburg, F.W.G.	2020	Control of Puccinia recondita in winter wheat in the Netherlands, 2020 Eurofins, Netherlands, Report No. S20-02815-01 ADAMA Makhteshim Ltd, Report No. NL20FETRZAW011A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-065 Submitted under KCP 6.1-032	Kay, C.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in the UK, 2019 OAT, United Kingdom, Report No. 19-1034A-ADA ADAMA Makhteshim Ltd, Report No. UK19FETRZAW344A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-066 Submitted under KCP 6.1-033	Kay, C.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in the UK, 2019 OAT, United Kingdom, Report No. 19-1034B-ADA ADAMA Makhteshim Ltd, Report No. UK19FETRZAW344B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-067 Submitted under KCP 6.1-034	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1022-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW300A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-068	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRT (brown rust) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1023-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW302A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-069	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1024-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW304A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-070	Armstrong, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in the UK, 2020 Armstrong Fisher, United Kingdom, Report No. 1024-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW304B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-071	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1025-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW306A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2- 072	Joynt, R.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in the UK, 2020 ADAS, United Kingdom, Report No. GT20/031 ADAMA Makhteshim Ltd, Report No. UK20FETRZAW309A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 073	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in the UK, 2020 Eurofins, Derby, United Kingdom, Report No. S20-02732-01 ADAMA Makhteshim Ltd, Report No. UK20FETRZAW309B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 074 Submitted under KCP 6.1- 035	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in the UK in 2021 OAT, United Kingdom, Report No. 21-1074-ADA ADAMA Makhteshim Ltd, Report No. UK21FETRZAW300A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 075	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Puccrt (Brown rust) on winter wheat in the UK in 2021 OAT, United Kingdom, Report No. 1075-21-ADA ADAMA Makhteshim Ltd, Report No. UK21FETRZAW301A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 076	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PuccSI (Yellow rust) on winter wheat in the UK in 2021 OAT, United Kingdom, Report No. 21-1076-ADA ADAMA Makhteshim Ltd, Report No. UK21FETRZAW302A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-077	Joynt, R.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in the UK in 2021 ADAS, United Kingdom, Report No. GT21-035 ADAMA Makhteshim Ltd, Report No. UK21FETRZAW303A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-078	Joynt, R.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium and Microdochium in winter wheat at T3 in the UK in 2021 ADAS, United Kingdom, Report No. GT21-036 ADAMA Makhteshim Ltd, Report No. UK21FETRZAW305A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-079 Submitted under KCP 6.1-036	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in Poland, 2020 Staphyt, Poland, Report No. APK-20-44718-PL01 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW060A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-080 Submitted under KCP 6.1-037	Rusek, K.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in Poland 2020 Fertico, Poland, Report No. 57_01_F20_77 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW060B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-081	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A and ADM.01352.F.3.A in fungal diseases control in winter wheat, Poland 2020 Poznań University, Poland, Report No. AF/20/PO/19/BR/061A ADAMA Makhteshim Ltd, Report No. PL20FETRZAW061A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-082	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of Puccrt (brown rust) on winter wheat in Poland 2020 Fertico, Poland, Report No. 58_01_F20_78 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW061B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-083	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PuccSI (yellow rust) on winter wheat in Poland, 2020 Staphyt, Poland, Report No. APK-20-44719-PL01 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW062A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-084	Kukuła, A.	2020	The evaluation of efficacy of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of fungal diseases on winter wheat Agreco, Poland, Report No. 20ADA0692-1 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW062B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-085	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A in fungal diseases control in winter wheat cultivation, Poland 2020 Poznań University, Poland, Report No. AF/20/PO/19/Pr/063A ADAMA Makhteshim Ltd, Report No. PL20FETRZAW063A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-086	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in Poland, 2020 Fertico, Poland, Report No. 59_01_F20_79 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW063B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-087	Kukuła, A.	2020	The evaluation of efficacy of ADM.03503.F.1.A , ADM.01352.F.3.A for the control of fungal diseases on winter wheat Agreco, Poland, Report No. 20ADA0693-1 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW064A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-088	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (Pyrenophora tritici-repentis) on winter wheat in Poland, 2020 Staphyt, Poland, Report No. APK-20-44720-PL01 PHA ADAMA Makhteshim Ltd, Report No. PL20FETRZAW064B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-089	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A in fungal diseases control in winter wheat cultivation, Poland 2020 Poznań University, Poland, Report No. AF/20/PO/19/Pr/065A ADAMA Makhteshim Ltd, Report No. PL20FETRZAW065A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-090	Kukuła, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in Poland, 2020 Agreco, Poland, Report No. 20ADA0694-1 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW065B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-091 Submitted under KCP 6.1-038	Rusek, K	2021	Efficacy evaluation of ADM.03503.F.1.A against Zymoseptoria tritici (SEPTTR) on winter wheat in Poland, 2021 Fertico, Poland, Report No. 71_01_F21_178 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW023B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-092	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter wheat cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/PO/9/Pr/024A ADAMA Makhteshim Ltd, Report No. PL21FETRZAW024A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-093	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PuccRT (Brown rust) on winter wheat in Poland in 2021 Staphyt, Poland, Report No. MP2-21-50274-PL01 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW024B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-094	Gajek, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PuccSI (Yellow rust) on winter wheat in Poland in 2021 Agro Research Consulting, Poland, Report No. ARC21_TRZAW_ADAM_09 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW025A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-095	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against Puccinia striiformis tritici (PuccSI) on winter wheat in Poland, 2021 Fertico, Poland, Report No. 72_01_F21_179 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW025B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-096	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in Poland in 2021 Staphyt, Poland, Report No. MP2-21-50275-PL01 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW026A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-097	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against Pyrenophora tritici repentis (PYRNTR) on winter wheat in Poland, 2021 Fertico, Poland, Report No. 73_01_F21_180 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW027A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-098	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium and Microdochium in winter wheat at T3 in Poland in 2021 Staphyt, Poland, Report No. MP2-21-50278-PL01 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW028A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-099	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter wheat cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/PO/9/Pr/028B ADAMA Makhteshim Ltd, Report No. PL21FETRZAW028B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-100	Nagy, Z.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-116-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW511A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-101	Makó, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-117-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW511B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-102	Rábai, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Puccinia (yellow rust) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-112-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW512A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP.6.2- 103	Németh, S.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-115-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW514B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP.6.2- 104	Juhász, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in Hungary, 2020 SGS, Hungary, Report No. 20-FE-04-SG1 ADAMA Makhteshim Ltd, Report No. HU20FETRZAW514C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP.6.2- 105	Nagy, Z.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Puccrt (Brown rust) on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-090-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW301A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP.6.2- 106	Ritecz, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Puccrt (Brown rust of wheat) on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-091-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW302A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP.6.2- 107	Makó, I.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-093-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW304A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2- 108	Nagy, Z.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium and Microdochium in winter wheat at T3 in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-096-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW305A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 109 Submitted under KCP 6.1- 039	Tuna, V.	2019	Determination of Efficacy of ADM.3503.f.1.A compared to the equivalent tank mix, applied post-emergence against Zymoseptoria tritici (SEPTTR) in Winter Wheat, outdoor 2019 Eurofins, Romania, Report No. S19-03922-01 ADAMA Makhteshim Ltd, Report No. RO19FETRZAW169A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 110 Submitted under KCP 6.1- 040	Tuna, V.	2019	Determination of Efficacy of ADM.3503.F.1.A compared to the equivalent tank mix, applied post-emergence against Yellow-rust (PUCCST) in Winter Wheat, outdoor 2019 Eurofins, Romania, Report No. S19-03923-01 ADAMA Makhteshim Ltd, Report No. RO19FETRZAW170A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 111 Submitted under KCP 6.1- 041	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW248A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 112 Submitted under KCP 6.1- 042	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW248B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2- 113	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Puccrt (brown rust) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW249A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 114	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Puccrt (brown rust) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW249B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 115	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Puccsi (yellow rust) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW250A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 116	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Puccsi (yellow rust) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW250B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 117	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ErysGT (powdery mildew) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW251A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2- 118	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW251B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 119	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW252A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 120	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW252B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 121	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02895-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW213A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 122	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02895-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW213B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2- 123 Submitted under KCP 6.1- 043	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02892-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW215A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 124 Submitted under KCP 6.1- 044	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02892-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW215B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 125	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PuccRT (Brown rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02893-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW216A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 126	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PuccRT (Brown rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02893-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW216B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 127	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PuccST (Yellow rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02894-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW217B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2- 128	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PuccSI (Yellow rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02894-03 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW217C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 129	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium and Microdochium in winter wheat at T3 in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02896-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW219A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 130 Submitted under KCP 6.1- 045	Hudec, K.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Brown rust (PuccRT) on winter wheat in Slovakia, 2019 Blumeria Consulting, Slovakia ADAMA Makhteshim Ltd, Report No. SK19FETRZAW345A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 131 Submitted under KCP 6.1- 046	Ondisová, M.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in Slovakia, 2020 UKSUP, Slovakia, Report No. KE-F-04-2020 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW301A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 132 Submitted under KCP 6.1- 047	Hudec, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in Slovakia, 2020 Blumeria Consulting, Slovakia, Report No. ADA-301B-O ADAMA Makhteshim Ltd, Report No. SK20FETRZAW301B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 133	Kovacova, D.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PuccRT (brown rust) on winter wheat in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE-103202016 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW303A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2-134	Tóth, F.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT (brown rust) on winter wheat in Slovakia, 2020 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FETRZAW303B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-135	Kovacova Holcikova, D	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCSI (yellow rust) on winter wheat in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE103202017 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW305A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-136	Forgáčová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCSI (yellow rust) on winter wheat in Slovakia, 2020 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FETRZAW305B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-137	Malovcová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in Slovakia, 2020 NPPC - VURV Piestany, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FETRZAW306A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-138	Kovacova, D.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE-103202018 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW309A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-139 Submitted under KCP 6.1-048	Forgáčová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in (Slovakia) in 2021 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW300A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2-140	Forgáčová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Puccrt (Brown rust) on winter wheat in (Slovakia) in 2021 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW301A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-141	Tóth, F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PuccSI (Yellow rust) on winter wheat in (Slovakia) in 2021 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW302A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-142	Malovcová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in (Slovakia) in 2021 NPPC - VURV Piestany, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW303A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-143	Hudec, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium and Microdochium in winter wheat at T3 in (Slovakia) in 2021 Blumeria Consulting, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW305A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-144 Submitted under KCP 6.1-049	Bataille, C.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against net blotch on winter barley CRA W, Belgium, Report No. MAL HORVW 21 E 19 ADAMA Makhteshim Ltd, Report No. BE21FEHORVW035A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2-145	Roslapi, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley in the Czech Republic, 2020 ZZS Kujavy, Czech Republic, Report No. R20/04 ADAMA Makhteshim Ltd, Report No. CZ20FEHORVS311A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-146 Submitted under KCP 6.1-050	Čáp, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in the Czech Republic, 2020 ZS Nechanice, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ20FEHORVS315A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-147	Čáp, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in the Czech Republic in 2021 ZS Nechanice, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FEHORVS306A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-148	Bezdičková, A.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in the Czech Republic in 2021 Ditana, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FEHORVS307A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-149 Submitted under KCP 6.1-051	Negrini, P	2019	Efficacy comparison of ADM.3503.F.1.A to the equivalent tank mix for the control of RAMUCC and PYRNTE on Barley in France in 2019 Antedis, France, Report No. ADA-FE19OH-03109-CA ADAMA Makhteshim Ltd, Report No. FR19FEHORVX107A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2- 150 Submitted under KCP 6.1- 052	Flahaut, J.	2019	An efficacy comparison of ADM.03503.F.1.A compared to the equivalent tank mix for the control of <i>Pyrenophora teres</i> (PYRNTE) and <i>Rhynchosporium secalis</i> (RHYNSE) on barley in France, 2019 Staphyt, France, Report No. JFT 19 40084 FR01 ADAMA Makhteshim Ltd, Report No. FR19FEHORVX108A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 151	Lombart, L.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in France, 2020 Ephydia, France, Report No. FRM 20 F17 ADAMA Makhteshim Ltd, Report No. FR20FEHORVX510A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 152	Flahaut, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (leaf blotch) and PYRNTE (net blotch) on barley in FRANCE, 2020 Staphyt, France, Report No. JFT 20 45676 FR01 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW510B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 153 Submitted under KCP 6.1- 053	Voisin, J.F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in FRANCE, 2020 Agrotest, France, Report No. E 2018 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW512C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 154 Submitted under KCP 6.1- 054	Wallart, F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Leaf Blotch) on barley in France, 2020 Ephydia, France, Report No. FRM 20 F19 ADAMA Makhteshim Ltd, Report No. FR20FEHORVX514A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-155 Submitted under KCP 6.1-055	Biaunier, M.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in FRANCE, 2020 Qualiphyt, France, Report No. QUALI20100F25 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW514C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-156	Voisin, J.F.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in FRANCE, 2020 Agrotest, France, Report No. E-2020 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW516D GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-157 Submitted under KCP 6.1-056	Rouane, W.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on barley in France, 2020 Anadiag, France, Report No. FR203031PS303 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW517B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-158 Submitted under KCP 6.1-057	Wallart, F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on barley in France, 2020 Ephydia, France, Report No. FRM-20-F18 ADAMA Makhteshim Ltd, Report No. FR20FEHORVX512A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-159 Submitted under KCP 6.1-058	Negrini, P.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC on Barley in France in 2020 Antedis, France, Report No. ADA-FE20OH-05273-PR ADAMA Makhteshim Ltd, Report No. FR20FEHORVX517A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2- 160	Rouane, W.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in France in 2021 Anadiag, France, Report No. FR213045DP303 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW557B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 161	Lombart, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in France in 2021 Ephydia, France, Report No. FRM 21 F23 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW557C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 162 Submitted under KCP 6.1- 059	Wallart, F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in France in 2021 Ephydia, France, Report No. FRM 21 F19 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW558B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 163 Submitted under KCP 6.1- 060	Biaunier, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in FRANCE in 2021 Qualiphyt, France, Report No. QUALI21107D07 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW559A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 164 Submitted under KCP 6.1- 061	Biaunier, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in FRANCE in 2021 Qualiphyt, France, Report No. QUALI21107F15 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW559B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2- 165	Gouaille, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (<i>Blumeria graminis hordei</i>) on winter barley in France in 2021. Biotek Agriculture, France, Report No. BPE21/206/FGC01 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW560B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 166	Voisin J.F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in France in 2021 Agrotest, France, Report No. E-2156 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW560C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 167 Submitted under KCP 6.1- 062	Hetterich, A.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Rhynchosporium</i> (RHYNSE) on barley (Germany), 2019 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW909A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 168 Submitted under KCP 6.1- 063	Thomas Martin	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Rhynchosporium</i> (RHYNSE) on barley (Germany), 2019 Martin Feldversuchswesen, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW909B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 169 Submitted under KCP 6.1- 064	Peter Wolf	2019	Efficacy of ADM.3503.F.1.A compared to the equivalent active ingredients in tank mix for the control of <i>Pyrenophora teres</i> (PYRNTE) in Barley Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW910B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2-170	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on winter barley in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SN-WG-146 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW227A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-171	Holger Teresiak	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on winter barley in Germany, 2020 Agro-check, Germany, Report No. AC/20/090 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW227B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-172 Submitted under KCP 6.1-065	Magyaróvári, V.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on barley in Germany, 2020 Agrartest, Germany, Report No. S20-03247 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW228A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-173 Submitted under KCP 6.1-066	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-HE-WG-147 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW229A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-174	Lamers, K	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Germany, 2020 BioChem Agrar, Germany, Report No. 20 1069 5130 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW230A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2-175	Magyaróvári, V.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Germany, 2020 Agrartest, Germany, Report No. S20-03245 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW230B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-176 Submitted under KCP 6.1-067	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (Ramularia collo-cygni) on barley in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWG 20 ADA 231A ADAMA Makhteshim Ltd, Report No. DE20FEHORVW231A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-177 Submitted under KCP 6.1-068	Wolf, P.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (Ramularia collo-cygni) on Barley Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE20FEHORVW231B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-178	Martin, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (Ramularia collo-cygni) on barley in Germany in 2021 Martin Feldversuchswesen, Germany, Report No. HWG 21 ADA 506A ADAMA Makhteshim Ltd, Report No. DE21FEHORVW506A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-179	Wönckhaus, S.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in Germany in 2021 Agrartest, Germany, Report No. S21-02913-01 ADAMA Makhteshim Ltd, Report No. DE21FEHORVW506B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-180 Submitted under KCP 6.1-069	Martin, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (Ramularia collo-cygni) on barley in Germany in 2021 Martin Feldversuchswesen, Germany, Report No. FWG 21 ADA 507A ADAMA Makhteshim Ltd, Report No. DE21FEHORVX507A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-181 Submitted under KCP 6.1-070	Perner, J.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in Germany in 2021 U.A.S., Germany, Report No. 148_21_Z ADAMA Makhteshim Ltd, Report No. DE21FEHORVX508A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-182	Torkler, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in Germany in 2021 Quintus, Germany, Report No. K-136-QUI-21-236 ADAMA Makhteshim Ltd, Report No. DE21FEHORVX509A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-183	Ommen, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium secalis) on barley in Germany in 2021 Plantus, Germany, Report No. 21F-2-PLA-016 ADAMA Makhteshim Ltd, Report No. DE21FEHORVX509B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-184 Submitted under KCP 6.1-071	Ommen, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (Ramularia) on barley in Germany in 2021 Plantus, Germany, Report No. 21F-2-PLA-017 ADAMA Makhteshim Ltd, Report No. DE21FEHORVX510A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2- 185 Submitted under KCP 6.1- 072	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RAMUCC (Ramularia collo-cygni) on barley in Ireland, 2020 Eurofins, Ireland, Report No. S20-02702-01 ADAMA Makhteshim Ltd, Report No. IE20FEHORVX318A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 186 Submitted under KCP 6.1- 073	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03032-01 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX323A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 187 Submitted under KCP 6.1- 074	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03032-02 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX323B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 188 Submitted under KCP 6.1- 075	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (Ramularia) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03303-01 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX325A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 189 Submitted under KCP 6.1- 076	Joynt, R.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Rhynchosporium (RHYNSE) on barley in the UK, 2019 ADAS, Ireland, Report No. WA19-WB-Adama 9T (348) ADAMA Makhteshim Ltd, Report No. UK19FEHORVX348A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2- 190	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1026A-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX310A- GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 191	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in the UK, 2020 OAT, United Kingdom, Report No. 20-1026B-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX310B- GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 192 Submitted under KCP 6.1- 077	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1028A-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX314A- GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 193	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1029-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX316A- GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 194	Joynt, R.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in the UK, 2020 ADAS, United Kingdom, Report No. GT20/024 ADAMA Makhteshim Ltd, Report No. UK20FEHORVX316B- GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP.6.2- 195 Submitted under KCP.6.1- 078	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (Ramularia collo-eygmi) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1030-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX317A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP.6.2- 196	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in the UK in 2021 OAT, United Kingdom, Report No. 1077-21-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX306A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP.6.2- 197 Submitted under KCP.6.1- 079	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in the UK in 2021 OAT, United Kingdom, Report No. 21-1079B-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX308B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP.6.2- 198 Submitted under KCP.6.1- 080	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in the UK in 2021 Eurofins, Derby, United Kingdom, Report No. S21-03034-01 ADAMA Makhteshim Ltd, Report No. UK21FEHORVX308C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP.6.2- 199	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in the UK in 2021 OAT, United Kingdom, Report No. 21-1080-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX309A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2- 200	Joynt, R.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in the UK in 2021 ADAS, United Kingdom, Report No. HM21-063 ADAMA Makhteshim Ltd, Report No. UK21FEHORVX309B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 201	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in Poland, 2020 Fertico, Poland, Report No. 60_01_F20_80 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW066A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 202	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in Poland, 2020 Staphyt, Poland, Report No. APK-20-44721-PL01 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW066B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 203 Submitted under KCP 6.1- 081	Sawinska, Z.	2020	The evaluation of efficacy ADM.03503.F.1.A and ADM.01352.F.3.A in fungal diseases control in winter barley cultivation, Poland 2020 Poznań University, Poland, Report No. AF/20/JO/19/Pr/067A ADAMA Makhteshim Ltd, Report No. PL20FEHORVW067A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 204 Submitted under KCP 6.1- 082	Kukuła, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on barley in Poland, 2020 Agreco, Poland, Report No. 20ADA0677-1 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW067B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2-205 Submitted under KCP 6.1-083	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Poland, 2020 Fertico, Poland, Report No. 61_01_F20_81 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW068A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-206 Submitted under KCP 6.1-084	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Poland, 2020 Staphyt, Poland, Report No. APK-20-44722-PL01 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW068B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-207	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Poland, 2020 Fertico, Poland, Report No. 62_01_F20_82 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW069A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-208	Kukuła, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Poland, 2020 Agreco, Poland, Report No. 20ADA0678-1 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW069B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-209	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against Puccinia hordei (PUCCHD) on winter barley in Poland, 2021 Fertico, Poland, Report No. 74_01_F21_181 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW029A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-210	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter barley cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/JO/9/Br/029B ADAMA Makhteshim Ltd, Report No. PL21FEHORVW029B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2-211 Submitted under KCP 6.1-085	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Rhynchosporium secalis</i> (RHYNSE) on winter barley in Poland, 2021 Fertico, Poland, Report No. 75_01_F21_182 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW030A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-212 Submitted under KCP 6.1-086	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter barley cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/JO/9/ZI/030B ADAMA Makhteshim Ltd, Report No. PL21FEHORVW030B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-213 Submitted under KCP 6.1-087	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Pyrenophora teres</i> (PYRNTE) on winter barley in Poland, 2021 Fertico, Poland, Report No. 76_01_F21_183 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW031A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-214	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Blumeria graminis hordei</i> (ERYSGH) on winter barley in Poland, 2021 Fertico, Poland, Report No. 77_01_F21_184 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW032A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-215	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Blumeria graminis hordei</i> (ERYSGH) on winter barley in Poland, 2021 Fertico, Poland, Report No. 77_02_F21_185 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW032B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-216	Benezés, B.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-124-002FE ADAMA Makhteshim Ltd, Report No. HU20FEHORVX520C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2- 217	Ritecz, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Pyrenophora teres) on barley in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-098-002FE ADAMA Makhteshim Ltd, Report No. HU21FEHORVW309A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 218 Submitted under KCP 6.1- 088	Tuna, V.	2019	Determination of Efficacy of ADM.3503.F.1.A compared to the equivalent tank mix, applied post-emergence against Pyrenophora teres (PYRNTE) in barley, outdoor 2019 Eurofins, Romania, Report No. S19-03924-01 ADAMA Makhteshim Ltd, Report No. RO19FEHORVW171A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 219	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW245A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 220	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW245B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 221 Submitted under KCP 6.1- 089	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (Rhynchosporium secalis) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW246B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 222 Submitted under KCP 6.1- 090	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW247A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2- 223 Submitted under KCP 6.1- 091	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW247B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 224	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02897-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW210A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 225	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02897-02 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW210B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 226 Submitted under KCP 6.1- 092	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02898-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW211A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 227 Submitted under KCP 6.1- 093	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02898-02 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW211B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2- 228 Submitted under KCP 6.1- 094	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02899-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW212A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 229	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02901-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW218A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 230	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02901-02 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW218B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 231 Submitted under KCP 6.1- 095	Holcikova, D.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Rhynchosporium (RHYNSE) on barley Slovakia, 2019 FYSE,Slovakia, Report No. FYSE-103201915 ADAMA Makhteshim Ltd, Report No. SK19FEHORVW348A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 232	Malovcova, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Slovakia, 2020 NPPC - VURV Piestany,Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVS316A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2-233	Forgáčová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley in Slovakia, 2020 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW311A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-234 Submitted under KCP 6.1-096	Kovacova Holcikova, D.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (Rhynchosporium secalis) on barley in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE103202015 ADAMA Makhteshim Ltd, Report No. SK20FEHORVW313A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-235 Submitted under KCP 6.1-097	Tóth, F.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (Rhynchosporium secalis) on barley in Slovakia, 2020 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW313B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-236 Submitted under KCP 6.1-098	Forgáčová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in Slovakia, 2020 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW315A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-237	Malovcová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in (Slovakia) in 2021 NPPC - VURV Piestany, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FEHORVS309A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-238	Hudec, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in (Slovakia) in 2021 Blumeria Consulting, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FEHORVW306A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-239	Tóth, F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in (Slovakia) in 2021 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FEHORVW306B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-240 Submitted under KCP 6.1-099	Kováčová Holčíková, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in (Slovakia) in 2021 Berberis, Slovakia, Report No. SK21FEHORVW307A - ZV04 ADAMA Makhteshim Ltd, Report No. SK21FEHORVW307A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-241 Submitted under KCP 6.1-100	Kováčová Holčíková, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in (Slovakia) in 2021 Berberis, Slovakia, Report No. SK21FEHORVW308A- ZV03 ADAMA Makhteshim Ltd, Report No. SK21FEHORVW308A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-242 Submitted under KCP 6.1-101	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on rye in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WR-148 ADAMA Makhteshim Ltd, Report No. DE20FESECSS232A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-243 Submitted under KCP 6.1-102	Magyaróvári, V.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on rye in Germany, 2020 Agrartest, Germany, Report No. S20-03246-01 ADAMA Makhteshim Ltd, Report No. DE20FESECSS232B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-244 Submitted under KCP 6.1-103	Wied, H.M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRE (Puccinia recondita) on rye in Germany in 2021 Staphyt, Germany, Report No. HWD-21-50086-DE01 ADAMA Makhteshim Ltd, Report No. DE21FESECSS511A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-245 Submitted under KCP 6.1-104	Zöllner, H.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on rye in Germany in 2021 Field Research Support, Germany, Report No. FRS105/21 ADAMA Makhteshim Ltd, Report No. DE21FESECSS511B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-246 Submitted under KCP 6.1-105	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A and ADM.01352.F.3.A in fungal diseases control in winter rye , Poland, 2020 Poznań University, Germany, Report No. AF/20/ŻO/19/BR/070A ADAMA Makhteshim Ltd, Report No. PL20FESECSS070A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-247 Submitted under KCP 6.1-106	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter rye cultivation, Poland, 2021 Poznań University, Germany, Report No. AF/21/ŻO/9/Br/033A ADAMA Makhteshim Ltd, Report No. PL21FESECSS033A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-248 Submitted under KCP 6.1-107	Maesim, C.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on rye in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02902-01 ADAMA Makhteshim Ltd, Report No. RO21FESECSS214A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2- 249 Submitted under KCP 6.1- 408	Macsim, C.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on rye in ROMANIA in 2021 Eurofins, Romania, Report No. S21-04520-01 ADAMA Makhteshim Ltd, Report No. RO21FESECSS250A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 250	Ramanauskienė, J.	2020	Efficacy of ADM.03503.F.1.A for Rhynchosporium secalis control in winter rye in Lithuania in 2020 LRCAF, Lithuania ADAMA Makhteshim Ltd, Report No. LT20FESECSS517A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 251	Brauna-Mozevska, E.	2021	Efficacy of ADM.03503.F.1.A for Rhynchosporium secalis control in winter rye in Latvia in 2021 LAAPC, Latvia, Report No. F-21-02-OT-3817 ADAMA Makhteshim Ltd, Report No. LV21FESECSS460A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 252	Čáp, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (Pyrenophora tritici-repentis) on triticale the Czech republic, 2020 ZS Nechanice, Czech Republic, Report No. CZOR-ATA20- TTLSS-036NEC ADAMA Makhteshim Ltd, Report No. CZ20FETTLWI324A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 253	Teresiak, H.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRE (brown rust) on triticale in Germany, 2020 Agro-check, Czech Republic, Report No. AC/20/091 ADAMA Makhteshim Ltd, Report No. DE20FETTLSS233A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2-254	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (Pyrenophora tritici-repentis) on triticale in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-TR-149 ADAMA Makhteshim Ltd, Report No. DE20FETTLSS234A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-255	Zöllner, H.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium secalis) on triticale in Germany in 2021 Field Research Support, Germany, Report No. FRS106/21 ADAMA Makhteshim Ltd, Report No. DE21FETTLSS512A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-256	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRE (brown rust) on triticale in Poland, 2020 Fertico, Poland, Report No. 63_01_F20_83 ADAMA Makhteshim Ltd, Report No. PL20FETTLSS071A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-257	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (Pyrenophora tritici-repentis) on triticale in Poland, 2020 Fertico, Poland, Report No. 64_01_F20_84 ADAMA Makhteshim Ltd, Report No. PL20FETTLSS072A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-258	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (Pyrenophora tritici-repentis) on triticale in Poland, 2020 Staphyt, Poland, Report No. APK-20-44723-PL01 ADAMA Makhteshim Ltd, Report No. PL20FETTLSS072B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2-259	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Puccre (Brown rust) on triticale in Poland in 2021 Staphyt, Poland, Report No. MP2-21-50285-PL01 ADAMA Makhteshim Ltd, Report No. PL21FETTLSS034A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-260	Ritecz, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Puccre (brown rust) on triticale in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-126-002FE ADAMA Makhteshim Ltd, Report No. HU20FETTLW1540A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-261	Makó, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (Pyrenophora tritici-repentis) on triticale in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-127-002FE ADAMA Makhteshim Ltd, Report No. HU20FETTLW1541A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-262	Németh, S.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (Pyrenophora tritici-repentis) on triticale in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-128-002FE ADAMA Makhteshim Ltd, Report No. HU20FETTLW1541B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-263	Ritecz, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Puccre (Brown rust) on triticale in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-100-002FE ADAMA Makhteshim Ltd, Report No. HU21FETTLW312A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2-264	Maesim, C.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Puccre (Brown rust) on triticale in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02903-01 ADAMA Makhteshim Ltd, Report No. RO21FETTLSS220A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.2- 265	Jørgensen, L.N.	2021	Efficacy evaluation of ADM.03503.F.1.A for brown rust (PUCCTR) control in triticale in Denmark in 2021 Aarhus University, Denmark, Report No. 32723421 ADAMA Makhteshim Ltd, Report No. DK21FETTLSS206A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 266	Treikale, O.	2020	Efficacy evaluation of fungicide ADM.03503.F.1.A for Pyrenophora tritici-repens control in winter triticale in Latvia in 2020 LAAPC, Latvia, Report No. F-20-03-OT-3604 ADAMA Makhteshim Ltd, Report No. LV20FETTLSS506A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 267	Brauna-Mozevska, E.	2021	Efficacy of ADM.03503.F.1.A for Pyrenophora tritici-repens control in winter triticale in Latvia in 2021 LAAPC, Latvia, Report No. F-21-03-OT-3818 ADAMA Makhteshim Ltd, Report No. LV21FETTLSS462A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 268	Broms, C.	2021	Efficacy of ADM.03503.F.1.A against ERYSGR in triticale in Sweden 2020 Husec, Sweden, Report No. HUM065 ADAMA Makhteshim Ltd, Report No. SE20FETTLSS252A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.2- 269	Vilka, L.	2021	Efficacy of ADM.03503.F.1.A for Pyrenophora tritici-repentis control in winter triticale in Sweden in 2020 Agrolab, Sweden, Report No. 2674 ADAMA Makhteshim Ltd, Report No. SE20FETTLSS253A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.3-001	Felsenstein F.G. Jaser B.	2016	Sensitivity of Septoria tritici in different regions of Europe towards prochloraz, tebuconazole, difenoconazole, propiconazole and prothioconazole, 2016 EpiLogic, Germany GEP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B, Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 ADM.03502.F.1.A, ADM.03509.F.1.A and ADM.03501.F.1.A. Data protection has not expired	ADM
KCP 6.3-002	Felsenstein F.G. Jaser B.	2017	Sensitivity of Septoria tritici in different regions of Europe towards prochloraz, tebuconazole, difenoconazole, and prothioconazole, 2017 EpiLogic, Germany GEP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B, Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 ADM.03502.F.1.A, ADM.03509.F.1.A and ADM.03501.F.1.A. Data protection has not expired	ADM
KCP 6.3-003	Felsenstein F.G. Jaser B.	2018	Sensitivity of Septoria tritici in different regions of Europe towards prochloraz, tebuconazole, difenoconazole and prothioconazole, 2018 EpiLogic, Germany GEP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B, Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 ADM.03502.F.1.A, ADM.03509.F.1.A and ADM.03501.F.1.A. Data protection has not expired	ADM

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KCP 6.3-004	Felsenstein F.G. Jaser B.	2020	Sensitivity of (Zymo)Septoria tritici in different regions of Europe towards difenoconazole and prothioconazole 2020 EpiLogic, Germany GEP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03509.F.1.A and ADM.03501.F.1.A. Data protection has not expired	ADM
KCP 6.4-001 Submitted under KCP 6.2-001	Herzmaier, C.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of Puccinia triticina (brown rust) on winter wheat, GEP Trial, AUSTRIA, 2020 Staphyt, Austria, Report No. HWD-20-45585-AT01 ADAMA Makhteshim Ltd, Report No. AT20FETRZAW221A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-002 Submitted under KCP 6.2-002	Kempernek, H.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of Pyrenophora tritici-repentis (DTR) on winter wheat, GEP Trial, AUSTRIA, 2020 Staphyt, Austria, Report No. HWD-20-45586-AT01 ADAMA Makhteshim Ltd, Report No. AT20FETRZAW224A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-003 Submitted under KCP 6.2-003	Bataille, C.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against brown rust on winter wheat CRA W, Belgium, Report No. MAL2021-04 ADAMA Makhteshim Ltd, Report No. BE21FETRZAW034A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-004 Submitted under KCP 6.1-011	Hrabovsky, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in the Czech Republic, 2020 ZZS Kujavy, Czech Republic, Report No. 20H25 ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW301A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-005 Submitted under KCP 6.2-005	Bezdíčková, B.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Puccinia (brown rust) on winter wheat in the Czech Republic, 2020 Ditana, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW303A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-006 Submitted under KCP 6.2-006	Bauer, T.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (Pyrenophora tritici-repentis) on winter wheat in the Czech Republic, 2020 InTec Agro Trials, Czech Republic, Report No. F-20-G-574-01 ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW308A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-007 Submitted under KCP 6.2-007	Bezdíčková, A.	2020	An efficacy evaluation of ADM.03503.F.1.A against Fusarium and Microdochium at T3 on winter wheat in the Czech Republic, 2020 Ditana, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW309A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-008 Submitted under KCP 6.1-012	Čáp, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in the Czech Republic in 2021 ZS Nechanice, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FETRZAW300A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-009 Submitted under KCP 6.2-009	Bezdíčková, A.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium and Microdochium in winter wheat at T3 in the Czech Republic in 2021 Ditana, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FETRZAW305A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-010 Submitted under KCP 6.1-013	Gouille, L.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Puccinia striiformis</i> (PUCCST) on winter wheat in France, 2019 Biotek Agriculture, France, Report No. BPE19/286/FGC01 ADAMA Makhteshim Ltd, Report No. FR19FETRZAW110A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-011 Submitted under KCP 6.1-014	Varret, F.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat, in France 2019. Staphyt, France, Report No. FVT 19 40058 FR01 ADAMA Makhteshim Ltd, Report No. FR19FETRZAX108A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-012 Submitted under KCP 6.1-015	Varret, F.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat, in France 2019 Staphyt, France, Report No. FVT 19 40058 FR02 ADAMA Makhteshim Ltd, Report No. FR19FETRZAX108B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-013 Submitted under KCP 6.1-016	Boeuf, V.	2019	Efficacy comparison of ADM.3503.F.1.A with its equivalent tank mix for the control of Brown rust (PUCCRE) on winter wheat in France in 2019 Antedis, France, Report No. ADA FE19BT 03107 AR ADAMA Makhteshim Ltd, Report No. FR19FETRZAX109A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-014 Submitted under KCP 6.1-017	Deberny, E.	2019	Efficacy comparison of ADM.3503.F.1.A with its equivalent tank mix for the control of Brown rust (PUCCRE) on winter wheat in France in 2019 Antedis, France, Report No. ADA FE19BT 03108 CA ADAMA Makhteshim Ltd, Report No. FR19FETRZAX109B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-015 Submitted under KCP 6.1-018	Ternois, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in FRANCE, 2020 Ephydia, France, Report No. FRM 20 F13 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW500A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-016 Submitted under KCP 6.1-019	Flahaut, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in FRANCE, 2020 Staphyt, France, Report No. JFT 20 45675 FR01 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW500B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-017 Submitted under KCP 6.2-017	Biaunier, M.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in FRANCE, 2020 Qualiphyt, France, Report No. QUALI20098A21 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW502A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-018 Submitted under KCP 6.2-018	Crepin, D.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A against brown rust on winter wheat, in France in 2020 Essais +, France, Report No. 20 38 F 13 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW502B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-019 Submitted under KCP 6.2-019	Lombart, L.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in France, 2020 Ephydia, France, Report No. FRM 20 F14 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW504A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-020 Submitted under KCP 6.2-020	Maitte, B.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PuccSI (yellow rust) on winter wheat in FRANCE, 2020 Promo Vert, France, Report No. 20F FCEADA FR15 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW504C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-021 Submitted under KCP 6.2-021	Lombart, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in France, 2020 Ephydia, France, Report No. FRM 20 F15 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW506A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-022 Submitted under KCP 6.2-022	Jondot, A.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT on Winter Wheat in France in 2020 Antedis, France, Report No. ADA FE20BT 05271 SV ADAMA Makhteshim Ltd, Report No. FR20FETRZAW506B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-023 Submitted under KCP 6.2-023	Ballan, J.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT, SEPTTR and PuccSI on Winter Wheat in France in 2020 Antedis, France, Report No. ADA FE20BT 05272 JA ADAMA Makhteshim Ltd, Report No. FR20FETRZAW506C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-024 Submitted under KCP 6.2-024	Lombart, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in France, 2020 Ephydia, France, Report No. FRM 20 F16 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW509A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-025 Submitted under KCP 6.2-025	Biaunier, M.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in FRANCE, 2020 Qualiphyt, France, Report No. QUALI20099H07 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW509C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-026 Submitted under KCP 6.1-020	Lombart, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in France in 2021 Ephydia, France, Report No. FRM 21 F20 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW551A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-027 Submitted under KCP 6.1-021	Flahaut, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in France in 2021 Staphyt, France, Report No. JET 21 50445 FR01 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW551C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-028 Submitted under KCP 6.2-028	Crepin, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PuccRT (Brown rust) on winter wheat in FRANCE in 2021 Essais +, France, Report No. 21 38 F 27 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW552A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-029 Submitted under KCP 6.2-029	Voisin, J.F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PuccRT (Brown rust) on winter wheat in FRANCE in 2021 Agrotest, France, Report No. E 2154 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW552C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-030 Submitted under KCP 6.2-030	Gouaille, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCSI (Puccinia striiformis tritici) on winter wheat in France in 2021. Biotek Agriculture, France, Report No. BPE21/205/FGC01 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW553B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-031 Submitted under KCP 6.2-031	Lombart, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) and SEPTTR (Septoria) on winter wheat in France in 2021. Ephydia, France, Report No. FRM-21-F21 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW554A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-032 Submitted under KCP 6.2-032	Biaunier, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium (FUSACU in artificial contamination) in winter wheat at T3 in FRANCE in 2021. Qualiphyt, France, Report No. QUALI21106E23 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW556B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-033 Submitted under KCP 6.1-022	Labusch, U.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in (Germany), 2019 BioChem Agrar, Germany, Report No. 19-1069-5062 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW905A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-034 Submitted under KCP 6.1-023	Rohr, J.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in (Germany), 2019 Trial Tee, Germany, Report No. 19-ADA-HE-WW-071 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW905B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-035 Submitted under KCP 6.1-024	Hetterich, A.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Brown rust (PuccrT) on winter wheat in (Germany), 2019 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE19FETRZAW906A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-036 Submitted under KCP 6.1-025	Wolf, P.	2019	Efficacy of ADM.3503.F.1.A in comparison to the equivalent tank mix vs. Yellow Rust (PuccSI) in Winter Wheat Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE19FETRZAW907A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-037 Submitted under KCP 6.1-026	Perner, J.	2019	Efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Pyrenophora (Drechslera) tritici-repentis (PYRNTR) on winter wheat in Germany, 2019 U.A.S., Germany, Report No. 170_19_Z ADAMA Makhteshim Ltd, Report No. DE19FETRZAW908A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-038 Submitted under KCP 6.1-027	Rohr, J.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Pyrenophora (Drechslera) tritici-repentis (PYRNTR) on winter wheat in (Germany), 2019 Trial-Tec, Germany, Report No. 19-ADA-HE-WW-072 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW908B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-039 Submitted under KCP 6.2-039	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PuccrT (brown rust) on winter wheat in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWW 20 ADA 221A ADAMA Makhteshim Ltd, Report No. DE20FETRZAW221A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-040 Submitted under KCP 6.2-040	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of Puccinia (brown rust) on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WW-141 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW221B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-041 Submitted under KCP 6.2-041	Magyaróvári, V.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of Puccinia (yellow rust) on winter wheat in Germany, 2020 Agrartest, Germany, Report No. S20-03244-01 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW222A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-042 Submitted under KCP 6.2-042	Lamers, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of Puccinia (yellow rust) on winter wheat in Germany, 2020 BioChem Agrar, Germany, Report No. 20 1069 5128 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW222B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-043 Submitted under KCP 6.2-043	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Erysiphe (powdery mildew) on winter wheat in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWW 20 ADA 223A ADAMA Makhteshim Ltd, Report No. DE20FETRZAW223A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-044 Submitted under KCP 6.2-044	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Erysiphe (powdery mildew) on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WW-142 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW223B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-045 Submitted under KCP 6.2-045	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (Pyrenophora tritici-repentis) on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WW-143 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW224A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-046 Submitted under KCP 6.2-046	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (Pyrenophora tritici-repentis) on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-HE-WW-144 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW224B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-047 Submitted under KCP 6.2-047	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (Pyrenophora tritici-repentis) on winter wheat in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWW 20 ADA 224C ADAMA Makhteshim Ltd, Report No. DE20FETRZAW224C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-048 Submitted under KCP 6.2-048	Lamers, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in Germany, 2020 BioChem Agrar, Germany, Report No. 20 1069 5129 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW225A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-049 Submitted under KCP 6.2-049	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-HE-WW-145 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW225B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-050 Submitted under KCP 6.1-028	Rohr, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in Germany in 2021 Trial-Tec, Germany, Report No. 21-ADA-SH-WW-222 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW500A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-051 Submitted under KCP 6.2-051	Hapke, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in Germany in 2021 Acceres, Germany, Report No. F21NMW35 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW501A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-052 Submitted under KCP 6.2-052	Endres, U.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in Germany in 2021 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE21FETRZAW501B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-053 Submitted under KCP 6.2-053	Torkler, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in Germany in 2021 Quintus, Germany, Report No. K-136-QUI-21-235 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW502A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-054 Submitted under KCP 6.2-054	Wolf, P.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Zymoseptoria tritici (SEPTTR) on winter wheat in Germany in 2021 Agricola, Germany, ADAMA Makhteshim Ltd, Report No. DE21FETRZAW503A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-055 Submitted under KCP 6.2-055	Perner, J.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in Germany in 2021 U.A.S., Germany, Report No. 147_21_Z ADAMA Makhteshim Ltd, Report No. DE21FETRZAW503B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-056 Submitted under KCP 6.2-056	Rohr, H.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTR (DTR) on winter wheat in Germany in 2021 Trial-Tec, Germany, Report No. 21-ADA-SH-WW-223 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW504A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-057 Submitted under KCP 6.2-057	Maleck, A.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR on winter wheat in Germany in 2021 Agro-check, Germany, Report No. AC/21/050 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW504B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-058 Submitted under KCP 6.2-058	Zickart, U.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR on winter wheat in Germany in 2021 BioChem Agrar, Germany, Report No. 21 1064 1192 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW504C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-059 Submitted under KCP 6.2-059	Rohr, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium and Microdochium in winter wheat at T3 in Germany in 2021 Trial-Tec, Germany, Report No. 21-ADA-HE-WW-224 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW505A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-060 Submitted under KCP 6.2-060	Endres, U.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium and Microdochium in winter wheat at T3 in Germany in 2021 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE21FETRZAW505B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-061 Submitted under KCP 6.1-029	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in Ireland, 2020 Eurofins, Ireland, Report No. S20-02701-01 ADAMA Makhteshim Ltd, Report No. IE20FETRZAW301A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-062	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in Ireland in 2021 Eurofins, Ireland, Report No. S21-03031-01 ADAMA Makhteshim Ltd, Report No. IE21FETRZAW322A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-063 Submitted under KCP 6.1-030	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in Ireland in 2021 Eurofins, Ireland, Report No. S21-03031-02 ADAMA Makhteshim Ltd, Report No. IE21FETRZAW322B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-064 Submitted under KCP 6.1-031	Van Tilburg, F.W.G.	2020	Control of Zymoseptoria tritici in winter wheat in the Netherlands, 2020 Eurofins, Netherlands, Report No. S20-02814-01 ADAMA Makhteshim Ltd, Report No. NL20FETRZAW010A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-065 Submitted under KCP 6.2-064	Van Tilburg, F.W.G.	2020	Control of Puccinia recondita in winter wheat in the Netherlands, 2020 Eurofins, Netherlands, Report No. S20-02815-01 ADAMA Makhteshim Ltd, Report No. NL20FETRZAW011A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-066 Submitted under KCP 6.1-032	Kay, C.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in the UK, 2019 OAT, United Kingdom, Report No. 19-1034A-ADA ADAMA Makhteshim Ltd, Report No. UK19FETRZAW344A- GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-067 Submitted under KCP 6.1-033	Kay, C.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in the UK, 2019 OAT, United Kingdom, Report No. 19-1034B-ADA ADAMA Makhteshim Ltd, Report No. UK19FETRZAW344B- GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-068 Submitted under KCP 6.1-034	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1022-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW300A- GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-069 Submitted under KCP 6.2-068	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PuccRT (brown rust) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1023-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW302A- GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-070 Submitted under KCP 6.2-069	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PuccSI (yellow rust) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1024-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW304A- GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-071 Submitted under KCP 6.2-070	Armstrong, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of Puccinia (yellow rust) on winter wheat in the UK, 2020 Armstrong Fisher, United Kingdom, Report No. 1024-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW304B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-072 Submitted under KCP 6.2-071	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Erysiphe (powdery mildew) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1025-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW306A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-073 Submitted under KCP 6.2-072	Joynt, R.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in the UK, 2020 ADAS, United Kingdom, Report No. GT20/031 ADAMA Makhteshim Ltd, Report No. UK20FETRZAW309A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-074 Submitted under KCP 6.2-073	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in the UK, 2020 Eurofins, Derby, United Kingdom, Report No. S20-02732-01 ADAMA Makhteshim Ltd, Report No. UK20FETRZAW309B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-075 Submitted under KCP 6.1-035	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in the UK in 2021 OAT, United Kingdom, Report No. 21-1074-ADA ADAMA Makhteshim Ltd, Report No. UK21FETRZAW300A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-076 Submitted under KCP 6.2-075	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Puccrt (Brown rust) on winter wheat in the UK in 2021 OAT, United Kingdom, Report No. 1075-21-ADA ADAMA Makhteshim Ltd, Report No. UK21FETRZAW301A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-077 Submitted under KCP 6.2-076	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PuccSI (Yellow rust) on winter wheat in the UK in 2021 OAT, United Kingdom, Report No. 21-1076-ADA ADAMA Makhteshim Ltd, Report No. UK21FETRZAW302A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-078 Submitted under KCP 6.2-077	Joynt, R.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ErySGT (Powdery mildew) on winter wheat in the UK in 2021 ADAS, United Kingdom, Report No. GT21-035 ADAMA Makhteshim Ltd, Report No. UK21FETRZAW303A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-079 Submitted under KCP 6.2-078	Joynt, R.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium and Microdochium in winter wheat at T3 in the UK in 2021 ADAS, United Kingdom, Report No. GT21-036 ADAMA Makhteshim Ltd, Report No. UK21FETRZAW305A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-080 Submitted under KCP 6.1-036	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in Poland, 2020 Staphyt, Poland, Report No. APK-20-44718-PL01 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW060A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-081 Submitted under KCP 6.1-037	Rusek, K.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in Poland 2020 Fertico, Poland, Report No. 57_01_F20_77 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW060B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-082 Submitted under KCP 6.2-081	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A and ADM.01352.F.3.A in fungal diseases control in winter wheat, Poland 2020 Poznań University, Poland, Report No. AF/20/PO/19/BR/061A ADAMA Makhteshim Ltd, Report No. PL20FETRZAW061A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-083 Submitted under KCP 6.2-082	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRT (brown rust) on winter wheat in Poland 2020 Fertico, Poland, Report No. 58_01_F20_78 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW061B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-084 Submitted under KCP 6.2-083	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in Poland, 2020 Staphyt, Poland, Report No. APK-20-44719-PL01 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW062A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-085 Submitted under KCP 6.2-084	Kukuła, A.	2020	The evaluation of efficacy of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of fungal diseases on winter wheat Agreco, Poland, Report No. 20ADA0692-1 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW062B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-086 Submitted under KCP 6.2-085	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A in fungal diseases control in winter wheat cultivation, Poland 2020 Poznań University, Poland, Report No. AF/20/PO/19/Pr/063A ADAMA Makhteshim Ltd, Report No. PL20FETRZAW063A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-087 Submitted under KCP 6.2-086	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in Poland, 2020 Fertico, Poland, Report No. 59_01_F20_79 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW063B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-088 Submitted under KCP 6.2-087	Kukuła, A.	2020	The evaluation of efficacy of ADM.03503.F.1.A , ADM.01352.F.3.A for the control of fungal diseases on winter wheat Agreco, Poland, Report No. 20ADA0693-1 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW064A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-089 Submitted under KCP 6.2-088	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (Pyrenophora tritici-repentis) on winter wheat in Poland, 2020 Staphyt, Poland, Report No. APK-20-44720-PL01 PHA ADAMA Makhteshim Ltd, Report No. PL20FETRZAW064B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-090 Submitted under KCP 6.2-089	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A in fungal diseases control in winter wheat cultivation, Poland 2020 Poznań University, Poland, Report No. AF/20/PO/19/Pr/065A ADAMA Makhteshim Ltd, Report No. PL20FETRZAW065A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-091 Submitted under KCP 6.2-090	Kukuła, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in Poland, 2020 Agreco, Poland, Report No. 20ADA0694-1 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW065B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-092	Gajek, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in Poland in 2021 Agro Research Consulting, Poland, Report No. ARC21_TRZAW_ADAM_23 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW023A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-093 Submitted under KCP 6.1-038	Rusek, K	2021	Efficacy evaluation of ADM.03503.F.1.A against Zymoseptoria tritici (SEPTTR) on winter wheat in Poland, 2021 Fertico, Poland, Report No. 71_01_F21_178 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW023B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-094 Submitted under KCP 6.2-092	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter wheat cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/PO/9/Pr/024A ADAMA Makhteshim Ltd, Report No. PL21FETRZAW024A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-095 Submitted under KCP 6.2-093	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Puccinia (Brown rust) on winter wheat in Poland in 2021 Staphyt, Poland, Report No. MP2-21-50274-PL01 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW024B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-096 Submitted under KCP 6.2-094	Gajek, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Puccinia (Yellow rust) on winter wheat in Poland in 2021 Agro Research Consulting, Poland, Report No. ARC21_TRZAW_ADAM_09 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW025A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-097 Submitted under KCP 6.2-095	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Puccinia striiformis tritici</i> (PUCCSI) on winter wheat in Poland, 2021 Fertico, Poland, Report No. 72_01_F21_179 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW025B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-098 Submitted under KCP 6.2-096	Pszczołkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>ERYSGT</i> (Powdery mildew) on winter wheat in Poland in 2021 Staphyt, Poland, Report No. MP2-21-50275-PL01 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW026A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-099	Gajek, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>ERYSGT</i> (Powdery mildew) on winter wheat in Poland in 2021 Agro Research Consulting, Poland, Report No. ARC21_TRZAW_ADAM_24 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW026B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-100 Submitted under KCP 6.2-097	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Pyrenophora tritici repentis</i> (PYRNTR) on winter wheat in Poland, 2021 Fertico, Poland, Report No. 73_01_F21_180 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW027A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-101	Gajek, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>PYRNTR</i> (DTR) on winter wheat in Poland in 2021 Agro Research Consulting, Poland, Report No. ARC21_TRZAW_ADAM_25 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW027B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-102 Submitted under KCP 6.2-098	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium and Microdochium in winter wheat at T3 in Poland in 2021 Staphyt, Poland, Report No. MP2-21-50278-PL01 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW028A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-103 Submitted under KCP 6.2-099	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter wheat cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/PO/9/Pr/028B ADAMA Makhteshim Ltd, Report No. PL21FETRZAW028B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-104	Varga, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-113-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW510A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-105	Juhász, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in Hungary, 2020 SGS, Hungary, Report No. 20-FE-03-SG1 ADAMA Makhteshim Ltd, Report No. HU20FETRZAW510B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-106 Submitted under KCP 6.2-100	Nagy, Z.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-116-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW511A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-107 Submitted under KCP 6.2-101	Makó, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-117-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW511B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-108 Submitted under KCP 6.2-102	Rábai, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PuccSI (yellow rust) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-112-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW512A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-109	Juhász, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PuccSI (yellow rust) on winter wheat in Hungary, 2020 SGS, Hungary, Report No. 20 FE 02 SG1 ADAMA Makhteshim Ltd, Report No. HU20FETRZAW512B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-110	Nagy, Z.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PuccRT (brown rust) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-111-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW513A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-111	Juhász, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PuccRT (brown rust) on winter wheat in Hungary, 2020 SGS, Hungary, Report No. 20 FE 01 SG1 ADAMA Makhteshim Ltd, Report No. HU20FETRZAW513B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-112	Németh, S.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (Pyrenophora tritici-repentis) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-114-135FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW514A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-113 Submitted under KCP 6.2-103	Németh, S.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (Pyrenophora tritici-repentis) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-115-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW514B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4- 114 Submitted under KCP 6.2- 104	Juhász, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (Pyrenophora tritici-repentis) on winter wheat in Hungary, 2020 SGS, Hungary, Report No. 20 FE 04 SG1 ADAMA Makhteshim Ltd, Report No. HU20FETRZAW514C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 115	Varga, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-109-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW515A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 116	Makó, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-110-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW515B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 117 Submitted under KCP 6.2- 105	Nagy, Z.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PuccrT (Brown rust) on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-090-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW301A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 118 Submitted under KCP 6.2- 106	Ritecz, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PuccrT (Brown rust of wheat) on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-091-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW302A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4- 119	Varga, A.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-092-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW303A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 120 Submitted under KCP 6.2- 107	Makó, I.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-093-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW304A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 121	Ritecz, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTR (DTR) on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-094-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW304B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 122	Németh, S.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTR (DTR) on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-095-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW304C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 123 Submitted under KCP 6.2- 108	Nagy, Z.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium and Microdochium in winter wheat at T3 in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-096-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW305A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4- 124 Submitted under KCP 6.1- 039	Tuna, V.	2019	Determination of Efficacy of ADM.3503.f.1.A compared to the equivalent tank mix, applied post-emergence against <i>Zymoseptoria tritici</i> (SEPTTR) in Winter Wheat, outdoor 2019 Eurofins, Romania, Report No. S19-03922-01 ADAMA Makhteshim Ltd, Report No. RO19FETRZAW169A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 125 Submitted under KCP 6.1- 040	Tuna, V.	2019	Determination of Efficacy of ADM.3503.F.1.A compared to the equivalent tank mix, applied post-emergence against Yellow rust (PUCCST) in Winter Wheat, outdoor 2019 Eurofins, Romania, Report No. S19-03923-01 ADAMA Makhteshim Ltd, Report No. RO19FETRZAW170A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 126 Submitted under KCP 6.1- 041	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW248A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 127 Submitted under KCP 6.1- 042	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW248B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 128 Submitted under KCP 6.2- 113	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT (brown rust) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW249A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4- 129 Submitted under KCP 6.2- 114	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Puccrt (brown rust) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW249B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 130 Submitted under KCP 6.2- 115	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Puccsi (yellow rust) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW250A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 131 Submitted under KCP 6.2- 116	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Puccsi (yellow rust) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW250B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 132 Submitted under KCP 6.2- 117	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Erysgt (powdery mildew) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW251A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 133 Submitted under KCP 6.2- 118	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Erysgt (powdery mildew) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW251B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4- 134 Submitted under KCP 6.2- 119	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW252A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 135 Submitted under KCP 6.2- 120	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW252B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 136 Submitted under KCP 6.2- 121	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02895-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW213A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 137 Submitted under KCP 6.2- 122	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02895-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW213B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 138 Submitted under KCP 6.1- 043	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02892-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW215A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4- 139 Submitted under KCP 6.1- 044	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02892-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW215B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 140 Submitted under KCP 6.2- 125	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02893-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW216A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 141 Submitted under KCP 6.2- 126	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02893-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW216B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 142	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCSI (Yellow rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02894-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW217A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 143 Submitted under KCP 6.2- 127	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCST (Yellow rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02894-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW217B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4- 144 Submitted under KCP 6.2- 128	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PuccSI (Yellow rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02894-03 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW217C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 145 Submitted under KCP 6.2- 129	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium and Microdochium in winter wheat at T3 in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02896-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW219A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 146 Submitted under KCP 6.1- 045	Hudec, K.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Brown rust (PUCCRT) on winter wheat in Slovakia, 2019 Blumeria Consulting, Slovakia ADAMA Makhteshim Ltd, Report No. SK19FETRZAW345A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 147 Submitted under KCP 6.1- 046	Ondisová, M.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in Slovakia, 2020 UKSUP, Slovakia, Report No. KE-F-04-2020 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW301A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 148 Submitted under KCP 6.1- 047	Hudec, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (Zymoseptoria tritici) on winter wheat in Slovakia, 2020 Blumeria Consulting, Slovakia, Report No. ADA-301B-O ADAMA Makhteshim Ltd, Report No. SK20FETRZAW301B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 149 Submitted under KCP 6.2- 133	Kovacova, D.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT (brown rust) on winter wheat in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE-103202016 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW303A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-150 Submitted under KCP 6.2-134	Tóth, F.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT (brown rust) on winter wheat in Slovakia, 2020 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FETRZAW303B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-151 Submitted under KCP 6.2-135	Kovacova Holcikova, D	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCSI (yellow rust) on winter wheat in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE103202017 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW305A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-152 Submitted under KCP 6.2-136	Forgáčová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCSI (yellow rust) on winter wheat in Slovakia, 2020 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FETRZAW305B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-153 Submitted under KCP 6.2-137	Malovcová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in Slovakia, 2020 NPPC - VURV Piestany, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FETRZAW306A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-154 Submitted under KCP 6.2-138	Kovacova, D.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Fusarium and Microdochium at T3 on winter wheat in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE-103202018 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW309A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-155 Submitted under KCP 6.1-048	Forgáčová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (Zymoseptoria tritici) on winter wheat in (Slovakia) in 2021 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW300A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-156 Submitted under KCP 6.2-140	Forgáčová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in (Slovakia) in 2021 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW301A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-157 Submitted under KCP 6.2-141	Tóth, F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCSI (Yellow rust) on winter wheat in (Slovakia) in 2021 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW302A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-158 Submitted under KCP 6.2-142	Malovcová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in (Slovakia) in 2021 NPPC - VURV Piestany, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW303A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-159 Submitted under KCP 6.2-143	Hudec, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Fusarium and Microdochium in winter wheat at T3 in (Slovakia) in 2021 Blumeria Consulting, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW305A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-160 Submitted under KCP 6.1-049	Bataille, C.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against net blotch on winter barley CRA-W, Belgium, Report No. MAL-HORVW-21-E-19 ADAMA Makhteshim Ltd, Report No. BE21FEHORVW035A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-161 Submitted under KCP 6.2-145	Roslupil, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley in the Czech Republic, 2020 ZZS Kujavy, Czech Republic, Report No. R20/04 ADAMA Makhteshim Ltd, Report No. CZ20FEHORVS311A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-162 Submitted under KCP 6.1-050	Čáp, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in the Czech Republic, 2020 ZS Nechanice, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ20FEHORVS315A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-163 Submitted under KCP 6.2-147	Čáp, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in the Czech Republic in 2021 ZS Nechanice, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FEHORVS306A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-164 Submitted under KCP 6.2-148	Bezdičková, A.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in the Czech Republic in 2021 Ditana, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FEHORVS307A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-165 Submitted under KCP 6.1-051	Negrini, P	2019	Efficacy comparison of ADM.3503.F.1.A to the equivalent tank mix for the control of RAMUCC and PYRNTE on Barley in France in 2019 Antedis, France, Report No. ADA-FE19OH-03109-CA ADAMA Makhteshim Ltd, Report No. FR19FEHORVX107A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4- 166	Aingueneau, L.	2019	Efficacy comparison of ADM.3503.F.1.A to the equivalent tank mix for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on Barley in France in 2019 Antedis, France, Report No. ADA-FE19OH-03334-BR ADAMA Makhteshim Ltd, Report No. FR19FEHORVX107B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 167 Submitted under KCP 6.1- 052	Flahaut, J.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Pyrenophora teres</i> (PYRNTE) and <i>Rhynchosporium secalis</i> (RHYNSE) on barley in France, 2019 Staphyt, France, Report No. JFT-19-40084-FR01 ADAMA Makhteshim Ltd, Report No. FR19FEHORVX108A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 168 Submitted under KCP 6.2- 151	Lombart, L.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in France, 2020 Ephydia, France, Report No. FRM-20-F17 ADAMA Makhteshim Ltd, Report No. FR20FEHORVX510A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 169 Submitted under KCP 6.2- 152	Flahaut, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (leaf blotch) and PYRNTE (net blotch) on barley in FRANCE, 2020 Staphyt, France, Report No. JFT-20-45676-FR01 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW510B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 170 Submitted under KCP 6.1- 053	Voisin, J.F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in FRANCE, 2020 Agrotest, France, Report No. E-2018 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW512C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4- 171 Submitted under KCP 6.1- 054	Wallart, F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Leaf Blotch) on barley in France, 2020 Ephydia, France, Report No. FRM 20 F19 ADAMA Makhteshim Ltd, Report No. FR20FEHORVX514A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 172 Submitted under KCP 6.1- 055	Biaunier, M.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in FRANCE, 2020 Qualiphyt, France, Report No. QUALI20100F25 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW514C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 173	Biaunier, M.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in FRANCE, 2020 Qualiphyt, France, Report No. QUALI20101H08 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW516B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 174 Submitted under KCP 6.2- 156	Voisin, J.F.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in FRANCE, 2020 Agrotest, France, Report No. E 2020 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW516D GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 175 Submitted under KCP 6.1- 056	Rouane, W.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on barley in France, 2020 Anadiag, France, Report No. FR203031PS303 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW517B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4- 176 Submitted under KCP 6.1- 057	Wallart, F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on barley in France, 2020 Ephydia, France, Report No. FRM 20 F18 ADAMA Makhteshim Ltd, Report No. FR20FEHORVX512A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 177 Submitted under KCP 6.1- 058	Negrini, P.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC on Barley in France in 2020 Antedis, France, Report No. ADA FE20OH 05273 PR ADAMA Makhteshim Ltd, Report No. FR20FEHORVX517A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 178 Submitted under KCP 6.2- 160	Rouane, W.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in France in 2021 Anadiag, France, Report No. FR213045DP303 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW557B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 179 Submitted under KCP 6.2- 161	Lombart, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in France in 2021 Ephydia, France, Report No. FRM 21 F23 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW557C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 180 Submitted under KCP 6.1- 059	Wallart, F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in France in 2021 Ephydia, France, Report No. FRM 21 F19 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW558B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-181 Submitted under KCP 6.1-060	Biaunier, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in FRANCE in 2021 Qualiphyt, France, Report No. QUALI21107D07 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW559A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-182 Submitted under KCP 6.1-061	Biaunier, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in FRANCE in 2021 Qualiphyt, France, Report No. QUALI21107F15 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW559B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-183 Submitted under KCP 6.2-165	Gouaille, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Blumeria graminis hordei) on winter barley in France in 2021. Biotek Agriculture, France, Report No. BPE21/206/FGC01 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW560B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-184 Submitted under KCP 6.2-166	Voisin J.F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in France in 2021 Agrotest, France, Report No. E-2156 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW560C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-185 Submitted under KCP 6.1-062	Hetterich, A.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Rhynchosporium (RHYNSE) on barley (Germany), 2019 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW909A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-186 Submitted under KCP 6.1-063	Thomas Martin	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Rhynchosporium (RHYNSE) on barley (Germany), 2019 Martin Feldversuchswesen, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW909B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-187 Submitted under KCP 6.1-064	Peter Wolf	2019	Efficacy of ADM.3503.F.1.A compared to the equivalent active ingredients in tank mix for the control of Pyrenophora teres (PYRNTE) in Barley Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW910B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-188 Submitted under KCP 6.2-170	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on winter barley in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SN-WG-146 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW227A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-189 Submitted under KCP 6.2-171	Holger Teresiak	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on winter barley in Germany, 2020 Agro-check, Germany, Report No. AC/20/090 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW227B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-190 Submitted under KCP 6.1-065	Magyaróvári, V.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on barley in Germany, 2020 Agrartest, Germany, Report No. S20-03247 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW228A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-191 Submitted under KCP 6.1-066	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-HE-WG-147 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW229A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-192 Submitted under KCP 6.2-172	Lamers, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Germany, 2020 BioChem Agrar, Germany, Report No. 20 1069 5130 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW230A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-193 Submitted under KCP 6.2-175	Magyaróvári, V.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Germany, 2020 Agrartest, Germany, Report No. S20-03245 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW230B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-194 Submitted under KCP 6.1-067	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (Ramularia collo-cygni) on barley in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWG 20 ADA 231A ADAMA Makhteshim Ltd, Report No. DE20FEHORVW231A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-195 Submitted under KCP 6.1-068	Wolf, P.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (Ramularia collo-cygni) on Barley Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE20FEHORVW231B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-196 Submitted under KCP 6.2-178	Martin, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (Ramularia collo-cygni) on barley in Germany in 2021 Martin Feldversuchswesen, Germany, Report No. HWG 21 ADA 506A ADAMA Makhteshim Ltd, Report No. DE21FEHORVW506A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-197 Submitted under KCP 6.2-179	Wönckhaus, S.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in Germany in 2021 Agrartest, Germany, Report No. S21-02913-01 ADAMA Makhteshim Ltd, Report No. DE21FEHORVW506B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-198 Submitted under KCP 6.1-069	Martin, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (Ramularia collo-cygni) on barley in Germany in 2021 Martin Feldversuchswesen, Germany, Report No. FWG 21 ADA 507A ADAMA Makhteshim Ltd, Report No. DE21FEHORVX507A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-199 Submitted under KCP 6.1-070	Perner, J.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in Germany in 2021 U.A.S., Germany, Report No. 148_21_Z ADAMA Makhteshim Ltd, Report No. DE21FEHORVX508A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-200 Submitted under KCP 6.2-182	Torkler, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in Germany in 2021 Quintus, Germany, Report No. K-136-QUI-21-236 ADAMA Makhteshim Ltd, Report No. DE21FEHORVX509A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-201 Submitted under KCP 6.2-183	Ommen, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium secalis) on barley in Germany in 2021 Plantus, Germany, Report No. 21F-2-PLA-016 ADAMA Makhteshim Ltd, Report No. DE21FEHORVX509B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-202 Submitted under KCP 6.1-071	Ommen, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (Ramularia) on barley in Germany in 2021 Plantus, Germany, Report No. 21F-2-PLA-017 ADAMA Makhteshim Ltd, Report No. DE21FEHORVX510A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-203	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (Rhynchosporium secalis) on barley in Ireland, 2020 Eurofins, Ireland, Report No. S20-02703-01 ADAMA Makhteshim Ltd, Report No. IE20FEHORVX313A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-204	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in Ireland, 2020 Eurofins, Ireland, Report No. S20-02704-01 ADAMA Makhteshim Ltd, Report No. IE20FEHORVX315A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-205 Submitted under KCP 6.1-072	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RAMUCC (Ramularia collo-cygni) on barley in Ireland, 2020 Eurofins, Ireland, Report No. S20-02702-01 ADAMA Makhteshim Ltd, Report No. IE20FEHORVX318A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-206	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RAMUCC (Ramularia collo-cygni) on barley in Ireland, 2020 Eurofins, Ireland, Report No. S20-02702-02 ADAMA Makhteshim Ltd, Report No. IE20FEHORVX318B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-207 Submitted under KCP 6.1-073	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03032-01 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX323A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-208 Submitted under KCP 6.1-074	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03032-02 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX323B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-209 Submitted under KCP 6.1-075	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (Ramularia) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03303-01 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX325A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-210 Submitted under KCP 6.1-076	Joynt, R.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Rhynchosporium (RHYNSE) on barley in the UK, 2019 ADAS, Ireland, Report No. WA19-WB-Adama 9T (348) ADAMA Makhteshim Ltd, Report No. UK19FEHORVX348A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-211	Joynt, R.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Pyrenophora teres (PYRNTE) on barley in the UK, 2019 ADAS, Ireland, Report No. HM19/WB13 ADAMA Makhteshim Ltd, Report No. UK19FEHORVX349A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4- 212 Submitted under KCP 6.2- 190	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1026A-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX310A- GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 213 Submitted under KCP 6.2- 191	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in the UK, 2020 OAT, United Kingdom, Report No. 20-1026B-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX310B- GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 214	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1027-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX312A- GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 215 Submitted under KCP 6.1- 077	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1028A-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX314A- GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 216 Submitted under KCP 6.2- 193	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1029-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX316A- GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4- 217 Submitted under KCP 6.2- 194	Joynt, R.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in the UK, 2020 ADAS, United Kingdom, Report No. GT20/024 ADAMA Makhteshim Ltd, Report No. UK20FEHORVX316B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 218 Submitted under KCP 6.1- 081	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (Ramularia collo-eygii) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1030-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX317A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 219 Submitted under KCP 6.2- 196	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in the UK in 2021 OAT, United Kingdom, Report No. 1077-21-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX306A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 220	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in the UK in 2021 OAT, United Kingdom, Report No. 21-1078-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX307A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 221 Submitted under KCP 6.1- 079	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in the UK in 2021 OAT, United Kingdom, Report No. 21-1079B-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX308B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4- 222 Submitted under KCP 6.1- 080	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in the UK in 2021 Eurofins, Derby, United Kingdom, Report No. S21-03034-01 ADAMA Makhteshim Ltd, Report No. UK21FEHORVX308C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 223 Submitted under KCP 6.2- 199	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in the UK in 2021 OAT, United Kingdom, Report No. 21-1080-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX309A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 224 Submitted under KCP 6.2- 200	Joynt, R.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in the UK in 2021 ADAS, United Kingdom, Report No. HM21-063 ADAMA Makhteshim Ltd, Report No. UK21FEHORVX309B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 225	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (Ramularia) on barley in the UK in 2021 OAT, United Kingdom, Report No. 21-1081-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX310A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 226 Submitted under KCP 6.2- 201	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in Poland, 2020 Fertico, Poland, Report No. 60_01_F20_80 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW066A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-227 Submitted under KCP 6.2-202	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in Poland, 2020 Staphyt, Poland, Report No. APK-20-44721-PL01 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW066B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-228 Submitted under KCP 6.1-079	Sawinska, Z.	2020	The evaluation of efficacy ADM.03503.F.1.A and ADM.01352.F.3.A in fungal diseases control in winter barley cultivation, Poland 2020 Poznań University, Poland, Report No. AF/20/JO/19/Pr/067A ADAMA Makhteshim Ltd, Report No. PL20FEHORVW067A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-229 Submitted under KCP 6.1-082	Kukuła, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on barley in Poland, 2020 Agreco, Poland, Report No. 20ADA0677-1 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW067B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-230 Submitted under KCP 6.1-083	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Poland, 2020 Fertico, Poland, Report No. 61_01_F20_81 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW068A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-231 Submitted under KCP 6.1-084	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Poland, 2020 Staphyt, Poland, Report No. APK-20-44722-PL01 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW068B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-232 Submitted under KCP 6.2-207	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Poland, 2020 Fertico, Poland, Report No. 62_01_F20_82 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW069A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-233 Submitted under KCP 6.2-208	Kukuła, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Poland, 2020 Agreco, Poland, Report No. 20ADA0678-1 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW069B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-234 Submitted under KCP 6.2-209	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against Puccinia hordei (PUCCHD) on winter barley in Poland, 2021 Fertico, Poland, Report No. 74_01_F21_181 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW029A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-235 Submitted under KCP 6.2-210	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter barley cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/JO/9/Br/029B ADAMA Makhteshim Ltd, Report No. PL21FEHORVW029B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-236 Submitted under KCP 6.1-085	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against Rhynchosporium secalis (RHYNSE) on winter barley in Poland, 2021 Fertico, Poland, Report No. 75_01_F21_182 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW030A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-237 Submitted under KCP 6.1-086	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter barley cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/JO/9/ZI/030B ADAMA Makhteshim Ltd, Report No. PL21FEHORVW030B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-238 Submitted under KCP 6.1-087	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against Pyrenophora teres (PYRNTE) on winter barley in Poland, 2021 Fertico, Poland, Report No. 76_01_F21_183 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW031A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-239	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in POLAND in 2021 Staphyt, Poland, Report No. MP2-21-50283-PL01 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW031B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-240 Submitted under KCP 6.2-214	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against Blumeria graminis hordei (ERYSGH) on winter barley in Poland, 2021 Fertico, Poland, Report No. 77_01_F21_184 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW032A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-241 Submitted under KCP 6.2-215	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against Blumeria graminis hordei (ERYSGH) on winter barley in Poland, 2021 Fertico, Poland, Report No. 77_02_F21_185 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW032B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-242	Rábai, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of powdery mildew on barley in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-123-002FE ADAMA Makhteshim Ltd, Report No. HU20FEHORVX520A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-243	Juhász, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Hungary, 2020 SGS, Hungary, Report No. 20-FE-05-SG1 ADAMA Makhteshim Ltd, Report No. HU20FEHORVX520B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4- 244 Submitted under KCP 6.2- 216	Benezés, B.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-124-002FE ADAMA Makhteshim Ltd, Report No. HU20FEHORVX520C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 245	Olasz, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-118-002FE ADAMA Makhteshim Ltd, Report No. HU20FEHORVX521A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 246	Varga, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-121-002FE ADAMA Makhteshim Ltd, Report No. HU20FEHORVX522A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 247	Nagy, Z.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-122-002FE ADAMA Makhteshim Ltd, Report No. HU20FEHORVX522B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 248	Varga, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (Rhynchosporium secalis) on barley in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-119-002FE ADAMA Makhteshim Ltd, Report No. HU20FEHORVX523A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 249	Makó, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (Rhynchosporium secalis) on barley in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-120-002FE ADAMA Makhteshim Ltd, Report No. HU20FEHORVX523B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4- 250	Németh, S.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Leaf blotch of cereals) on barley in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-097-002FE ADAMA Makhteshim Ltd, Report No. HU21FEHORVW306A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 251 Submitted under KCP 6.2- 217	Ritecz, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Pyrenophora teres) on barley in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-098-002FE ADAMA Makhteshim Ltd, Report No. HU21FEHORVW309A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 252 Submitted under KCP 6.1- 088	Tuna, V.	2019	Determination of Efficacy of ADM.3503.F.1.A compared to the equivalent tank mix, applied post-emergence against Pyrenophora teres (PYRNTE) in barley, outdoor 2019 Eurofins, Romania, Report No. S19-03924-01 ADAMA Makhteshim Ltd, Report No. RO19FEHORVW171A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 253 Submitted under KCP 6.2- 219	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW245A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 254 Submitted under KCP 6.2- 220	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW245B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4- 255	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (Rhynchosporium secalis) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW246A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 256 Submitted under KCP 6.1- 089	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (Rhynchosporium secalis) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW246B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 257 Submitted under KCP 6.1- 090	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW247A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 258 Submitted under KCP 6.1- 091	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW247B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 259 Submitted under KCP 6.2- 224	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02897-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW210A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4- 260 Submitted under KCP 6.2- 225	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02897-02 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW210B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 261 Submitted under KCP 6.1- 092	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02898-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW211A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 262 Submitted under KCP 6.1- 093	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02898-02 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW211B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 263 Submitted under KCP 6.1- 094	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02899-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW212A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 264 Submitted under KCP 6.2- 229	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02901-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW218A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4- 265 Submitted under KCP 6.2- 230	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02901-02 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW218B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 266 Submitted under KCP 6.1- 095	Holcikova, D.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Rhynchosporium (RHYNSE) on barley Slovakia, 2019 FYSE,Slovakia, Report No. FYSE-103201915 ADAMA Makhteshim Ltd, Report No. SK19FEHORVW348A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 267 Submitted under KCP 6.2- 232	Malovcova, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Slovakia, 2020 NPPC - VURV Piestany,Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVS316A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 268 Submitted under KCP 6.2- 233	Forgáčová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley in Slovakia, 2020 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW311A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 269 Submitted under KCP 6.1- 096	Kovacova Holcikova, D.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (Rhynchosporium secalis) on barley in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE103202015 ADAMA Makhteshim Ltd, Report No. SK20FEHORVW313A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 270 Submitted under KCP 6.1- 097	Tóth, F.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (Rhynchosporium secalis) on barley in Slovakia, 2020 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW313B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-271 Submitted under KCP 6.1-098	Forgáčová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in Slovakia, 2020 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW315A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-272	Hudec, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in Slovakia, 2020 Blumeria Consulting, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW315B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-273 Submitted under KCP 6.2-237	Malovcová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in (Slovakia) in 2021 NPPC - VURV Piestany, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FEHORVS309A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-274 Submitted under KCP 6.2-238	Hudec, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in (Slovakia) in 2021 Blumeria Consulting, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FEHORVW306A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-275 Submitted under KCP 6.2-239	Tóth, F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in (Slovakia) in 2021 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FEHORVW306B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-276 Submitted under KCP 6.1-099	Kováčová Holčíková, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on barley in (Slovakia) in 2021 Berberis, Slovakia, Report No. SK21FEHORVW307A - ZV04 ADAMA Makhteshim Ltd, Report No. SK21FEHORVW307A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-277 Submitted under KCP 6.1-100	Kováčová Holčíková, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in (Slovakia) in 2021 Berberis, Slovakia, Report No. SK21FEHORVW308A- ZV03 ADAMA Makhteshim Ltd, Report No. SK21FEHORVW308A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-278 Submitted under KCP 6.1-101	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on rye in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WR-148 ADAMA Makhteshim Ltd, Report No. DE20FESECSS232A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-279 Submitted under KCP 6.1-102	Magyaróvári, V.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Rhynchosporium secalis) on rye in Germany, 2020 Agrartest, Germany, Report No. S20-03246-01 ADAMA Makhteshim Ltd, Report No. DE20FESECSS232B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-280 Submitted under KCP 6.1-103	Wied, H.M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRE (Puccinia recondita) on rye in Germany in 2021 Staphyt, Germany, Report No. HWD-21-50086-DE01 ADAMA Makhteshim Ltd, Report No. DE21FESECSS511A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-281 Submitted under KCP 6.1-104	Zöllner, H.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on rye in Germany in 2021 Field Research Support, Germany, Report No. FRS105/21 ADAMA Makhteshim Ltd, Report No. DE21FESECSS511B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-282 Submitted under KCP 6.1-105	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A and ADM.01352.F.3.A in fungal diseases control in winter rye , Poland, 2020 Poznań University, Germany, Report No. AF/20/ŻO/19/BR/070A ADAMA Makhteshim Ltd, Report No. PL20FESECSS070A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-283 Submitted under KCP 6.1-106	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter rye cultivation, Poland, 2021 Poznań University, Germany, Report No. AF/21/ŻO/9/Br/033A ADAMA Makhteshim Ltd, Report No. PL21FESECSS033A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-284	Rábai, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (Rhynchosporium secalis) on rye in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-125-002FE ADAMA Makhteshim Ltd, Report No. HU20FESECCW530A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-285 Submitted under KCP 6.1-107	Maesim, C.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on rye in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02902-01 ADAMA Makhteshim Ltd, Report No. RO21FESECSS214A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4- 286 Submitted under KCP 6.1- 408	Macsim, C.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium) on rye in ROMANIA in 2021 Eurofins, Romania, Report No. S21-04520-01 ADAMA Makhteshim Ltd, Report No. RO21FESECSS250A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 287 Submitted under KCP 6.2- 252	Čáp, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (Pyrenophora tritici-repentis) on triticale the Czech republic, 2020 ZS Nechanice, Czech Republic, Report No. CZOR-ATA20- TTLSS-036NEC ADAMA Makhteshim Ltd, Report No. CZ20FETTLWI324A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 288 Submitted under KCP 6.2- 253	Teresiak, H.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRE (brown rust) on triticale in Germany, 2020 Agro-check, Czech Republic, Report No. AC/20/091 ADAMA Makhteshim Ltd, Report No. DE20FETTLSS233A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 289 Submitted under KCP 6.2- 254	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (Pyrenophora tritici- repentis) on triticale in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-TR-149 ADAMA Makhteshim Ltd, Report No. DE20FETTLSS234A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 290 Submitted under KCP 6.2- 255	Zöllner, H.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Rhynchosporium secalis) on triticale in Germany in 2021 Field Research Support, Germany, Report No. FRS106/21 ADAMA Makhteshim Ltd, Report No. DE21FETTLSS512A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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KCP 6.4-291 Submitted under KCP 6.2-256	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of Puccinia recondita (brown rust) on triticale in Poland, 2020 Fertico, Poland, Report No. 63_01_F20_83 ADAMA Makhteshim Ltd, Report No. PL20FETTLSS071A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-292 Submitted under KCP 6.2-257	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (Pyrenophora tritici-repentis) on triticale in Poland, 2020 Fertico, Poland, Report No. 64_01_F20_84 ADAMA Makhteshim Ltd, Report No. PL20FETTLSS072A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-293 Submitted under KCP 6.2-258	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (Pyrenophora tritici-repentis) on triticale in Poland, 2020 Staphyt, Poland, Report No. APK-20-44723-PL01 ADAMA Makhteshim Ltd, Report No. PL20FETTLSS072B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-294 Submitted under KCP 6.2-259	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Puccinia recondita (Brown rust) on triticale in Poland in 2021 Staphyt, Poland, Report No. MP2-21-50285-PL01 ADAMA Makhteshim Ltd, Report No. PL21FETTLSS034A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-295 Submitted under KCP 6.2-260	Ritecz, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Puccinia recondita (brown rust) on triticale in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-126-002FE ADAMA Makhteshim Ltd, Report No. HU20FETTLW1540A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4- 296 Submitted under KCP 6.2- 261	Makó, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (Pyrenophora tritici-repentis) on triticale in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-127-002FE ADAMA Makhteshim Ltd, Report No. HU20FETTLW1541A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 297 Submitted under KCP 6.2- 262	Németh, S.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (Pyrenophora tritici-repentis) on triticale in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-128-002FE ADAMA Makhteshim Ltd, Report No. HU20FETTLW1541B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 298	Rábai, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (Pyrenophora tritici-repentis) on triticale in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-129-002FE ADAMA Makhteshim Ltd, Report No. HU20FETTLW1541C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 299 Submitted under KCP 6.2- 263	Ritecz, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Puccinia (Brown rust) on triticale in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-100-002FE ADAMA Makhteshim Ltd, Report No. HU21FETTLWSW312A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 300 Submitted under KCP 6.2- 264	Maesim, C.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Puccinia (Brown rust) on triticale in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02903-01 ADAMA Makhteshim Ltd, Report No. RO21FETTLSS220A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4- 301	Flahaut, J.	2021	Evaluation of the influence of a fungicide product ADM.03503.F.1.A on the quality of bread making on winter wheat, in France 2021 Staphyt, France, Report No. JFT-21-50809-FR01 ADAMA Makhteshim Ltd, Report No. FR21FPTRZAW563A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-302	Flahaut, J.	2021	Evaluation of the influence of a fungicide product ADM.03503.F.1.A on the quality of bread making on winter wheat, in France 2021 Staphyt, France, Report No. JFT-21-50809-FR02 ADAMA Makhteshim Ltd, Report No. FR21FPTRZAW563B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-303	Flahaut, J.	2021	Evaluation of the influence of a fungicide product ADM.03503.F.1.A on the quality of bread making on winter wheat, in France 2021 Staphyt, France, Report No. JFT-21-50809-FR03 ADAMA Makhteshim Ltd, Report No. FR21FPTRZAW563C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-304	Flahaut, J.	2020	Evaluate of the influence of ADM.03503.F.1.A and ADM.02154.F.2.C on the quality of beer making on spring barley, in France 2020 Staphyt, France, Report No. JFT-20-46079-FR01 ADAMA Makhteshim Ltd, Report No. FR20FPHORVS502A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-305	Flahaut, J.	2020	Evaluate of the influence of ADM.03503.F.1.A and ADM.02154.F.2.C on the quality of beer making on spring barley, in France 2020 Staphyt, France, Report No. JFT-20-46079-FR02 ADAMA Makhteshim Ltd, Report No. FR20FPHORVS502B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-306	Flahaut, J.	2020	Evaluate of the influence of ADM.03503.F.1.A and ADM.02154.F.2.C on the quality of beer making on spring barley, in France 2020 Staphyt, France, Report No. JFT-20-46079-FR03 ADAMA Makhteshim Ltd, Report No. FR20FPHORVS502C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-307	Flahaut, J.	2020	Evaluate of the influence of ADM.03503.F.1.A and ADM.02154.F.2.C on the quality of beer making on winter barley, in France 2020 Staphyt, France, Report No. JFT-20-46078-FR01 ADAMA Makhteshim Ltd, Report No. FR20FPHORVW501A GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-308	Flahaut, J.	2020	Evaluate of the influence of ADM.03503.F.1.A and ADM.02154.F.2.C on the quality of beer making on winter barley, in France 2020 Staphyt, France, Report No. JFT-20-46078-FR02 ADAMA Makhteshim Ltd, Report No. FR20FPHORVW501B GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-309	Flahaut, J.	2020	Evaluate of the influence of ADM.03503.F.1.A and ADM.02154.F.2.C on the quality of beer making on winter barley, in France 2020 Staphyt, France, Report No. JFT-20-46078-FR03 ADAMA Makhteshim Ltd, Report No. FR20FPHORVW501C GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 6.4-310	Gless, A.E.	2019	Study of unintentional effects of ADM.02154.F.2.C and ADM.03503.F.1.A products applied on winter and spring barley, harvest 2020, on malt and beer quality and process IFBM, France, Report No. R-A-F-1144 ADAMA Makhteshim Ltd, Report No. R-A-F-1144 GEP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 7.1.1/01		2021a	Acute oral toxicity study of ADM.03503.F.1.A (Fluxapyroxad 75 prothioconazole 150 g/L EC) in rats (acute toxic class method) GLP Unpublished	Y	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.2/01	██████████	2021b	Acute dermal toxicity study of ADM.03503.F.1.A (Fluxapyroxad 75 Prothioconazole 150 g/L EC) in rats (fixed dose procedure) Test Facility Study No. 401-1-01-27461 (Waiver report), Sponsor ██████████ GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 7.1.3/01	██████████	2021a	Acute inhalation toxicity study of ADM.03503.F.1.A (Fluxapyroxad 75 Prothioconazole 150 g/L EC) in rats (acute toxic class method) ██████████ GLP Unpublished	Y	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 7.1.4/01	██████████	2021a	In vitro skin corrosion test of ADM.03503.F.1.A (Fluxapyroxad 75 Prothioconazole 150 g/L EC) using reconstructed human epidermis tissues (RhE) ██████████ GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 7.1.4/02	██████████	2021b	In vitro skin irritation test of ADM.03503.F.1.A (Fluxapyroxad 75 Prothioconazole 150 g/L EC) using reconstructed human epidermis tissues (RhE) ██████████ GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 7.1.4/03	██████████	2021c	Acute dermal irritation study of ADM.03503.F.1.A (Fluxapyroxad 75 Prothioconazole 150 g/L EC) in rabbits ██████████ GLP Unpublished	Y	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.5/01	██████████	2021b	In vitro eye irritation test of ADM.03503.F.1.A (Fluxapyroxad 75 Prothioconazole 150 g/L EC) using bovine corneal opacity and permeability test ██████████ GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 7.1.5/02	██████████	2021d	Acute eye irritation study of ADM.03503.F.1.A (Fluxapyroxad 75 Prothioconazole 150 g/L EC) in rabbits ██████████ GLP Unpublished	Y	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 7.1.6/01	██████████	2021c	In vitro skin sensitisation study of ADM.03503.F.1.A (Fluxapyroxad 75 Prothioconazole 150 g/L EC): keratinocyte based ARE-NRF2 luciferase reporter gene test ██████████ GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 7.1.6/02	██████████	2021d	In chemico skin sensitisation of ADM.03503.F.1.A (Fluxapyroxad 75 Prothioconazole 150 g/L EC): Direct peptide reactivity assay (DPRA) ██████████ GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 7.1.6/03	██████████	2021c	Skin sensitisation study of ADM.03503.F.1.A (Fluxapyroxad 75 Prothioconazole 150 g/L EC) by local lymph node assay in mice ██████████ GLP Unpublished	Y	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.3/01		2021a	The In Vitro Percutaneous Absorption of Radiolabelled Fluxapyroxad in a Concentrate and Two In-Use Dilutions of the Fluxapyroxad 75 g/L + Prothioconazole 150 g/L EC Formulation (ADM.03503.F.1.A) Through Human Split-Thickness Skin GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 7.3/02		2021b	The In Vitro Percutaneous Absorption of Radiolabelled Prothioconazole-desthio in Two In-Use Dilutions of the Fluxapyroxad 75 g/L + Prothioconazole 150 g/L EC Formulation (ADM.03503.F.1.A) Through Human Split-Thickness Skin GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 7.4	Anonymous	2022	Safety Data Sheet ADM.03503.F.1.A Version 2.01 Revision date 16-Mar-2022 ADAMA Makhteshim Ltd Non-GLP Unpublished	N	N		ADM
KCP 8/ KCA 6.1/01	Klimmek, S. and Gizler, A.	2017	Freezing storage stability & validation of residues of 1,2,4-Triazole, Triazole Alanine, Triazole Acetic Acid and Triazole Lactic Acid in water, acid and dry matrix: cucumber, grapes and dry bean at 0, 3, 6, 12, 18, 24 and 36 months. Report No.: S12-00072, sponsor no.: 000074067 (R-30330) Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B, Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 ADM.03502.F.1.A, ADM.03509.F.1.A and ADM.03501.F.1.A. Data protection has not expired	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8/ KCA 6.1/02	Lefresne, S.	2020	Freezing storage stability of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio in plant matrices at/below -18°C during 24 months (0, 1, 3, 12, 18 and 24 months): Wheat whole plant (high water content), wheat grain (high starch content), wheat straw (difficult commodity), oilseed rape grain (high oil content), strawberry (high acid content) and dry bean (high protein content). Report No.: B18S-A4-P-02, sponsor no.: R-39653 POLLENIZ/GIRPA, Beaucozè Cedex, France GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B, Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 ADM.03502.F.1.A, ADM.03509.F.1.A and ADM.03501.F.1.A. Data protection has not expired	ADM
KCP 8/ KCA 6.1/03	Lindner, M.	2022	Storage stability of prothioconazole and azoxystrobin in pollen, nectar, flowers and honey under deep frozen conditions Study no.: S19-02145, MAC-1931L, sponsor no.: 000104133 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	ADM
KCP 8/ KCA 6.1/04	Lindner, M.	2021	Storage Stability of Fluxapyroxad in Flowers, Nectar and Pollen under Deep Frozen Conditions. Report no.: S21-00224 (MAC-211L), sponsor no.: 000107309 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 8/ KCA 6.3.1/01	Amic, S.	2020b	Residue study of prothioconazole and its metabolites in wheat whole plant and Raw Agricultural Commodity after one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) - 2 harvest and 2 decline trials – Northern Europe (France, Hungary and Poland) – 2019.. Report no.: BPL19/762/GC, sponsor no.: 000102751 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 and ADM.03501.F.1.A. Data protection has not expired	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8/ KCA 6.3.1/02	Yozgatli, H.P.	2021d	Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (RAC whole plant, grain and straw) following one application of ADM.3500.F.2.B (250g a.s./L of prothioconazole) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Hungary and Poland) 2019 Study no: S19-00733 (MAC-1908), sponsor no.: 000102783 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	ADM
KCP 8/ KCA 6.3.1/03	Le Mineur, A.	2022a	Residue study of Prothioconazole and Fluxapyroxad and their respective metabolites in wheat Raw Agricultural Commodities after foliar application of ADM.03503.F.1.A under field conditions –Northern Europe – 2021 Study no.: BPL21/954/GC, sponsor no.: 000107608 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 (for a.s. prothioconazole) Data protection has not expired	ADM
KCP 8/ KCA 6.3.1/04	Le Mineur, A.	2022b	Residue study of prothioconazole, difenoconazole and their metabolites in wheat whole plant and raw agricultural commodities after foliar application of ADM.03501.F.1.A under field conditions – Northern Europe - 2021 Study no.: BPL21/958/GC, EFSA-2021-00000558, sponsor no.: 000107612 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Data protection has not expired	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8/ KCA 6.3.2/01	Amic, S.	2020d	Residue study of prothioconazole and its metabolites in barley whole plant and Raw Agricultural Commodity after one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) - 2 harvest and 2 decline trials – Northern Europe (France, Hungary and Poland) – 2019. Report no.: BPL19/764/GC, sponsor no.: 000102753 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 and ADM.03501.F.1.A. Data protection has not expired	ADM
KCP 8/ KCA 6.3.2/02	Yozgatli, H.P.	2021g	Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (RAC whole plant, grain and straw) following one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Hungary and Poland) 2019 Study no.: S19-00735 (MAC-1910), sponsor no.: 000102785 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	ADM
KCP 8/ KCA 6.3.2/03	Huaultmé, J.-M.	2021a	Residue study of Prothioconazole and its metabolites, and Fenpropidin in barley whole plant and Raw Agricultural Commodity after one foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) - 2 harvest and 2 decline trials – Northern Europe (France, Poland and Hungary) - 2020. Report no.: BPL20/844/GC, sponsor no.: 000105350 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 and ADM.03502.F.1.A Data protection has not expired	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8/ KCA 6.3.2/04	Yozgatli, H.P.	2021h	Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (RAC whole plant, grain and straw) following one foliar application of ADM.3502.F.1.A (175g a.s./L of prothioconazole and 250 g/L fenpropidin) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Poland and Hungary), 2020 Study no.: S20-01302 (MAC -2005), sponsor no.: 000105545 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Sorate1 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	ADM
KCP 8/ KCA 6.3.2/05	Barbier, G.	2022	Analysis of prothioconazole and its metabolites in barley after application of ADM.3502.F.1.A (prothioconazole and fenpropidin) in trial in Northern - 2020 Study no.: B21G-A4-P-05 EFSA-2021-00005296. sponsor no.: 000108763 GIRPA, Beaucoûzé Cedex, France GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Sorate1 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	ADM
KCP 8/ KCA 6.3.2/06	Huauilmé, J.-M.	2022a	Residue study of fluxapyroxad and prothioconazole and their metabolites in barley raw agricultural commodities after application of ADM.03503.F.1.A under field conditions - Northern Europe - 2021 Study no.: BPL21/962/GC, EFSA-2021-00000512. sponsor no.: 000107616 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Sorate1 250 EC, Reg. no. 156/2023 dated 18.09.23 (for a.s. prothioconazole) Data protection has not expired	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8/ KCA 6.5.1/01	Bloß, K.	2019	Prothioconazole-desthio: Aqueous Hydrolysis of [¹⁴ C]Prothioconazole-desthio at 90, 100 and 120 °C. Report no.: S18-07655, sponsor no.: 000101817 Eurofins Agrosience Services EcoChem GmbH, Niefern- Öschelbronn, Germany GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B. Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 ADM.03502.F.1.A, ADM.03509.F.1.A and ADM.03501.F.1.A. Data protection has not expired	ADM
KCP 8/ KCA 6.6.2/01	Semrau, J.	2021	Determination of Residues of Prothioconazole and its Metabolites after One Application of MCW-2073 on Bare Soil in Rotational Crops (Radish, Leaf lettuce and Barley) at 2 Sites in Northern Europe and 2 Sites in Southern Europe 2018/2019 Study no.: S18-02513, sponsor no.: 000109154 (R-39638) Eurofins Agrosience Services GmbH, Stade, Germany GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	ADM
KCP 8/ KCA 6.6.2/02	Semrau, J.	2022	Determination of residues of prothioconazole metabolites in rotational crops (radish, lettuce, barley) after one application of Prothioconazole 250 EC (ADM.03500.F.2.B) on bare soil at 1 site in Northern Europe and 1 site in Southern Europe 2021 Study no.: S21-00408, sponsor no.: 000107470 Eurofins Agrosience Services GmbH, Stade, Germany GLP Unpublished	N	Y	Study was submitted before to Poland to support product registration under EU Regulation 1107/2009 of ADM.03500.F.2.B Soratel 250 EC, Reg. no. 156/2023 dated 18.09.23 Data protection has not expired	ADM
KCP 8/ KCA 6.6.2/03	Anonymous	2022	Position Paper: 1,2,4-Triazole residues in crop residue trials and rotational crops following the use of Prothioconazole Sponsor no.: 000110079 ADAMA Agricultural Solutions Ltd., Airport City, Israel Not GLP Unpublished	N	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.4 / 01	Brauer, M., Jarvis, T.	2022a	Fluxapyroxad - Predicted environmental concentrations in groundwater after post-emergence application of fluxapyroxad to cereals in the Central Zone of the European Union - FOCUS groundwater calculations Exponent report no.: 2005459.UK0-6014 Sponsor no: 000110467 Exponent International Ltd., Basel, Switzerland Not GLP, not published	N	N		ADM
KCP 9.2.4 / 02	Brauer, M., Jarvis, T.	2022b	Prothioconazole - Predicted environmental concentrations in groundwater after post-emergence application of prothioconazole to cereals in the Central Zone of the European Union - FOCUS groundwater calculations Exponent report no.: 2005459.UK0-6810 Sponsor no: 000110468 Exponent International Ltd., Basel, Switzerland Not GLP, not published	N	N		ADM
KCP 9.2.5 / 01	Brauer, M., Weber, D., Jarvis, T.	2022c	Fluxapyroxad - Predicted environmental concentrations in surface water after post-emergence application of fluxapyroxad to cereals in the Central Zone of the European Union - FOCUS Step 1-2 calculations Exponent report no.: 2005459.UK0-8413 Sponsor no: 000110469 Exponent International Ltd., Basel, Switzerland Not GLP, not published	N	N		ADM
KCP 9.2.5 / 02	Brauer, M., Weber, D., Jarvis, T.	2022d	Prothioconazole - Predicted environmental concentrations in surface water after post-emergence application of prothioconazole to cereals in the Central Zone of the European Union - FOCUS Step 1-2 calculations Exponent report no.: 2005459.UK0-0492 Sponsor no: 000110471 Exponent International Ltd., Basel, Switzerland Not GLP, not published	N	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.5 / 03	Weber, D., Brauer, M., Jarvis, T.	2022a	Predicted environmental concentrations in surface water after post-emergence application of fluxapyroxad to winter and spring cereals in the Central Zone of the European Union - FOCUS Step 3-4 calculations Exponent report no.: 2005459.UK0-0194 Sponsor no: 000110472 Exponent International Ltd., Basel, Switzerland Not GLP, not published Exponent report no.: 2005459.UK0-0194	N	N		ADM
KCP 9.2.5 / 04	Weber, D., Brauer, M., Jarvis, T.	2022b	Predicted environmental concentrations in surface water after post-emergence application of prothioconazole to winter and spring cereals in the Central Zone of the European Union - FOCUS Step 3-4 calculations Exponent report no.: 2005459.UK0-7090 Sponsor no: 000110473 Exponent International Ltd., Basel, Switzerland Not GLP, not published Exponent report no.: 2005459.UK0-7090	N	N		ADM
KCP 10.2.1/01	██████████	2021a	Acute toxicity of ADM.03503.F.1.A to <i>Oncorhynchus mykiss</i> in a 96-hour semi-static test ██████████ GLP Unpublished	Y	N		ADM
KCP 10.2.1/02	Juckeland, D.	2021b	Acute toxicity of ADM.03503.F.1.A to <i>Daphnia magna</i> in a 48-hour static test Test facility report No. 20 48 ADL 0005 (incl. Amendment No. 1), Sponsor report no. 000105070 BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2.1/03	Juckeland, D.	2021c	Effects of ADM.03503.F.1.A on <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test Test facility report No. 20 48 AAL 0007, Sponsor report no. 000105071 BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 10.3.1.1./01	Franke, M.	2020	Acute toxicity of ADM.03503.F.1.A to the honeybee <i>Apis mellifera</i> L. under laboratory conditions Test facility report No. 20 48 BAA 0026, Sponsor report no. 000105072 BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 10.3.1.2./01	Dreßler, K.	2021	Chronic toxicity of ADM.03503.F.1.A to the honeybee <i>Apis mellifera</i> L. under laboratory conditions Test facility report No. 20 48 BAC 0010, Sponsor report no. 000105073 BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 10.3.1.3./01	Hänsel, M.	2021	ADM.03503.F.1.A – Repeated exposure of honeybee larvae (<i>Apis mellifera</i> L.) under laboratory conditions Test facility report No. 20 48 BLC 0012 (incl. Amendment No. 1), Sponsor report no. 000105074 BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 10.3.1.5/01	Persigehl, M.; Beinert, M.; Hotopp, I.	2022a	Study on the Effect of ADM.03503.F.1.A on Honey Bee Colonies (<i>Apis mellifera</i> L.) under Semi-Field Conditions in Germany Test facility report No. B20F026, Sponsor report no. 000107305 tier3 solutions GmbH, Leverkusen, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1.5/0 2	Persigehl, M.; Beinert, M.; Hotopp, I.	2022b	Study on the Effect of ADM.03503.F.1.A on Honey Bee Colonies (<i>Apis mellifera</i> L.) under Semi-Field Conditions in Spain Test facility report No. B20F027, Sponsor report no. 000107306 tier3 solutions GmbH, Leverkusen, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 10.3.2.1./0 1	Röhlig, U.	2020a	Effects of ADM.03503.F.1.A on the parasitic wasp <i>Aphidius rhopalosiphi</i> (DESTAFANI-PEREZ) in a laboratory test Test facility report No. 20 48 NAL 0004, Sponsor report no. 000105076 BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 10.3.2.1./0 2	Röhlig, U.	2020b	Effects of ADM.03503.F.1.A on the predatory mite <i>Typhlodromus pyri</i> SCHEUTEN in a laboratory test Test facility report No. 20 48 NTL 0004, Sponsor report no. 000105075 BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 10.4.1.1./0 1	Friedrich, S.	2020a	Effects of ADM.03503.F.1.A on the reproduction of the earthworm <i>Eisenia fetida</i> in artificial soil Test facility report No. 20 48 TEC 0033, Sponsor report no. 000105077 BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 10.4.2.1./0 1	Friedrich, S.	2020b	Effects of ADM.03503.F.1.A on the reproduction of the collembolan <i>Folsomia candida</i> Test facility report No. 20 48 TCC 0023, Sponsor report no. 000105078 BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.4.2.1./0 1	Schulz, L.	2020a	Effects of ADM.03503.F.1.A on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> Test facility report No. 20 48 THC 0019, Sponsor report no. 000105079 BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 10.5./01	Schulz, L.	2020b	Effects of ADM.03503.F.1.A on the activity of soil microflora (Nitrogen transformation test) Test facility report No. 20 48 SMN 0020, Sponsor report no. 000105080 BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 10.6.2./01	Friedemann, A..	2021a	Effects of ADM.03503.F.1.A on seedling emergence and seedling growth of six non-target terrestrial plant species under greenhouse conditions Test facility report No. 20 48 PSE 0004, Sponsor report no. 000105081 BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM
KCP 10.6.2./02	Friedemann, A..	2021a	Effects of ADM.03503.F.1.A on vegetative vigour of six non-target terrestrial plant species under greenhouse conditions Test facility report No. 20 48 PVV 0006, Sponsor report no. 000105082 BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany GLP Unpublished	N	Y	Data/study report never used before by Poland to support a product authorization	ADM

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List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Refer to Part B.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
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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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
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