

REGISTRATION REPORT

Part A

Risk Management

Product code: ADM.03502.F.1.A

(alternative code: MCW-2091)

Product name: Forapro 425 EC

Chemical active substance:

Prothioconazole, 175 g/L

Fenpropidin, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorisation)

Applicant: ADAMA Polska Sp. z o.o.

Submission date: September 2021, updated: May 2022, October 2022

MS Finalisation date: December 2022 (initial National Assessment)

May 2023 (final National Assessment)

Version history

When	What
September 2021	Initial dRR – ADAMA Polska Sp. z o.o.
May 2022	Updated dRR – ADAMA Polska Sp. z o.o. (changes and additions are highlighted in green)
October 2022	Updated dRR – ADAMA Polska Sp. z o.o. (changes and additions are highlighted in yellow)
December 2022	<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 the product label are highlighted in grey, while not agreed use pattern is struck through and shaded.</p> <p>Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.</p>
May 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>

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PART A

RISK MANAGEMENT

1 Details of the application

This application was submitted by ADAMA Polska Sp. z o.o. on behalf of ADAMA Makhteshim Ltd. in September 2021. The application is to support the authorisation of ADM.03502.F.1.A, an emulsifiable concentrate formulation (EC) containing 175 g/L prothioconazole and 250 g/L fenpropidin, in Poland.

Applicant details

Name:	ADAMA Polska Sp. z o.o.
Address:	39 Sienna St. 00-121 Warsaw Poland

This document describes the specific conditions of use and labelling required in Poland for the registration of ADM.03502.F.1.A.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 0-10 and Part C of the core assessment for ADM.03502.F.1.A. National addenda containing national specific data and assessments are not required for the evaluation of ADM.03502.F.1.A in Poland.

1.1 Application background

This application under Article 33 of Regulation (EC) No 1107/2009 for authorisation of the plant protection product ADM.03502.F.1.A (EC formulation containing 175 g/L prothioconazole and 250 g/L fenpropidin) follows the data requirements laid down in:

- Regulation (EC) No 544/2011 for the active substance prothioconazole
- Regulation (EC) No 544/2011 for the active substance fenpropidin
- Regulation (EC) No 284/2013 for the plant protection product ADM.03502.F.1.A.

The uses of ADM.03502.F.1.A applied for in Poland comprise the application of this product on cereals for the control of various fungi as further specified in 2.6.

Poland acts as the zonal rapporteur member state for the evaluation of this submission. In parallel, the dossier was submitted to the following concerned member states of the central zone: Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, The Netherlands and Slovakia.

The active substance **prothioconazole** is approved under Reg. (EC) No 1107/2009 with effective date 1 August 2008 (Commission Implementing Regulations (EU) No 540/2011).

Bayer Crop Science was the main notifier of the 1st EU review process. For the active ingredient prothioconazole, the applicant relies on data for which data protection period following Annex I listing has expired. As laid down in Commission Implementing Regulation (EU) No. 540/2011 and amending Commission Implementing Regulation (EU) 2021/745, the current expiry date of the approval of prothioconazole is 31st of July 2022.

There is no assessment of equivalence required for prothioconazole, since the source used in the product

has already been assessed for equivalence by RMS UK. For further information on the source of prothioconazole used in ADM.03502.F.1.A please refer to the confidential Part C.

The active substance **fenpropidin** is approved under Reg. (EC) No 1107/2009 with effective date 1 January 2009 (Commission Implementing Regulations (EU) No 540/2011).

Syngenta Ltd. was the main notifier of the 1st EU review process. Within this application the applicant ADAMA has the right to refer to the relevant data and endpoints of the first EU review of this active substance. As laid down in Commission Implementing Regulation (EU) No. 540/2011 and amending Commission Implementing Regulation (EU) 2021/1449, the current expiry date of the approval of fenpropidin is 31st of December 2022.

There is no assessment of equivalence required for fenpropidin, since the source used in the product has already been assessed for equivalence by RMS Sweden. For further information on the source of fenpropidin used in ADM.03502.F.1.A please refer to the confidential Part C.

Besides, all relevant data on ADM.03502.F.1.A are provided with this application for authorisation of the product ADM.03502.F.1.A.

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

All studies and data provided with this application are requested by current guidelines for re-authorisation of a plant protection product (here: ADM.03502.F.1.A) in EU countries.

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. Claims for data protection for individual studies are listed in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	ADM.03502.F.1.A
Product name in MS	Forapro 425 EC
Authorization number	-
Function	Fungicide
Applicant	ADAMA Polska Sp. z o.o.
Active substance(s) (incl. content)	Prothioconazole 175 g/L Fenpropidin 250 g/L
Formulation type	Emulsifiable concentrate [EC]
Packaging	0.5, 1, 5, 10, 15 and 20 L HDPE/PA and HDPE/EVOH
Coformulants of concern for national authorizations	None
Restrictions related to identity	Not applicable
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	No recommendation concerning particular possible tank mixes is intended to appear on the label.

2.2 Conclusion

The authorisation of ADM.03502.F.1.A for the uses specified in 2.6 of this document can be granted.

2.3 Substances of concern for national monitoring

Not relevant.


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:	Skin corrosion/irritation	Cat. 2
	Serious eye damage/eye irritation	Cat. 1
	Skin sensitisation	Cat. 1B
	Specific Target Organ Toxicity – Single Exposure	Cat. 3
	Specific Target Organ Toxicity – Repeated Exposure	Cat. 2
	Acute aquatic toxicity	Cat. 1
	Chronic aquatic toxicity	Cat. 1

The following labelling information is derived from the classification and to be mentioned in the safety data sheet.

Hazard pictograms or Code(s) for hazard pictogram(s):	
Signal word:	Danger
Hazard statement(s):	H315 – Causes skin irritation H317 – May cause an allergic skin reaction H318 – Causes serious eye damage H335 – May cause respiratory irritation H373 – May cause damage to organs through prolonged or repeated exposure H410 – Very toxic to aquatic life with long lasting effects
Precautionary statement(s):	P102 – Keep out of reach of children P260 – Do not breathe dust/fume/gas/mist/vapors/spray P280 – Wear protective gloves protective clothing and eye/face protection P302 + P352 – IF ON SKIN: Wash with plenty of soap and water P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P391-Collect spillage P410 – Protect from sunlight P501 – Dispose of contents/container to an approved waste disposal plant
Additional labelling phrases:	EUH401 – To avoid risks to man and the environment, comply with the instructions for use.
	SP1 – 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).

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
Additional information	None

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).
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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 authorisation of the PPP is linked to the following conditions (mandatory labelling):

Operator protection	
	Results of risk assessment: Operator wearing workwear covering arms, body and legs during mixing/loading and application Precautionary measures based on classification & labelling: Due to the classification of the product with H315, H317 and H318 protective gloves, protective clothing and eye protection/face protection should be worn when handling the product.
Worker protection	
	No PPE - Work wear covering arms, body and legs
Resident, bystander protection	
	None
Integrated pest management (IPM)/sustainable use:	
	Follow strictly the instructions of use on the label
Environmental protection	
SP1	SP1 – 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).
Other specific restrictions	
SPe3	To protect aquatic organisms, respect an vegetated filter strip of 20 m to surface water bodies. To protect aquatic organisms respect 40 m non-sprayed buffer zone including an vegetated filter strip of 10 m to surface water bodies combined with 75% drif reduction using appropriate drift reducing techniques.

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

Integrated pest management (IPM)/sustainable use:	
	None

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.
SPe3	To protect aquatic organisms, respect an vegetated filter strip of 20 m to surface water bodies. To protect aquatic organisms respect 40 m non-sprayed buffer zone including an vegetated filter strip of 10 m to surface water bodies combined with 75% drif reduction using appropriate drift reducing techniques	All intended uses.

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): ADM.03502.F.1.A
Active substance 1: Prothioconazole
Active substance 2: Fenpropidin
Safener: --
Synergist: --
Applicant: ADAMA Polska Sp. z o.o.
Zone(s): Central ^(d)
Verified by MS: yes
Field of use: Fungicide

GAP rev. 3 ^a date: April 2023 ~~December 2022~~
Formulation type: Emulsifiable concentrate (EC) ^(a, b)
Conc. of as 1: 175 g/L ^(c)
Conc. of as 2: 250 g/L ^(c)
Conc. of safener: --
Conc. of synergist: --
Professional use: ☒
Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use -No. (e)	Member state(s)	Crop and/or situation (crop 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. safener/synergist per ha e.g. recommended or mandatory tank mixtures (f)	Overall conclusion							
					Method / Kind	Timing/ Growth stage of crop (BBCH) & season	Max. number a) per use b) per crop / season	Min. interval between applications (days)	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/ season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/ season	Water L/ha min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					
23	Poland	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Septoria tritici</i> <i>Erysiphe graminis</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Puccinia striiformis</i> <i>Puccinia recondita</i>	foliar, sprayin, overall	~/ BBCH 30-65 spring	a) 1 b) 1	--	a) 1 L/ha b) 1 L/ha	a) 175 / 250 b) 175 / 250	100-400			A	A	A	A	A	R Aquatic	A	A TRZAW: SEPTTR ERYSGR PYRNTR PUCCST PUCCRT TRZAS: SEPTTR ERYSGR PYRNTR
																			A Remaining organism		N TRZAS: PUCCST PUCCRT
24	Poland	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Erysiphe graminis</i> <i>Rhynchosporium secalis</i> <i>Helminthosporium gramineum</i> (Pyrenophora teres) <i>Puccinia hordei</i>	foliar, sprayin, overall	~/ BBCH 30-65 spring	a) 1 b) 1	--	a) 1 L/ha b) 1 L/ha	a) 175 / 250 b) 175 / 250	100-400			A	A	A	A	A	R Aquatic	A	A HORVW: HORVS: ERYSGR RHYNSE PYRNTE PUCCHD
																			A Remaining organism		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use -No. (e)	Membe r 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. safener/syner gist per ha e.g. recommende d or mandatory tank mixtures (f)	Overall conclusion							
					Method / Kind	Timing/ Growth stage of crop (BBCH) & season	Max. numbe r a) per use b) per crop / season	Min. interval between applicatio ns (days)	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/ season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/ season	Water L/ha min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
25	Poland	Triticale (TTLSS)	F	<i>Erysiphe graminis</i> <i>Septoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, sprayi ng, overall	-/ BBCH 30-65 spring	a) 1 b) 1	--	a) 1 L/ha b) 1 L/ha	a) 175 / 250 b) 175 / 250	100- 400			A	A	A	A	A	R Aquatic	A	A TTLWI ERYSGR SEPTTR PUCCRE PUCCST
																			A Remaining organism		N TTLSO ERYSGR SEPTTR PUCCRE
																					N TTLSO PUCCST (possible registration under art. 51)

**Remarks
table
heading:**

- (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife
International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l

- (d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should
be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be
crossed out when the notifier no longer supports this use.

* Explanation for column 15 "Overall conclusion"	
A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible

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 yellow homogenous transparent liquid. It is not explosive and has no oxidising properties. It has an auto ignition temperature of 372°C. In aqueous solution, it has a pH value around 7.3. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 2 weeks at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data support a shelf life of at least 2 years at ambient temperature when stored in HDPE/PA containers. Its technical characteristics are acceptable for an emulsion concentrate formulation.

The concentration of the spray mixture for the intended uses in Poland is 0.25% to 1.0%. This concentration is covered by the test concentrations as used in the tests on the physical, chemical and technical properties on the formulated product ADM.03502.F.1.A.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No precautionary statements according to Regulation (EC) No. 1272/2008 are needed with regard to the physical/chemical data of the product.

Compliance with FAO specifications

The product ADM.03502.F.1.A complies with FAO specifications.

3.2 Efficacy (Part B, Section 3)

3.2.1 Efficacy data

In 224 (145 efficacy trials used for the national assessment) of 292 submitted trials carried out to evaluate the efficacy of ADM.03502.F.1.A against the target fungal pathogens at different rates, it is shown, that the intended target dose rates of 1.0 L/ha in small grain cereals is required for a comprehensive successful protection of the target crops.

At the target dose rate, ADM.03502.F.1.A achieves good to very good efficiency for the control of the target fungal diseases on small grain cereals. Compared to the untreated check, it reduces the level of infestations of all target pathogens significantly, is fully comparable to the authorised standard product in small grain cereals and comparable to superior to other additionally applied authorised reference products applied at the same conditions.

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

The risk for the development of resistance of target species was analysed following EPPO guideline PP1/213(4). The procedure follows the proposal of the German Authorities. The evaluation for ADM.03502.F.1.A shows low inherent risk for *Puccinia* species, and *Rhynchosporium secalis*, medium inherent risk for *Zymoseptoria tritici*, *Pyrenophora teres*, and *Pyrenophora tritici repentis*, and medium to high inherent risk for *Blumeria graminis*. The agronomic risk analysis shows ADM.03502.F.1.A to be of medium risk for the development of resistance if it would be used unrestrictedly.

Taking into consideration inherent and agronomical risk for resistance development and based on the long-term experience available, it could be concluded that measures for a resistance management in the indications concerned should be established for ADM.03502.F.1.A.

A resistance management for ADM.03502.F.1.A was defined following the recommendation of the

Fungicide Resistance Action Committee. It is not foreseen to establish a separate monitoring program, since the SBI resistance situation of the major target pathogens is observed and published regularly.

If ADM.03502.F.1.A is used according to the use instructions and under consideration of the proposed anti-resistance modifiers, the resistance risk of the target pathogens to develop resistance to ADM.3502.F.1.A is considered low.

3.2.3 Adverse effects on treated crops

Based on the results from efficacy trials, ADM.03502.F.1.A can be safely used on the target cereal crops, without risk of adverse effect on the crop, crop yield, yield quality parameters.

3.2.4 Observations on other undesirable or unintended side-effects

If the product is used correctly and in the designated way, relevant residues in harvested plants or plant products can be excluded. Special investigations on possible effects on transformation processes are not required.

Since the market introduction of the active ingredients prothioconazole and fenpropidin, any cases of negative influences on parameters influencing the processing procedure of target crop plants or grains were reported, neither from practical use nor from trial experience.

3.3 Methods of analysis (Part B, Section 5)

Sufficiently sensitive and selective analytical methods are available for the active substance and relevant impurities in the plant protection product.

3.3.1 Analytical method for the formulation

An HPLC-DAD method was successfully validated for the determination of the content of the active substances prothioconazole and fenpropidin in the formulated product ADM.03502.F.1.A with regard to linearity, precision, accuracy, non-analyte interference and specificity. It is considered to be acceptable.

Two analytical methods for the determination of the relevant impurities prothioconazole-desthio and toluene in the formulated product ADM.03502.F.1.A in the presence of the active substances prothioconazole and fenpropidin have been successfully validated. The methods are based on HPLC-MS/MS (prothioconazole-desthio) and GC-FID (toluene). Both methods are considered to be acceptable.

3.3.2 Analytical methods for residues

Prothioconazole

The endpoints reported in EFSA Scientific Report (2007) 106 are still valid for the ongoing evaluations. However, taking into account conclusions EFSA regarding residue definitions presented in EFSA Journal 2020;18(2):5999, EFSA Journal 2014;12(5):3689 and EFSA Journal 2018;16(7):5376, based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and degradation products, the residue definitions for plant products were proposed as ‘prothioconazole-desthio (sum of isomers)’ for enforcement and, as follows, for the risk assessment:

1) sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)

2) Triazole alanine (TA) and triazole lactic acid (TLA)

3) Triazole acetic acid (TAA)

4) 1,2,4-triazole (1,2,4-T).

Since all compounds included in the residue definitions are a mixture of enantiomers and since there are no enantiospecific analytical methods, the residue definitions are expressed as “sum of isomers”.

Although the residue definition for risk assessment includes consideration of all metabolites containing a common moiety, it is not possible to develop a common moiety method to meet the residue definition for risk assessment. For this reason, all the analytes have to be determined separately. 6 analytes, representing the major portion of the TRR (Total Radioactive Residue) for prothioconazole in the plant metabolism studies, should be determined in residue trials. These are: prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio (including all their acid-hydrolysable conjugates).

The residue definition for enforcement in animal products was set as prothioconazole-desthio (sum of isomers) for all the livestock matrices (EFSA Journal 2014;12(5):3689).

For risk assessment, the residue was defined in all commodities of animal origin as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).

During the peer review under Directive 91/414/EEC, an analytical methods were evaluated and validated for the determination of prothioconazole-desthio in plant matrices and in food of animal origin. The available analytical methods are not enantioselective, hence the sum of isomers will be analyzed (EFSA Journal 2014;12(5):3689).

In EFSA Scientific Report (2007) 106, 1-98, “Conclusion on the peer review of prothioconazole” it is stated that:

„Methods are available to monitor all compounds given in the respective residue definition for food of plant origin, water, soil and air. Residues in food of plant origin can be determined with a multimethod (The German S19 method has been validated for prothioconazole-desthio). Only single methods are available to determine residues of prothioconazole-desthio, in products of animal origin and prothioconazole, prothioconazole-desthio in soil water and air. A method is not available to monitor the glucuronide conjugate in products of animal origin. Also if the active is classified as toxic then methods for body fluids and tissues would need to be considered.”

EFSA Scientific Report (2007):

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Weeren, Pelz 2000 (GC-MS, JAU6476-desthio) LOQ Wheat, Barley (Forage, Straw): 0.05 mg/kg LOQ Wheat, Barley (Grain), Canola (Seed), Tomato, Orange (Fruit): 0.02 mg/kg
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Heinemann 2001b (HPLC-MS/MS, JAU6476-desthio, JAU6476-3 hydroxy-desthio, JAU6476-4-hydroxy-desthio) LOQ Milk: 0.004 mg/kg LOQ Meat, Liver, Kidney, Fat: 0.01 mg/kg Open: there is no method available for the glucuronide conjugate
Soil (principle of method and LOQ)	Schramel 2000 (HPLC-MS/MS, JAU6476, JAU6476-desthio, JAU6476-S-methyl*) * for monitoring not needed LOQ Soil: 0.006 mg/kg Add'l method: Steinhauer 2001 (GC-MS, JAU6476-desthio) LOQ Soil: 0.01 mg/kg
Water (principle of method and LOQ)	Sommer 2001b (HPLC-MS/MS, JAU6476, JAU6476-desthio) LOQ Surface and Drinking water: 0.1 µg/L for JAU6476 and 0.05 µg/L for JAU6476-desthio
Air (principle of method and LOQ)	Maasfeld 2002a (HPLC-MS/MS, JAU6476)

	LOQ Air: 0.015 mg/m ³ Additional method: Maasfeld 2002b (HPLC-MS/MS, JAU6476-desthio) LOQ Air: 0.0006 mg/m ³
Body fluids and tissues (principle of method and LOQ)	Open, data will be required if ECB classify the active as toxic

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 for crops 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, the Applicant has 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, KCP 5.2/02, Watson, G., 2022a, KCP 5.2/03).

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

Note:

- According to the EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of Prothioconazole, the point regarding analytical methods for body fluids and tissues for prothioconazole is open, data will be required if ECB classify the active substance as toxic.

The active substance prothioconazole was evaluated at the EU level according to the old data requirements. The Commission Regulation (EU) No 284/2013 is applicable now.

In Regulation (EU) No 283/2013 it is stated that "...methods, with a full description, shall be submitted

for the analysis in body fluids and tissues for the active substance and relevant metabolites” and this is a new requirement of SANTE/2020/12830. According to the SANTE/2020/12830: “*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 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 HPLC-MS/MS analytical method (with its ILV) for the 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.03502.F.1.A.

Fenpropidin

In EFSA Scientific Report (2007) 124, 1-84, “Conclusion on the peer review of Fenpropidin” it is stated that: *A multi-residue method like the Dutch MM1 or the German S19 is not applicable due the nature of the residues. Residues of fenpropidin in products of plant origin are analysed by LC-MS/MS with an LOQ of 0.01 mg/kg. For products of animal origin fenpropidin and CGA 2892673 were analysed by LC-MS/MS with an LOQ of 0.005 mg/kg in milk and an LOQ of 0.01 mg/kg in muscle, kidney, liver, fat and eggs. There was also a GC-NPD method for milk, eggs and fat with an LOQ of 0.005 mg/kg in milk and 0.01 mg/kg in eggs and fat. Soil is analysed for fenpropidin by LC-MS/MS with an LOQ of 0.01 mg/kg. Drinking/groundwater can be analysed for by HPLC-UV with confirmation by GC- MS with an LOQ of 0.05 µg/L. Surface water can be analysed for fenpropidin by HPLC-UV with confirmation by GC-MS the LOQ is 0.1 µg/L. Air is analysed for fenpropidin by LC-MS/MS with an LOQ of 0.15 µg/m³.*

Fenpropidin list of end points (Nov 2006):

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	GC with nitrogen phosphorus detector (NPD) LOQ: 0.02 mg/kg (cereal grain)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	GC with nitrogen phosphorus detector (NPD) LOQ: 0.01 mg/kg (tissues, fat), 0.005 mg/kg (milk)
Soil (analytical technique and LOQ)	GC with nitrogen phosphorus detector (NPD) LOQ: 0.05 mg/kg
Water (analytical technique and LOQ)	<u>Fenpropidin</u> HPLC-UV LOQ 0.05 µg/l (drinking water), 0.1 µg/l (surface water) <u>CGA289267¹</u> HPLC-UV

¹ CGA 289267: 2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]-propionic acid.

Air (analytical technique and LOQ)	LOQ 0.05 µg/l (drinking water), 0.1 µg/l (surface water)
	GC with nitrogen phosphorus detector (NPD) LOQ 1 µg/m ³
Body fluids and tissues (analytical technique and LOQ)	Not required (fenpropidin is not classified as toxic or highly toxic)

The Applicant submitted a number of methods for analysis of residues of fenpropidin for the generation of pre-authorization data and methods for post-authorization control and monitoring purposes.

Methods for post-authorization control and monitoring purposes

According to the Reg. 283/2013 an analytical method for the residues of fenpropidin in body fluids and tissues is required.

- A body fluids method for the determination of residues of fenpropidin, CGA289267 and CGA289268 in blood (Cross, M., 2017, report no CEMR-8288) has been submitted by Applicant. The limit of quantification was established at 0.01 mg/kg.

Additionally:

- Applicant submitted the analytical method GRM024.03A (with its ILV) for the determination of fenpropidin and CGA289267 in surface, drinking and ground water (Richardson, M., 2007) with LOQ of 0.05 µg/L.

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.03502.F.1.A.

3.4 Mammalian toxicology (Part B, Section 6)

Based on acute toxicity data on ADM.03502.F.1.A relevant for classification, ADM.03502.F.1.A requires classification for skin irritation Category 2 with H315 “Causes skin irritation“, for eye irritation Category 1 with H318 “Causes serious eye damage“ and skin sensitization Category 1 with H317 “May cause an allergic reaction” according to Regulation (EC) No. 1272/2008.

Due to the content of fenpropidin additional classification and labelling of ADM.03502.F.1.A as STOT – SE Category 3 with H335 “May cause respiratory irritation” and STOT – RE Category 2 with H373 “May cause damage to organs (central nervous system) through prolonged or repeated exposure” is required according to Regulation (EC) No. 1272/2008.

The risk assessment is fully covered by the core assessment. No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in the table below are applied.

Summary of evaluation, including risk management measures		
Scenario	Result	PPE / Risk mitigation measures
Operators	Acceptable	Results of risk assessment: Operator wearing workwear covering arms, body and legs during mixing/loading and application and gloves during mixing/loading. Precautionary measures based on classification & labelling: Due to the classification of the product with H315, H317 and H318 protective gloves, protective clothing and eye protection/face protection should be worn when handling the product.
Workers	Acceptable	No PPE - Work wear covering arms, body and legs
Bystanders	Acceptable	None Risk mitigation measures as buffer strip of 5 m or drift reduction nozzles
Residents	Acceptable	None Risk mitigation measures as buffer strip of 5 m or drift reduction nozzles

3.4.1 Acute toxicity

The following acute toxicity data on ADM.03502.F.1.A relevant for classification and labelling were generated:

Type of test, species, model system (Guideline)	Result		Classification (acc. to the criteria in Reg. 1272/2008)
Acute oral toxicity (Alternative approach acc. to Reg. 1272/2008)	LD ₅₀ (calculated): > 2000 mg/kg bw		None
Acute dermal toxicity (Alternative approach acc. to Reg. 1272/2008)	None of the ingredients is classified for dermal toxicity		None
Acute inhalation toxicity, rat (OECD 403)	LC ₅₀ > 5.36 mg/L (analysed conc.)		None
Skin irritation Reconstructed human epidermis EpiDerm™ (OECD 439)	Irritant		Skin Irritation Cat. 2 H315 "Causes skin irritation"
Eye irritation, rabbit (OECD 405)	Irritant		Eye Irritation Cat. 1 H318 "Causes serious eye damage"
Skin sensitisation (Alternative approach acc. Reg. 1272/2008)	Sensitising (based on data on ingredients)		Skin Sens. Cat. 1B H317 "May cause an allergic skin reaction"
Supplementary studies for combinations of plant protection products	No data – not required		

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
Acute oral toxicity, rat (OECD 423)	LD ₅₀ > 2000 mg/kg bw ¹	Yes	None	...
Acute dermal toxicity, rat (OECD 402)	LD ₅₀ > 2000 mg/kg bw ²	Yes	None	...
Acute inhalation toxicity, rat (OECD 403)	LC ₅₀ > 5.36 mg/L (analysed conc.) ³	Yes	None	...
Skin irritation, rabbit	No study available	Based on WoE	Skin Irritation Cat. 2	n.a.

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
(OECD 404)			H315 “Causes skin irritation”	
Eye irritation, rabbit (OECD 405)	Irritant	Yes	Eye Irrit. 1 H318 “Causes serious eye damage”	...
Skin sensitisation, mouse (OECD 429, LLNA)	Weak sensitizer	Yes	Skin Sens. 1 H317 “May cause an allergic skin reaction”	...
Supplementary studies for combinations of plant protection products	No data – not required			

3.4.2 Operator exposure

Operator exposure was modelled in the core assessment in consideration of the critical GAP uses of ADM.03502.F.1.A in cereals and using the EFSA Guidance. All uses relevant for Poland are covered with the core assessment.

Summary of the assessment for critical GAP uses in cereals:

According to the model calculations, the use of ADM.03502.F.1.A results in acceptable exposure levels for prothioconazole, fenpropidin and prothioconazole-desthio in consideration of work wear covering arms, body and legs during mixing/loading and application.

Due to the classification of the product with H315, H317 and H318 protective gloves, protective clothing and eye protection/face protection should be worn when handling the product.

3.4.3 Worker exposure

Worker exposure was modelled in the core assessment in consideration of the critical GAP uses of ADM.03502.F.1.A and using the EFSA Guidance. All uses relevant for Poland are covered with the core assessment.

Summary of the assessment for critical GAP uses in cereals:

According to the model calculations, the use of ADM.03502.F.1.A results in acceptable exposure levels for prothioconazole, fenpropidin and prothioconazole-desthio in consideration of work wear covering arms, body and legs.

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

3.4.4 Bystander and resident exposure

Bystander and resident exposure was modelled in the core assessment in consideration of the critical GAP uses of ADM.03502.F.1.A and using the EFSA Guidance. All uses relevant for Poland are covered with the core assessment.

Summary of the assessment for critical GAP uses in cereals:

According to the model calculations, the use of ADM.03502.F.1.A in cereals results in acceptable exposure levels for fenpropidin, prothioconazole and prothioconazole-desethio without consideration of risk management measures.

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

This dossier is presented to support the product ADM.03502.F.1.A for the use in cereals. Supplementary studies are submitted with this dossier and complete study summaries are provided.

The current EU MRLs for prothioconazole are defined in Commission Regulation (EU) 2019/552 of 04.04.2019 amending Reg. (EU) 396/2005. For fenpropidin, the current EU MRLs are defined in Commission Regulation (EU) 61/2014 of 24.01.2014. Input values for the consumer risk assessments are summarised in Part B.7, chapters 7.2.8.1 and 7.3.8.1. The data available for the applied uses are considered sufficient for risk assessment with regard to fenpropidin and prothioconazole and any other relevant metabolite exclusively linked to the parent compound. A relevant exceedance of the current MRLs for fenpropidin or prothioconazole as laid down in Reg. (EU) 2019/552 is not expected. With regard to the risk assessment for triazole derivative metabolites (TDMs) triazole alanine (TA), triazole acetic acid (TAA), triazole lactic acid (TLA) and 1,2,4-triazole (1,2,4-T) newly included in the residue definition for risk assessment of prothioconazole, the data available for the applied uses are also considered sufficient.

Prothioconazole

Based on the calculations made to estimate the risk for consumer through diet and other means with regard to prothioconazole and any other relevant metabolite exclusively linked to the parent compound as well as with regard to triazole alanine (TA), triazole acetic acid (TAA), triazole lactic acid (TLA) and 1,2,4-triazole (1,2,4-T), it can be concluded that the use of the product ADM.03502.F.1.A does not lead to any unacceptable risk for consumers when applied according to the recommendations.

Summary for prothioconazole

Critical GAP number*	Use-No.**	Crop	Plant metabolites covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
Critical GAP (1)	23, 25	Spring and winter wheat (TRZAS, TRZAW), triticale (TTLSS)	Y	Y	n.a.	Y	Y	N	N
Critical GAP (2)	24	Spring and winter barley (HORVS, HORVW)	Y	Y	n.a.	Y	Y		N

* Critical GAP nos. in accordance with the list of critical GAPs in Part B, Section 7, chapter 7.1.1. Only cGAPs involving GAP uses in Poland are included here.

** Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0.

Fenpropidin

Based on the calculations made to estimate the risk for consumer through diet and other means with regard to fenpropidin it can be concluded that the use of the product ADM.03502.F.1.A does not lead to any unacceptable risk for consumers when applied according to the recommendations.

Summary for fenpropidin

Critical GAP number*	Use-No.**	Crop	Plant metabolisms covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
Critical GAP (1)	23, 25	Spring and winter wheat (TRZAS, TRZAW), triticale (TTLSS)	Y	Y	n.a.	Y	Y	N	N
Critical GAP (2)	24	Spring and winter barley (HORVS, HORVW)	Y	Y	n.a.	Y	Y		N

* Critical GAP nos. in accordance with the list of critical GAPs in Part B, Section 7, chapter 7.1.1. Only cGAPs involving GAP uses in Poland are included here.

** Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0.

3.5.1 Residues

Prothioconazole

Residue Definitions (EFSA 2020; Reg EU 2019/552):

Monitoring (Mo): Prothioconazole-desthio (sum of isomers)

Risk Assessment (RA):

1) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014)

2) TDMs (EFSA, 2018), with separate assessment of:

- Triazole alanine (TA) and triazole lactic acid (TLA)

- Triazole acetic acid (TAA)

- 1,2,4-triazole (1,2,4-T)

Trials on wheat and barley previously presented and evaluated in DAR (2004) were conducted according to the residue definition for monitoring only (trials measuring levels of prothioconazole-desthio only; there are no data on prothioconazole-hydroxy-destio) and were conducted at more critical GAPs than envisaged in this dossier.

To address all potential residues, new additionally residue studies conducted according to the plant residue definitions for enforcement and for risk assessment as proposed by EFSA (2018 and 2020) were submitted by Applicant in the framework of this application.

Wheat and triticale and rye

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 150-200 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 wheat grain at harvest were <0.01 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 **and triticale** of 0.1 mg/kg ~~and on rye~~ of 0.05 (Reg. (EU) 2019/552) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed uses.

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

Residues of TLA in grain between <0.01 mg/kg and 0.1 mg/kg.

Residues of TA in grain were between 0.18 and 0.42 mg/kg.

Residues of TAA in grain were between 0.05 and 0.22 mg/kg.

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

The proposed uses on wheat **and 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 150-200 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 0.18 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.

Remark:

In SANTE/2019/12752, in ANNEX I clarifications on “old/new” data requirements, it is stated that “50% of residue trials should be decline studies, if the consumable part is exposed during application of the plant protection product under the proposed conditions of use.” It means that Applicant should have provided at least 4 decline studies.

For TDMs, not all submitted trials were covered by the storage stability data for the metabolites (for 1,2,4-T). For 1,2,4-T, only 2 decline studies were within the maximum storage period. However, the

residue levels in grains were < LOQ in all trials. Taking into above account, zRMS is of the opinion that the available residue data is sufficient to support the proposed use on barley.

The proposed use on barley is considered acceptable.

Fenpropidin

Residue Definitions (EFSA 2007, 2011; Reg EU 61/2014):

Monitoring (Mo) and Risk Assessment (RA): Sum of fenpropidin and its salts, expressed as fenpropidin

Wheat and triticale and rye

Wheat and rye are **is** 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 (8 trials) were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 250 g a.s. /ha, application at BBCH 65, outdoor. The trials are supported by valid storage stability data and validated analytical method.

Residues of fenpropidin in wheat grain at harvest were <0.01 mg/kg.

Available results show that the in force MRL of fenpropidin on wheat and rye **triticale** of 0.1 mg/kg (Reg. (EU) 61/2014) will not be exceeded. The current EU MRL for fenpropidin is sufficient to support the proposed uses.

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

Remark:

In SANTE/2019/12752, in ANNEX I clarifications on “old/new” data requirements, it is stated that “50% of residue trials should be decline studies, if the consumable part is exposed during application of the plant protection product under the proposed conditions of use.” It means that Applicant should have provided at least 4 decline studies.

For fenpropidin only 2 decline studies were provided by Applicant. However, the residue levels in grains were < LOQ in all trials. Taking into above account, zRMS is of the opinion that the available residue data is sufficient to support the proposed use on wheat, rye and triticale.

Barley

Barley and oat are **is** 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 barley can be used for extrapolation to oat before and after forming of the edible part.~~

Sufficient trials on barley (8 trials) were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 250 g a.s. /ha, application at BBCH 65, outdoor. The trials are supported by valid storage stability data and validated analytical method. More details of the residue studies on barley are provided in Appendix 2.

Residues of fenpropidin in barley grain at harvest were between <LOQ and 0.042 mg/kg.

Available results show that the in force MRL of fenpropidin on barley of 0.6 mg/kg ~~and on oat of 0.3 mg/kg~~ (Reg. (EU) 61/2014) will not be exceeded. The current EU MRL for fenpropidin is sufficient to support the proposed uses.

The proposed uses on barley and oat are **is considered acceptable.**

3.5.2 Consumer exposure

Prothioconazole

Exposure of consumers to prothioconazole (residue definition for risk assessment part 1 as given in EC

Review Report, 2021²: Prothioconazole and any other relevant metabolite exclusively linked to the parent compound, i.e. ‘Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)’ has been calculated with EFSA PRIMo rev. 3.1, which also includes the chronic risk assessment according to the Rees Day - model.

The estimated consumer intake levels do not exceed the EU agreed ADI of 0.01 mg/kg bw/day for prothioconazole-desthio. With the current EFSA model the chronic risk assessment ranges from 1 to 15 % of the ADI (IEDI, normal mode). The diet with the highest IEDI is “NL Toddler” with 15 % of the ADI. For this diet, the highest contributor is “milk: cattle” with 3 % of ADI. The diet with the second highest IEDI is “GEMS/Food G11” with 11 % of ADI where “soyabeans” are the major contributor with 4 % of ADI.

The diet with the highest NEDI/NTMDI according to the Rees Day-model is “UK infant” with 16 % of the ADI (main contributor: beans).

The results of the IESTI calculations demonstrate that in no case the IESTI is above the acute reference dose (ARfD) of prothioconazole-desthio of 0.01 mg/kg bw including a safety factor of 100. Thus, the acute risk to the consumer based on the short-term intake of residues of the active substance prothioconazole is considered to be acceptable.

Exposure of consumers to TDMs triazole alanine (TA), triazole acetic acid (TAA), triazole lactic acid (TLA) and 1,2,4-triazole (1,2,4-T) (residue definition for risk assessment part 2, 3 and 4²):

- 2) TA and TLA, since these compounds share the same toxicity;
- 3) TAA;
- 4) 1,2,4-T

has been calculated with EFSA PRIMo rev. 3.1. Besides residues determined in trials conducted according to the envisaged GAP uses, calculations were based on input values as used during evaluation of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data (UK, 2018³) and thus represent a worst case situation.

Triazole alanine (TA):

The estimated consumer intake levels do not exceed the EU agreed ADI of 0.3 mg/kg bw/day for TA. With the current EFSA model the chronic risk assessment ranges from 0.3 to 5 % of the ADI (IEDI, normal mode). The diet with the highest IEDI is “NL Toddler” with 5 % of the ADI. For this diet, the highest contributor is “maize/corn” with 1 % of ADI. The diet with the second highest IEDI is “GEMS/Food G06” with 4 % of ADI where “wheat” is the major contributor with 1 % of ADI.

The results of the IESTI calculations demonstrate that in no case the IESTI is above the acute reference dose (ARfD) of 0.3 mg/kg bw for TA including a safety factor of 100. Thus, the acute risk to the consumer based on the short-term intake of residues TA is considered to be acceptable.

Triazole acetic acid (TAA):

The estimated consumer intake levels do not exceed the EU agreed ADI of 1.0 mg/kg bw/day for TAA. With the current EFSA model the chronic risk assessment ranges from 0 to 1 % of the ADI (IEDI, normal mode). The diet with the highest IEDI is “NL Toddler” with 1 % of the ADI. For this diet, the highest contributor is “maize/corn” with 0.6 % of ADI. The diet with the second highest IEDI is “DK child” with 0.9 % of ADI where “rye” is the major contributor with 0.4 % of ADI.

The results of the IESTI calculations demonstrate that in no case the IESTI is above the acute reference

² EC (European Commission), 2021: Review report for prothioconazole, SANCO/3923 /07 – final (10 December 2007, update 26 January 2021).

³ United Kingdom, 2018b. Triazole Derivate Metabolites, addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom in the framework of Regulation (EC) No 1107/2009, revised version of February 2018.

dose (ARfD) of 1.0 mg/kg bw for TAA including a safety factor of 100. Thus, the acute risk to the consumer based on the short-term intake of residues TAA is considered to be acceptable.

Triazole lactic acid (TLA):

The estimated consumer intake levels do not exceed the EU agreed ADI of 0.3 mg/kg bw/day for TLA. With the current EFSA model the chronic risk assessment ranges from 0.1 to 1 % of the ADI (IEDI, normal mode). The diet with the highest IEDI is “NL Toddler” with 1 % of the ADI. For this diet, the highest contributor is “milk:cattle” with 0.6 % of ADI. The diet with the second highest IEDI is “NL child” with 0.6 % of ADI where “milk:cattle” is the major contributor with 0.2 % of ADI.

The results of the IESTI calculations demonstrate that in no case the IESTI is above the acute reference dose (ARfD) of 0.3 mg/kg bw for TLA including a safety factor of 100. Thus, the acute risk to the consumer based on the short-term intake of residues TLA is considered to be acceptable.

1,2,4-triazole (1,2,4-T):

The estimated consumer intake levels do not exceed the EU agreed ADI of 0.023 mg/kg bw/day for 1,2,4-T. With the current EFSA model the chronic risk assessment ranges from 0.5 to 51 % of the ADI (IEDI, normal mode). The diet with the highest IEDI is “NL Toddler” with 51 % of the ADI. For this diet, the highest contributor is “milk:cattle” with 42 % of ADI. The diet with the second highest IEDI is “UK infant” with 31 % of ADI where “milk:cattle” is the major contributor with 27 % of ADI.

The results of the IESTI calculations demonstrate that in no case the IESTI is above the acute reference dose (ARfD) of 0.1 mg/kg bw for 1,2,4-T including a safety factor of 300. Thus, the acute risk to the consumer based on the short-term intake of residues 1,2,4-T is considered to be acceptable.

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.

Fenpropidin

Exposure of consumers to fenpropidin has been calculated with EFSA PRIMo rev. 3.1, which also includes the chronic risk assessment according to the Rees Day - model.

The estimated consumer intake levels do not exceed the EU agreed ADI of 0.02 mg/kg bw/day for fenpropidin. With the current EFSA model the chronic risk assessment ranges from 0.7 to 19 % of the ADI (IEDI, normal mode). The diet with the highest IEDI is “NL Toddler” with 19 % of the ADI. For this diet, the highest contributor is “milk: cattle” with 6 % of ADI. The diet with the second highest IEDI is “NL child” with 11 % of ADI where “sugar beet roots” are the major contributor with 3 % of ADI. The diet with the highest NEDI/NTMDI according to the Rees Day-model is “UK infant” with 20 % of the ADI (main contributor: Milk: cattle).

The results of the IESTI calculations demonstrate that in no case the IESTI is above the acute reference dose (ARfD) of fenpropidin of 0.02 mg/kg bw including a safety factor of 100. Thus, the acute risk to the consumer based on the short-term intake of residues of the active substance fenpropidin is considered to be acceptable.

Product ADM.03502.F.1.A

Based on the different calculations made to estimate the risk for consumer through diet and other means it can be concluded that the use of product ADM.03502.F.1.A does not lead to unacceptable risks for consumers when applied according to the recommendations.

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

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

Soil exposure for prothioconazole and fenpropidin and its soil metabolites JAU-S-methyl, JAU-desthio and CGA 289267 was calculated using approach described in respective FOCUS guidance for the intended uses of ADM.0350.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 prothioconazole and fenpropidin and its metabolites JAU-S-methyl, JAU-desthio and CGA 289267 was assessed using FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and FOCUS MACRO 5.5.4 on the basis of the EU agreed input parameters or modified input parameters and intended use pattern of ADM.03502.F.1.A. Endpoints deviating from the EU data were all agreed by the zRMS.

Performed calculations resulted with PEC_{GW} values <0.1 µg/L in all relevant Polish scenarios. Since all PEC_{GW} were <0.001 µg/L for prothioconazole, simulations performed using single model are deemed sufficient, in line with indications of the Central Zone guidance document in area of efate (2018).

Based on the performed assessment no unacceptable leaching of prothioconazole and fenpropidin and its metabolites is expected when ADM.03502.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.03502.F.1.A in line with recommendations of respective FOCUS guidance documents using most up-to-date versions of the models.

PEC_{SW} and PEC_{SED} for the active substance prothioconazole were calculated up to FOCUS Step 3. For the metabolite JAU-desthio PEC_{SW} and PEC_{SED} calculations were calculated up to FOCUS Step 4. FOCUS Step 4 was also necessary for the active substance fenpropidin. For the metabolites JAU-S-methyl, 1,2,4-triazole and CGA 289267 PEC_{SW} and PEC_{SED} calculations were calculated only up to FOCUS Step 2.

The application windows assumed by the Applicant for Step 3 and 4 modelling for prothioconazole and fenpropidin do not cover surface water exposure for the later BBCH stages. Therefore Step 3 and 4 surface water modelling was performed by the zRMS for the last possible dates of application for spring and winter cereals.

The active substance fenpropidin has a vapour pressure of 1.7×10^{-2} Pa and is therefore volatile. Hence exposure of surface water due to volatilization/deposition were considered in FOCUS Step 4 calculation for both spring and winter cereals for early and late application.

The results for PEC surface water for the active substances and its metabolites were used for the ecotoxicological risk assessment.

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

The vapour pressure of prothioconazole at 20 °C is < 10^{-5} Pa. (4×10^{-7} Pa). Hence, prothioconazole is regarded as non-volatile. Therefore, an assessment of the exposure of adjacent surface waters and terrestrial ecosystems due to volatilisation with subsequent deposition is not triggered and not performed.

The long-range transport potential has to be considered in case the DT₅₀ in air >2 days. Since the photochemical oxidative half-life of prothioconazole in air is 1.1 hours no long-range transport potential is indicated.

The vapour pressure of fenpropidin at 25°C is $> 10^{-5}$ Pa. (1.7×10^{-2} Pa). Hence, fenpropidin is regarded as semi-volatile. However, only the neutral form of fenpropidin is potentially volatile. The pKa of fenpropidin is 10.1 and at environmentally relevant pH fenpropidin will predominantly be present in protonated, non-volatile form (EFSA Scientific Report (2007) 124, 1-84). The pH of the product ADM.03502.F.1.A in 1% v/v deionized water is shown to be 7.3. It is thus justified to assume that fenpropidin is predominately protonated under real use conditions and that volatilisation is not relevant.

3.7 Ecotoxicology (Part B, Section 9)

A safe use could be shown after application of ADM.03502.F.1.A in all relevant organism groups considering the appropriate mitigation measures (for details, please refer to chapter 3.7.2 “Effects on aquatic species”).

3.7.1 Effects on terrestrial vertebrates

The risk assessment for terrestrial vertebrates 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). No unacceptable risk for birds and mammals is expected for acute or long-term exposure to contaminated food indicated by TER_A and TER_{LT} values above the corresponding trigger values, even if considering mixture toxicity. Furthermore, no unacceptable risks are expected arising from other routes of direct exposure or secondary poisoning (residue uptake from drinking water or bioaccumulation in food chains). In conclusion, an acceptable overall risk for birds and mammals (and other terrestrial vertebrates) is indicated for the intended GAP uses of ADM.03502.F.1.A in cereals.

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 (EFSA Journal 2013;11(7):3290). Based on PEC/RAC calculations for the active substances prothioconazole and fenpropidin as well as the metabolites potentially relevant in aquatic systems, no unacceptable risk for aquatic or sediment-dwelling organisms for scenarios relevant for Poland such as D3, D4, R1 is indicated, if 40 meter vegetative non-sprayed buffer zone including an vegetated filter strip of 10 m to surface water bodies combined with 75% drift reduction using appropriate drift reducing techniques for spring and winter cereals.

Finally, the risk arising from bioaccumulation of the active substance as well as its metabolites potentially of concern in aquatic systems is considered to be low.

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 (SANCO/10329/2002 rev.2 (final), October 17, 2002). Based on the Tier-1 risk assessment, it can be reasonably concluded that the intended GAP uses of ADM.03502.F.1.A are of acceptable acute risk for bees under field conditions. Chronic and larval toxicity data for honeybees were submitted with product, since they are data requirements.

However, as for spray applications there is not noted EFSA guidance document, no deterministic chronic risk assessment for bees is required for Poland at the moment.

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 (SANCO/10329/2002 rev 2 (final), October 17, 2002). Based on the results of worst-case laboratory tests with the standard test species *Aphidius rhopalosiphi* and *Typhlodromus pyri*, an overall acceptable risk for non-target arthropods colonised both in-field and off-field habitats can be concluded considering the intended GAP uses of ADM.03502.F.1.A

in cereals. Risk mitigation measures are not required.

3.7.5 Effects on soil organisms

The evaluation of the risk for soil organisms was performed in accordance with the recommendations of the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2 (final), October 17, 2002). Assessments were performed in consideration of the worst-case application scenario leading to maximum soil load, i.e. $1 \times 1.0 \text{ L prod./ha}$ (BBCH 30-65, 80 % crop interception) in cereals.

Soil macro- and mesofauna

All TER_{LT} values calculated for the active substances and their metabolites potentially relevant in soil are above the trigger values of 5, established for long-term exposure. Thus, an acceptable overall risk for earthworms and other soil organisms is indicated for the intended GAP uses of ADM.03502.F.1.A in cereals.

Soil microorganisms

Effects within a range of $\pm 25\%$ compared to the control were observed at exposure levels which exceed the maximum PEC values in soil calculated in consideration of the above-mentioned worst-case exposure scenario. Thus, an acceptable overall risk for soil microorganisms is indicated for the intended GAP uses of ADM.03502.F.1.A in cereals.

3.7.6 Effects on non-target terrestrial plants

The evaluation of the risk for non-target terrestrial plants 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). Based on the screening step recommended by the SANCO guideline for fungicides, a safe use (with respect to an acceptable risk for terrestrial non-target plants) can be concluded for the intended GAP uses of ADM.03502.F.1.A in cereals. Risk mitigation measures are not required.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

No further data/studies/calculations on non-target species are required and thus not provided.

3.8 Relevance of metabolites (Part B, Section 10)

The prothioconazole metabolites prothioconazole-desthio (JAU-Desthio) and prothioconazole-S-methyl (JAU-S-methyl) as well as the fenpropidin metabolite CGA 289267 are predicted to occur in groundwater at concentrations below $0.1 \mu\text{g/L}$ (see chapter 3.6.2 above). Therefore, the relevance of these metabolites in groundwater does not need to be assessed. For the envisaged national GAP uses it can be concluded that metabolites JAU-S-methyl, JAU-desthio and CGA 289267 will not leach to groundwater to any environmentally hazardous extent under environmentally relevant conditions.

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

Not relevant for ADM.03502.F.1.A since prothioconazole and fenpropidin are not candidates for substitution.

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.

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 kolorem, fragmenty usunięte zostały ~~przekreślone~~ i zaznaczone szarą czcionką.

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 w opakowaniach wykonanych z HDPE/PA na podstawie zaakceptowanego 2 letniego badania stabilności. Zgodnie z zapisami wytycznej Ministerstwa Rolnictwa i Rozwoju Wsi w sprawie zasad zatwierdzania opakowań środków ochrony roślin z dnia 18/10/2021 możliwa jest ekstrapolacja wyników badań stabilności wykonanych dla środka przechowywanego w HDPE/PA na HDPE/EVOH. W związku z powyższym, wszystkie opakowania wymienione, w punktach 2.1 dokumentu A i 4.4 Sekcji 1 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 zapisów nazw grup chemicznych, do których przyporządkowano substancje czynne. Dodano zawartości substancji czynnych wyrażone jako %w/w (gęstość środka zgodnie z danymi zawartymi w punkcie 2.6.1 Sekcji 1,2,4 wynosi 1,04).
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. Zgodnie z strategią zarządzania odpornością, dla środków zawierających substancje czynne z grupy FRAC 3 oraz 5, preferowane jest stosowanie w zabiegach profilaktycznych, a należy unikać stosowania w zabiegach interwencyjnych czy leczniczych. Powyższe zalecenia zostały uwzględnione przez wnioskodawcę w zapisach dla strategii zarządzania odpornością. ~~Na tej podstawie z rozdziału:~~ **W rozdziale OPIS DZIAŁANIA podkreślono, że środek przeznaczony jest do stosowania głównie zapobiegawczego.** ~~usunięto informacje o stosowaniu interwencyjnym i wyniszczającym środka.~~ Uzupełniono opis klasyfikacji substancji czynnych w tym samym rozdziale.
2. W rozdziale STOSOWANIE ŚRODKA:
 - zmodyfikowano zapisy dotyczące zastosowania środka w pszenicy jarej i ozimej, uwzględniające wykluczenie zastosowania środka w ochronie przed rdzą brunatną i rdzą żółtą w pszenicy jarej (z uwagi na brak badań, nie uznano wskazanych zastosowań w pszenicy jarej),
 - dopisano informację o średnim poziomie zwalczania chorób: septoriozy paskowanej liści pszenicy i brunatnej plamistości liści w pszenicy.
 - **Zmieniono zapis: Zalecane opryskiwanie średniokropliste na drobnokropliste, zgodnie z prośbą wnioskodawcy przedstawioną w Reporting Table, part A, podczas etapu komentowania oceny środka.**
3. Do oceny skuteczności działania środka wykorzystano badania przeprowadzone w strefie EPPO północno-wschodniej (Polska, Litwa, Łotwa) oraz w krajach sąsiednich (Czechy, Niemcy, Słowacja). Dla zdecydowanej większości wnioskowanych zastosowań (za wyjątkiem rynchosporiozy w jęczmieniu jarym), dostępne były wyniki badań ze strefy EPPO północno-wschodniej. Do oceny środka w zwalczaniu rynchosporiozy w jęczmieniu jarym, zgodnie z zasadą ekstrapolacji wykorzystano wyniki z 1 badania, przeprowadzonego w Czechach (wniosek o ocenę środka Forapro został złożony w sierpniu 2021 roku, przed aktualizacją zapisów ustaleń harmonizacyjnych w tym zapisów dotyczących lokalizacji badań dla środków zawierających nową mieszaninę substancji czynnych)
4. Na podstawie przeprowadzonej oceny, nie uznano zastosowania środka w pszenicy jarej do ochrony przed septoriozą paskowaną liści, mączniakiem prawdziwym, rdzą brunatną i rdzą żółtą – na podstawie etykiety środka, w domyśle pszenżyto jare nie jest wnioskowane dla Polski. Jednak biorąc pod uwagę tabelę GAP gdzie wskazano kod TTLSS, odnoszący się ogólnie do pszenżyta, wnioski z oceny wykonano w stosunku do obu form pszenżyta. W przedłożonej dokumentacji jest tylko 1 badanie wykonane w pszenicy jarej w Niemczech, w którym wystąpiły rdza żółta oraz mączniak prawdziwy. Jednak na podstawie tego badania nie można pokazać miarodajnych wyników skuteczności działania środka po 1 zabiegu, z uwagi na zbyt niskie porażenie (pest severity znacznie poniżej 5%), są jedynie wyniki po 2

zabiegu przy odpowiednim porażeniu na kontroli. Z uwagi na to, że rdza żółta w pszenżycie jarym jest wymieniona jako zastosowanie małoobszarowe w rozporządzeniu Ministra Rolnictwa i Rozwoju Wsi z dnia 18 września 2019 r. zmieniającym rozporządzenie w sprawie zastosowań małoobszarowych środka ochrony roślin, istnieje możliwość rejestracji tego zastosowania w trybie art. 51 rozporządzenia 1107/2009.

5. Zmodyfikowano i rozszerzono zapisy w ramach strategii zarządzania odpornością – zgodnie z zapisami zaproponowanymi przez wnioskodawcę i zaakceptowanymi przez zRMS w części B3 dRR.

Sekcja metody analityczne:

1. Brak uwag.

Sekcja toksykologia i istotność toksykologiczna metabolitów:

1. W części dotyczącej zwrotów wskazujących środki ostrożności zmieniono zwrot „Zapobieganie” na P260 ze względu na klasyfikację zagrożeń H373
2. W części dotyczącej **PIERWSZA POMOC** dodano zwrot „W przypadku złego samopoczucia zasięgnąć porady/zgłosić się pod opiekę lekarza” wynikający z klasyfikacji zagrożeń H373

Sekcja pozostałości

1. Wprowadzono do etykiety zapis dotyczący roślin uprawianych następnie. „Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie: Nie dotyczy”.

Sekcja los i zachowanie w środowisku:

1. Brak uwag.

Sekcja ekotoksykologia:

1. Zmieniono zapisy dotyczące zarządzania ryzykiem dla organizmów wodnych.
Wprowadzono 40 metrową strefę ochronną, w tym zadarnioną na szerokość 10 metrów od zbiorników i cieków wodnych wraz z użyciem rozpylaczy redukujących znoszenie cieczy użytkowej o 75%.
2. Dodano zwroty P391 i P501.

Posiadacz zezwolenia:

ADAMA Polska Sp. z o.o., ul. Sienna 39, 00-121 Warszawa, tel.: +48 22 395 66 60, infolinia: +48 22 395 66 66, e-mail: biuro@adama.com, www.adama.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie:

.....

FORAPRO 425 EC


Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

Fenpropidyna – związek z grupy morfolin - 250 g/l (24,0%)

Protiokonazol - związek z grupy triazoli– 175 g/l (16,8%)

Zezwolenie MRiRW nr R - /2023 z dnia2023 r.

	
Niebezpieczeństwo	
H315 H317 H318 H335 H373 H410	Działa drażniąco na skórę. Może powodować reakcję alergiczną skóry. Powoduje poważne uszkodzenie oczu. Może powodować podrażnienie dróg oddechowych. Może powodować uszkodzenie narządów poprzez długotrwałe lub narażenie powtarzane Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia
P261 P260 P280 P302+P352 P305+P351+P338 P391 P410 P501	Unikać wdychania pyłu/dymu/gazu/mgły/par/rozpylonej cieczy. Nie wdychać pyłu/dymu/gazu/mgły/par/rozpylonej cieczy. Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy. W PRZYPADKU KONTAKU ZE SKÓRĄ: Umyć dużą ilością wody/mydłem W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. Zebrać wyciek 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 **głównie** zapobiegawczego, **a także interwencyjnego oraz wyniszczającego.**

Zgodnie z klasyfikacją FRAC substancja czynna fenpropidyna zaliczana jest do grupy 5 (fungicydy SBI - II, morfoliny), a substancja czynna protiokonazol zaliczana jest do grupy 3 (fungicydy SBI - I, DMI fungicydy).

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego

Pszenica ozima, pszenica jara

septorioza paskowana liści pszenicy (średni poziom zwalczania), brunatna plamistość liści (średni poziom zwalczania), ~~rdza żółta, rdza brunatna~~, mączniak prawdziwy zbóż i traw

Pszenica ozima

rdza żółta, rdza brunatna

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 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: 100-400 l/ha.

Zalecane opryskiwanie: : ~~średnioskropliste~~ **drobnokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Jęczmień ozimy, jęczmień jary

mączniak prawdziwy zbóż i traw, ryńchosporioza zbóż, plamistość siatkowa jęczmienia, rdza jęczmienia
Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 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: 100-400 l/ha.

Zalecane opryskiwanie: ~~średniokropliste~~ **drobnokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Pszenżyto ozime

mączniak prawdziwy zbóż i traw, septorioza paskowana liści pszenicy, rdza brunatna, rdza żółta,
Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 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: 100-400 l/ha.

Zalecane opryskiwanie: ~~średniokropliste~~ **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 dotyczy

Podczas stosowania środka nie dopuścić do:

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

Środek zawiera substancję czynną fenpropidyna z grupy morfolin (fungicydy inhibitory biosyntezy steroli, **inhibitory** reduktazy i izomerazy, SBI- II, wg FRAC Grupa 5) oraz protiokonazol z grupy triazoli (fungicydy inhibitory biosyntezy steroli - inhibitory demetylacji, SBI- I DMI **fugicydy**, wg FRAC grupa 3),

W ramach strategii antyodpornościowej zaleca się m. in.:

- stosowanie środka głównie do zabiegów zapobiegawczych (tj. na początku okresów infekcji pierwotnych lub wtórnych). Należy unikać stosowania środka w zabiegach interwencyjnych lub leczniczych, tj. w późnych fazach rozwoju choroby,

- ~~nie stosowanie środka w dawkach innych niż jest zalecana,~~ w pełnej zalecanej dawce, także w przypadku stosowania środka w mieszaninach zbiornikowych,

- Ponieważ dopuszczalny jest tylko jeden zabieg środkiem Forapro w sezonie, zaleca się włączenie do przyjętego programu ochrony środków grzybobójczych, zawierających substancje czynne z innych grup, o odmiennych mechanizmach działania, dla których nie występuje ryzyko odporności krzyżowej patogenu na środki z grupy 3 oraz 5 FRAC (SBI-DMI, SBI-morfoliny) (stosowanie przemienne lub w mieszaninie zbiornikowej),

- w przypadku zaobserwowania zmniejszonej skuteczności środka Forapro i podejrzenia występowania mniej wrażliwych ras patogenu, środek powinien być stosowany wyłącznie w mieszaninach

zbiornikowych lub przemiennie ze skutecznymi środkami z innych grup, dla których nie występuje ryzyko odporności krzyżowej patogenu na środki z grupy 3 i 5 FRAC (SBI-DMI, SBI-morfoliny),
- celem zmniejszenia presji infekcyjnej patogenów, należy włączyć niechemiczne metody ochrony jak np. stosowanie odmian odpornych, właściwe zmianowanie, a także przestrzegać zasad dobrej praktyki rolniczej.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wleciu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy, ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą 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.

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 trakcie przygotowywania cieczy użytkowej.

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

Unikać zanieczyszczenia oczu.

Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

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 uwolnienia do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie ~~zadarnionej~~ strefy ochronnej o szerokości 40 metrów, w tym zadarnionej o szerokości 10 metrów wraz z użyciem rozpylaczy redukujących znoszenie cieczy użytkowej o 75% od zbiorników i cieków wodnych.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 10 m wraz z jednoczesną redukcją znosu z chmurą oprysku o 75% za pomocą odpowiednich technik antyznoszeniowych.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach, w prawidłowo wentylowanych, suchych i chłodnych miejscach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- 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.

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 kontaktu ze skórą (lub z włosami) zdjąć całą zanieczyszczoną odzież. Spłukać skórę strumieniem wody (lub prysznicem).

W przypadku złego samopoczucia zasięgnąć porady/zgłosić się pod opiekę lekarza.

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 2.2.1/01	Tzur, L.	2020	Explosive and oxidising properties of Prothioconazole 175 + Fenpropidin 250 EC Report no. -, Sponsor no. - ADAMA Agricultural Solutions Ltd., Beer-Sheva, Israel Not GLP Unpublished	N	N		ADM	
KCP 2.2.2/01 filed in KCP 2.2.1/01	Tzur, L.	2020	Explosive and oxidising properties of Prothioconazole 175 + Fenpropidin 250 EC Report no. -, Sponsor no. - ADAMA Agricultural Solutions Ltd., Beer-Sheva, Israel Not GLP Unpublished	N	N		ADM	
KCP 2.3.1/01 filed in KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 2.3.3/01	Halbwachs, P.	2020	Auto-ignition temperature of liquids on fenpropidine 250 + prothioconazol 175 EC (ADM.03502.F.1.A) Report no. 20-913017-012, Sponsor no. 000105554 DEFITRACES, Brindas, France 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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 2.4.2/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 2.5.1/01 filed in KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 2.5.2/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 2.6.1/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 2.7.1/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 2.7.4/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 2.7.5/01	Tsesin, N.	2022	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at ambient temperature for two years. Report no. 000105030.062FL, Sponsor no. 000105030 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 2.8.2/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 2.8.6.1/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 2.8.6.2/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 2.8.6.3/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 4.2/01	Anonymous	2022	Safety Data Sheet – ADM.03502.F.1.A- – Revision date 07-Jul-2022 Report no. FNG56966-M ADAMA Makhteshim Ltd., Beer-Sheva, Israel Not GLP 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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 5.1.1/01 (filed in KCP 2.1/01)	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 5.1.1/02	Tsesin, N.	2020	Analytical method validation and quantification of toluene in Prothioconazole 175 g/L + Fenpropidin 250 g/L EC (ADM.03502.F.1.A) Report no. 000105028.064FL, Sponsor no.: 000105028 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 5.1.2/01 (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.: R-30330 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 5.1.2/02 (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.: R-39653 POLLENIZ/GIRPA, Beaucouzé Cedex, France GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 5.1.2/03 (filed in KCA 6.3.1/01)	Huauilmé, J.-M.	2020	Residue study of prothioconazole and its metabolites, and fenpropidin in wheat whole plant and RAC (grain and straw) after one foliar application of ADM.3502.F.1.A - 2 HS and 2 DCS - Northern Europe (France, Poland and Hungary) - 2019 Report no.: BPL19/770/GC, sponsor no.: 000102759 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 5.1.2/04 (filed in KCA 6.3.2/01)	Huauilmé, J.-M.	2020	Residue study of prothioconazole and its metabolites, and fenpropidin in barley whole plant and RAC (grain and straw) after one foliar application of ADM.3502.F.1.A - 2 harvest and 2 decline trials - Northern Europe (France, Poland and Hungary) - 2019. Report no.: BPL19/772/GC, sponsor no.: 000102761 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	Y for prothioconazole evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022 N for fenpropidin

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 5.1.2/05 (filed in KCA 6.3.2/02)	Huauilmé, J.-M.	2021	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 - 2 harvest and 2 decline trials – Northern Europe (FR, PL, HU) - 2020. Report no.: BPL20/844/GC, sponsor no.: 000105350 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	Y for prothioconazole evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022 N for fenpropidin
KCP 5.1.2/06 (filed in KCP 7.2.2.2/01)	Anonymous	2010	Development of air sampling methodology in support of determining risk of bystander and resident exposure to pesticides SID 5 (Rev. 07/10), DEFRA Project PS2023 Non-GLP Published	N	N		--	N
KCP 5.1.2/07 (filed in KCP 9.1.1.1/01)	Morlock, G.	2006a	Degradation of Fenpropidin in 3 different soils under aerobic conditions at 20° C in the dark Report No 20051244/01-CABJ, sponsor no. 00012949 GLP Unpublished	N	Y	Data protection started with authorisation of Artemis 450 EC (R-10/2016 dated 26.01.2016)	IRVITA*	N
KCP 5.1.2/08 (filed in KCP 9.1.1.1/02)	Morlock, G.	2006b	Degradation of Fenpropidin in one soil under aerobic conditions at 20° C in the dark Report No 20051244/02-CABJ, sponsor no. 00012950 GLP Unpublished	N	Y	Data protection started with authorisation of Artemis 450 EC (R-10/2016 dated 26.01.2016)	IRVITA*	N
KCP 5.1.2/09 (filed in KCP 9.1.1.1/03)	Flörchinger M.	2008	Degradation of Fenpropidin Acid in 3 Different Soils under Aerobic Conditions at 20°C in the Dark Eurofins-GAB GmbH Report No.S08-01156, sponsor no. 00016350 GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	IRVITA*	N
KCP 5.1.2/10 (filed in KCP 10.2.1/01)	...	2020a	Acute toxicity of ADM.03502.F.1.A to <i>Oncorhynchus mykiss</i> in a 96-hour semi-static test Report no GLP Unpublished	Y	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 5.1.2/11 (filed in KCP 10.2.1/02)	Renner, P.	2020b	Acute toxicity of ADM.03502.F.1.A to <i>Daphnia magna</i> in a 48-hour semi-static test Report no 2048ADL0008, Sponsor no.: 000104840 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 5.1.2/12 (filed in KCP KCP 10.2.1/03)	Scheerbaum, D.	2021	ADM.03502.F.1.A - Alga, Growth Inhibition Test with <i>Desmodesmus subspicatus</i> , 72 hours Report no. SO21519 / SSO19707, Sponsor no.: 000108687 Noack Laboratorien GmbH, Sarstedt, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 5.1.2/13 (filed in KCP 10.2.1/04)	Renner, P.	2021	Effects of ADM.03502.F.1.A on <i>Lemna gibba</i> in a growth inhibition test under semi-static test conditions Report no 2048ALE0006, Sponsor no.: 000104842 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 5.1.2/14 (filed in KCP 10.3.1.2/01)	Dreßler, K.	2020	Chronic oral toxicity of ADM.03502.F.1.A to the honey bee <i>Apis mellifera</i> L. under laboratory conditions Report no.: 2048BAC0011, Sponsor no.: 000104844 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 5.1.2/15 (filed in KCP 10.3.1.3/01)	Hänsel, M.	2021	ADM.03502.F.1.A – Repeated exposure of honey bee larvae (<i>Apis mellifera</i> L.) under laboratory conditions Report no.: 2048BLC0013, Sponsor no.: 000104845 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 5.1.2/16 (filed in KCP 10.6.1/01)	Kästner, K.	2020a	Effects of ADM.03502.F.1.A on seedling emergence and seedling growth of six non-target terrestrial plant species under greenhouse conditions Report no.: 2046PSE0007, Sponsor no.: 000104852 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 5.1.2/17 (filed in KCP 10.6.1/02)	Kästner, K.	2020b	Effects of ADM.03502.F.1.A on vegetative vigour of six non-target terrestrial plant species under greenhouse conditions Report no.: 2035CRX0012, Sponsor no.: 000104853 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 5.1.2/18	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, Beaucozé Cedex, France GLP Unpublished	N	Y	Study submitted in February 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC) and April 2022 for support registration of product ADM.03503.F.1.A (Avastel 225 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 5.1.2/19	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 submitted in February 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 5.1.2/20 (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.: R-39638 Eurofins Agrosience Services GmbH, Stade, Germany GLP, Unpublished	N	Y	Study submitted in February 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC) and April 2022 for support registration of product ADM.03503.F.1.A (Avastel 225 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022

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KCP 5.2/01	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, Sponsor no.: 000109608 ResChem Analytical Limited, Derby, UK GLP Unpublished	N	Y	Study submitted in February 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC) and April 2022 for support registration of product ADM.03503.F.1.A (Avastel 225 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 5.2/02	Lefresne, S.	2020	Validation of an analytical method for the determination of prothioconazole residues in wheat (whole plant, grain, straw), oilseed rape (grain), strawberry and dried bean Report no.: B18S-A4-P-01, Sponsor no.: R-39651 FREDON Pays de la Loire / GIRPA, Beaucoz� Cedex, Israel GLP Unpublished	N	Y	Study submitted in February 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 5.2/03	Watson, G.	2022	Independent laboratory validation of an analytical method B18S-A4-P-01 (Adama study No- R-39651) for the determination of residues of prothioconazole-desthio in crops by LC-MS/MS Report no.: RES-00393, Sponsor no.: 000110772 ResChem Analytical Limited, Derby, UK GLP Unpublished	N	Y	Study submitted in October 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 5.2/04	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 submitted in October 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022

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KCP 5.2/05	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 Agroscience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	Y	Study submitted in October 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 5.2/06	Lefresne, S.	2021	Validation of an analytical method for the determination of prothioconazole residues in honey Report no.: B21S-A4-P-04, Sponsor no.: 000108774 FREDON Pays de la Loire / GIRPA, Beaucouzé Cedex, Israel GLP Unpublished	N	Y	Study submitted in April 2022 for support of registration of product ADM.03503.F.1.A (Avastel 225 EC) and October 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 5.2/07	Lindner, M.	2022	Independent Laboratory Validation of an Analytical Method for Determination of Prothiconazole Residues in Honey Report no.: S21-06313 (MAC-2144V), Sponsor no.: 000108775 Eurofins Agroscience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	Y	Study submitted in April 2022 for support of registration of product ADM.03503.F.1.A (Avastel 225 EC) and October 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022

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KCP 5.2/08	Krebber, C., Sansau, C.	2015	Modification M002 of analytical method 01387 for the determination of various pesticides in drinking and surface water by HPLC-MS/MS Report no.: MR-15/025 Bayer CropScience AG, Monheim am Rhein, Germany GLP Unpublished	N	Y	Study submitted in October 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC). Data protection has not yet started.	BCS/A DM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 5.2/09	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, Leverkusen, Germany GLP Unpublished	N	Y	Study submitted in April 2022 for support of registration of product ADM.03503.F.1.A (Avastel 225 EC) and October 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC). Data protection has not yet started.	BCS/A DM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 5.2/10	Richardson, M.	2007	Fenpropidin (CGA114900) - Residue method for the determination of Fenpropidin and metabolite CGA289267 in water. Final determination by LC-MS/MS Report no.: GRM024.03A, Sponsor no.: - Syngenta, Jealott's Hill International Research Centre, Bracknell, Berkshire, UK Not GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	SYN/A DM	N
KCP 5.2/11	Devine, T.	2016	Fenpropidin (CGA114900) - Independent Laboratory Validation of an Analytical Method GRM024.03A for the Determination of Residues of Fenpropidin (CGA114900) and its Metabolite CGA289267 in Water by LC-MS/MS Report no.: RES-00373, Sponsor no.: - CEM Analytical Services Limited (CEMAS), Wokingham, UK GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	SYN/A DM	N

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KCP 5.2/12	Cross, M.	2017	Fenpropidin: Validation of Analytical Method REM 164.10 for the Determination of Residues of Fenpropidin and its Metabolites CGA289267 and CGA289268 in Blood by LC-MS/MS Report no.: CEMR-8288, Sponsor no.: - CEM Analytical Services Limited (CEMAS), Wokingham, UK GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	SYN/ADM	N
KCP 6.0	Nelgen, N.	2021	Biological Assessment Dossier of ADM.3502.F.1.A (Part B, Section 7– Core assessment - Central Zone / Southern Zone / Northern Zone) Dr. Norbert Nelgen Scientific Consulting Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/001	BAROU, JL	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (Puccinia) on winter wheat in France, 2019 FR19FETRZAX329B Agrotest France GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/002	BAROU, JL	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (Puccinia) on winter wheat in France, 2019 FR19FETRZAX329C Agrotest France GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/003	Brož, M.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTSP) on triticale in the Czech Republic, 2019 CZ19FETTLSS212A ZZS Kujawy GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/004	Cáp, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> and/or <i>Puccinia hordei</i> on barley, Czech republic, 2018 CZ18FEHORVX921A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/005	Cáp, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in the Czech Republic, 2019 CZ19FETRZAW200A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/006	Cáp, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in the Czech Republic, 2019 CZ19FETRZAW203A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/007	Cáp, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in the Czech Republic, 2019 CZ19FEHORVS207A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/008	Cáp, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTSP) on triticale in the Czech Republic, 2019 CZ19FETTLWI212B ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/009	Cáp, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on triticale in the Czech Republic, 2019 CZ19FETTLWI215A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/010	Cáp, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia c.</i> (PUCCCO) on oat in the Czech Republic, 2019 ZS Nechanice / CZ19FEAVESA216B GEP / not published	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1	Von Hörsten, D.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia c.</i> (PUCCCO) on oat in (Germany), 2019 DE19FEAVESA216C FRS Wunstorf GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/011	Endres, U.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria tritici</i> on wheat, in Germany in 2018. DE18FETRZAW919B Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/012	Endres, U.	2019	Efficacy evaluation of different MCW-2091 formulation against <i>Puccinia</i> ssp. on wheat, in Germany in 2018. DE18FETRZAW920B Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/013	Furman-Fratczak, K.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> on wheat, in Poland in 2018. PL18FETRZAW020A Biotek Agriculture GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/014	GOUAILLE, L.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown leaf rust (PUCCRE) and Septoria tritici (SEPTTR) on winter wheat in France, 2019 Biotek Agriculture France / FR19FETRZAX328B GEP / not published	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/015	GOUAILLE, L.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) and <i>Rhynchosporium</i> (RHYNSE) on barley in France, 2019 FR19FEHORVX318B Biotek Agriculture France GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/016	Halmágyi, T.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Puccinia</i> ssp. on wheat, in Hungary in 2018. HU18FETRZAW112A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/017	Halmágyi, T.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Puccinia hordei</i> on barley, in Hungary in 2018. HU18FEHORVW114B Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/018	Hetterich, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Pyrenophora tritici-repentis (PYRNTR (DTR)) on winter wheat in (Germany), 2019 Hetterich Fieldworks / DE19FETRZAW202B GEP / not published	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/019	Hetterich, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in (Germany), 2019 DE19FETRZAW203B Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/020	Holcikova, D.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> and/or <i>Puccinia hordei</i> on spring barley in Slovakia in 2018. SK18FEHORVS921A Fyse Ltd. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/023	Hrabovský, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> on wheat, Czech republic, 2018. CZ18FETRZAW921B ZZS Kujavy GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/024	Hrabovský, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in the Czech Republic, 2019 CZ19FETRZAW201A ZZS Kujavy GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/025	Hruška, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> on wheat, Czech republic, 2018 CZ18FETRZAW921A ZS Trutnov GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/026	Hruška, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in the Czech Republic, 2019 CZ19FETRZAW201B ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/027	Hruška, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in the Czech Republic, 2019 CZ19FETRZAW203B ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/028	Hruška, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRE) on triticale in the Czech Republic, 2019 CZ19FETTLWI215B ZS Trutnov GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/029	Kukula, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in Poland, 2019 PL19FEHORVW424A AGRECO SP. Z O.O. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/030	Kukula, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in Poland, 2019 PL19FEHORVW424B AGRECO SP. Z O.O. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/032	Labusch, U.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria tritici</i> on wheat, in Germany in 2018. DE18FETRZAW919C BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/033	Labusch, U.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Puccinia</i> ssp. on wheat, in Germany in 2018. DE18FETRZAW920C BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/034	Laug, S.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> on wheat, in Germany in 2018. DE18FETRZAW921B Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/035	Legros, C.	2019	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> (ERYSGT) on wheat, in France in 2018. FR18FETRZAX342A SAS (SARL) EPHYDIA GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/036	LUNZENFICHTER, C.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> (ERYSGT) on wheat, in France in 2018. FR18FETRZAX342D QUALIPHYT GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/037	Magyaróvári, V.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on rye in (Germany), 2019 DE19FESECSS211E Agrartest GmbH GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/038	Makó, I.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in Hungary, 2019 HU19FEHORVX113A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/039	Malovcova, L.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> and/or <i>Puccinia hordei</i> on spring barley in Slovakia in 2018. SK18FEHORVS921B NPPC VURV Piestany GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/040	Martin, T.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in (Germany), 2019 DE19FETRZAW201C Martin Feldversuchswesen GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/041	Martin, T.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in (Germany), 2019 DE19FETRZAW203C Martin Feldversuchswesen GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/042	Martin, T.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on rye in (Germany), 2019 DE19FESECSS209D Martin Feldversuchswesen GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/043	Martin, T.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on rye in (Germany), 2019 DE19FESECSS211D Martin Feldversuchswesen GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/044	Nagy, Z.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Puccinia</i> ssp. on wheat, in Hungary in 2018. HU18FETRZAW112B Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/045	Nagy, Z.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> on wheat, in Hungary in 2018. HU18FETRZAW114B Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/046	Nagy, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (PUCCRT) on winter wheat in Hungary, 2019 HU19FETRZAW114A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/047	Németh, S.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> on wheat, in Hungary in 2018. HU18FETRZAW114A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/048	Pawlak, A.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> on wheat, in Poland in 2018. PL18FETRZAW020B Staphyt Poland GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/049	Pawlak, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (PuccRT) on winter wheat in Poland, 2019 PL19FETRZAW420A Staphyt Poland GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/050	Pawlak, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (PuccRT) on winter wheat in Poland, 2019 PL19FETRZAW420B Staphyt Poland GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/051	Perner, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Puccinia</i> ssp. on wheat, in Germany in 2018. DE18FETRZAW920D U.A.S. Jena GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/052	Perner, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in (Germany), 2019 DE19FETRZAW200A U.A.S. Jena GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/053	Perner, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in (Germany), 2019 U.A.S. Jena / DE19FETRZAW202C GEP / not published	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/054	Perner, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in (Germany), 2019 DE19FEHORVW208B U.A.S. Jena GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/055	Perner, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on rye in (Germany), 2019 DE19FESECSS211C U.A.S. Jena GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/056	Ramanauskienė, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria tritici</i> on winter wheat in Lithuania in 2018 LT18FETRZAW927A IA LRC, Kedainiai GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/057	Rancane, R.	2018	Efficacy evaluation of different MCW-2091 formulations against Blumeria graminis on winter wheat in Latvia in 2018 LPPRC Riga / LV18FETRZAW918A GEP / not published	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/058	Raue, C.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in (Germany), 2019 DE19FEHORVW205C SynTech DE GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/059	Raue, C.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on rye in (Germany), 2019 DE19FESECSS209E SynTech DE GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/060	Rivet, J.; Crepin, D.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in France, 2019 FR19FETRZAX327B Essais+ GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/061	Rivet, J.; Crepin, D.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in France, 2019 FR19FETRZAX327C Essais+ GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/062	Rivet, J.; Crepin, D.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in France, 2019 FR19FEHORVX319A Essais+ GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/063	Rivet, J.; Crepin, D.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in France, 2019 FR19FEHORVX319B Essais+ GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/064	Rivet, J.; Crepin, D.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in France, 2019 FR19FEHORVX319C Essais+ GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/065	Rohr, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria tritici</i> on wheat, in Germany in 2018. DE18FETRZAW919A Agrartest GmbH GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/066	Rohr, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Puccinia</i> ssp. on wheat, in Germany in 2018. DE18FETRZAW920A Agrartest GmbH GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/067	Rohr, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> on wheat, in Germany in 2018. DE18FETRZAW921A Agrartest GmbH GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/068	Rohr, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> and/or <i>Puccinia hordei</i> on barley, in Germany in 2018. DE18FEHORVW921A Agrartest GmbH GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/069	Rohr, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in (Germany), 2019 DE19FETRZAW201B Trial-Tec GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/070	Rohr, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (PuccRT) on winter wheat in (Germany), 2019 DE19FETRZAW204A Trial-Tec GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/071	Rohr, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in (Germany), 2019 DE19FEHORVW208A Trial-Tec GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/072	Rohr, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on rye in (Germany), 2019 DE19FESECSS209B Trial-Tec GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/073	Ronis, A.	2018	Efficacy evaluation of different MCW-2091 formulations against <i>Blumeria graminis</i> on spring wheat in Lithuania in 2018 LT18FETRZAS928A IA LRC, Kedainiai GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/074	ROUANE, W.	2019	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria tritici</i> (SEPTTR) on wheat, in France in 2018. ANADIAG FRANCE / FR18FETRZAX341C GEP / not published	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/075	ROUANE, W.	2019	Efficacy evaluation of different MCW-2091 formulation against <i>Puccinia</i> ssp. on wheat, in France in 2018. FR18FETRZAX341D ANADIAG FRANCE GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/077	Sawinska, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in Poland, 2019 PL19FETRZAW417A Poznan University of Life Sciences GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/078	Sawinska, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in Poland, 2019 PL19FETRZAW417B Poznan University of Life Sciences GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/079	Sawinska, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on triticale in Poland, 2019 PL19FETTLSS428A Poznan University of Life Sciences GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/080	Sawinska, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on triticale in Poland, 2019 PL19FETTLSS428B Poznan University of Life Sciences GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/081	Semaskiene, R.	2018	Efficacy evaluation of different MCW-2091 formulations against <i>Blumeria graminis</i> on spring barley in Lithuania in 2018 LT18FEHORVS929A IA LRC, Kedainiai GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/082	SGS Hungária Kft.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in Hungary, 2019 HU19FETRZAW112B SGS Hungary GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/083	SGS Hungária Kft.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in Hungary, 2019 HU19FEHORVX113B SGS Hungary GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/084	Tuna, V.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on triticale in ROMANIA, 2019 RO19FETTLSS162A EAS Romania GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/088	Tvaruzek, L.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> and/or <i>Puccinia hordei</i> on barley, Czech republic, 2018. CZ18FEHORVX921B ZVU Kromeriz GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/089	Tvaruzek, L.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in the Czech Republic, 2019 CZ19FETRZAW200B ZVU Kromeriz GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/090	Vadász, Z.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> and/or <i>Puccinia hordei</i> on barley, in Hungary in 2018 HU18FEHORVW114A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/091	Varga, A.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria tritici</i> on wheat, in Hungary in 2018. HU18FETRZAW110B Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/092	VARRET, F.	2019	Efficacy evaluation of different MCW-2091 formulations against <i>Puccinia striiformis</i> (PUCCST) and <i>Puccinia recondita</i> (PUCCRE) on wheat, in France in 2018. FR18FETRZAX341A STAPHYT GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/093	VARRET, F.	2019	Efficacy evaluation of different MCW-2091 formulations against <i>Puccinia recondita</i> (PUCCRE) on wheat, in France in 2018. FR18FETRZAX341B STAPHYT GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/094	Viosin, J.F.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> on barley, in France in 2018. FR18FEHORVX315A Agrotest France GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/095	Viosin, J.F.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> on barley, in France in 2018. FR18FEHORVX315B Agrotest France GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/096	Von Hörsten, D.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in (Germany), 2019 DE19FEHORVW207D FRS Wunstorf GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/097	WALLART, F.	2019	EFFICACY EVALUATION OF ADM.3502.F.1.A FOR THE CONTROL OF BROWN RUST (PUCCRT) ON WINTER WHEAT IN FRANCE, 2019 FR19FETRZAX329A SAS (SARL) EPHYDIA GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/098	WALLART, F.	2019	EFFICACY EVALUATION OF ADM.3502.F.1.A FOR THE CONTROL OF <i>BLUMERIA GRAMINIS</i> TRITICI (ERYSGT) ON WINTER WHEAT IN FRANCE, 2019 FR19FETRZAX327D SAS (SARL) EPHYDIA GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/100	Wallart, G.	2019	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria tritici</i> on wheat, in France in 2018. FR18FETRZAX340B SAS (SARL) EPHYDIA GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/101	Wöllmann, S.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (PuccRT) on winter wheat in (Germany), 2019 DE19FETRZAW204B(AC-19-096) Agro-check GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/102	Wöllmann, S.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in (Germany), 2019 DE19FEHORVW208C_2(AC-19-097) Agro-check GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/103	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in (Germany), 2019 DE19FETRZAW202A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/104	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in (Germany), 2019 DE19FETRZAW201A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/105	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in (Germany), 2019 BioChem Agrar / DE19FEHORVW205A GEP / not published	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/106	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in (Germany), 2019 DE19FEHORVW208D BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/107	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on rye in (Germany), 2019 DE19FESECSS209A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/108	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on rye in (Germany), 2019 DE19FESECSS211A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/109	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTSP) on triticale in (Germany), 2019 DE19FETTLSS212A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/110	Zöllner, H.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTSP) on triticale in (Germany), 2019 FRS Wunstorf / DE19FETTLSS212C GEP / not published	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.1/111	Zsuzsanna, H.P.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (Puccrt) on winter wheat in Hungary, 2019 HU19FETRZAW114B Növénypathyka GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.1/112	Zsuzsanna, H.P.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in Hungary, 2019 HU19FETRZAW111B Növénypathyka GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /005 6.4.1 /005 6.4.2 /004	Bauer, T.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (Puccst) on winter wheat in the Czech republic, 2020 CZ20FETRZAW271B InTec Agro GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /006 6.4.1 /006 6.4.2 /005	Benczés, B.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in Hungary, 2020 HU20FEHORVW421A CPR Europe Kft. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /007 6.4.1 /007 6.4.2 /006	Benczés, B.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in Hungary, 2020 HU20FETRZAW413A CPR Europe Kft. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /008 6.4.1/008 6.4.2 /007	Bezdičková, A.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in the Czech republic, 2020 CZ20FEHORVS236B Ditana spol. s r. o. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /009 6.4.1/009 6.4.2 /008	Botos, I.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Puccinia</i> ssp. on wheat, in Hungary in 2018. HU18FETRZAW112C Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /010 6.4.1/010 6.4.2 /009	Brož, M.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTSP) on triticale in the Czech Republic, 2019 CZ19FETTLSS212A ZZS Kujavy GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /011 6.4.1/011 6.4.2 /010	Cáp, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> and/or <i>Puccinia hordei</i> on barley, Czech republic, 2018 CZ18FEHORVX921A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /012 6.4.1/012 6.4.2 /011	Cáp, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in the Czech Republic, 2019 CZ19FETRZAW200A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /013 6.4.1/013 6.4.2 /012	Cáp, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in the Czech Republic, 2019 CZ19FETRZAW203A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /014 6.4.1/014 6.4.2 /013	Cáp, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGH) on barley in the Czech Republic, 2019 CZ19FEHORVS206A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /015 6.4.1/015 6.4.2 /014	Cáp, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in the Czech Republic, 2019 CZ19FEHORVW205B ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /016 6.4.1/016 6.4.2 /015	Cáp, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in the Czech Republic, 2019 CZ19FEHORVS207A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /017 6.4.1/017 6.4.2 /016	Cáp, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTSP) on triticale in the Czech Republic, 2019 CZ19FETTLWI212B ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /018 6.4.1/018 6.4.2 /017	Cáp, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on triticale in the Czech Republic, 2019 CZ19FETTLWI213B ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /019 6.4.1/019 6.4.2 /018	Cáp, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on triticale in the Czech Republic, 2019 CZ19FETTLWI215A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /020 6.4.1/020 6.4.2 /019	Cáp, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia c.</i> (PUCCCO) on oat in the Czech Republic, 2019 CZ19FEAVESA216A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /021 6.4.1/021 6.4.2 /020	Cáp, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia c.</i> (PUCCCO) on oat in the Czech Republic, 2019 CZ19FEAVESA216B ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /022 6.4.1/022 6.4.2 /021	Cáp, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in the Czech republic, 2020 CZ20FEHORVS273B ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /023 6.4.1/023 6.4.2 /022	Cáp, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on triticale in the Czech republic, 2020 CZ20FETTLWI243C ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /024 6.4.1/024 6.4.2 /023	Cáp, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on triticale in the Czech republic, 2020 CZ20FETTLWI244B ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /025 6.4.1/025 6.4.2 /024	Cáp, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia c.</i> (PUCCCO) on oat in the Czech republic, 2020 CZ20FEAVESA246A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /026 6.4.1/026 6.4.2 /025	Cáp, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia c.</i> (PUCCCO) on oat in the Czech republic, 2020 CZ20FEAVESA246C ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /027 6.4.1/027 6.4.2 /026	Cáp, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in the Czech republic, 2020 CZ20FEHORVW236A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /040 6.4.1/040 6.4.2 /031	Endres, U.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria tritici</i> on wheat, in Germany in 2018. DE18FETRZAW919B Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /041 6.4.1/041 6.4.2 /032	Endres, U.	2019	Efficacy evaluation of different MCW-2091 formulation against <i>Puccinia</i> ssp. on wheat, in Germany in 2018. DE18FETRZAW920B Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /042 6.4.1/042 6.4.2 /033	Flahaut, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in FRANCE, 2020 FR20FETRZAW307A STAPHYT France GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /043 6.4.1/043 6.4.2 /034	Forgacova, L.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in Slovakia, 2020 SK20FEHORVW238B BERBERIS s.r.o. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /044 6.4.1/044 6.4.2 /035	Furman-Fratczak, K.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> on wheat, in Poland in 2018. PL18FETRZAW020A Biotek Agriculture GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /045 6.4.1/045 6.4.2 /036	Gajek, D.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on triticale in Poland, 2019 PL19FETTLSS426A Agro Research Consulting GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 6.2 /047 6.4.1/047 6.4.2 /038	Gezova, V.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in the Czech Republic, 2019 CZ19FEHORVW207B InTec Agro GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /048 6.4.1/048 6.4.2 /039	Gezova, V.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on triticale in the Czech Republic, 2019 CZ19FETTLSS214B InTec Agro GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /052 6.4.1/052 6.4.2 /041	Gulbis	2021	Efficacy evaluation of ADM.3502.F.1.A (MCW-2091) for <i>D.terres</i> control in spring barley in Latvia in 2019 LV19FEHORVS484B LPPRC Riga GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /054 6.4.1/054 6.4.2 /043	Gulbis, K.	2019	Efficacy evaluation of ADM.3502.F.1.A (MCW-2091) for <i>Erysiphe graminis</i> control in winter wheat in Latvia in 2019 LV19FETRZAX482A LPPRC Riga GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /056 6.4.1/056 6.4.2 /045	Gulbis, K.	2020	Efficacy evaluation of ADM.3502.F.1.A for <i>Blumeria graminis</i> control in winter barley in Latvia in 2020 LV20FEHORVX476A LPPRC Riga GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /058 6.4.1/058 6.4.2 /047	Gulbis, K.	2020	Efficacy evaluation of ADM.3502.F.1.A for <i>Blumeria graminis</i> control in spring wheat in Latvia in 2020 LV20FETRZAX473A LPPRC Riga GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /061 6.4.1/061 6.4.2 /050	Halmágyi, T.	2018	Efficacy evaluation of different MCW 2091 formulation against <i>Septoria tritici</i> on wheat, in Hungary in 2018. HU18FETRZAW110A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /062 6.4.1/062 6.4.2 /051	Halmágyi, T.	2018	Efficacy evaluation of different MCW 2091 formulation against <i>Puccinia ssp.</i> on wheat, in Hungary in 2018. HU18FETRZAW112A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /063 6.4.1/063 6.4.2 /052	Halmágyi, T.	2018	Efficacy evaluation of different MCW 2091 formulation against <i>Puccinia hordei</i> on barley, in Hungary in 2018. HU18FEHORVW114B Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /064 6.4.1/064 6.4.2 /053	Heger, V.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on titalc in the Czech republic, 2020 CZ20FETTLWI243B Zemservis ZS Domaninek s.r.o. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /065 6.4.1/065 6.4.2 /054	Heger, V.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGH) on barley in the Czech republic, 2020 CZ20FEHORVS237A Zemservis ZS Domaninek s.r.o. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /066 6.4.1/066 6.4.2 /055	Hetterich, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in (Germany), 2019 DE19FETRZAW202B Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /067 6.4.1/067 6.4.2 /056	Hetterich, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in (Germany), 2019 DE19FETRZAW203B Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /068 6.4.1/068 6.4.2 /057	Hetterich, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in (Germany), 2019 DE19FEHORVW205B Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /069 6.4.1/069 6.4.2 /058	Hetterich, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in (Germany), 2019 DE19FEHORVW207B Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /070 6.4.1/070 6.4.2 /059	Hetterich, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on titcale in (Germany), 2019 DE19FETTLSS213B Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /073 6.4.1/073 6.4.2 /062	Hetterich, A.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on rye in (Germany); 2020 DE20FESECSS239D Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /074 6.4.1/074 6.4.2 /063	Hetterich, A.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on rye in (Germany); 2020 DE20FESECSS239E Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /075 6.4.1/075 6.4.2 /064	Hetterich, A.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on rye in (Germany); 2020 DE20FESECSS240D Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /076 6.4.1/076 6.4.2 /065	Hetterich, A.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on rye in (Germany); 2020 DE20FESECSS239C Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2./077 6.4.1/077 6.4.2./066	Hetterich, A.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on rye in (Germany), 2020 DE20FESECSS240E Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2./078 6.4.1/078 6.4.2./067	Hetterich, A.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on rye in (Germany), 2020 DE20FESECSS241E Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2./079 6.4.1/079 6.4.2./068	Hetterich, A.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on titcale in (Germany), 2020 DE20FETTLSS243A Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2./080 6.4.1/080 6.4.2./069	Holcikova, D.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> and/or <i>Puccinia hordei</i> on spring barley in Slovakia in 2018. SK18FEHORVS921A Fyse Ltd. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2./083 6.4.1/083 6.4.2./072	Hrabovsky, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on titcale in the Czech republic, 2020 CZ20FETTLWI243A ZZS Kujavy GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 6.2 /084 6.4.1/084 6.4.2 /073	Hrabovský, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> on wheat, Czech republic, 2018. CZ18FETRZAW921B ZZS Kujavy GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /085 6.4.1/085 6.4.2 /074	Hrabovský, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in the Czech Republic, 2019 CZ19FETRZAW201A ZZS Kujavy GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /086 6.4.1/086 6.4.2 /075	Hrabovský, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on triticale in the Czech Republic, 2019 CZ19FETTLSS213A ZZS Kujavy GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /087 6.4.1/087 6.4.2 /076	Hrabovský, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in the Czech republic, 2020 CZ20FETRZAW270A ZZS Kujavy GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /088 6.4.1/088 6.4.2 /077	Hrabovský, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in the Czech republic, 2020 CZ20FETRZAW271A ZZS Kujavy GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 6.2 /089 6.4.1/089 6.4.2 /078	Hruška, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> on wheat, Czech republic, 2018. CZ18FETRZAW921A ZS Trutnov GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /090 6.4.1/090 6.4.2 /079	Hruška, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in the Czech Republic, 2019 CZ19FETRZAW201B ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /091 6.4.1/091 6.4.2 /080	Hruška, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in the Czech Republic, 2019 CZ19FETRZAW203B ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /092 6.4.1/092 6.4.2 /081	Hruška, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on rye in the Czech Republic, 2019 CZ19FESECCW210A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /093 6.4.1/093 6.4.2 /082	Hruška, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on triticale in the Czech Republic, 2019 CZ19FETTLWI214A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 6.2 /094 6.4.1/094 6.4.2 /083	Hruška, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRE) on triticale in the Czech Republic, 2019 CZ19FETTLWI215B ZS Trutnov GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /095 6.4.1/095 6.4.2 /084	Hruška, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on triticale in the Czech republic, 2020 CZ20FETTLWI244A ZS Trutnov GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /096 6.4.1/096 6.4.2 /085	Hudec, K.; Mihóc, M.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in Slovakia, 2020 SK20FEHORVW273B Blumeria Consulting GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /097 6.4.1/097 6.4.2 /086	Hudec, K.; Mihóc, M.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in Slovakia, 2020 SK20FETRZAW235B Blumeria Consulting GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /098 6.4.1/098 6.4.2 /087	Hudec, K.; Mihóc, M.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in Slovakia, 2020 SK20FETRZAW269B Blumeria Consulting GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 6.2 /103 6.4.1/103 6.4.2 /092	Jovic, M.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in (Germany), 2019 DE19FETRZAW202E SynTech DE GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /104 6.4.1/104 6.4.2 /093	Juhász, I.J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGH) on barley in Hungary, 2019 HU19FEHORVX111B SGS Hungary GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /105 6.4.1/105 6.4.2 /094	Kolarik, P.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia c.</i> (PUCCCO) on oat in the Czech republic, 2020 CZ20FEAVESA246B ZVU Kromeriz GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /106 6.4.1/106 6.4.2 /095	Konvalinkova, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in the Czech Republic, 2019 CZ19FEHORVW205A ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /107 6.4.1/107 6.4.2 /096	Kovacova Holicova, D.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in Slovakia, 2020 SK20FEHORVW273A Fyse Ltd. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 6.2 /108 6.4.1/108 6.4.2 /097	Kovacova Holicova, D.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in Slovakia, 2020 SK20FETRZAW235A Fyse Ltd. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /109 6.4.1/109 6.4.2 /098	Kovacova, D.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in Slovakia, 2020 SK20FEHORVW238A Fyse Ltd. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /110 6.4.1/110 6.4.2 /099	Kovacova, D.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in Slovakia, 2020 SK20FETRZAW269A Fyse Ltd. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /111 6.4.1/111 6.4.2 /100	Kukula, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in Poland, 2019 PL19FETRZAW416A AGRECO SP. Z O.O. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /112 6.4.1/112 6.4.2 /101	Kukula, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in Poland, 2019 PL19FETRZAW416B AGRECO SP. Z O.O. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 6.2 /113 6.4.1/113 6.4.2 /102	Kukula, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in Poland, 2019 PL19FETRZAW419A AGRECO SP. Z O.O. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /114 6.4.1/114 6.4.2 /103	Kukula, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in Poland, 2019 PL19FETRZAW419B AGRECO SP. Z O.O. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /115 6.4.1/115 6.4.2 /104	Kukula, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in Poland, 2019 PL19FEHORVW421A AGRECO SP. Z O.O. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /116 6.4.1/116 6.4.2 /105	Kukula, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in Poland, 2019 PL19FEHORVW421B AGRECO SP. Z O.O. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /117 6.4.1/117 6.4.2 /106	Kukula, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in Poland, 2019 PL19FEHORVW424A AGRECO SP. Z O.O. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 6.2 /118 6.4.1/118 6.4.2 /107	Kukula, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in Poland, 2019 PL19FEHORVW424B AGRECO SP. Z O.O. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /119 6.4.1/119 6.4.2 /108	Kukula, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on titicale in Poland, 2019 PL19FETTLSS426B AGRECO SP. Z O.O. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /124 6.4.1/124 6.4.2 /113	Labant, A.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in Hungary, 2020 HU20FEHORVW421B Növénypatyka GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /127 6.4.1/127 6.4.2 /116	Labusch, U.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria tritici</i> on wheat, in Germany in 2018. DE18FETRZAW919C BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /128 6.4.1/128 6.4.2 /117	Labusch, U.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Puccinia</i> ssp. on wheat, in Germany in 2018. DE18FETRZAW920C BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /129 6.4.1/129 6.4.2 /118	Labusch, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in (Germany), 2019 DE19FETRZAW203A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 6.2 /130 6.4.1/130 6.4.2 /119	Laug, S.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> on wheat, in Germany in 2018. DE18FETRZAW921B Hetterich Fieldworks GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /146 6.4.1/146 6.4.2 /129	Magyaróvári, V.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on rye in (Germany), 2019 DE19FESECSS211E Agrartest GmbH GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /147 6.4.1/147 6.4.2 /130	Magyaróvári, V.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on triticale in (Germany), 2019 DE19FETTLSS215C Agrartest GmbH GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /148 6.4.1/148 6.4.2 /131	Magyaróvári, V.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTSP) on triticale in (Germany), 2020 DE20FETTLSS242C Agrartest GmbH GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /149 6.4.1/149 6.4.2 /132	Magyaróvári, V.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on triticale in (Germany), 2020 DE20FETTLSS244C Agrartest GmbH GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /150 6.4.1/150 6.4.2 /133	Makó, L.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in Hungary, 2019 HU19FETRZAW113A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 6.2 /151 6.4.1/151 6.4.2 /134	Makó, I.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in Hungary, 2019 HU19FEHORVX113A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /153 6.4.1/153 6.4.2 /136	Makó, I.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow-rust (PUCCST) on winter wheat in Hungary, 2020 HU20FETRZAW412A CPR-Europe Kft. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /154 6.4.1/154 6.4.2 /137	Malovcova, L.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> and/or <i>Puccinia hordei</i> on spring barley in Slovakia in 2018 SK18FEHORVS921B NPPC VURV Piestany GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /155 6.4.1/155 6.4.2 /138	Malovcova, L.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGH) on barley in Slovakia, 2020 SK20FEHORVS237A NPPC VURV Piestany GEP / not published	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /156 6.4.1/156 6.4.2 /139	Malovcova, L.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in Slovakia, 2020 SK20FETRZAW270A NPPC VURV Piestany GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 6.2 /159 6.4.1/159 6.4.2 /142	Martin, T.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in (Germany), 2019 DE19FETRZAW200B Martin Feldversuchswesen GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /160 6.4.1/160 6.4.2 /143	Martin, T.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in (Germany), 2019 DE19FETRZAW201C Martin Feldversuchswesen GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /161 6.4.1/161 6.4.2 /144	Martin, T.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in (Germany), 2019 DE19FETRZAW202D Martin Feldversuchswesen GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /162 6.4.1/162 6.4.2 /145	Martin, T.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in (Germany), 2019 DE19FETRZAW203C Martin Feldversuchswesen GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /163 6.4.1/163 6.4.2 /146	Martin, T.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on rye in (Germany), 2019 DE19FESECSS209D Martin Feldversuchswesen GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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\$	Previously used Y/N If yes, for which data point?
KCP 6.2 /164 6.4.1/164 6.4.2 /147	Martin, T.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on rye in (Germany), 2019 DE19FESECS211D Martin Feldversuchswesen GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /165 6.4.1/165 6.4.2 /148	Martin, T.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTSP) on triticale in (Germany), 2019 DE19FETTLSS212B Martin Feldversuchswesen GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /166 6.4.1/166 6.4.2 /149	Martin, T.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in (Germany), 2020 DE20FETRZAW235B Martin Feldversuchswesen GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /167 6.4.1/167 6.4.2 /150	Martin, T.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia c.</i> (PUCCCO) on oat in (country), 2020 DE20FEAVESA246A Martin Feldversuchswesen GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /168 6.4.1/168 6.4.2 /151	Martin, T.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in (Germany), 2020 DE20FETRZAW235A Martin Feldversuchswesen GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2/173 6.4.1/173 6.4.2/154	Nagy, Z.	2018	Efficacy evaluation of different MCW 2091 formulation against <i>Puccinia</i> ssp. on wheat, in Hungary in 2018. HU18FETRZAW112B Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2/174 6.4.1/174 6.4.2/155	Nagy, Z.	2018	Efficacy evaluation of different MCW 2091 formulation against <i>Blumeria graminis</i> on wheat, in Hungary in 2018. HU18FETRZAW114B Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2/175 6.4.1/175 6.4.2/156	Nagy, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (Puccinia) on winter wheat in Hungary, 2019 HU19FETRZAW114A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2/176 6.4.1/176 6.4.2/157	Nagy, Z.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in Hungary, 2020 HU20FETRZAW414B CPR Europe Kft. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2/177 6.4.1/177 6.4.2/158	Nagy, Z.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGH) on barley in Hungary, 2020 HU20FEHORVW420A CPR Europe Kft. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2/180 6.4.1/180 6.4.2/161	Nagy, Z.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (Puccinia) on winter wheat in Hungary, 2020 HU20FETRZAW411A CPR Europe Kft. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 6.2 /181 6.4.1/181 6.4.2 /162	Nagy, Z.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in Hungary, 2020 HU20FETRZAW410A CPR Europe Kft. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /182 6.4.1/182 6.4.2 /163	Németh, S.	2018	Efficacy evaluation of different MCW 2091 formulation against <i>Blumeria graminis</i> on wheat, in Hungary in 2018. HU18FETRZAW114A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /183 6.4.1/183 6.4.2 /164	Németh, S.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in Hungary, 2019 HU19FETRZAW111A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /184 6.4.1/184 6.4.2 /165	Németh, S.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in Hungary, 2019 HU19FETRZAW110A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /185 6.4.1/185 6.4.2 /166	Németh, S.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in Hungary, 2019 HU19FEHORVX110A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /186 6.4.1/186 6.4.2 /167	Németh, S.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in Hungary, 2020 HU20FEHORVW423A CPR Europe Kft. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /187 6.4.1/187 6.4.2 /168	Németh, S.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in Hungary, 2020 HU20FEHORVW422B CPR Europe Kft. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /190 6.4.1/190 6.4.2 /171	Ólasz, L.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in Hungary, 2020 HU20FEHORVW422A CPR Europe Kft. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /191 6.4.1/191 6.4.2 /172	Pawlak, A.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> on wheat, in Poland in 2018. PL18FETRZAW020B Staphyt Poland GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /192 6.4.1/192 6.4.2 /173	Pawlak, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (PUCCRT) on winter wheat in Poland, 2019 PL19FETRZAW420A Staphyt Poland GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /193 6.4.1/193 6.4.2 /174	Pawlak, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (PUCCRT) on winter wheat in Poland, 2019 PL19FETRZAW420B Staphyt Poland GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /194 6.4.1/194 6.4.2 /175	Pawlak, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGH) on barley in Poland 2019 PL19FEHORVW422A Staphyt Poland GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /195 6.4.1/195 6.4.2 /176	Pawlak, A.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on triticale in Poland, 2019 PL19FETTLSS427A Staphyt Poland GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /200 6.4.1/200 6.4.2 /181	Pawlak, A.	2021	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGH) on barley in Poland 2019 PL19FEHORVW422B Staphyt Poland GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /201 6.4.1/201 6.4.2 /182	Perner, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Puccinia</i> ssp. on wheat, in Germany in 2018. DE18FETRZAW920D U.A.S. Jena GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /202 6.4.1/202 6.4.2 /183	Perner, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in (Germany), 2019 DE19FETRZAW200A U.A.S. Jena GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /203 6.4.1/203 6.4.2 /184	Perner, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in (Germany), 2019 DE19FETRZAW202C U.A.S. Jena GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /204 6.4.1/204 6.4.2 /185	Perner, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in (Germany), 2019 DE19FEHORVW208B U.A.S. Jena GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /205 6.4.1/205 6.4.2 /186	Perner, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCRR) on rye in (Germany), 2019 DE19FESECSS211C U.A.S. Jena GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /206 6.4.1/206 6.4.2 /187	Perner, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCRR) on rye in (Germany), 2020 DE20FESECSS241D U.A.S. Jena GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /207 6.4.1/207 6.4.2 /188	Perner, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on rye in (Germany), 2020 DE20FESECSS240C U.A.S. Jena GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /208 6.4.1/208 6.4.2 /189	Perner, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on titalce in (Germany), 2020 DE20FETTLSS243B U.A.S. Jena GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /209 6.4.1/209 6.4.2 /190	Rábai, A.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in Hungary, 2020 HU20FETRZAW413B CPR Europe Kft. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /214 6.4.1/214 6.4.2 /195	Raue, C.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in (Germany), 2019 DE19FEHORVW205C SynTech DE GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /215 6.4.1/215 6.4.2 /196	Raue, C.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on rye in (Germany), 2019 DE19FESECSS209E SynTech DE GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /216 6.4.1/216 6.4.2 /197	Raue, C.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on tritcale in (Germany), 2019 DE19FETTLSS214C SynTech DE GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /224 6.4.1/224 6.4.2 /202	Rohr, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria tritici</i> on wheat, in Germany in 2018. DE18FETRZAW919A Agrartest GmbH GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /225 6.4.1/225 6.4.2 /203	Rohr, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Puccinia</i> ssp. on wheat, in Germany in 2018. DE18FETRZAW920A Agrartest GmbH GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /226 6.4.1/226 6.4.2 /204	Rohr, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> on wheat, in Germany in 2018. DE18FETRZAW921A Agrartest GmbH GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /227 6.4.1/227 6.4.2 /205	Rohr, J.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> and/or <i>Puccinia hordei</i> on barley, in Germany in 2018. DE18FEHORVW921A Agrartest GmbH GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /228 6.4.1/228 6.4.2 /206	Rohr, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in (Germany), 2019 DE19FETRZAW201B Trial-Tec GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /229 6.4.1/229 6.4.2 /207	Rohr, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (PuccRT) on winter wheat in (Germany), 2019 DE19FETRZAW204A Trial-Tec GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /230 6.4.1/230 6.4.2 /208	Rohr, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGH) on barley in (Germany), 2019 DE19FEHORVW206B Trial-Tec GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /231 6.4.1/231 6.4.2 /209	Rohr, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in (Germany), 2019 DE19FEHORVW208A Trial-Tec GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /232 6.4.1/232 6.4.2 /210	Rohr, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on rye in (Germany), 2019 DE19FESECSS210C Trial-Tec GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /233 6.4.1/233 6.4.2 /211	Rohr, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on rye in (Germany), 2019 DE19FESECSS209B Trial-Tec GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /234 6.4.1/234 6.4.2 /212	Rohr, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on titicale in (Germany), 2019 DE19FETTLSS213C Trial-Tec GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /236 6.4.1/236 6.4.2 /214	Ronis, A.	2020	Efficacy evaluation of ADM.3502.F.1.A for <i>Pyrenophora avenae</i> control in oat in Lithuania in 2020 LT20FEAVESP480A IA LRC, Kedainiai GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /237 6.4.1/237 6.4.2 /215	Ronis, A.	2020	Efficacy evaluation of ADM.3502.F.1.A for <i>Pyrenophora avenae</i> control in oat in Lithuania in 2020 LT20FEAVESP480B IA LRC, Kedainiai GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /238 6.4.1/238 6.4.2 /216	Roslupil, J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGH) on barley in the Czech Republic, 2019 CZ19FEHORVS206B ZZS Kujavy GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /239 6.4.1/239 6.4.2 /217	Roslupil, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in the Czech republic, 2020 CZ20FEHORVS238A ZZS Kujavy GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /240 6.4.1/240 6.4.2 /218	Roslapil, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in the Czech republic, 2020 CZ20FEHORVS273A ZZS Kujavy GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /249 6.4.1/249 6.4.2 /223	Rusek, K.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (DTR) on winter wheat in Poland, 2019 PL19FETRZAW418A Fertico GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /250 6.4.1/250 6.4.2 /224	Rusek, K.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (DTR) on winter wheat in Poland, 2019 PL19FETRZAW418B Fertico GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /258 6.4.1/258 6.4.2 /232	Sawinska, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in Poland, 2019 PL19FETRZAW417A Poznan University of Life Sciences GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /259 6.4.1/259 6.4.2 /233	Sawinska, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in Poland, 2019 PL19FETRZAW417B Poznan University of Life Sciences GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 6.2 /260 6.4.1/260 6.4.2 /234	Sawinska, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in Poland, 2019 PL19FEHORVW423A Poznan University of Life Sciences GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /261 6.4.1/261 6.4.2 /235	Sawinska, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in Poland, 2019 PL19FEHORVW423B Poznan University of Life Sciences GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /262 6.4.1/262 6.4.2 /236	Sawinska, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTSP) on triticale in Poland, 2019 PL19FETTLSS425A Poznan University of Life Sciences GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /263 6.4.1/263 6.4.2 /237	Sawinska, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTSP) on triticale in Poland, 2019 PL19FETTLSS425B Poznan University of Life Sciences GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /264 6.4.1/264 6.4.2 /238	Sawinska, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on triticale in Poland, 2019 PL19FETTLSS428A Poznan University of Life Sciences GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /265 6.4.1/265 6.4.2 /239	Sawinska, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on triticale in Poland, 2019 PL19FETTLSS428B Poznan University of Life Sciences GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /266 6.4.1/266 6.4.2 /240	Sawinska, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on triticale in Poland, 2019 PL19FETTLSS427B Poznan University of Life Sciences GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /267 6.4.1/267 6.4.2 /241	Semaskiene, R.	2018	Efficacy evaluation of different MCW-2091 formulations against <i>Blumeria graminis</i> on spring barley in Lithuania in 2018 LT18FEHORVS929A IA LRC, Kedainiai GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /268 6.4.1/268 6.4.2 /242	SGS Hungária Kft.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in Hungary, 2019 HU19FETRZAW113B SGS Hungary GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /269 6.4.1/269 6.4.2 /243	SGS Hungária Kft.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in Hungary, 2019 HU19FETRZAW110C SGS Hungary GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /270 6.4.1/270 6.4.2 /244	SGS Hungária Kft.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in Hungary, 2019 HU19FETRZAW112B SGS Hungary GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /271 6.4.1/271 6.4.2 /245	SGS Hungária Kft.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in Hungary, 2019 HU19FEHORVX110B SGS Hungary GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /272 6.4.1/272 6.4.2 /246	SGS Hungária Kft.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in Hungary, 2019 HU19FEHORVX112B SGS Hungary GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /273 6.4.1/273 6.4.2 /247	SGS Hungária Kft.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in Hungary, 2019 HU19FEHORVX113B SGS Hungary GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /274 6.4.1/274 6.4.2 /248	Subr. J.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGH) on barley in the Czech Republic, 2019 CZ19FEHORVW206C ZS Nechanice GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /275 6.4.1/275 6.4.2 /249	Subr. J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in the Czech republic, 2020 CZ20FETRZAW270C ZS Trutnov GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /276 6.4.1/276 6.4.2 /250	Teresiak, H.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on triticale in (Germany), 2020 DE20FETTLSS245C Agro-check / GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /277 6.4.1/277 6.4.2 /251	Tóth, F.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in Slovakia, 2020 SK20FEHORVW236A GEMERPRODUKT Valice OVD GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /278 6.4.1/278 6.4.2 /252	Tóth, F.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (PUCCRT) on winter wheat in Slovakia, 2020 SK20FETRZAW272A GEMERPRODUKT Valice OVD GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /279 6.4.1/279 6.4.2 /253	Trojan, Z.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in the Czech republic, 2020 CZ20FETRZAW270B Zemservis ZS Domaninek s.r.o. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /280 6.4.1/280 6.4.2 /254	Funa, V.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTSP) on triticale in ROMANIA, 2019 RO19FETTLSS159A EAS Romania GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /281 6.4.1/281 6.4.2 /255	Tuna, V.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on triticale in ROMANIA, 2019 RO19FETTLSS162A EAS Romania GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /282 6.4.1/282 6.4.2 /256	Tuna, V.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on triticale in ROMANIA, 2019 RO19FETTLSS161A EAS Romania GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /283 6.4.1/283 6.4.2 /257	Tuna, V.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on triticale in Romania, 2019 RO19FETTLSS160A EAS Romania GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /296 6.4.1/296 6.4.2 /270	Tvaruzek, L.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Blumeria graminis</i> and/or <i>Puccinia hordei</i> on barley, Czech republic, 2018. CZ18FEHORVX921B ZVU Kromeriz GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /297 6.4.1/297 6.4.2 /271	Tvaruzek, L.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in the Czech Republic, 2019 CZ19FETRZAW200B ZVU Kromeriz GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /298 6.4.1/298 6.4.2 /272	Tvaruzek, L.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on rye in the Czech Republic, 2019 CZ19FESECSS210B ZVU Kromeriz GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /299 6.4.1/299 6.4.2 /273	Vadász, Z.	2018	Efficacy evaluation of different MCW 2091 formulation against <i>Blumeria graminis</i> and/or <i>Puccinia hordei</i> on barley in Hungary in 2018 HU18FEHORVW114A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /300 6.4.1/300 6.4.2 /274	Vadász, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in Hungary, 2019 HU19FETRZAW110B Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /301 6.4.1/301 6.4.2 /275	Vadász, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGH) on barley in Hungary, 2019 HU19FEHORVX111A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /302 6.4.1/302 6.4.2 /276	Vadász, Z.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in Hungary, 2019 HU19FEHORVX112A Syntech HU GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /303 6.4.1/303 6.4.2 /277	Varga, A.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria tritici</i> on wheat, in Hungary in 2018. HU18FETRZAW110B Syntech HU GEP / not published	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /307 6.4.1/307 6.4.2 /279	Verikaite, K.	2019	Efficacy evaluation of ADM.3502.F.1.A (MCW-2091) for <i>B. graminis</i> control in spring barley in Lithuania in 2019 LT19FEHORVS487A IA LRC, Kedainiai GEP / not published	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /308 6.4.1/308 6.4.2 /280	Verikaite, K.	2019	Efficacy evaluation of ADM.3502.F.1.A (MCW-2091) for <i>B. graminis</i> control in spring barley in Lithuania in 2019 LT19FEHORVS487B IA LRC, Kedainiai GEP / not published	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /311 6.4.1/311	Von Hörsten, D.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNT) on barley in (Germany), 2019 DE19FEHORVW207D FRS Wunstorf GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /312 6.4.1/312 6.4.2 /281	Von Hörsten, D.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia c.</i> (PUCCCO) on oat in (Germany), 2019 DE19FEAVESA216C FRS Wunstorf GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /313 6.4.1/313 6.4.2 /282	Wallart, F.	2019	Efficacy evaluation of ADM.3502.F.1.A. for the control of yellow-rust (PUCCST) on winter wheat in France, 2019 FR19FETRZAX328A SAS (SARL) EPHYDIA GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /320 6.4.1/320 6.4.2 /285	Wolf, P.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in (Germany), 2020 DE20FETRZAW235G Agricola GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /321 6.4.1/321 6.4.2 /286	Wöllmann, S.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (PUCCRT) on winter wheat in (Germany), 2019 DE19FETRZAW204B(AC-19-096) Agro-check GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /322 6.4.1/322 6.4.2 /287	Wöllmann, S.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in (Germany), 2019 DE19FEHORVW208C_2(AC-19-097) Agro-check GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /323 6.4.1/323 6.4.2 /288	Zdenek, T.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in the Czech republic, 2020 CZ20FEHORVS238B ZS Domanínek GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /324 6.4.1/324 6.4.2 /289	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (PYRNTR (DTR)) on winter wheat in (Germany), 2019 DE19FETRZAW202A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /325 6.4.1/325 6.4.2 /290	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in (Germany), 2019 DE19FETRZAW201A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /326 6.4.1/326 6.4.2 /291	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in (Germany), 2019 DE19FEHORVW207A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /327 6.4.1/327 6.4.2 /292	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in (Germany), 2019 DE19FEHORVW205A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /328 6.4.1/328 6.4.2 /293	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGH) on barley in (Germany), 2019 DE19FEHORVW206A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /329 6.4.1/329 6.4.2 /294	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in (Germany), 2019 DE19FEHORVW208D BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2./330 6.4.1/330 6.4.2./295	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on rye in (Germany), 2019 DE19FESECSS210A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2./331 6.4.1/331 6.4.2./296	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on rye in (Germany), 2019 DE19FESECSS209A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2./332 6.4.1/332 6.4.2./297	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on rye in (Germany), 2019 DE19FESECSS211A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2./333 6.4.1/333 6.4.2./298	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTSP) on triticale in (Germany), 2019 DE19FETTLSS212A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2./334 6.4.1/334 6.4.2./299	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on triticale in (Germany), 2019 DE19FETTLSS215A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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KCP 6.2 /335 6.4.1/335 6.4.2 /300	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PuccST) on triticale in (Germany), 2019 DE19FETTLSS214A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /336 6.4.1/336 6.4.2 /301	Zickart, U.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on triticale in (Germany), 2019 DE19FETTLSS213A BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /339 6.4.1/339 6.4.2 /304	Zickart, U.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGR) on rye in Germany, 2020 DE20FESECSS240B BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /340 6.4.1/340 6.4.2 /305	Zickart, U.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on rye in (Germany), 2020 DE20FESECSS239B BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /341 6.4.1/341 6.4.2 /306	Zickart, U.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia recondita</i> (PUCCRR) on rye in (Germany), 2020 DE20FESECSS241B BioChem Agrar GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 6.2 /342 6.4.1/342 6.4.2 /307	Zöllner, H.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTSP) on triticale in (Germany), 2019 DE19FETTLSS212C FRS Wunstorf GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /343 6.4.1/343 6.4.2 /308	Zöllner, H.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia c.</i> (PUCCCO) on oat in (Germany), 2020 DE20FEAVESA246C FRS Wunstorf GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /344 6.4.1/344 6.4.2 /309	Zsuzsanna, H.P.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (PUCCRT) on winter wheat in Hungary, 2019 HU19FETRZAW114B Növénypathyka GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.2 /345 6.4.1/345 6.4.2 /310	Zsuzsanna, H.P.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in Hungary, 2019 HU19FETRZAW111B Növénypathyka GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.3/001	Anomynous	2020	FRAC Code List 2020: Fungal control agents sorted by cross resistance pattern and mode of action (including FRAC Code numbering). available in the internet in Nov. 2020 under http://www.frac.info Published	N	-	-	-	-
KCP 6.3/002	Anomynous	2020	FRAC Pathogen List 2019. available in the internet in Nov. 2020 under http://www.frac.info Published	N	-	-	-	-

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 6.3/003	FRAC SBI Working Group	2020	Minutes from Annual Meeting on January 24th, 2020, updated on September 23rd available on the internet in Nov. 2020 under http://www.frac.info and Minutes from Annual Meeting on September 21th, 2022, available on the internet in Nov. 2022 under http://www.frac.info Published	N	-	-	-	-
KCP 6.3/004	Felsenstein, F.G.; Jaser, B.	2007	Fungizidresistenz bei pilzlichen Getreidepathogenen und Wirksamkeit der vertikalen (qualitativen) Mehлтаuresistenz bei Weizen und Gerste – Situationsbericht 2007. available in the internet in Nov. 2020 under http://www.epilogic.de Published	N	-	-	-	-
KCP 6.3/005	Felsenstein, F.G., Jaser,B.	2016	RESEARCH REPORT: Sensitivity of Septoria tritici in different regions of Europe towards prochloraz, tebuconazole, difenoconazole, propiconazole, and prothioconazole 2016. EpiLogic GmbH Agrobiol. Research and Consulting, Hohenbachernstr. 19-21, D-85354 Freising-Weißenstephan Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.3/006	Felsenstein, F.G., Jaser,B.	2017	RESEARCH REPORT: Sensitivity of Septoria tritici in different regions of Europe towards prochloraz, tebuconazole, difenoconazole and prothioconazole 2017. EpiLogic GmbH Agrobiol. Research and Consulting, Hohenbachernstr. 19-21, D-85354 Freising-Weißenstephan Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.3/007	Felsenstein, F.G., Jaser,B.	2018	RESEARCH REPORT: Sensitivity of Septoria tritici in different regions of Europe towards prochloraz, tebuconazole, difenoconazole and prothioconazole 2018. EpiLogic GmbH Agrobiol. Research and Consulting, Hohenbachernstr. 19-21, D-85354 Freising-Weißenstephan Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADAM A Agriculture	N

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KCP 6.3/008	Leroux P., Walker A.S., Albertini C., Gredt M,	2006	Resistance to fungicides in European populations of Septoria tritici, the causal agent of wheat leaf blotch. Analysis of populations sent by MAKHTESHIM AGAN in 2006. INRA, Unité de Phytopharmacie et Médiateurs Chimiques 78026 Versailles Cedex, 2006; Unpublished yet	N	-	-	-	-
KCP 6.3/009	Heick T.M., Matzen N., Jørgensen L.N.	2020	Reduced field efficacy and sensitivity of demethylation inhibitors in the Danish and Swedish Zymoseptoria tritici populations. Eur. J. Plant Pathol. 157, 625–636; 2020 Published	N	-	-	-	-
KCP 6.3/010	Heimbach U., Kral G., Niemann P.	2000	Implementation of resistance risk analysis of plant protection products in the German authorization procedure: Proceedings of the Brighton Crop Protection Conference - Pests and Diseases, pp 771-776, 2000 Published	N	-	-	-	-
KCP 6.5.1 (filed in KCP 10.6.1/01)	Kästner, K.	2020a	Effects of ADM.03502.F.1.A on seedling emergence and seedling growth of six non-target terrestrial plant species under greenhouse conditions Report no.: 2046PSE0007, Sponsor no.: 000104852 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 6.5.2 (filed in KCP 10.6.1/02)	Kästner, K.	2020b	Effects of ADM.03502.F.1.A on vegetative vigour of six non-target terrestrial plant species under greenhouse conditions Report no.: 2035CRX0012, Sponsor no.: 000104853 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 7.1.1/01	2020a	Acute oral toxicity (Acute Toxic Class Method) in the Rat with ADM.3502.F.1.A Report no.: GLP Unpublished	Y	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 7.1.2/01	...	2020b	Acute dermal toxicity (Acute Toxic Class Method) in the Rat with ADM.3502.F.1.A Report no.: GLP Unpublished	Y	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 7.1.3/01	...	2021	Acute inhalation toxicity study in Wistar rats - OECD 403 Report no.: GLP Unpublished	Y	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 7.1.4/01	Groß, C.	2021	<i>In vitro</i> skin irritation: Human Skin Model Test (EpiDerm TM) with ADM.3502.F.1.A Test Guideline: OECD 439, report no. STUGC20AA1348-2, sponsor no.: 000104837 Eurofins BioPharma Product Testing Munich GmbH, Planegg, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 7.1.5/01	Julienne, S.	2020	Bovine corneal opacity and permeability assay for identifying test item inducing serious eye damage and test item not requiring classification— OECD 437 Report no.: B20-0481; sponsor no.: 000104835 Eurofins BioPharma Product Testing Munich GmbH, Planegg, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 7.1.5/02	2021	Acute Eye Irritation/Corrosion in the Rabbit with ADM.03502.F.1.A Report no.: GLP Unpublished	Y	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 7.1.6/01		2021	Prothioconazole 175 g/L + Fenpropidin 250 g/L EC (ADM.03502.F.1.A): Local Lymph Node Assay (LLNA) in CBA/Ca MICE Report no.:... GLP Unpublished	Y	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 7.2.2.2/01	Anonymous	2010	Development of air sampling methodology in support of determining risk of bystander and resident exposure to pesticides SID 5 (Rev. 07/10), DEFRA Project PS2023 Non-GLP Published	N	N		--	
KCP 7.2.2.2/02	Bedos, C.; Rouseau-Djabri, M.-F.; Loubet, B.; Durand, B.; Flura, D.; Briand, O. and Barriuso, E.	2010	Fungicide Volatilization Measurements: Inverse Modeling, Role of Vapor Pressure, and State of Foliar Residue Environmental Science and Technology, 44, 7, 2522-2528 Non-GLP Published	N	N		--	
KCP 7.3/01	Maas, W.J.M.	2021a	The <i>in vitro</i> percutaneous absorption of radiolabelled Prothioconazole-desthio in one in-use dilution of the Prothioconazole 175 g/L + Fenpropidin 250 g/L EC formulation (ADM.03502.F.1.A) through human split-thickness skin. Report no.: 20275164; sponsor no.: 000107008 Charles River Laboratories Den Bosch BV, DD 's-Hertogenbosch, The Netherlands GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 7.3/02	Maas, W.J.M.	2021b	The <i>in vitro</i> percutaneous absorption of radiolabelled Fenpropidin in a concentrate formulation and one in-use dilution of the Prothioconazole 175 g/L + Fenpropidin 250 g/L EC formulation (ADM.03502.F.1.A) through human split-thickness skin. Report no.: 20275166; sponsor no.: 000107009 Charles River Laboratories Den Bosch BV, DD 's-Hertogenbosch, The Netherlands GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	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.: R-30330 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
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, Beaucouzé Cedex, France GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 8/ KCA 6.3.1/01	Huauilmé, J.-M.	2020	Residue study of prothioconazole and its metabolites, and fenpropidin in wheat whole plant and RAC (grain and straw) after one foliar application of ADM.3502.F.1.A - 2 HS and 2 DCS - Northern Europe (France, Poland and Hungary) - 2019 Report no.: BPL19/770/GC, sponsor no.: 000102759 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 8/ KCA 6.3.1/02	Mahlow, S.	2021	Determination of the residues 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 foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin), in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Poland and Hungary), 2019 Report no.: S19-00750, sponsor no.: 000102792 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N
KCP 8/ KCA 6.3.1/03	Le Mineur, A.	2021	Residue study of Prothioconazole and its metabolites, and Fenpropidin in wheat Raw Agricultural Commodities after foliar application of ADM.03502.F.1.A under field conditions - Northern Europe – 2021. Report no.: BPL21/956/GC, sponsor no.: 000107610 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	N

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 8/ KCA 6.3.1/04	Le Mineur, A.	2022	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. Report no.: BPL21/958/GC, sponsor no.: 000107612 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished	N	Y	Study submitted in February 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC) and April 2022 for support registration of product ADM.03503.F.1.A (Avastel 225 EC). Data protection has not yet started.	ADM	Y for prothioconazole evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022; N for TDMs
KCP 8/ KCA 6.3.2/01	Huauilmé, J.-M.	2020	Residue study of prothioconazole and its metabolites, and fenpropidin in barley whole plant and RAC (grain and straw) after one foliar application of ADM.3502.F.1.A - 2 harvest and 2 decline trials - Northern Europe (France, Poland and Hungary) - 2019. Report no.: BPL19/772/GC, sponsor no.: 000102761 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	Y for prothioconazole evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022; N for fenpropidin
KCP 8/ KCA 6.3.2/02	Mahlow, S.	2021	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 (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Poland and Hungary), 2019. Study no.: S19-00752, sponsor no.: 000102794 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	Y	Study submitted in February 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022

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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 8/ KCA 6.3.2/03	Huauilmé, J.-M.	2021	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 - 2 harvest and 2 decline trials – Northern Europe (FR, PL, HU) - 2020. Report no.: BPL20/844/GC, sponsor no.: 000105350 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	Y for prothioconazole evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022; N for fenpropidin
KCP 8/ KCA 6.3.2/04	Yozgatli, H.P.	2021	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, sponsor no.: 000105545 Eurofins Agroscience Services EcoChem GmbH, Niefern-Öschelbronn, Germany GLP Unpublished	N	Y	Study submitted in February 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC) and April 2022 for support registration of product ADM.03503.F.1.A (Avastel 225 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 8/ KCA 6.3.2/05	Huauilmé, J.-M.	2022	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. Report no.: BPL21/962/GC, sponsor no.: 000107616 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished	N	Y	Study submitted in February 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC) and April 2022 for support registration of product ADM.03503.F.1.A (Avastel 225 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022

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KCP 8/ KCA 6.3.2/06	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, sponsor no.: 000108763 GIRPA, Beaucouzé Cedex, France GLP Unpublished	N	Y	Study submitted in February 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC) and April 2022 for support registration of product ADM.03503.F.1.A (Avastel 225 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 8/ KCA 6.3.2/07	Huauilmé, J.-M.	2022	Residue study of prothioconazole, difenoconazole and their metabolites in barley Raw Agricultural Commodities after foliar application of ADM.03501.F.1.A under field conditions – Northern Europe – 2021. Report no.: BPL21/960/GC, sponsor no.: 000107614 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished	N	Y	Study submitted in February 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
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 Agroscience Services EcoChem GmbH, Niefern-Öschelbronn, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
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.: R-39638 Eurofins Agroscience Services GmbH, Stade, Germany GLP Unpublished	N	Y	Study submitted in February 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC) and April 2022 for support registration of product ADM.03503.F.1.A (Avastel 225 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022

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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 Agroscience Services GmbH, Stade, Germany GLP Unpublished	N	Y	Study submitted in February 2022 r. to Poland for support registration of product ADM.3500.F.2.B (Soratel 250 EC) and April 2022 for support registration of product ADM.03503.F.1.A (Avastel 225 EC). Data protection has not yet started.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
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	n.a.	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 9.1.1.1/01	Morlock, G.	2006a	Degradation of Fenpropidin in 3 different soils under aerobic conditions at 20° C in the dark Report No 20051244/01 CABI, sponsor no. 00012949 GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	IRVITA *	
KCP 9.1.1.1/02	Morlock, G.	2006b	Degradation of Fenpropidin in one soil under aerobic conditions at 20° C in the dark Report No 20051244/02 CABI, sponsor no. 00012950 GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	IRVITA *	
KCP 9.1.1.1/03	Flörchinger M.	2008	Degradation of Fenpropidin Acid in 3 Different Soils under Aerobic Conditions at 20°C in the Dark Eurofins GAB GmbH Report No.S08-01156, sponsor no. 00016350 GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	IRVITA *	

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KCP 9.2.4/01	Penne, C.	2021	Predicted environmental concentrations in groundwater (PECgw) of prothioconazole, fenpropidin and metabolites using FOCUS PELMO 5.5.3, FOCUS PEARL 4.4.4 and FOCUS MACRO 5.5.4 for critical GAP uses of ADM.03502.F.1.A in different crops in the Central zone. Report no.: ADM-210621-01, sponsor no. 000108619 EBRC Consulting GmbH, Hannover, Germany Not GLP Unpublished	N	N	-	ADM	
KCP 9.2.5/01	Penne, C.	2021	Predicted environmental concentrations in surface water (PECsw) and sediment (PECsed) prothioconazole, fenpropidin and metabolites using STEPS 1-2 in FOCUS (v3.2), FOCUS SWASH 5.3 and SWAN v5.0 for critical GAP uses of ADM.03502.F.1.A in different crops in the Central zone. Report no.: ADM-210621-02, sponsor no. 000108620 EBRC Consulting GmbH, Hannover, Germany Not GLP Unpublished	N	N	-	ADM	
KCP 10.2.1/01	2020a	Acute toxicity of ADM.03502.F.1.A to <i>Oncorhynchus mykiss</i> in a 96-hour semi-static test Report no GLP Unpublished	Y	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 10.2.1/02	Renner, P.	2020b	Acute toxicity of ADM.03502.F.1.A to <i>Daphnia magna</i> in a 48-hour semi-static test Report no 2048ADL0008, Sponsor no.: 000104840 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 10.2.1/03	Scheerbaum, D.	2021	ADM.03502.F.1.A - Alga, Growth Inhibition Test with <i>Desmodesmus subspicatus</i> , 72 hours Report no. SO21519 / SSO19707, Sponsor no.: 000108687 Noack Laboratorien GmbH, Sarstedt, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 10.2.1/04	Renner, P.	2021	Effects of ADM.03502.F.1.A on <i>Lemna gibba</i> in a growth inhibition test under semi-static test conditions Report no 2048ALE0006, Sponsor no.: 000104842 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 10.2.3/01	Wellmann, P., Hommen, P., Böhmer, W.,	2006	Community level study with Fenpropidin in outdoor aquatic mesocosm ponds Fraunhofer-Institute Molecular Biology and Applied Ecology (IME), Schmalleberg, Germany Report No: FEI-010/4-52 GLP Unpublished	N	Y	Data protection started with authorisation of Artemis 450 EC (R-10/2016 dated 26.01.2016)	ADM	
KCP 10.2.3/02	Arts, G.H.P and Brock, T.C.M.	2009	Evaluation of the reports: Neumann Ch. (1997): CGA 114900 EC 750 (A-7516 A): Outdoor aquatic mesocosm study of the environmental fate and ecological effects. Novartis Crop Protection AG, Sector of Unit R&D, Ecotoxicology Department, Switzerland. Project No 95N001. (Syngenta file No. CGA 114900/0500) including Ashwell J., Hamer M. And Coulson M., 2007. Fenpropidin: Syngenta response to Evaluation Table rev. 0-0 (19.02.2007). Data requirement 5.2 – statistical analysis of mesocosms study by Neumann 1997.and Huber, W. (1995): Effects of A-7503 C in aquatic outdoor microcosms. Technical University Munich-Weihenstephan. Institute for Landscape and Botany, Germany. Report No. (Syngenta file No. CGA 64250/2997) and Wellmann P. (2006): Community level study with Fenpropidin in outdoor aquatic mesocosm ponds, Fraunhofer-Institute Schmalleberg, Germany & Gaia, Aachen, Germany Alterra, Wageningen University and Research Centre, Centre for Water and Climate P.O. Box 47, 6700 AA Wageningen, The Netherlands Report no: n.a. Non-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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 10.3.1.1/01	Franke, M.	2020	Acute toxicity of ADM.03502.F.1.A to the honeybee <i>Apis mellifera</i> L. under laboratory conditions Report no.: 2048BAA0028, Sponsor no.: 000104843 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 10.3.1.2/01	Dreßler, K.	2020	Chronic oral toxicity of ADM.03502.F.1.A to the honey bee <i>Apis mellifera</i> L. under laboratory conditions Report no.: 2048BAC0011, Sponsor no.: 000104844 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 10.3.1.3/01	Hänsel, M.	2021	ADM.03502.F.1.A – Repeated exposure of honey bee larvae (<i>Apis mellifera</i> L.) under laboratory conditions Report no.: 2048BLC0013, Sponsor no.: 000104845 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 10.3.2.2/01	Röhlig, U.	2020a	Effects of ADM.03502.F.1.A on the parasitic wasp <i>Aphidius rhopalosiphi</i> (DESTEFANI-PEREZ) in a laboratory test Report no.: 2048NAL0006, Sponsor no.: 000104847 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 10.3.2.2/02	Röhlig, U.	2020b	Effects of ADM.03502.F.1.A on the predatory mite <i>Typhlodromus pyri</i> SCHEUTEN in a laboratory test Report no.: 2048NTL0006, Sponsor no.: 000104846 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 10.4.1.1/01	Friedrich, S.	2020a	Effects of ADM.03502.F.1.A on the mortality, growth and reproduction of the earthworm <i>Eisenia fetida</i> in artificial soil Report no.: 2048TEC0035, Sponsor no.: 000104848 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 10.4.1.1/02	Friedrich, S.	2021	Effects of ADM.03502.F.1.A on the mortality, growth and reproduction of the earthworm <i>Eisenia fetida</i> in artificial soil Report no.: 21 48 TEC 0034, Sponsor no.: 000108316 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 10.4.2.1/01	Friedrich, S.	2020b	Effects of ADM.03502.F.1.A on the mortality and reproduction of the collembolan <i>Folsomia candida</i> Report no.: 2048TCC0025, Sponsor no.: 000104849 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 10.4.2.1/02	Schulz, L.	2020a	Effects of ADM.03502.F.1.A on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> Report no.: 2048THC0021, Sponsor no.: 000104850 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 10.5/01	Schulz, L.	2020b	Effects of ADM.03502.F.1.A on the activity of soil microflora (Nitrogen transformation test) Report no.: 2048SMN0022, Sponsor no.: 000104851 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	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 ^{\$}	Previously used Y/N If yes, for which data point?
KCP 10.6.1/01	Kästner, K.	2020a	Effects of ADM.03502.F.1.A on seedling emergence and seedling growth of six non-target terrestrial plant species under greenhouse conditions Report no.: 2046PSE0007, Sponsor no.: 000104852 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
KCP 10.6.1/02	Kästner, K.	2020b	Effects of ADM.03502.F.1.A on vegetative vigour of six non-target terrestrial plant species under greenhouse conditions Report no.: 2035CRX0012, Sponsor no.: 000104853 BioChem agrar, Machern/Gerichshain, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM	
-	EBRC Consulting GmbH	2023	Updated exposure and risk assessment for aquatic organisms considering volatilisation and deposition of fenpropidin in Step 4 PECsw modelling. Sponsor: Adama-Makteshim Ltd., Isreal, 17 April 2023. EBRC no.: ADM-230417-01	N	ADAMA	Required by e fate Section and need to risk assessment for aquatic organism	ADM	N

^{\$} ADM = Data owned by ADAMA;

* IRVITA, now ADAMA Irvita N.V., company of ADAMAGroup

BCS/ADM = Study is co-owned by Bayer Crop Science and ADAMA Agricultural Solution and all affiliates

SYN/ADM = Study is co-owned by Syngenta Ltd and ADAMA Agricultural Solution and all affiliates

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

Data point (DAR ref. no)	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 6/01 (IIA, 6.0/01)	Heinemann, O.	2001	18 months storage stability of residues of JAU 6476 and JAU 6476-desthio during frozen storage in/on wheat matrices Report No. : MR-282/00 Bayer AG GLP Unpublished	N	N		BCS
KCP 8/ KCA 6/02 (IIA, 6.1.2/01)	Haas, M.	2001	Metabolism of [phenyl-UL-14C]JAU 6476 in peanuts Report No.: MR-193/01 Bayer AG GLP Unpublished	N	N		BCS
KCP 8/ KCA 6/03 (IIA, 6.1.1/01)	Haas, M.; Bornatsch, W.	2000	Metabolism of JAU 6476 in spring wheat (after foliar application) Report no.: MR-198/99 Bayer AG GLP Unpublished	N	N		BCS
KCP 8/ KCA 6/04 (IIA, 6.1.1/03)	Vogeler, K.; Sakamoto, H.; Brauner, A.	1993	Metabolism of SXX 0665 in summer wheat Report No.: PF3906 Bayer AG GLP Unpublished	N	N		BCS
KCP 8/ KCA 6/05 (IIA, 6.1.1/02)	Haas, M.	2001	Metabolism of JAU 6476 in spring wheat after seed dressing Report No.: MR-467/99 Bayer AG GLP Unpublished	N	N		BCS
KCP 8/ KCA 6/06 (IIA, 6.6./01)	Haas, M.	2001	Confined rotational crop study with JAU 6476 Report No.: MR-159/00 Bayer AG GLP Unpublished	N	N		BCS

Data point (DAR ref. no)	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 6/07 (IIA 6.2.2.1/01)	...	2001	[Phenyl-UL-14C]JAU 6476 Absorption, distribution, excretion and metabolism in the lactating goat Report No.: ... GLP Unpublished	N	N		BCS
KCP 8/ KCA 6/08 (IIA, 6.2.2.2/01)	...	2002	[Phenyl-UL-14C] JAU 6476-desthio Absorption, distribution, excretion, and metabolism in the lactating goat Report no. .. GLP Unpublished	N	N		BCS
KCP 8/ KCA 6/09 (IIA, 6.2.2.3/01)	...	2001	[Phenyl-UL-14C]JAU 6476 Absorption, distribution, excretion and metabolism in laying hens Report No.: GLP Unpublished	N	N		BCS
KCP 8/ KCA 6/10 (IIA, 6.4/01)	2001	JAU 6476-desthio – Dairy cattle feeding study Report No.: ... Report includes trial no.: ... GLP Unpublished	N	N		BCS
KCP 8/ KCA 6/11 (IIA, 6.5/01)	Gilges, M.	2001	Hydrolysis of JAU 6476 under conditions of processing Report No.: MR-166/00 Bayer AG GLP Unpublished	N	N		BCS

BCS = Bayer CropScience

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

Data point (DAR ref. no)	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 5.1.2/01 (filed in KCP 8/ KCA 6/06 (IIA, 6.1/01))	Gross, D.	1994a	Distribution and degradation of [N-2methylpropyl-3- ¹⁴ C] CGA 114900 in spring wheat. Report No.: 17/94 Ciba-Geigy AG, CH-4002 Basel GLP Unpublished	N	N		SYN
KCP 5.1.2/02 (filed in KCP 8/ KCA 6/07 (IIA, 6.1/02))	Gross, D.	1994b	Distribution and degradation of [2,6- ¹⁴ C-piperidine] CGA 114900 in spring wheat. Report No.: 18/94 Ciba-Geigy AG, CH-4002 Basel GLP Unpublished	N	N		SYN
KCP 8/ KCA 6/01 (IIA, 6.0/01)	Tribolet, R.	1995	Residue stability study for fenpropidin (CGA 114900) in weathered grapes under freezer storage conditions. Report No.: 122/92 Ciba-Geigy AG, CH-4002 Basel GLP Unpublished	N	N		SYN
KCP 8/ KCA 6/02 (IIA, 6.0/02)	Walser, M.	1995	Residue stability study for CGA 114900 (Fenpropidin) in wine under freezer storage conditions. Report No.: 147/93 Ciba-Geigy AG, CH-4002 Basel GLP Unpublished	N	N		SYN
KCP 8/ KCA 6/03 (IIA, 6.0/03)	Walser, M.	1996a	Stability of residues of fenpropidin (CGA 114900) in stored analytical specimens of bananas (pulp and peel). Report No.: 128/94 Ciba-Geigy AG, CH-4002 Basel GLP Unpublished	N	N		SYN
KCP 8/ KCA 6/04 (IIA, 6.0/04)	Walser, M.	1996b	Residue stability study for CGA 114900 (Fenpropidin) in wheat under freezer storage conditions. Report No.: 137/93 Ciba-Geigy AG, CH-4002 Basel GLP Unpublished	N	N		SYN

Data point (DAR ref. no)	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 6/05 (IIA, 6.0/05)	1996c	Residues in milk, blood and tissues (muscle, fat, liver, kidney) of dairy cattle resulting from a feeding of three levels of CGA 114900. Report No.: GLP Unpublished	N	N		SYN
KCP 8/ KCA 6/06 (IIA, 6.1/01)	Gross, D.	1994a	Distribution and degradation of [N-2methylpropyl-3-14C] CGA 114900 in spring wheat. Report No.: 17/94 Ciba-Geigy AG, CH-4002 Basel GLP Unpublished	N	N		SYN
KCP 8/ KCA 6/07 (IIA, 6.1/02)	Gross, D.	1994b	Distribution and degradation of [2,6-14C-piperidine] CGA 114900 in spring wheat. Report No.: 18/94 Ciba-Geigy AG, CH-4002 Basel GLP Unpublished	N	N		SYN
KCP 8/ KCA 6/08 (IIA, 6.1/03)	Kiffe, M.	2000	Metabolism of CGA 114900 in greenhouse grown spring wheat after treatment with [2,6-14C-piperidine] labelled material. Report No.: Addendum to Report No. 18/94 Novartis Crop Protection AG, CH-4002 Basel GLP Unpublished	N	N		SYN
KCP 8/ KCA 6/09 (IIA 6.6/01)	Krauss, J.	2000a	Outdoor confined accumulation study on rotational crops after bareground application of [N-2-methylpropyl-3-14C] CGA 114900. Report No.: 98JK21 Novartis Crop Protection AG., CH-4002 Basel. GLP Unpublished.	N	N		SYN
KCP 8/ KCA 6/10 (IIA 6.6/02)	Krauss, J.	2000a	Outdoor confined accumulation study on rotational crops after bareground application of [Piperidine-2-6-14C] CGA 114900. Report No.: 98JK22 Novartis Crop Protection AG., CH-4002 Basel. GLP Unpublished.	N	N		SYN

Data point (DAR ref. no)	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 6/11 (IIA 6.5/01)	Reischmann, F.-J.	2000	Hydrolysis of [Piperidine-2,6-14C]-labelled CGA 114900 under processing conditions. Report No.: 00RF03 Novartis Crop Protection AG., CH-4002 Basel. GLP Unpublished.	N	N		SYN
KCP 8/ KCA 6/12 (IIA 6.2/01)	...	2002	Fenpropidin metabolism in the goat. Report No.: ... Unpublished	Y	N		SYN
KCP 8/ KCA 6/13 (IIA 6.2/02)	...	1997a	Metabolism of [3-14C-propyl]piperidine]CGA 114900 after multiple oral administration to laying hens. Report No... GLP Unpublished	N	N		SYN
KCP 8/ KCA 6/14 (IIA 6.2/03)	...	1997b	Metabolism of [2,6-14C-piperidine]CGA 114900 after multiple oral administration to laying hens. Report No.: .. GLP Unpublished	N	N		SYN
KCP 8/ KCA 6/15 (IIA 6.4/01)	1996c	Residues in milk, blood and tissues (muscle, fat, liver, kidney) of dairy cattle resulting from a feeding of three levels of CGA 114900. Report No.... GLP Unpublished	Y	N		SYN
KCP 8/ KCA 6/16 (IIA 6.4/01)	1999	Amendment 1 to Report 106/96. Report No.: 106/96 GLP Unpublished	Y	N		SYN
KCP 8/ KCA 6/17 (IIA 6.4/01)	...	2001	Amendment 2 to Report 106/96. Report No... GLP Unpublished	Y	N		SYN

SYN = Syngenta

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review of triazole derivative metabolites (TDMs)

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
For the relevant studies please refer to the EU peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018, amended 2019)							

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
KCP 6.2/003	BAROU, JL	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGH) on barley in France, 2019 FR19FEHORVX317D Agrotest France GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/004	BAROU, JL	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGH) on barley in France, 2019 FR19FEHORVX317E Agrotest France GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/028	Caprio, G.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in Italy, 2020 IT20FETRZAW348D Biofarm S.r.l. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2 /029	Caprio, G.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (PUCCRT) on winter wheat in Italy, 2020 IT20FETRZAW349D Biofarm S.r.l. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/032	Desogus, S.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in Italy, 2020 IT20FETRZAW346A SAGEA GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	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 6.2/033	Desogus, S.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in Italy, 2020 IT20FEHORVW350A SAGEA GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/034	Desogus, S.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in Piedmont - Italy, 2020 IT20FEHORVW351A SAGEA GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/035	Desogus, S.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia striiformis</i> (PUCCST) on winter wheat in Italy, 2020 IT20FETRZAW348A SAGEA GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/036	Desogus, S.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (PUCCRT) on winter wheat in Italy, 2020 IT20FETRZAW349A SAGEA GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/037	Desogus, S.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in Italy, 2020 IT20FETRZAW347A SAGEA GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.1/014 6.2/049	GOUAILLE, L.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown leaf rust (PUCCRE) and <i>Septoria tritici</i> (SEPTTR) on winter wheat in France, 2019 FR19FETRZAX328B Biotek Agriculture France GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	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 6.2/050	GOUAILLE, L.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in France, 2019 FR19FETRZAX328C Biotek Agriculture France GEP / not published	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/053	Gulbis, K.	2019	Efficacy evaluation of ADM.3502.F.1.A (MCW-2091) for <i>Septoria tritici</i> control in winter wheat in Latvia in 2019 LV19FETRZAW483A LPPRC Riga GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/055	Gulbis, K.	2019	Efficacy evaluation of ADM.3502.F.1.A (MCW-2091) for <i>D.teres</i> control in spring barley in Latvia in 2019 LV19FEHORVS484A LPPRC Riga GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/057	Gulbis, K.	2020	Efficacy evaluation of ADM.3502.F.1.A for <i>Puccinia hordei</i> control in spring barley in Latvia in 2020 LV20FEHORVX477A LPPRC Riga GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/059	Gulbis, K.	2020	Efficacy evaluation of ADM.3502.F.1.A for <i>Zymoseptoria tritici</i> control in winter wheat in Latvia in 2020 LV20FETRZAX474A LPPRC Riga GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/060	Gulbis, K.	2020	Efficacy evaluation of ADM.3502.F.1.A for <i>Pyrenophora tritici-repentis</i> control in winter wheat in Latvia in 2020 LV20FETRZAX475A LPPRC Riga GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	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 6.2/099	Jørgensen, L.N.	2020	Efficacy: Control of PUCST in winter wheat ADM.3502.F.1.A. in Denmark in 2020 DK20FETRZAX212A University of Aarhus GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/100	Jørgensen, L.N.	2020	Efficacy: Control of PUCST in winter wheat ADM.3502.F.1.A., in Denmark in 2020 DK20FETRZAX212B University of Aarhus GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/101	Jørgensen, L.N.	2020	Control of ERYSGT in winter wheat ADM.3502.F.1.A, in Denmark in 2020 DK20FETRZAX211A University of Aarhus GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/102	Jørgensen, L.N.	2021	Efficacy: Control of RHYNSE and PUCCHD in winter barley ADM.3502.F.1.A in Denmark in 2020 DK20FEHORVX213A University of Aarhus GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/131	Legros, C.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria tritici</i> on wheat, in France in 2018. FR18FETRZAX340A SAS (SARL) EPHYDIA GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/132	Legros, C.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria</i> (SEPTTR/LEPTNO) on wheat, in France in 2018. FR18FETRZAX342B SAS (SARL) EPHYDIA GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	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 6.2/134	Lombart, L.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in France, 2020 FR20FETRZAW306A SAS (SARL) EPHYDIA GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/135	Lopolito, P.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in Italy, 2020 IT20FETRZAW346C ProAGRI S.r.l. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/136	Lopolito, P.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in Italy, 2020 IT20FETRZAW348C ProAGRI S.r.l. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2 /137	Lopolito, P.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (PUCCRT) on winter wheat in Italy, 2020 IT20FETRZAW349C ProAGRI S.r.l. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2 /138	Lopolito, P.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in Italy, 2020 IT20FETRZAW347C ProAGRI S.r.l. GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2 /141	LUNZENFICHTER, C.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria tritici</i> on wheat, in France in 2018. FR18FETRZAX340C QUALIPHYT GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	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 6.2/142	LUNZENFICHTER, C.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria tritici</i> on wheat, in France in 2018. FR18FETRZAX340D QUALIPHYT GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/144	Lunzenfichter, D.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in France, 2019. FR19FETRZAX326A QUALIPHYT GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/145	Lunzenfichter, D.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in France, 2019. FR19FETRZAX326B QUALIPHYT GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/157	Marchi, D.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in Italy, 2020 IT20FEHORVW351B Agri 2000 GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/158	Marchi, D.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Blumeria graminis tritici</i> (ERYSGT) on winter wheat in Italy, 2020 IT20FETRZAW347B Agri 2000 GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/169	Moreno, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in Spain, 2020 SP20FEHORVW340C AGROTECNICA DEL SUR GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM

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KCP 6.2/172	Moreno, J.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in Spain 2020 SP20FETRZAW337A AGROTECNICA DEL SUR GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/211	Ramanauskienė, J.	2020	Efficacy evaluation of ADM.3502.F.1.A (MCW-2091) for <i>Blumeria graminis</i> control in winter wheat in Lithuania in 2019 LT19FETRZAW486A IA LRC, Kedainiai GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/212	Rancane, R.	2018	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria tritici</i> on winter wheat in Latvia in 2018 LV18FETRZAW917A LPPRC Riga GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.1/057 6.2/213	Rancane, R.	2018	Efficacy evaluation of different MCW-2091 formulations against <i>Blumeria graminis</i> on winter wheat in Latvia in 2018 LV18FETRZAW918A LPPRC Riga GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/219	Rivet, J.; Crepin, D.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on barley in France, 2019 FR19FEHORVX316A Essais+ GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/220	Rivet, J.; Crepin, D.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of Net blotch (PYRNTE) on barley in France, 2019 FR19FEHORVS318A Essais+ GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	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 6.1/074 6.2/241	ROUANE, W.	2019	Efficacy evaluation of different MCW-2091 formulation against <i>Septoria tritici</i> (SEPTTR) on wheat, in France in 2018. FR18FETRZAX341C ANADIAG FRANCE GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/243	ROUANE, W.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Erysiphe graminis</i> (ERYSGH) and <i>Rhynchosporium secalis</i> (RHYNSE) on barley in France, 2019 FR19FEHORVX317B ANADIAG FRANCE GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/244	ROUANE, W.	2019	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Pyrenophora graminea</i> (PYRNGR) on barley in France, 2019 FR19FEHORVX317A ANADIAG FRANCE GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/245	Rugiano, M.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Septoria tritici</i> (SEPTTR) on winter wheat in Italy, 2020 IT20FETRZAW346B Agri 2000 GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/246	Rugiano, M.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Brown rust (PUCCRT) on winter wheat in Italy, 2020 IT20FETRZAW349B Agri 2000 GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 6.2/247	Rugiano, M.	2020	Efficacy evaluation of ADM.3502.F.1.A for the control of Yellow rust (PUCCST) on winter wheat in Italy, 2020 IT20FETRZAW348B Agri 2000 GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM

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KCP 6.2/248	Rugiano, M.	2021	Efficacy evaluation of ADM.3502.F.1.A for the control of <i>Puccinia hordei</i> (PUCCHD) on barley in Italy 2020 IT20FEHORVW352B Agri 2000 GEP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 9.1.1.1/01	Morlock, G.	2006a	Degradation of Fenpropidin in 3 different soils under aerobic conditions at 20° C in the dark Report No 20051244/01-CABJ, sponsor no. 00012949 GLP Unpublished	N	N	Not applicable	IRVITA*
KCP 9.1.1.1/02	Morlock, G.	2006b	Degradation of Fenpropidin in one soil under aerobic conditions at 20° C in the dark Report No 20051244/02-CABJ, sponsor no. 00012950 GLP Unpublished	N	N	Not applicable	IRVITA*
KCP 9.1.1.1/03	Flörchinger M.	2008	Degradation of Fenpropidin Acid in 3 Different Soils under Aerobic Conditions at 20°C in the Dark Eurofins-GAB GmbH Report No.S08-01156, sponsor no. 00016350 GLP Unpublished	N	N	Not applicable	IRVITA*
KCP 10.3.1.5/01	Persigehl, M., Beinert, M., Hotopp, I., Zumkier, U.	2021	Study on the Effect of ADM.3500.F.2.B on Honey bee Colonies (<i>Apis mellifera</i> L.) under Semi-Field Conditions in Germany report no.: B19010-3, sponsor no.: 000102470 tier3 solutions GmbH, Leverkusen, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM
KCP 10.3.1.5/02	Hecht-Rost, S.	2020	Semi-field study to evaluate potential effects of ADM.1351.F.1.A (Spyrale) on the development of honeybee colonies (<i>Apis mellifera</i> L.), Germany report no.: R1940026, sponsor no.: 000102476 RIFCON GmbH, Hirschberg, Germany GLP Unpublished	N	Y	Study was never submitted before to Poland to support PPP product registration under EU Regulation 1107/2009	ADM

* IRVITA, now ADAMA Irvita N.V., ADM is ADAMA Makhteshim Ltd. All ADAMA affiliates are member of ADAMA Agricultural Solutions Ltd.

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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