

# REGISTRATION REPORT

## **Part A**

### **Risk Management**

Product code: CA3301

Product name(s): JOUST 250 EC

Chemical active substance:

Prothioconazole, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

New Authorisation (Art. 33)

Applicant: Nufarm Polska Sp. z o.o.

Submission date: 23/12/2021

MS Finalisation date: October 2022 (initial National Assessment)

January 2023, updated May 2023 (final National Assessment)

### Version history

When	What
December 2021	First submission
October 2022	Initial zRMS assessment  In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table, the product label are highlighted in grey, while not agreed use pattern <del>is struck through and shaded</del> .
January 2023	Final report (National Assessment updated following the commenting period).  Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant <del>is struck through and shaded</del> .
May 2023	Update resulting from re-analysis of submitted data for Poland (all changes are highlighted in blue)

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# **PART A**

## **RISK MANAGEMENT**

### **1 Details of the application**

#### **1.1 Application background**

This application is submitted by Nufarm Polska Sp. z o.o. A notification for zonal evaluation was submitted to Poland and the Poland accepted to be Zonal RMS for the Central zone submission. This application is submitted also to the concerned Member States: Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Romania, Slovakia, and Northern Ireland.

This application is submitted for the approval under Art.33 of EU Regulation 1107/2009 of the product with commercial name Joust (developmental code CA3301), an emulsifiable concentration (EC) formulation containing prothioconazole 250 g/L.

CA3301 is a fungicide with protective and curative mode of action that it is intended to be used on Cereals and Oilseed rape against a number of foliar and ear diseases.

The risk assessment conclusions are based on the information, data and assessments provided in Draft Registration Report, Part B Sections 0-10 and Part C and where appropriate the addendum specific for each country.

#### **1.2 Letters of Access**

Most data are owned by the applicant. The applicant provided Letter(s) of Access as appropriate where it is not the data owner (see Appendix 3).

#### **1.3 Justification for submission of tests and studies**

All the tests and studies submitted are necessary for this application.

#### **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.

Confidential information presented in Part C is proprietary information belonging to Nufarm and may not be published or otherwise be made available to any third party without the written permission of Nufarm or its representative.

Data protection and confidentiality are claimed on the basis of commercial value, industrial secret, and including intellectual property.

## 2 Details of the authorization decision

### 2.1 Product identity

Product code	CA3301
Product name in MS	JOUST
Authorization number	-
Function	fungicide
Applicant	Nufarm Polska Sp. z o.o.
Active substance(s) (incl. content)	Prothioconazole 250 g/L
Formulation type	EC
Packaging	0.5 L bottle: HDPE/ cylindrical / approx. 69 mm diameter x 186.5 mm 1 L bottle: HDPE/ cylindrical / approx. 88 mm diameter x 234 mm 5 L bottle: HDPE/ rectangular / approx. 305 mm height x 142 mm depth x 193 mm width 10 L bottle: PE-PA/ rectangular / approx. 370 mm height x 179 mm depth x 240 mm width 20 L bottle: HDPE/ rectangular / approx. 400 mm height x 245 mm depth x 293 mm width
Coformulants of concern for national authorizations	NA
Restrictions related to identity	none
Mandatory tank mixtures	NA
Recommended tank mixtures	NA

### 2.2 Conclusion

The evaluation of the application for Joust 250 EC resulted in the decision to grant the authorisation for below uses: winter barley (RAMUCC, PUCCHD, RHYNSE, PYRNTE, ERYSGH), spring barley (RAMUCC, PUCCHD, PYRNTE, ERYSGH, RHYNSE), winter wheat (SEPTTR, PUCCRE, ERYSGR, FUSASP, PYRNTR), durum wheat (ERYSGR), winter triticale (SEPTTR, ERYSGR, FUSASP, PUCCRE), winter rye (RHYNSE, **PUCCRE/PUCRR**) and winter oilseed rape (SCLESC, ALTEBA, LEPTMA).

### 2.3 Substances of concern for national monitoring

Not applicable, no substance of concern.

### 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 Irrit. 2 Eye Irrit. 2 STOT SE 3
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label** is **formatted bold**:

Hazard pictograms:	GHS07 GHS09
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Signal word:	Warning
Hazard statement(s):	H315 H319 H335 H400 'Very toxic to aquatic life' H410 'Very toxic to aquatic life,' with long-lasting effects'
Precautionary statement(s):	P261 - Avoid breathing spray, mist. P264 - Wash hands, forearms and face thoroughly after handling. P271 - Use only outdoors or in a well-ventilated area. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 - IF ON SKIN: Wash with plenty of soap and water. P332+P313 - If skin irritation occurs: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 - Call a POISON CENTRE or doctor if you feel unwell. P391 - Collect spillage. P403+P233 - Store in a well-ventilated place. Keep container tightly closed. P405 - Store locked up. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] <del>— Operators must wear adequate work clothing during mixing/loading</del> - Operator must wear a work wear, protective gloves and face/eye protection when mixing, loading and handling and work wear during application - Workers should wear adequate work wear when entering in treated area Do not re-enter in treated areas before surfaces have completely dried. Respect a buffer zone of 5 m from residential areas

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:	
-	N/A

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
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## 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

	Refer to point 2.5.1
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## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

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

Operator protection:	
respective code if available : N/A	Operators must wear adequate work clothing during mixing/loading
Worker protection:	
respective code if available : N/A	Workers should wear adequate work wear when entering in treated area Do not re-enter in treated areas before surfaces have completely dried.
Integrated pest management (IPM)/sustainable use:	
respective code if available : N/A	FRAC Group 3 (G1)
Environmental protection	
SPe3	<ul style="list-style-type: none"> <li>For the use of 1-2 applications to winter and spring cereals: 20-m no-spray-buffer zone and a 20-m vegetative-filter strip.</li> <li>For the use of 1-2 applications on flax 20-m no-spray-buffer zone and 20-m vegetative-filter strip.</li> <li>For the use of 1 application on spring oilseed rape, and 1 and 2 applications to winter oilseed rape (autumn and spring application and 2 spring applications), and 1 and 2 applications to cameline, mustard, and other seed-producing Brassicaceae (autumn and spring application): 10-m no-spray-buffer zone and 10-m vegetative-filter strip.</li> </ul>
Other specific restrictions	
	Respect a buffer zone of 5 m from residential areas

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

Integrated pest management (IPM)/sustainable use:	
respective code if available	-

## 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.
respective code if available	-	-
Environmental protection:		Relevant for use no.
	<ul style="list-style-type: none"> <li>Refer to point 2.5.1</li> </ul>	-



GAP rev. 3 ± 1, date: January 2023 ~~October 2022~~ ~~December 2021~~

Formulation type: EC  
 Conc. of as 250 g/L <sup>(c)</sup>  
 Professional use: ☒  
 Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No.	Regulator y region	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/syne rgist per ha	Phys-chem	Analytical methods	Toxicology	Residues	Groundwater	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max										

[illegible]

		Tritordeum		<i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuiformis</i> (PSDCHA) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)																N LEPTNO PUCST PSDCHA  All pathogens in Wheat spring, Spelt, Einkorn, Emmer and Tritordeum possible authorization in based on the art. 51 - minor uses for spelt, einkorn, emmer and tritordeum	
48	PL	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30-69 (spring)	a) 1-2 b) 1-2	14-21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100-400	35		A	A	A	A	A	A	A	A ERYSGR  N SEPTTR PUCCRT FUSASP possible authorization in based on the art. 51 - minor uses
58	PL	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch	foliar spray	BBCH 30-69 (spring)	a) 1-2 b) 1-2	14-21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100-400	35		A	A	A	A	A	A	A	A SEPTTR PUCCRT ERYSGR FUSASP

				<i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCCST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)																N  RHYNSE PUCCST LEPTNO  All pathogens in spring triticales possible authorization based on the art. 51 minor uses for PUCCST	
68	PL	Rye (winter & spring),	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <del><i>Puccinia coronata</i> (PUCCCO)</del> <b><i>Puccinia recondita</i> (PUCCRE/PUCCRR)</b> Eyespot <i>Oculimacula acutiformis</i> (PSDCHA) Powdery mildew <i>Blumeria graminis</i> (ERYSGR)	foliar spray	BBCH 30-69 (spring)	a) 1-2 b) 1-2	14-21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100-400	35		A	A	A	A	A	A	A	A  RHYNSE PUCCRE/ UCCRR SEPTTR  N  SEPTTR PSDCHA ERYSGR  All pathogens in spring rye possible authorization based on the art. 51 minor uses
78	PL	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14-18 (autumn) BBCH 30-69 (spring)	a) 1-2 b) 1-2	90	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100-400	56	First application in Autumn; Second application in Spring	A	A	A	A	A	A	A	A  LEPTMA SCLESC  N  ERYSCR ALTEBA PYRPBR
88	PL	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew	foliar spray	BBCH 30-69 (spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100-400	56		A	A	A	A	A	A	A	A  LEPTMA SCLESC ALTEBA ERYSCR

				<i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																															
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<b>Remarks</b>	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
<b>table heading:</b>	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
	(c)	g/kg or g/l

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

**Remarks  
columns:**

- 1 Numeration necessary to allow references
- 2 Use official codes/nomenclatures of EU Member States
- 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
- 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
- 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
- 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
- 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- 8 The maximum number of application possible under practical conditions of use must be provided.
- 9 Minimum interval (in days) between applications of the same product
- 10 For specific uses other specifications might be possible, e.g.: g/m<sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
- 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
- 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
- 13 PHI - minimum pre-harvest interval
- 14 Remarks may include: Extent of use/economic importance/restrictions
- 15 Overall conclusions - explanation for the column 15 is below\*

\* Explanation for column 15 “Overall conclusions”

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Regulatory region	Crop—and/ or-situation  (crop destination /—purpose of-crop)	F,—Fn, Fpn G,—Gn, Gpn I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application-rate			P H I (d ay s)	Remarks:  e.g.-g safener/synergist-per-ha
					Method—/ Kind	Timing———/ Growth-stage-of crop-&-season	Max. number a) per use b)——per crop/ season	Min.——interval between applications (days)	L-product-/ha a) max.-rate-per appl. b)——max.—total rate———per crop/season	g-as/ha a) max.-rate per-appl. b)——max.: total——rate per crop/season	Water-L/ha min-/max		

Zonal uses (field or outdoor uses, certain types of protected crops)												
1	C-EU S-EU N-EU	Barley winter	F	Leaf-spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acutiformis</i> (PSDCHA) Brown-Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf-Blotch <i>Rhynchosporium secalis</i> (RHYNSE-) Fusarium ear-blight <i>Fusarium spp.</i> (FUSASP) Net-Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30—61 (Spring)	a) 1-2 b) 1-2	14—21	a) 0.6 b) 1.2	a) 150 b) 300	100-400	35
2	C-EU S-EU N-EU	Barley spring	F	Leaf-spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acutiformis</i> (PSDCHA) Brown-Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf-Blotch <i>Rhynchosporium secalis</i> (RHYNSE-) Net-Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30—61 (Spring)	a) 1-2 b) 1-2	14—21	a) 0.6 b) 1.2	a) 150 b) 300	100-400	35
3	C-EU S-EU N-EU	Oat—(winter & spring)	F	Crown-Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acutiformis</i> (PSDCHA)	foliar spray	BBCH 30—61 (Spring)	a) 1-2 b) 1-2	14—21	a) 0.6 b) 1.2	a) 150 b) 300	100-400	35

4	C-EU S-EU N-EU	Wheat (winter—& spring)  Spelt  Einkorn wheat  Emmer Wheat  Tritordeum	F	Septoria-leaf-spot <i>Zymoseptoria-tritici</i> <i>Mycosphaerella-graminicola</i> -(SEPTTR) Glume-blotch <i>Stagonospora-nodorum</i> -(LEPTNO) Brown-Rust <i>Puccinia-recondita</i> <i>Puccinia-tritici</i> -(PUCCRT) Yellow-Rust <i>Puccinia-striiformis</i> -(PUCGST) Powdery-mildew <i>Blumeria-graminis</i> -(ERYSGR) Eyespot <i>Oculimacula-acuiformis</i> -(PSDCHA) Tan-Spot <i>Pyrenophora-tritici-repentis</i> -(PYRNTR) Fusarium-ear-blight <i>Fusarium-spp.</i> -(FUSASP)	foliar spray	BBCH-30—69 (Spring)	a)-1-2 b)-1-2	14—21	a)-0.6-0.8 b)-1.2-1.6	a)-150-200 b)-300-400	100-400	35	
5	C-EU S-EU N-EU	Durum Wheat	F	Septoria-leaf-spot <i>Zymoseptoria-tritici</i> <i>Mycosphaerella-graminicola</i> (SEPTTR) Brown-Rust <i>Puccinia-recondita</i> <i>Puccinia-tritici</i> -(PUCCRT) Powdery-mildew <i>Blumeria-graminis</i> -(ERYSGR) Fusarium-ear-blight <i>Fusarium-spp.</i> -(FUSASP)	foliar spray	BBCH-30—69 (Spring)	a)-1-2 b)-1-2	14—21	a)-0.6-0.8 b)-1.2-1.6	a)-150-200 b)-300-400	100-400	35	
6	C-EU S-EU N-EU	Triticale (winter—& spring)	F	Septoria-leaf-spot <i>Zymoseptoria-tritici</i> <i>Mycosphaerella-graminicola</i> -(SEPTTR) Brown-Rust <i>Puccinia-recondita</i> <i>Puccinia-tritici</i> -(PUCCRT) Leaf-blotch <i>Rhynchosporium-secalis</i> -(RHYNSE) Yellow-Rust <i>Puccinia-striiformis</i> -(PUCGST) Glume-blotch <i>Stagonospora-nodorum</i> -(LEPTNO) Powdery-mildew <i>Blumeria-graminis</i> -(ERYSGR) Fusarium-ear-blight <i>Fusarium-spp.</i> -(FUSASP)	foliar spray	BBCH-30—69 (Spring)	a)-1-2 b)-1-2	14—21	a)-0.6-0.8 b)-1.2-1.6	a)-150-200 b)-300-400	100-400	35	



[illegible]

10	C-EU S-EU N-EU	Oilseed Rape (spring)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Foliar spray	BBCH 20—69	a) 1 b) 1	n/a	a) 0.6-0.7 b) 0.6-0.7	a) 150-175 b) 150-175	100-400	56	Minor Use
11	C-EU S-EU	Flax —(for fiber production only)	F	Powdery mildew flax <i>Erysiphe spp</i> (ERYSPP)	Foliar spray	BBCH 33—51	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100-400	N A	Minor Use, linked to OSR
12	C-EU S-EU N-EU	Mustard, Camelina and —other seed- producing Brassicaceae	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Foliar spray	BBCH —14-18 (Autumn) BBCH 20—69 (Spring)	a) 1-2 b) 1-2	14—28 ■	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100-400	56	Minor Use, linked to OSR

## **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 yellow, odourless liquid. Based on the constituents of the formulation, it has no explosive or oxidising properties. It has a self-ignition temperature of over 400 °C. It has a pH value around 6 in a 1 % aqueous solution. The stability data indicate a shelf life of at least 2 years at ambient temperature. Its technical characteristics are acceptable for an emulsifiable concentrate formulation. It is recommended to mix the product before use. Triple rinsing procedure is recommended. The intended concentration of use is 0.15% v/v to 0.8% v/v.

### **3.2 Efficacy (Part B, Section 3)**

#### **Description of active substances**

CA3301 is an emulsifiable concentrate (EC) containing 250 g/l of prothioconazole for use on crops for use as a fungicide on winter wheat, durum wheat, triticale, rye, oat, barley, oilseed rape and relevant minor crops (flax, minor seed-producing Brassicaceae). Prothioconazole belongs to the triazolinthiones group.

#### **Mode of action**

Prothioconazole is a systemic fungicide molecule from the chemical group of triazolinthiones. It is very polyvalent on the cereals pathogens. It acts on the endoplasmic reticulum of the cell. Its mode of action is interference with the synthesis of ergosterol in the target fungi by inhibition of CYP51, which catalyses demethylation at C14 of lanosterol or 24-methylene dihydrolanosterol, leading to morphological and functional changes in the fungal cell membrane (FAO; BAYER).

#### **Description of the target diseases**

CA3301 is intended to provide preventive and curative control over broad range of foliar and ear diseases on Cereals and Oilseed rape. The diseases against CA3301 is efficient are detailed in the Part B3 document.

#### **Information on trials submitted (3.1 Efficacy data)**

A total of 534 trials were conducted on cereals and 146 on oilseed rape in several countries of the 4 EPPO zones to evaluate the fungicidal activity of the formulation CA3301 against several target diseases. Mediterranean trials were included in this dossier at the suggestion of zRMS Poland since cMS Slovakia may considered these as supportive data.

#### **3.2.1 Efficacy data**

##### **Preliminary tests**

No preliminary tests are presented in this dossier.

Considering that prothioconazole has been widely used since many years and is now very well known; implementing preliminary tests was considered unnecessary.

##### **Minimum Effective Dose**

On winter barley, 6 foliar diseases and several crop quality parameters were assessed in 156 trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2.

Consistent dose rate trend was observed for higher disease control with higher dose rates. The rate of 0.6

l/ha generally gave significantly better control compared to the rate of 0.48 l/ha. In much of the dataset there were no statistical differences between the dose rates of 0.6 l/ha (100% dose rate) and 0.8 l/ha (133% dose rate), even if in some assessments a numerical increase was observed with CA3301 at 0.8 l/ha. Moreover, in circumstances of high disease pressure the rate of 0.6 l/ha showed sufficient efficacy to control the disease and maintain good crop growth conditions until harvest.

The data demonstrates overall similar effects for the targeted diseases regardless of EPPO zone. Same dose rate trends were observed for improving green leaf area in situations of infection from a single pathogen or in cases of disease complexes.

The proposed dose rate of 0.6 l/ha did not involve negative effects on the crop quality parameters observed at harvest. Same observations were made in the sections assessing the efficacy of CA3301 against the same pathogens on spring barley and are supportive of the proposed dose rate of 0.6 l/ha. **Therefore, a minimum effective dose rate of 0.6 l/ha is proposed for CA3301 on winter barley in each of the EPPO zones.**

On spring barley, 6 foliar diseases and several crop quality parameters were assessed in 106 trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2.

Consistent dose rate trend was observed for higher disease control with higher dose rates. The rate of 0.6 l/ha generally gave significantly better control compared to the rate of 0.48 l/ha. In much of the dataset there were no statistical differences between the dose rates of 0.6 l/ha (100% dose rate) and 0.8 l/ha (133% dose rate), even if in some assessments a numerical increase was observed with CA3301 at 0.8 l/ha. Moreover, in circumstances of high disease pressure the rate of 0.6 l/ha showed sufficient efficacy to control the disease and maintain good crop growth conditions until harvest.

The data demonstrates overall similar effects for the targeted diseases regardless of EPPO zone. Same dose rate trends were observed for improving green leaf area in situations of infection from a single pathogen or in cases of disease complexes.

The proposed dose rate of 0.6 l/ha did not involve negative effects on the crop quality parameters observed at harvest. **Therefore, a minimum effective dose rate of 0.6 l/ha is proposed for CA3301 on spring barley in each of the EPPO zones, in order to allow optimum efficacy in relation to disease occurrence.**

On oat, 3 foliar diseases were assessed in 12 valid trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2.

Consistent dose rate trend was observed for higher disease control with higher dose rates. The rate of 0.6 l/ha generally gave higher disease control compared to the rate of 0.48 l/ha. In most instances, no statistical differences were observed between the dose rates of 0.6 l/ha (100% dose rate) and 0.8 l/ha (133% dose rate), even if in some assessments a numerical increase was observed with CA3301 at 0.8 l/ha. Moreover, in circumstances of high disease pressure the rate of 0.6 l/ha provided sufficient efficacy to control the disease and maintain good crop growth conditions until harvest.

The data demonstrated overall comparable performance for the targeted diseases regardless of EPPO zone. Same dose rate trends were observed for improving green leaf area in situations of infection from a single pathogen or in cases of disease complexes.

The proposed dose rate of 0.6 l/ha did not involve negative effects on the crop quality parameters observed at harvest. **Considering all elements presented, CA3301 applied at 0.6 l/ha is the minimum effective dose to control a range of foliar diseases on oat.**

On winter wheat, 6 foliar diseases and 3 ears diseases were assessed in 176 trials across 4 EPPO zones. Disease severity or incidence (for *Blumeria graminis*) was assessed and analysed on the main foliar levels 1 and 2 and on inoculated or non-inoculated ears.

Consistent dose rate trend was observed for higher disease control with higher dose rates. The rates of 0.6-0.8 l/ha generally gave significantly better control compared to the rate of 0.48 l/ha. In much of the dataset there was no statistical differences between the dose rates of 0.6 l/ha or 0.8 l/ha, however it was frequently observed that where disease incidence was higher a significant benefit was derived from increasing the dose rate from 0.6 to 0.8 l/ha while in circumstances of low disease pressure, the 0.6 l/ha dose rate was sufficient to give comparable disease control. Due to the importance of the diseases and given the possibility of resistance in some of the pathogens assessed, the higher rate may be deemed more

appropriate and should be available for users according to disease development conditions, historical control and cultivar tolerance to the pathogens.

The data demonstrates overall similar effects for the targeted diseases regardless of EPPO zone. Same dose rate trends were observed for improving green leaf area in situations of infection from a single pathogen or in cases of disease complexes.

**Therefore, a minimum effective dose rate of 0.6-0.8 l/ha is proposed for CA3301 on winter wheat in each of the EPPO zones, in order to allow optimum efficacy in relation to disease occurrence.**

On durum wheat, 4 foliar diseases were assessed in 18 trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2, whereas for *Blumeria graminis* were considered all leaf foliar levels 1, 2, 3 and 4.

A trend of decreasing disease severity when increasing the dose rates was observed with CA3301 applied at 0.6 l/ha or 0.8 l/ha. In fact, in overall the rate of 0.8 l/ha was not statistically different from 0.6 l/ha dose rate but both provided a better disease control than the lower rate of 0.48 l/ha. In circumstances of low disease pressure, the 0.6 l/ha rate may be sufficient to give comparable disease control, but due to the importance of the diseases and given the possibility of resistance in some pathogens assessed, the high rate of 0.8 l/ha may be deemed more appropriate and should be available for user according to disease development conditions, historical control and cultivar tolerance to the pathogen.

**In summary, 1-2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control a range of foliar and ear diseases on durum wheat.**

On triticale, 4 foliar diseases were assessed in 21 trials across 4 EPPO zones on foliar levels 1 and 2. The efficacy of CA3301 at 0.6-0.8 l/ha was medium to high. A trend of decreasing disease severity when increasing the dose rates was observed with CA3301 applied at 0.6 l/ha or 0.8 l/ha. The rate of 0.8 l/ha was not statistically different from 0.6 l/ha dose rate but both provided a better disease control than the lower rate of 0.48 l/ha. In circumstances of low disease pressure, the 0.6 l/ha rate may be sufficient to give comparable disease control, but due the importance of the diseases and given the possibility of resistance in some pathogens assessed the high rate of 0.8 l/ha may be deemed more appropriate and should be available for user according to disease development conditions, historical control and cultivar tolerance to the pathogen. **CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control a range of foliar and ear diseases on triticale.**

On oilseed rape, 5 diseases were assessed in 128 trials across 4 EPPO zones. CA3301 was applied according two different timings of application and the trials were separated in two groups: trials with 2 applications in spring and trials with one application in autumn and one application in spring. Disease severity was assessed and analysed on leaves, stems, pods and roots. A consistent trend of decreasing disease severity when increasing the dose rates was observed with CA3301 at 0.6-0.7 l/ha providing a better disease control than the lower rate of 0.5 l/ha. The rate of 0.6 l/ha was most of the time very comparable to the 0.7 l/ha rate nevertheless in some trials the differences were significant. Therefore, in circumstances of low to medium disease pressure the rate of 0.6 l/ha will provide sufficient efficacy to maintain crop quality whereas in more challenging condition 0.7 l/ha dose rate will be more appropriate.

Similarly, the same dose rate trends were observed for improving green leaf area in situations of infection from a single pathogen or in cases of disease complexes. **CA3301 applied at 0.6-0.7 l/ha is the minimum effective dose to control a range of foliar diseases on oilseed rape.**

For all crops, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications.

### **Efficacy trials**

On winter barley, 6 foliar diseases were assessed in 160 trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2. The efficacy of CA3301 at 0.6 l/ha was overall equivalent to the one provided by the approved reference standards and was in the majority of cases statistically comparable to the 0.8 l/ha rate (133% dose rate), although in limited cases the differences

were statistically significant. Moreover, in circumstances of high disease pressure the rate of 0.6 l/ha showed sufficient efficacy to maintain crop quality. The same observations were made in the sections assessing the efficacy of CA3301 against the same pathogens on spring barley and are supportive of the proposed dose rate of 0.6 l/ha. Finally, due to the importance of the diseases and given the possibility of resistance in several of the pathogens assessed, the 100% dose rate of 0.6 l/ha, demonstrated to provide equivalent control to authorised reference standards, is considered the most appropriate dose rate. **Considering all elements presented it is justified to claim the registration of 1 or 2 applications of CA3301 at 0.6 l/ha to control a range of foliar diseases on winter barley.**

On spring barley, 6 foliar diseases were assessed in 106 trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2. The efficacy of CA3301 at 0.6 l/ha was overall equivalent to the one provided by the approved reference standards used in the trials. and was in the majority of cases statistically comparable to the 0.8 l/ha rate (133% dose rate), although in limited cases the differences were statistically significant. Moreover, in circumstances of high disease pressure the rate of 0.6 l/ha showed sufficient efficacy to maintain crop quality. Finally, due to the importance of the diseases and given the possibility of resistance in several of the pathogens assessed, the 100% dose rate of 0.6 l/ha, demonstrated to provide equivalent control to authorised reference standards, is considered the most appropriate dose rate. **Considering all elements presented, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control a range of foliar diseases on spring barley.**

On oat, 3 foliar diseases were assessed in 28 valid trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2. The efficacy of CA3301 at 0.6 l/ha was high and equivalent to the one provided by the authorised reference products used in the trials, a trend of decreasing disease severity with increasing dose rate was observed with CA3301 at 0.6 l/ha providing a higher disease control than the lower rate of 0.48 l/ha although it was not always significant. The rate of 0.6 l/ha (100% dose rate) was in most instances statistically equivalent to the 0.8 l/ha rate (133% dose rate). Moreover, in circumstances of high disease pressure the rate of 0.6 l/ha showed sufficient efficacy to maintain crop quality. Finally, due to the importance of the diseases and given the possibility of resistance in some of the pathogens assessed, the 100% dose rate of 0.6 l/ha, demonstrated to provide equivalent control to authorised reference standards, is considered the most appropriate dose rate. **Considering all elements presented it is justified to claim the registration of 1-2 applications of CA3301 at 0.6 l/ha to control a range of foliar diseases on oat.**

On winter wheat, 6 foliar diseases and 3 ears diseases were assessed in 176 trials across 4 EPPO zones. Disease severity or incidence (for *Blumeria graminis*) was assessed and analysed on the main foliar levels 1 and 2 and on inoculated or non-inoculated ears. The efficacy of CA3301 was acceptable to very high with trend of decreasing disease severity when increasing the dose rate was observed with CA3301 applied at 0.6 l/ha or 0.8 l/ha. Although the rate of 0.8 l/ha overall reduced disease to a greater extent than the 0.6 l/ha rate, the differences were not always significant. The disease control obtained from applications of CA3301 was statistically comparable to that from authorised reference products. In some instances, CA3301 applied at 0.8 l/ha provided higher efficacy compared to the range of reference products while in some instances CA3301 applied at 0.6 l/ha provided comparable efficacy to the reference product. **Considering all elements presented it is justified to claim the registration of 1-2 applications of CA3301 at 0.6-0.8 l/ha to control a range of foliar and ears diseases on winter wheat.**

On durum wheat, 4 foliar diseases were assessed in 18 trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2, whereas for *Blumeria graminis* were considered all leaf foliar levels 1, 2, 3 and 4. The efficacy of CA3301 at 0.6-0.8 l/ha was acceptable to high. A trend of decreasing disease severity when increasing the dose rates was observed with CA3301 applied at 0.6 l/ha or 0.8 l/ha. In overall the rate of 0.8 l/ha was not statistically different from 0.6 l/ha dose rate but both provided a better disease control than the lower rate of 0.48 l/ha. In circumstances of low disease pressure, the 0.6 l/ha rate may be sufficient to give comparable disease control, but due the importance of the diseases and given the possibility of resistance in some pathogens assessed the high rate may be deemed more appropriate and should available for user according to disease development conditions, historical control and cultivar tolerance to the pathogen. The efficacy of CA3301 at 0.6-0.8 l/ha was

overall equivalent to that provided by the approved reference standards used in the trials. **Considering all elements presented it is justified to claim the registration of 1-2 applications of CA3301 at 0.6-0.8 l/ha to control a range of foliar and ear diseases on durum wheat.**

On triticale, 4 foliar diseases were assessed in 28 trials across 4 EPPO zones on foliar levels 1 and 2. The efficacy of CA3301 at 0.6 l/ha was acceptable to high, with trend of decreasing disease severity when increasing the dose rates was observed with CA3301 applied at 0.6 l/ha or 0.8 l/ha. The efficacy of CA3301 at 0.6-0.8 l/ha was overall equivalent to that provided by the approved reference standards used in the trials. **Considering all elements presented, it is justified to claim the registration of 1-2 applications of CA3301 at 0.6-0.8 l/ha to control a range of foliar and ears diseases on triticale.**

On rye, 4 foliar diseases were assessed in 23 trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2. The efficacy of CA3301 was acceptable to very high. with trend of decreasing disease severity when increasing the dose rate was observed with CA3301 applied at 0.6 l/ha or 0.8 l/ha. Although the rate of 0.8 l/ha overall reduced disease to a greater extent than the 0.6 l/ha rate, the differences were not always statistically significant. The efficacy of CA3301 at 0.6-0.8 l/ha was overall equivalent to that provided by the approved reference standards used in the trials. **Considering all elements presented it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control a range of foliar diseases on rye.**

On oilseed rape, 5 diseases were assessed in 141 trials across 4 EPPO zones. CA3301 was applied according two different timings of application and the trials were separated in two groups: trials with 2 applications in spring and trials with one application in autumn and one application in spring. Disease severity was assessed and analysed on leaves, stems, pods and roots. The efficacy of CA3301 at 0.6-0.7 l/ha was acceptable to very high, and overall equivalent to the one provided by the approved reference standards used in the trials. In many instances, a trend of decreasing disease severity when increasing the dose rates was observed with CA3301 at 0.6-0.7 l/ha providing a better disease control than the lower rate of 0.6 l/ha. The rate of 0.6 l/ha was most of the time very comparable to the 0.7 l/ha nevertheless in some trials the differences were significant. Therefore, in circumstances of common disease pressure the rate of 0.6 l/ha will provide sufficient efficacy to maintain crop quality whereas in more challenging conditions 0.7 l/ha dose rate will be more appropriate. Same dose rate trends were observed for improving green leaf area. **Considering all elements presented it is justified to claim the registration of CA3301 at 0.6-0.7 l/ha to control a range of foliar diseases on oilseed rape.**

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

The resistance risk assessment to prothioconazole contained in the proposed formulation CA3301 is presented hereinafter based on the requirements detailed in EPPO standard PP1/213(3) “Resistance risk analysis”.

#### **Mode of action**

Prothioconazole is a member of the FRAC fungicide Group 3 (G1-3) with mode of action of Sterol biosynthesis in membranes, C14-demethylase in sterol biosynthesis (erg11/cyp51). Specifically, prothioconazole is a triazolinthione DMI-fungicide (DeMethylation Inhibitors) (SBI: Class I). Prothioconazole is a systemic fungicide molecule which acts on the endoplasmic reticulum of the cell. The mode of action is interference with the synthesis of ergosterol in the target fungi by inhibition of CYP51, which catalyses demethylation at C14 of lanosterol or 24-methylene dihydrolanosterol, leading to morphological and functional changes in the fungal cell membrane.

#### **Evidence of resistance**

EPPO database information

Specifically for prothioconazole, 5 confirmed cases of resistance are reported on the EPPO resistance database which relate to SEPTTR on wheat (1 in Belgium, 1 in Denmark) and RAMUCC on barley (1 in Germany, 1 in Denmark and 1 in Austria).

For the fungicide group Group 3 to which prothioconazole belongs there are 23 cases reported on the database, although 11 of these are for pathogens on other crops such as fruit, vegetables and ornamentals which are not relevant for the use of CA3301. The 12 cases relevant for CA3301 are for FUSACU (1) on winter wheat from Belgium; powdery mildew (ERYSGR/ERYSGH) – 1 on winter wheat and 1 on barley in the UK, the 3 cases on RAMUCC on barley mentioned above for prothioconazole; and 6 cases for SEPTTR on wheat – 2 as mentioned above and 1 each from Austria, Germany, Sweden and UK.

FRAC information:

The most recent reports for DMI (Group 3) fungicides from the 2021 SBI working group relevant to CA3301 are summarised here:

### CEREALS

- *Blumeria graminis* (ERYSGR / ERYSGH / ERYSGS/ ERYSGT): High resistance factors have been observed only for particular DMIs especially in France, Germany and UK, but also to a lesser extend in Belgium.
- *Oculimacula acufiformis* (PSDCHA) and *O. yallundae* (PSDCHE): Some sensitivity change has been observed in the United Kingdom, France and Germany. However, overall, resistance factors still remain low and performance was not affected.
- *Pyrenophora teres* (PYRNTE): Lower sensitivities have been frequently detected in major French regions and in a single location in North-Eastern Germany.
- *Ramularia collo-cygni* (RAMUCC), according to FRAC, monitoring was carried out on barley, in various countries such as Denmark France, Germany, Hungary, Ireland, Italy, Lithuania, Poland, Slovakia, Spain, Sweden, Switzerland, and United Kingdom. Isolates were detected showing significant loss of sensitivity. Relevant CYP51-mutations explaining the effects have been identified (I325T, I328L, Y403C/Y405H).
- Results from bioassay and molecular analysis focusing on the most relevant mutations are:
  - no to low frequencies of resistance in Italy, Switzerland, and Spain
  - no to high frequencies of resistance in France
  - moderate to high frequencies of resistance in Germany and Sweden,
  - high frequencies of resistance in Czech Republic, Denmark, France, Hungary, Ireland, Lithuania, Slovakia and United Kingdom.Isolates highly resistant to triazoles were identified as early as 2015 following monitoring carried out exclusively in Germany. The strains most resistant to prothioconazole present very high IC<sub>50</sub>s, associated with a combination of mutations affecting cyp51 (I381T + I384L + Y459C or Y460H). These mutations were correlated with decreases in efficiency under controlled conditions. Other mutations (affecting codons 136, 459, 460 or 461) were also detected but have a low impact.
- *Zymoseptoria tritici* (SEPTTR): Higher DMI EC<sub>50</sub> sensitivity values found in the UK and Ireland with a gradient can be observed from North-West to South-East.

### **3.2.3 Adverse effects on treated crops**

#### **Phytotoxicity:**

Significant number of trials trials were carried out on winter and spring barley, oat, winter and durum wheat, triticale, rye and oilseed rape in all different EPPO zones.

CA3301 was applied at several doses, as per the intended GAP, without inducing phytotoxic effects.

It is concluded that when CA3301 is applied in accordance to the proposed GAP, it will not induce any phytotoxic symptoms

#### **Effect on the yield of treated plants or plant products**



Yield parameters (t/ha and the corresponding calculated %UNCK) were recorded in significant number of trials implemented to evaluate the effectiveness of CA3301 against number of foliar and ear diseases on winter and spring barley, oat, winter and durum wheat, triticale, rye and oilseed rape in all different EPPO zones.

It is concluded that when CA3301 is applied in accordance to the proposed GAP, it will not negatively affect yields and instead it delivers a positive effect.

### Effect on the yield of treated plants or plant products

The moisture content, compared to the untreated control was assessed in significant number of trials, in all EPPO zones, following application of CA3301 on winter and spring barley, oat, winter and durum wheat, triticale, rye and oilseed rape.

It is concluded that when CA3301 is applied in accordance to the proposed GAP, it will not negatively impact the moisture content in winter and spring barley, oat, winter and durum wheat, triticale, rye and oilseed rape.

### 3.2.4 Observations on other undesirable or unintended side-effects

No specific trials were carried out on cereals to assess the possible impact of CA3301 applications on succeeding crops. The absence of phytotoxicity and adverse effects on the yield, quality of plant products and processing operations allow to conclude that no negative impact on succeeding crops is expected if CA3301 is applied according the recommended conditions in this dossier.

### 3.3 Methods of analysis (Part B, Section 5)

The methods submitted meet the regulatory requirements for pre-registration data and post-registration monitoring.

#### 3.3.1 Analytical method for the formulation

Acceptable analytical method for the determination of the active substance and relevant impurities in the plant protection product has been submitted.

	<b>Prothioconazole</b>			
<b>Author(s), year</b>	Ge, H. (2019)			
<b>Principle of method</b>	HPLC-UV			
<b>Linearity</b> (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	The linearity of detector response was demonstrated using injections of five concentrations (in duplicate) of reference standard in the approximate range of 395 to 637 mg/L (equivalent to 19.8% w/w – 31.8% w/v prothioconazole in the test item), with a correlation coefficient (r) of 0.9997 (slope = 0.0091, intercept = 0.0224).			
		mg pure prothioconazole in L acetonitrile	% w/w pure prothioconazole in product CA3301*	g prothioconazole in L product CA 3301
	Lower standard	395 mg/L	19.8% w/w	196.5 g/L
	Higher standard	637 mg/L	31.8% w/w	316.7 g/L
	Nominal*	503 mg/L	25.1% w/w	250 g/L
	± 20% of nominal conc.	402-604 mg/L	20.1-30.2%	200 – 300 g/L
* Considering a test item solution at 2 mg product / L acetonitrile (100 mg in 50 mL) ** Considering a density of 0.9948 for product CA3301				
<b>Precision – Repeatability Mean n = 5</b>	Repeatability (precision) was determined from single determinations of five samples of CA3301.			

	<b>Prothioconazole</b>					
<b>(%RSD)</b>	Mean content: 25.45% RSD: 0.39% RSDr: 1.65% Hr (Horrat value): 0.24					
<b>Accuracy n = 5 at 3 levels (% Recovery)</b>	<b>Fortification Level</b>			<b>n</b>	<b>Mean Recovery (%)</b>	<b>RSD (%)</b>
	mg pure prothioconazole in L acetonitrile	% w/w pure prothioconazole in product CA3301 *	g prothioconazole in L product CA 3301			
	450	22.5	225	5	100.08	0.28
	500	25	250	5	99.68	0.5
	550	27.5	275	5	100.10	0.08
<b>Interference/ Specificity</b>	Samples of blank formulation, reference item solution and test item solution were analysed. No additional analytical signals in the mean retention time of the active substance were observed. Relevant chromatograms are provided.					
<b>Comment</b>	-					

### Conclusion

The validation of the method for analysis of prothioconazole in CA3301 has not been previously evaluated at EU level. It was performed under GLP according to Guideline SANCO/3030/99 rev.5 and was successfully validated.

The method is acceptable for the quantification of prothioconazole in CA3301.

### 3.3.2 Analytical methods for residues

Registration is sought for dry commodities, Barley, Oat, Wheat, Triticale, Rye, Flax in addition to high oil commodities, Oilseed Rape, Mustard, Cameline and other seed-producing Brassicaceae.

Fully validated pre-authorization residue methods are provided for the following relevant matrices:

<b>Matrix type</b>	<b>Method LOQ</b>	<b>Principle of method (i.e. GC-MS or HPLC-UV)</b>
Plants, plant products,... (Residues)	0.01 mg/kg prothioconazole and prothioconazole-desthio (wheat (grain), grapes, oilseed rape (seed), bean (dry) and cucumber)	LC-MS/MS
	0.01 mg/kg Prothioconazole- $\alpha$ -hydroxy-desthio, prothioconazole3-, -4-, -5- and -6-hydroxy-desthio in wheat (whole plant, grain and straw) and oilseed rape (seeds)	LC-MS/MS
	0.01 mg/kg 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid wheat (grain and straw), barley (grain and straw) grape (bunches) and oilseed rape	LC-DMS/MS/MS
	0.01 mg/kg 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid wheat (grain and straw), barley (grain	LC-DMS/MS/MS

Matrix type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)
	and straw) grape (bunches) and oilseed rape	

Residue methods for post authorisation control and monitoring purposes are available at active substance level in the Draft Assessment Report (DAR Prothioconazole – July 2005 - Volume 3 – B.5 (AS)) for high water, high acid, high oil and dry commodities, in addition to animal matrices.

Methods are also available for residues in soil, water and air that were reviewed at EU level for the generation of pre-authorization data and for post authorisation control and monitoring purposes.

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.”*

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

Additional validated methods used for the generation of pre-authorization data and for post authorisation control and monitoring purposes are submitted by the applicant in support of honey and pollinator matrices, including an ILV in honey matrix. The details of the evaluation of new and additional studies are referred in Appendix 2 of Part B5.

Since many MRLs have been lowered to 0.01 mg/kg, the validated LOQ of the EU agreed methods by Weeren and Pelz (2000) and Class (2001) is not sufficient to monitor these lowered MRLs for food of plant origin. To cover the current residue definition and MRL limits, the Applicant should provide 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.

In our opinion, the EU agreed primary methods by Weeren (2000) with LOQ of 0.02 mg/kg with an ILV are sufficient for intended uses for Joust 250 EC.

It should be noted that with the study by Winter & Giesler (2017, S16-04434), the Applicant has provided a suitable monitoring method, including confirmation for all major matrix groups with a lower LOQ equals 0.01 mg/kg. However, an ILV of this method is missing. In our opinion, an ILV to this method should be provided by the Applicant as a post-registration requirement.

**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.

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.

Additionally, an independent laboratory validation (ILV) for the method for the determination of residues of prothioconazole in drinking water is missing. Based on the indication of the SANTE/2020/12830, Rev.1 24. February 2021, the ILV for drinking water should be submitted.

In our opinion, it is necessary to supply the above-mentioned methods for determining the residues of prothioconazole in body fluids and tissues, in eggs, and ILV for drinking water at the renewal of the active substance and/or re-evaluation of plant production product.

### **3.4 Mammalian toxicology (Part B, Section 6)**

No acute toxicity data is available for CA3301. However, reliable data on the active substance prothioconazole and the co-formulants are available and used for the classification of the product according to the mixture rules calculation of Regulation (EC) No 1272/2008 (CLP).

CA3301 is of low acute oral, dermal and inhalation toxicity and is non sensitising. It is a skin (Skin Irritant 2) and eye irritant (Eye Irritant 2) and causes Respiratory tract irritation (STOT Cat.3)

Based on the results of the acute toxicity and non-dietary risk assessments conducted for CA3301, the following personal protective equipment (PPE)/risk management measures (RMM) are recommended:

Operator: Operators must wear adequate work wear clothing during mixing/loading.

Worker: Worker should use adequate work wear when entering in a treated area.

#### **3.4.1 Acute toxicity**

The acute toxicity of CA3301 has been assessed based on active substance and co-formulant data. The Table below summarises the acute toxicity of CA3301.

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral (calculation method)	> 2000 mg/kg bw	Yes	None	Registration Report - Part C
LD <sub>50</sub> dermal (calculation method)	> 2000 mg/kg bw	Yes	None	Registration Report - Part C
LC <sub>50</sub> inhalation (calculation method)	> 5 mg/L air	Yes	None	Registration Report - Part C
Skin irritation (calculation method)	Irritant	Yes	Skin Irrit. 2, H315	Registration Report - Part C
Eye irritation (calculation method)	Irritant	Yes	Eye Irrit. 2, H319	Registration Report - Part C
Skin sensitisation (calculation method)	Non-sensitising	Yes	None	Registration Report - Part C
Supplementary studies for combinations of plant protection products	No data – not required	--	--	--

CA3301 is of low acute oral, dermal and inhalation toxicity and is non sensitising. It is a skin (Skin Irritant 2; H315) and eye irritant (Eye Irritant 2, H319) according to CLP; in addition CA3301 is classified as H335.

### 3.4.2 Operator exposure

The estimated level of exposure to prothioconazole on operators applying CA3301 to Cereals and Oilseed rape using vehicle mounted sprayers is within the AOEL value when adequate work clothing is worn.

Prothioconazole-desthio is a relevant metabolite with toxicity effects which is formed following foliar spray application of prothioconazole containing products. Diluted prothioconazole can degrade to prothioconazole-desthio in solution, on plant surfaces, clothing or skin. Although prothioconazole-desthio is not part of the formulation, risk assessments were included for prothioconazole-desthio due to a lower AOEL compared to prothioconazole.

For prothioconazole-desthio the risk assessment indicates that operator exposure is below the AOEL value for potential exposure when adequate work wear clothing is used.

Discussed available experimental data (exposure studies by Maasfeld, cited in the dRR; study Maasfeld, 2002 (*Determination of exposure to JAU 6476 and JAU 6476-desthio (SXX 0665) during mixing/loading and application of JAU 6476 in cereals*)) indicate that conversion rates between 1% and 70% may be observed. Use of a conversion factor of 50%, which corresponds to the 90<sup>th</sup> percentile derived from the abovementioned complete data set from the studies by Maasfeld, is reliable to NDE assessment therefore additional NDE assessment taking into account conversion factor 50% has been included.

It is concluded that there is no undue risk to operators following the use and application of CA3301.

### 3.4.3 Worker exposure

The estimated level of exposure for workers are all below the AOEL value of prothioconazole where work wear (coveralls or long-sleeved jackets and trousers) is worn during crop re-entry activities.

Prothioconazole-desthio is a relevant metabolite with toxicity effects which is formed following foliar spray application of prothioconazole containing products. Diluted prothioconazole can degrade to prothioconazole-desthio in solution, on plant surfaces, clothing or skin. Although prothioconazole-desthio is not part of the formulation, risk assessments were included for prothioconazole-desthio due to a lower AOEL compared to prothioconazole.

For prothioconazole-desthio the risk assessment indicates that the estimated worker exposure is slightly above the AOEL when workers are wearing standard workwear. However, when calculating the equivalent application rate of prothioconazole-desthio a 100% conversion rate from prothioconazole was assumed. Using a more realistic approach, assuming a conversion value of 60%, then the estimate of worker exposure is below the AOEL for workers wearing standard workwear.

It is concluded that there is no undue risk to workers wearing standard workwear following the application of CA3301.

#### **3.4.4 Bystander and resident exposure**

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Therefore, exposure assessment for residents also covers bystander exposure.

For prothioconazole the estimate of resident (and bystander) exposure is below the AOEL value.

Prothioconazole-desthio is a relevant metabolite with toxicity effects which is formed following foliar spray application of prothioconazole containing products. Diluted prothioconazole can degrade to prothioconazole-desthio in solution, on plant surfaces, clothing or skin. Although prothioconazole-desthio is not part of the formulation, non-dietary risk assessments were included for prothioconazole-desthio due to a lower AOEL compared to prothioconazole.

For prothioconazole-desthio the estimate of resident exposure is acceptable for adults but is unacceptable for children, due to high exposure through spray drift and re-entry into treated crops. However, when calculating the equivalent application rate of prothioconazole-desthio a 100% conversion rate from prothioconazole was assumed. Using a more realistic approach, assuming a conversion value of 60%, the risk assessment value for resident child is only slightly above the AOEL. This risk assessment used the default DT<sub>50</sub> value of 30 days. Using a more realistic value of DT<sub>50</sub> of 14 days the risk assessment value for resident child is below the AOEL provided a buffer zone of 5 m from residential areas is accounted.

Discussed available experimental data (exposure studies by Maasfeld, one of them was cited in the dRR; study Maasfeld, 2002 (*Determination of exposure to JAU 6476 and JAU 6476-desthio (SXX 0665) during mixing/loading and application of JAU 6476 in cereals*)) indicate that conversion rates between 1% and 70% may be observed. Use of a conversion factor of 50%, which corresponds to the 90<sup>th</sup> percentile derived from the abovementioned complete data set from the studies by Maasfeld, is reliable to NDE assessment therefore additional NDE assessment taking into account conversion factor 50% has been included.

It is concluded that there is no undue risk to any resident (or bystander) during and/or following the application of CA3301.

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

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for prothioconazole as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of prothioconazole residues, including the triazole derivative metabolites, are unlikely to present a public health concern.

According to available data, no specific mitigation measures should apply.

**Table 3.5-1: Summary for prothioconazole**

Table S.5-1: Summary for prothioconazole								
Use- No.*	Crop	Plant metabolism 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?
1	Barley winter	Yes	Yes	Yes	Yes	Yes	No	No
2	Barley spring	Yes	Yes	Yes	Yes	Yes		No
3	Oat (winter & spring)	Yes	Yes	Yes	Yes	Yes		No
4	Wheat (winter & spring) Spelt Einkorn wheat Emmer Wheat Tritordeum	Yes	Yes	Yes	Yes	Yes		No
5	Durum Wheat	Yes	Yes	Yes	Yes	Yes		No
6	Triticale (winter & spring)	Yes	Yes	Yes	Yes	Yes		No
7	Rye (winter & spring)	Yes	Yes	Yes	Yes	Yes		No
8	Oilseed Rape (winter)	Yes	Yes	Yes	Yes	Yes		No
9	Oilseed Rape (winter)	Yes	Yes	Yes	Yes	Yes		No
10	Oilseed Rape (spring)	Yes	Yes	Yes	Yes	Yes		No
11	Flax (for fibre production only)	Not applicable - Non food/feed use						
12	Mustard, Cameline and other seed-producing Brassicaceae	Yes	Yes	Yes	Yes	Yes	No	No

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

The effects of processing on the nature of active substance residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

Regarding TDMs, studies show that they remained stable under the standard hydrolysis conditions. Studies on magnitude of residues in processed commodities in wheat, barley and oilseed rape after treatment with prothioconazole were presented in the confirmatory data. These data were not considered for the risk assessment (the most critical processing factors, considering data provided for all active substances belonging to the triazole group, was taken into account in the TDM EU risk assessment).

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that prothioconazole residues will be present in succeeding crops.

Regarding TDMs, in the framework of the confirmatory data, a number of field rotational crop trials have been conducted to investigate the magnitude of TDM residues in rotational crops after the use of triazole active substances. Residues of TA, TLA and TAA were found above 0.01 mg/kg in succeeding crops. These results were considered in the consumer risk assessment performed in the framework of the review of TDMs confirmatory data.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock for both prothioconazole and TDMs. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Regarding TDM arising from prothioconazole uses, as concluded by the UK, “further consideration is not

required due to the fact that none of the TDMs were identified” in the available livestock metabolism studies conducted with prothioconazole.

**Table 3.5-2: Information on CA3301 (KCA 6.8)**

Crop	PHI for CA3301 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CA3301 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Prothioconazole		
Barley (winter & spring)	35	Yes	35	-
Oat (winter & spring)	35	Yes	35	-
Wheat (winter & spring), Spelt, Einkorn wheat Emmer Wheat Tritordeum, Durum Wheat, Triticale (winter & spring)	35	Yes	35	-
Rye (winter & spring)	35	Yes	35	-
Oilseed rape (winter & spring)	56	Yes	56	-
Mustard, Cameline and other seed-producing Brassicaceae	56	Yes	56	-

NR: not relevant

\* Purpose of withholding period to be specified

\*\* F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

**Table 3.5-3: Waiting periods before planting succeeding crops**

Waiting period before planting succeeding crops				Overall waiting period proposed by zRMS for CA3301
Crop group	Led by prothioconazole	Led by active substance 2	Led by active substance 3	
All	Not needed	NR	NR	Not needed

NR: not relevant



## Consumer risk assessment

### Prothioconazole

The calculation of the TMDI using EFSA model (version 3.1) and MRLs values according to the Regulation (EU) 2019/552 and appropriate conversion factors for enforcement to risk assessment led to a utilisation of the ADI of 41% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is wheat with 8% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI for prothioconazole-desthio.

An acute consumer risk assessment was performed based on the highest residue values (HR) of barley, oat, wheat, rye, triticale, oilseed rape, mustard, linseed, poppy, gold of pleasure and animals commodities. The highest International Estimated Short-Term Intake (IESTI) is at 9% and 5% of the ARfD for the consumption of wheat by children and by adults respectively.

### TDMs

The dietary risk assessment was calculated using PRIMo rev 3.1 for each TDM. Toxicological reference values and input values from EFSA conclusion on confirmatory data on TDMs (EFSA, 2018) and for TA only, STMR value for oilseed rape were taken into account.

The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of prothioconazole residues and TDMs are unlikely to present a public health concern. The intended uses of CA3301 / Joust are accepted.

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

The environmental exposure was assessed from uses of CA3301 (JOUST), its active substance, prothioconazole and all relevant metabolites. All data were taken from the EFSA 2007 conclusion (EFSA Scientific Report (2007) 106, 1-98) and associated DAR. No new active substance data were submitted or required.

### 3.6.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)

The use of CA3301 (JOUST) on cereals and oilseed rape results in soil exposure of prothioconazole and the relevant soil metabolites, prothioconazole-S-methyl and prothioconazole-desthio. PEC<sub>soil</sub> values have been calculated following the FOCUS guidance in European Commission Document 7617/VI/96. First-order degradation was used, following the agreed EU endpoints. The active substance and its metabolites are not persistent in soil and do not accumulate.

Worst-case application parameters were taken from the GAP. The worst-case PEC<sub>soil</sub> values occurred following autumn application to winter oilseed rape at BBCH 14-18 and are summarised in the table below.

**Table 3.6.1-1: Worst-case PEC<sub>soil</sub> values**

Substance	Worst-case PEC <sub>soil</sub> (mg/kg)
	(175 g as/ha, Oilseed rape, BBCH 14 (autumn) & BBCH 20 (spring) application timing, 40% and 80% interception respectively)
Prothioconazole	0.1400
Prothioconazole-S-methyl	0.0213
Prothioconazole-desthio	0.0725

The PEC<sub>soil</sub> reported in Table 3.7.1-1 can be used for the risk assessment of the non-target organisms. Please refer to Section B9.

### 3.6.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)

The use of CA3301 (JOUST) on cereals and oilseed rape results in potential groundwater exposure of

prothioconazole and the relevant soil metabolites, prothioconazole-S-methyl and prothioconazole-desthio. The risk to groundwater was assessed through simulations using the environmental fate models FOCUS-PEARL (v5.5.5), FOCUS-PELMO (v6.6.4) and FOCUS-MACRO (v5.5.4).

PEC<sub>gw</sub> values were <0.001 µg/L in all models, for all substances, scenarios, and crops. The risk to groundwater was determined to be acceptable for all uses of CA3301.

### **3.6.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)**

The use of CA3301 (JOUST) on cereals and oilseed rape results in surface water exposure of prothioconazole, plus the relevant metabolites, prothioconazole-S-methyl, prothioconazole-desthio and 1,2,4-triazole.

PEC<sub>sw</sub> values were calculated for single and multiple applications for uses on spring cereals, winter cereals, spring oilseed rape and winter oilseed rape, which provide a risk envelope for all uses in the GAP.

PEC values for prothioconazole and all relevant metabolites were determined at FOCUS STEPS 1-2. FOCUS STEP 3 and 4 models were performed for prothioconazole and the metabolite prothioconazole-desthio, covering all FOCUS scenarios relevant to the central zone. At STEP 3, the main exposure routes were drift (for the active substance) and runoff (for prothioconazole-desthio formed in soil). Due to potential risks from the metabolite prothioconazole-desthio, mitigation was modelled at STEP 4 using no spray buffer zones of 10m and 20m and 10m and 20m vegetated filter strips. The PEC values were suitable for use in aquatic risk assessment. Please refer to Section B9.

### **3.6.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)**

The EU agreed endpoint for vapour pressure was <4×10<sup>-7</sup> Pa at 20°C, below the minimum detectable level in the study. Hence the active substance is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance will be negligible. Any trace amounts reaching the air will quickly degrade in the atmosphere via reaction with OH radicals and there is no risk of long-range transport or atmospheric accumulation.

## **3.7 Ecotoxicology (Part B, Section 9)**

The risk is considered acceptable for terrestrial vertebrates, bees, non-target arthropods, soil organisms (including micro and macro-organism), and non-target plants measures. Any risk-mitigation measures are described briefly below and in greater detail in Part B, Section 9 of the core dossier.

### **3.7.1 Effects on terrestrial vertebrates**

The risk assessment for birds and mammals was carried out according to EFSA/2009/1438.

The acute and long-term risks to birds and mammals were assessed from toxicity-exposure ratio (TER) values, between toxicity endpoints, estimated from studies with prothioconazole (the active substance in the formulated product CA3301), and maximum residues occurring on food items, following applications according to the use pattern.

The screening acute TER (TER<sub>a</sub>) values for birds and mammals are greater than the Commission Regulation (EU) No. 546/2011 trigger of 10, indicating that there are acceptable acute risks to birds and mammals from prothioconazole and its metabolite, prothioconazole-desthio, for the proposed use pattern of the product CA3301 in cereals and oilseed rape.

For birds, long-term/reproductive TER (TER<sub>lt</sub>) values for prothioconazole and its metabolite

prothioconazole-desthio are greater than the Commission Regulation (EU) No. 546/2011 trigger of 5 during the Screening step/Tier 1 risk assessment, indicating that the long-term risk to birds is acceptable according to the proposed use pattern of CA3301 in cereals and oilseed rape.

For mammals, the screening  $TER_{lt}$  value for prothioconazole is greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that the long-term risk to mammals is acceptable, according to the proposed use pattern of CA3301 in cereals and oilseed rape. However, the screening  $TER_{lt}$  values for the metabolite prothioconazole-desthio are lower than the trigger of 5. Most long-term first-tier risk assessments for prothioconazole-desthio revealed  $TER_{lt}$  values greater than the trigger of 5, indicating that the long-term risk to mammals is acceptable according to the proposed use pattern. Only for use in cereals and oilseed rape at  $BBCH \geq 40$  the  $TER_{lt}$  value is below the trigger of 5 for the generic focal species small herbivorous mammal “vole”. A higher-tier refinement is carried out, based on standard worst-case assumptions of a 100% grass diet, a FIR/bw value of 1.33, a  $RUD_m$  value of 54.2, and a  $MAF_m \times TWA$  value of  $1.4 \times 0.53$ , as well as refined deposition factors of 0.1 (cereals) and 0.2 (oilseed rape), which result in acceptable  $TER_{lt}$  values for prothioconazole-desthio of 9.35 and 5.35, for use in cereals and oilseed rape, respectively.

Risk assessments for exposure of birds and mammals, via drinking water, showed acceptable acute and long-term risks to prothioconazole and two of its metabolites – prothioconazole-desthio and prothioconazole-S-methyl. Risk assessments for exposure of birds and mammals, via secondary poisoning (fish- and earthworm-eating mammals), showed acceptable long-term risks, following exposure to prothioconazole, prothioconazole-desthio, and prothioconazole-S-methyl from the proposed use of CA3301.

### 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).

An acceptable risk is concluded for all aquatic organism groups using FOCUS Step-1 or -2  $PEC_{sw}$  values, for the intended uses of CA3301 in cereals and oilseed rape, for the active substance prothioconazole and its metabolites, prothioconazole-S-methyl and 1,2,4-triazole, as well as the product CA3301.

However, for the metabolite prothioconazole-desthio, an acceptable aquatic risk can be demonstrated based on FOCUS Step-4  $PEC_{sw}$  values, for all relevant for Poland scenarios (D3, D4 and R1), considering the following mitigation measures:

- For the use of 1 application to winter and spring cereals: 10-m no-spray-buffer zone and 10-m vegetative-filter strip.
- For the use of 2 applications to winter and spring cereals: 20-m no-spray-buffer zone and a 20-m vegetative-filter strip.
- For the use of 2 applications on flax 20-m no-spray-buffer zone and 20-m vegetative-filter strip.
- For the use of 1 application on spring oilseed rape, and 1 application on flax, and 2 applications to winter oilseed rape (autumn and spring application and 2 spring applications), 2 applications to cameline, mustard, and other seed-producing Brassicaceae (autumn and spring application): 10-m no-spray-buffer zone and 10-m vegetative-filter strip.

Taking into consideration proposed use pattern, for uses where multiple applications were recommended, the maximum buffer zones and filter strips have been taken into account. Thus, following risk mitigation measures are required for Polish scenarios (D3, D4 and R1):

- For the use of 1-2 applications to winter and spring cereals: 20-m no-spray-buffer zone and a 20-m vegetative-filter strip;
- For the use of 1-2 applications on flax: 20-m no-spray-buffer zone and 20-m vegetative-filter strip;

- For the use of 1 application on spring oilseed rape, and 1 and 2 applications to winter oilseed rape (autumn and spring application and 2 spring applications), and 1 and 2 applications to cameline, mustard, and other seed-producing Brassicaceae (autumn and spring application): 10-m no-spray-buffer zone and 10-m vegetative-filter strip.

### 3.7.3 Effects on bees

A first-tier risk assessment was conducted in accordance with SANCO/10329/2002 and indicated acceptable acute contact and oral risks to adult honey and bumble bees (hazard quotient values  $\leq 50$ ).

The data requirements in accordance with Commission Regulation (EU) No 284/2013 for the chronic toxicity to adult honeybees and honeybee larvae are fulfilled.

### 3.7.4 Effects on other arthropod species other than bees

The risk assessment was conducted according to the “Guidance Document on Terrestrial Ecotoxicology,” as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

The risk of CA3301 to non-target arthropods was assessed in first-tier assessments, from hazard quotients, between toxicity endpoints that were estimated from laboratory studies with CA3301 and crop-specific use patterns. The assessment was conducted for the worst-case application patterns of 2 x 200 g a.s./ha (14-d interval), covering the risk for non-target arthropods from all other intended uses.

Acceptable in-field risks were not demonstrated for *T. pyri* and *A. rhopalosiphi* at the first tier, and a refined risk assessment, using extended laboratory studies, was conducted. However, risk assessments considering the above-mentioned refinement still showed potential risk to *T. pyri*, although not to *A. rhopalosiphi*, *C. carnea*, and *A. bilineata*. Consequently, extended-laboratory (aged-residue) studies with *T. pyri* and *C. carnea* were conducted, which demonstrated that there is an acceptable potential for recovery within an ecologically relevant period as mortality and reproductive effects at 0 DAT and 7 DAT were minimal at 9.2% and -1.1% corrected mortality (*T. pyri*), respectively, and no adverse effects on mortality in either bioassay on *C. carnea* (i.e., significantly less than 50%).

Acceptable off-field risks were demonstrated for *T. pyri* and *A. rhopalosiphi* at the first tier, therefore, the off-field risk to non-target arthropods was shown to be acceptable.

### 3.7.5 Effects on soil organisms

The risk to earthworms, *Folsomia candida*, and *Hypoaspis aculeifer* from exposure to prothioconazole (the active substance in CA3301) and its metabolites – prothioconazole-desthio and prothioconazole-S-methyl was assessed and demonstrated to be acceptable, when the maximum predicted concentration in soil was used. Worst-case soil exposure following autumn application to winter oilseed rape was used in a risk envelope approach. All TER<sub>it</sub> values were above the trigger of 5.

No significant effects (<25%) on soil microorganisms were shown for the proposed uses of CA3301 at concentrations greater than the predicted maximum soil concentrations. Therefore, the risk to soil microorganisms was considered acceptable.

### 3.7.6 Effects on non-target terrestrial plants

The risk assessment for non-target plants was considered acceptable using the maximum application rate of prothioconazole, using data from new vegetative-vigour and seedling-emergence studies. No adverse effects are expected from the worst-case GAP (200 g a.s./ha x 2), since worst-case TER values for

vegetative vigour and seedling emergence were >50.3 and >45.0, respectively (i.e., greater than the trigger value of 5).

### **3.7.7 Effects on other terrestrial organisms (Flora and Fauna)**

Further studies on other terrestrial organism are not required, as the risk to the standard organisms has been shown to be acceptable.

## **3.8 Relevance of metabolites (Part B, Section 10)**

Prothioconazole degrades in soil to form two metabolites that are present at levels >10% and are therefore potentially relevant in groundwater. The metabolites, prothioconazole-S-methyl and prothioconazole-desthio, were predicted to occur in groundwater at concentrations below 0.001 µg/L in all FOCUS scenarios for all uses in the GAP, according to the models FOCUS-PEARL (v5.5.5), FOCUS-PELMO (v6.6.4) and FOCUS-MACRO (v5.5.4). Please see Part B.8.8 for a full summary of the modelling. No further assessment of the relevance of these metabolites is therefore required, and groundwater risks are acceptable.

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

Prothioconazole is not listed as a candidate 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**

Noticed data gaps are:

### **1. Analytical Methods:**

- an analytical method for the determination of prothioconazole in body fluids and tissues is required according to the Commission Regulation (EU) No 284/2013 and should be provided at the renewal of the active substance and/or re-evaluation of plant production product;
- fully validated analytical method for the determination of prothioconazole-desthio in eggs is required according to the conclusions presented in EFSA Journal 2014;12(5):3689 and should be provided at the renewal of the active substance and/or re-evaluation of plant production product;
- an ILV of the method of determination of prothioconazole in drinking water is required according to the requirement of SANTE/2020/12830 and should be provided at the renewal of the active substance and/or re-evaluation of plant production product;
- an ILV of the method (Winter & Giesler (2017, S16-04434)) of determination of prothioconazole in all major matrix groups with an LOQ of 0.01 mg/kg is required according to the requirement of SANTE/2020/12830 and should be provided as a post-registration requirement.

## **Appendix 1    Copy of the product authorization**

## Appendix 2 Copy of the product label

### Komentarz oceniających:

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

Zakres zmian jest następujący:

### Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodne z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008r. nie jest wymagane.
2. Okres ważności: 2 lata w opakowaniach wykonanych z HDPE na podstawie zaakceptowanego 2 letniego badania stabilności [KCP 2.7.5/01, Wang, Q., 2021, Report no.: ABC-2019-020]. W związku z powyższym, wszystkie opakowania wymienione, w punktach 2.1 dokumentu A i 4.1 Sekcji 1 można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin. Na podstawie wyników powyższego badania konieczne jest umieszczenie poniższego zapisu „Ciecz użytkową przygotować bezpośrednio przed zastosowaniem. Przed użyciem wstrząsnąć zawartością opakowania”. Powyższe zalecenie zostało uwzględnione przez Wnioskodawcę w projekcie etykiety.
3. Brak uwag do punktów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin i opakowania oraz sporządzania cieczy użytkowej.
4. Brak uwag do zapisu nazwy grupy chemicznej, do której przyporządkowano substancję czynną i jej zawartości (gęstość środka ochrony roślin 0.9948 g/mL zgodnie z danymi zawartymi w punkcie 2.6.1 Sekcji 1,2,4).
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. Na podstawie przedłożonych badań możliwa jest rejestracja środka Joust 250 EC w zakresie sekcji skuteczność do ochrony zbóż oraz rzepaku ozimego przed chorobami w dawce 0,6-0,8 l/ha w przypadku zbóż oraz 0,6-0,7 l/ha w przypadku rzepaku w Polsce.
2. Analiza przedstawionej dokumentacji pozwala na akceptację 2 interwencyjnych zabiegów testowanym środkiem. Zgodnie z tabelą GAP, wnioskuje się o zakres 1-2 zabiegów, jednak ocena skuteczności po pierwszym zabiegu prowadzona była dla ograniczonej liczby patogenów w pszenicy ozimej oraz rzepaku ozimym. Z uwagi na niewystarczającą liczbę badań dla strefy północno-wschodniej, wykazanie skuteczności pojedynczego zabiegu dla całego wnioskowanego zakresu zastosowań jest w znacznym stopniu utrudnione. Zgodnie z wyjaśnieniem wnioskodawcy, celem prowadzonych badań było wykazanie zarówno prewencyjnego jak i interwencyjnego działania środka. Z uwagi na fakt, że na rynku dostępne są już środki zawierające protiokonazol przeznaczone do pojedynczego zastosowania, w opinii eksperta możliwe jest zalecenie zakresu 1-2 zabiegów na etykiecie środka Joust 250 EC. Niemniej jednak, należy zaznaczyć że pierwszy zabieg ma na celu przede wszystkim działanie prewencyjne.
3. Ze względu na niewystarczającą liczbę badań i brak możliwości ekstrapolacji z innych gatunków uprawnych, z zakresu zastosowań w etykiecie usunięto:
  - jęczmień ozimy: łamliwość źdźbła zbóż i traw (brak badań ze strefy NE lub krajów ościennych), fuzarioza kłosów (brak badań ze strefy NE lub krajów ościennych),
  - jęczmień jary: łamliwość źdźbła zbóż i traw (brak badań skuteczności; patogen posiada status małoobszarowego i możliwa jest rejestracja tego zastosowania w trybie art. 51),
  - owies jary: rdza koronowa (2 badania ze strefy NE i 3 badania z krajów ościennych), mączniak prawdziwy zbóż i traw (2 badania ze strefy NE i 1 badania z kraju ościennego), łamliwość źdźbła zbóż i traw (brak badań skuteczności); zgodnie z tabelą RT przedłożoną na etapie komentowania planowane są dodatkowe badania dla rdzy koronowej celem uzupełnienia zakresu danych. Proponujemy w tym przypadku zezwolenie warunkowe z obowiązkiem przedłożenia brakującego badania;
  - owies ozimy: brak badań skuteczności,
  - pszenica ozima: septorioza plew pszenicy (brak badań ze strefy NE lub krajów ościennych), rdza żółta zbóż i traw (1 badanie z NE, 3 badania z krajów ościennych), łamliwość źdźbła zbóż i traw (brak badań skuteczności),
  - pszenica jara: brak badań skuteczności,
  - orkisz, pszenica samopsza, pszenica płaskurka, pszenjęczmień: brak badań skuteczności; gatunki uznaje się

- za małoobszarowe i możliwa jest ich rejestracja w trybie art. 51,
- pszenica durum (twarda): septorioza paskowana liści pszenicy (brak badań ze strefy NE lub krajów ościennych), rdza brunatna pszenicy (brak badań ze strefy NE lub krajów ościennych), fuzarioza zbóż (brak badań skuteczności); pszenica durum jest gatunkiem małoobszarowym i możliwa jest rejestracja tych zastosowań w trybie art. 51,
  - pszenżyto ozime: rynchosporioza zbóż (brak badań skuteczności), rdza żółta zbóż i traw (brak badań ze strefy NE, 1 badanie z kraju ościennego), septorioza plew pszenicy (brak badań skuteczności),
  - pszenżyto jare: brak badań skuteczności (rdza żółta zbóż i traw w pszenżycie jarym posiada status patogenu małoobszarowego i możliwa jest rejestracja tego zastosowania w trybie art. 51),
  - żyto ozime: ~~septorioza paskowana liści pszenicy (3 badania z NE, 2 badania z krajów ościennych); rdza koronowa (brak badań skuteczności);~~ łamliwość źdźbła zbóż i traw (brak badań skuteczności), mączniak prawdziwy zbóż i traw (brak badań ze strefy NE lub krajów ościennych); **zgodnie z wcześniejszym wyjaśnieniem wnioskodawcy potwierdzonym w RT na etapie komentowania i akceptacją zRMS rdza koronowa zostaje zastąpiona rdzą brunatną zbóż,**
  - żyto jare: brak badań skuteczności; gatunek uznaje się za małoobszarowy i możliwa jest jego rejestracja w trybie art. 51,
  - rzepak ozimy (aplikacja jesień/wiosna): mączniak prawdziwy rzepaku (brak badań ze strefy NE lub krajów ościennych), cylindrosporioza roślin krzyżowych (brak badań ze strefy NE lub krajów ościennych), czerni krzyżowych (2 badania ze strefy NE, brak badań z krajów ościennych),
  - rzepak ozimy (aplikacja wiosenna): ~~mączniak prawdziwy rzepaku (brak badań ze strefy NE, 1 badanie z krajów ościennych);~~ cylindrosporioza roślin krzyżowych (brak badań ze strefy NE lub krajów ościennych).

Dla celów rejestracji środka w Polsce, należy przedłożyć minimum 6 badań skuteczności dla każdego z wnioskowanych zastosowań. W przypadku ekstrapolacji, niezbędne jest przedstawienie pełnej puli badań skuteczności dla uprawy, z której ekstrapolujemy oraz minimum 1-2 badań skuteczności dla gatunku ekstrapolowanego. **Zgodnie z informacją zawartą w RT na etapie komentowania w przypadku wszystkich powyżej wymienionych zastosowań małoobszarowych Wnioskodawca wystąpi o rejestrowane w trybie art. 51.**

4. W przypadku niektórych chorób, środek wykazywał średni poziom skuteczności. Informację tą wprowadzono do etykiety we właściwych miejscach.
5. W przedłożonych badaniach poziom nasilenia patogenów chorobotwórczych (PESSEV) był bardzo zróżnicowany, od bardzo niskiego (nieco ponad 5%) do bardzo wysokiego (100%). Przy wnioskowanym zakresie dawek środka, 0,6-0,8 l/ha (zboża) oraz 0,6-0,7 l/ha (rzepak), wyższą z dawek zaleca się stosować w przypadku bardziej wymagających warunków (m.in. wysoki PESSEV). Wyjątek stanowią jęczmień jary i ozimy dla których zaleca się tylko dawkę 0,6 l/ha.
6. Do etykiety wprowadzono UWAGI: informację o możliwości wystąpienia przemijających objawów fitotoksyczności na rzepaku ozimym oraz zalecenia strategii antyodpornościowej. **W etykiecie wprowadzono stosowane zmiany zgodnie z propozycją wnioskodawcy zawartą w RT na etapie komentowania.**
7. Dodano zapis o warunkach stosowania środka w temperaturze powyżej 12°C.
8. W przypadku rzepaku i zastosowania w terminie wiosennym, wykreślono początkową fazę BBCH 20 i zmieniono na fazę 30. Zgodnie z informacją, po uformowaniu rozety (do fazy BBCH 19) następuje okres spoczynku wegetacyjnego (zimowania) i wiosną wegetacja rozpoczyna się od fazy BBCH 30.
9. **Doprecyzowano termin stosowania środka w zbożach i rzepaku.**

#### **Sekcja metody analityczne:**

1. Brak uwag.

#### **Sekcja toksykologia i istotność toksykologiczna metabolitów:**

1. W części dotyczącej „środków ostrożności dla osób stosujących środek” odpowiedni zapis zmodyfikowano zgodnie z wymaganiami harmonizacyjnymi (patrz MRiRW „Toksykologia” stan na 26.10.2021).

#### **Sekcja pozostałości:**

1. Na podstawie przeprowadzonej oceny w zakresie pozostałości możliwe jest zaakceptowanie zastosowania środka w ochronie jęczmienia ozimego i jarego, owsa ozimego i jarego, pszenicy jarej i ozimej, orkisz, pszenicy samopsza, pszenicy płaskurki, pszenięczmienia (Tritordeum), pszenicy durum (twarda), pszenżyta jarego i ozimego, żyta jarego i ozimego, rzepaku ozimego oraz upraw małoobszarowych tj. rzepaku jarego, lnu, gorczycy, lnicznika siewnego i innych roślin krzyżowych uprawianych na nasiona.
2. Doprecyzowano zapis dotyczący okresu karencji dla lnu przeznaczonego na włókno.
3. Wprowadzono do etykiety zapis dotyczący roślin uprawianych następczo. „Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następczo: Nie dotyczy”.

#### **Sekcja los i zachowanie w środowisku:**



1. Nie wprowadzono zmian w etykiecie.

**Sekcja ekotoksykologia:**

1. Skorygowano odstęp między zabiegami dla zastosowania środka w gorczycy i innych roślinach krzyżowych.
2. Skorygowano zarządzanie ryzykiem z zakresu środowiska w zakresie stref ochronnych.

Załącznik do zezwolenia MRiRW nr R - ...../..... z dnia .....

**Posiadacz zezwolenia:**

Nufarm Polska Sp. z o.o., ul. Grójecka 1/3, 02-019 Warszawa, tel.: +48 22 620 32 52,  
fax: +48 22 654 07 97, [www.nufarm.pl](http://www.nufarm.pl)

**Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin**

.....

**Podmiot odpowiedzialny za końcowe etykietowanie środka ochrony roślin**

.....



## JOUST 250 EC

**Środek przeznaczony do stosowania przez użytkowników profesjonalnych**

Zawartość substancji czynnej:

**protiokonazol** (związek z grupy triazoli) - **250 g/l (25,0 %)**

Zezwolenie MRiRW nr R- /202... z dnia . .202.... r.

 	
<b>Uwaga</b>	
H315	Działa drażniąco na skórę.
H319	Działa drażniąco na oczy.
H335	Może powodować podrażnienie dróg oddechowych.
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia. Zawiera protiokonazol; n,n-dimetylo-9-dodekanamid
P261	Unikać wdychania rozpylonej cieczy.
P271	Stosować wyłącznie na zewnątrz lub w dobrze wentylowanym pomieszczeniu.
P280	Stosować rękawice ochronne, odzież ochronną i ochronę oczu.
P302 + P352	W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody z mydłem.
P304 + P340	W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.
P332 + P313	W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

P305 + P351 + P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P391	Zebrać wyciek.

## OPIS DZIAŁANIA

**JOUST 250 EC** jest fungicydem, w formie koncentratu do sporządzania emulsji wodnej (EC) do stosowania zapobiegawczego, interwencyjnego oraz wyniszczającego w zwalczaniu chorób grzybowych zbóż i rzepaku. Jest szybko pobierany przez tkanki rośliny i przemieszczany systemicznie w roślinie.

Środek zawiera substancję czynną: protiokonazol związek z grupy triazoli, inhibitor biosyntezy steroli - inhibitor demetylacji SBI-DMI (grupa FRAC 3 (G1)). ~~W ramach strategii antyodpornościowej zaleca się stosowanie środka Joust 250 EC tylko jako część przyjętego programu ochrony, do którego włączone są środki grzybobójcze, zawierające substancje czynne o innych mechanizmach działania (stosowanie środków przemiennie).~~

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

## STOSOWANIE ŚRODKA

### Jęczmień ozimy:

*Ramularia, ~~łamliwość źdźbła zbóż i traw~~, rdza jęczmienia, mączniak prawdziwy zbóż i traw, rynchosporioza zbóż, ~~fuzarioza kłosów~~, plamistość siatkowa jęczmienia*

Zalecana/maksymalna dawka środka dla jednorazowego zastosowania: 0,6 l l/ha

Środek wykazuje średni poziom skuteczności w zwalczaniu ramularii i mączniaka prawdziwego zbóż i traw.

Liczba zabiegów: 1-2 (~~pojedynczy zabieg jako działanie prewencyjne~~)

Odstęp między zabiegami: 14-21 dni

Termin stosowania środka: ~~środek stosować zapobiegawczo lub bezpośrednio po zauważeniu pierwszych objawów choroby~~ wiosną, w fazie BBCH 30-61

Zalecana ilość wody: **100-400 l/ha.**

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

### Jęczmień jary:

*Ramularia, ~~łamliwość źdźbła zbóż i traw~~, rdza jęczmienia, mączniak prawdziwy zbóż i traw, rynchosporioza zbóż, plamistość siatkowa jęczmienia.*

Zalecana/maksymalna dawka środka dla jednorazowego zastosowania: 0,6 l l/ha

Środek wykazuje średni poziom skuteczności w zwalczaniu mączniaka prawdziwego zbóż i traw **oraz ramularii.**

Liczba zabiegów: 1-2 (~~pojedynczy zabieg jako działanie prewencyjne~~)

Odstęp między zabiegami: 14-21 dni

Termin stosowania środka: ~~środek stosować zapobiegawczo lub bezpośrednio po zauważeniu pierwszych objawów choroby~~, w fazie BBCH 30-61

Zalecana ilość wody: **100-400 l/ha.**

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

### Owies jary i ozimy:

*Rdza koronowa, mączniak prawdziwy zbóż i traw, ~~łamliwość źdźbła zbóż i traw~~*

Zalecana/maksymalna dawka środka dla jednorazowego zastosowania: 0,6 l L/ha

Liczba zabiegów: 1-2

Odstęp między zabiegami: 14-21 dni

Termin stosowania środka: wiosną, BBCH 30-61

Zalecana ilość wody: 100-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

**Pszenica jara i ozima, orkisz, pszenica samopsza, pszenica płaskurka, pszenjęczmień (*Triticordeum*):**

*Septorioza paskowana liści pszenicy, septorioza plew pszenicy, rdza brunatna pszenicy, rdza żółta zbóż i traw, mączniak prawdziwy zbóż i traw, łamliwość źdźbła zbóż i traw, brunatna plamistość liści zbóż, fuzarioza zbóż*

Maksymalna dawka środka dla jednorazowego zastosowania: 0,8 l L/ha

Zalecana dawka środka dla jednorazowego zastosowania: 0,6-0,8 l L/ha

Środek wykazuje średni poziom skuteczności w zwalczaniu septoriozy paskowanej liści pszenicy, brunatnej plamistości liści zbóż i fuzariozy zbóż.

Dawkę środka 0,8 l/ha zaleca się stosować w warunkach wysokiego nasilenia patogenów chorobotwórczych.

Liczba zabiegów: 1-2 (pojedynczy zabieg jako działanie prewencyjne)

Odstęp między zabiegami: 14-21 dni

Termin stosowania środka: środek stosować zapobiegawczo lub bezpośrednio po zauważeniu pierwszych objawów choroby wiosną, w fazie BBCH 30-69

W przypadku ochrony przed fuzariozą zbóż środek stosować od fazy początku kłoszenia.

Zalecana ilość wody: 100-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

**Pszenica durum (twarda):**

*Septorioza paskowana liści pszenicy, rdza brunatna pszenicy, mączniak prawdziwy zbóż i traw, fuzarioza zbóż*

Maksymalna dawka środka dla jednorazowego zastosowania: 0,8 l L/ha

Zalecana dawka środka dla jednorazowego zastosowania: 0,6-0,8 l L/ha

Dawkę środka 0,8 l/ha zaleca się stosować w warunkach wysokiego nasilenia patogenów chorobotwórczych.

Liczba zabiegów: 1-2 (pojedynczy zabieg jako działanie prewencyjne)

Odstęp między zabiegami: 14-21 dni

Termin stosowania środka: środek stosować zapobiegawczo lub bezpośrednio po zauważeniu pierwszych objawów choroby wiosną, w fazie BBCH 30-69

Zalecana ilość wody: 100-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

**Pszenżyto jare i ozime:**

*Septorioza paskowana liści zbóż, rdza brunatna zbóż, rynehosporioza zbóż, rdza żółta zbóż i traw, septorioza plew pszenicy, mączniak prawdziwy zbóż i traw, fuzarioza zbóż*

Maksymalna dawka środka dla jednorazowego zastosowania: 0,8 l L/ha

Zalecana dawka środka dla jednorazowego zastosowania: 0,6-0,8 l L/ha

Środek wykazuje średni poziom skuteczności w zwalczaniu septoriozy paskowanej liści pszenicy i fuzariozy zbóż.

Dawkę środka 0,8 l/ha zaleca się stosować w warunkach wysokiego nasilenia patogenów chorobotwórczych.

Liczba zabiegów: 1-2 (pojedynczy zabieg jako działanie prewencyjne)

Odstęp między zabiegami: 14-21 dni

Termin stosowania środka: środek stosować zapobiegawczo lub bezpośrednio po zauważeniu pierwszych objawów choroby wiosną, w fazie BBCH 30-69

W przypadku ochrony przed fuzariozą zbóż środek stosować od fazy początku kłoszenia.

Zalecana ilość wody: 100-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

#### **Żyto jare i ozime:**

*Septorioza paskowana liści zbóż, rychosporioza zbóż, rdza koronowa, lamliwość źdźbła zbóż i traw, mączniak prawdziwy zbóż i traw, rdza brunatna zbóż*

Maksymalna dawka środka dla jednorazowego zastosowania: 0,8 l l/ha

Zalecana dawka środka dla jednorazowego zastosowania: 0,6-0,8 l l/ha

Dawkę środka 0,8 l/ha zaleca się stosować w warunkach wysokiego nasilenia patogenów chorobotwórczych.

Liczba zabiegów: 1-2 (pojedynczy zabieg jako działanie prewencyjne)

Odstęp między zabiegami: 14-21 dni

Termin stosowania środka: środek stosować zapobiegawczo lub bezpośrednio po zauważeniu pierwszych objawów choroby wiosną, w fazie BBCH 30-69

Zalecana ilość wody: 100-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

#### **Rzepak ozimy:**

*Sucha zgnilizna kapustnych, zgnilizna twardzikowa, mączniak prawdziwy rzepaku, czerń krzyżowych, cylindrosporioza roślin krzyżowych*

Maksymalna dawka środka dla jednorazowego zastosowania: 0,7 l l/ha

Zalecana dawka środka dla jednorazowego zastosowania: 0,6-0,7 l l/ha

Dawkę środka 0,7 l/ha zaleca się stosować w warunkach wysokiego nasilenia patogenów chorobotwórczych.

a) Zabieg dwuetapowy jesienny i wiosenny

Termin stosowania środka: I zabieg jesienią, BBCH 14-18

II zabieg wiosną BBCH 30-69

Liczba zabiegów: 1-2 (pojedynczy zabieg jako działanie prewencyjne)

Odstęp między zabiegami: 90 dni

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

b) zabieg tylko wiosenny

Termin stosowania środka: środek stosować zapobiegawczo lub bezpośrednio po zauważeniu pierwszych objawów choroby wiosną, w fazie BBCH 30-69

Liczba zabiegów: 1-2 (pojedynczy zabieg jako działanie prewencyjne)

Odstęp między zabiegami: 14-28 dni

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

W przypadku ochrony rzepaku ozimego przed zgnilizną twardzikową środek stosować w fazie

**kwitnienia.**

Zalecane opryskiwanie: drobnokropliste.


Zalecana ilość wody: **100-400 l/ha.**


**STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH  
I ZASTOSOWANIACH MAŁOObszarowych**

***Odpowiedzialność za skuteczność działania i fitotoksyczność  
środka ochrony roślin stosowanego w uprawach małoobszarowych  
ponosi wyłącznie jego użytkownik.***

**Rzepak jary**

*Sucha zgnilizna kapustnych, zgnilizna twardzikowa, mączniak prawdziwy rzepaku, czerń krzyżowych,  
cylindrosporioza roślin krzyżowych*

Maksymalna dawka środka dla jednorazowego zastosowania: 0,7 l  /ha

Zalecana dawka środka dla jednorazowego zastosowania: 0,6-0,7 l  /ha

Liczba zabiegów: 1

Termin stosowania środka: BBCH 20-69


Zalecana ilość wody: **100-400 l/ha.**


Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

**Len**

*Mączniak prawdziwy lnu*

Maksymalna dawka środka dla jednorazowego zastosowania: 0,7 l  /ha

Zalecana dawka środka dla jednorazowego zastosowania: 0,6-0,7 l  /ha

Liczba zabiegów: 1-2

Odstęp między zabiegami: 14-28 dni

Termin stosowania środka: BBCH 33-51


Zalecana ilość wody: **100-400 l/ha.**

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

**Gorczyca, lnicznik siewny i inne rośliny krzyżowe na nasiona**

*Sucha zgnilizna kapustnych, zgnilizna twardzikowa, mączniak prawdziwy rzepaku, czerń krzyżowych,  
cylindrosporioza roślin krzyżowych*

Maksymalna dawka środka dla jednorazowego zastosowania: 0,7 l  /ha

Zalecana dawka środka dla jednorazowego zastosowania: 0,6-0,7 l  /ha

Liczba zabiegów: 1-2

Odstęp między zabiegami: ~~14-28~~ **90** dni

Termin stosowania środka: I zabieg jesienią, BBCH 14-18

II zabieg wiosną BBCH 20-69

Zalecana ilość wody: **100-400 l/ha.**

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

### UWAGI

1. Informujemy że środek może powodować przemijające objawy fitotoksyczności (~~skarłowacenia, przebarwienia zmniejszenie objętości łanu~~) na roślinach rzepaku ozimego, które jednak nie wpływają negatywnie na jakość i ilość plonu.

2. Strategia antyodpornościowa:

W ramach zapobiegania zjawisku uodporniania się patogenów chorobotwórczych na stosowany środek ochrony roślin, zaleca się poniższe zabiegi:

- środek stosować maksymalnie 2 razy w sezonie wegetacyjnym, w rotacji z innymi środkami zawierającymi substancje czynne należące do innych grup chemicznych o odmiennym mechanizmie działania

- nie przekraczać maksymalnej zalecanej dawki środka

- dostosować dawkę środka do poziomu nasilenia patogenów chorobotwórczych na chronionej uprawie

- środek stosować w fazie BBCH wskazanej w etykiecie

- ~~prowadzić lustracje celem wykrycia objawów braku działania środka~~ monitorować skuteczność działania celem wykrycia objawów odporności na środek zgodnie z zaleceniami integrowanej ochrony roślin

- w miarę możliwości uprawiać odmiany odporne

- przestrzegać zaleceń dobrej praktyki rolniczej

### ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

Jęczmień ozimy, jęczmień jary, owies jary i ozimy, pszenica jara, pszenica ozima, orkisz, pszenica samopsza, pszenica płaskurka, pszenjęczmień (Tritordeum), pszenica durum, pszenżyto jare i ozime, żyto jare i ozime – **35 dni**

Rzepak jary i ozimy, gorczyca, ~~len~~, lnicznik siewny i inne Krzyżowe na nasiona – **56 dni**

Len przeznaczony na włókno – nie dotyczy

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:

Nie dotyczy

W sytuacji, gdy w przyjętym programie ochrony zaplanowano wykonanie tylko jednego zabiegu środkiem, w celu uzyskania zadowalającej skuteczności zabieg ten należy wykonać zapobiegawczo (prewencyjnie).

Środek zaleca się stosować w temperaturze powietrza powyżej 12°C.

### SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem. Przed użyciem wstrząsnąć zawartością opakowania.

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 mieszałem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszało 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 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 - należy dokładnie wypłukać zbiornik wodą, następnie zastosować środek zalecany do mycia opryskiwaczy, wypłukać i następnie po raz trzeci wypłukać wodą zbiornik i układ opryskiwacza.

W przypadku mycia aparatury przy użyciu środków myjących przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować zgodnie z instrukcją dołączoną do środka myjącego.

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

## **ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

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

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

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

~~Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, w trakcie przygotowywania cieczy użytkowej.~~

~~Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, w trakcie wykonywania zabiegu.~~

Nie wdychać rozpylonej cieczy użytkowej.

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.

**Zboża ozime i jare, len:**

W celu ochrony organizmów wodnych konieczne jest wyznaczenie nieopryskiwanej strefy ochronnej o szerokości 20 m, zadarnionej na szerokości 20 m, od zbiorników i cieków wodnych.

Rzepak ozimy i jary, gorczyca, Inicznik siewny i inne rośliny krzyżowe na nasiona

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

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości ~~5~~ **1** m od terenów nieużytkowanych rolniczo.

## **WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- 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 połknięcia natychmiast wypłukać usta wodą - nigdy nie wykonywać u osób nieprzytomnych.

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 złego samopoczucia skontaktować się z ośrodkiem zatruc lub lekarzem.

Okres ważności - 2 lata

Data produkcji - .....

Zawartość netto - .....

Nr partii - .....



## Appendix 3 Letter of Access



MINISTERSTWO ROLNICTWA I ROZWOJU WSI  
Departament Klimatu i Środowiska  
ul. Wspólna 30  
00-930 Warszawa  
Poland

### Letter of Access Prothioconazole Study Reports

Dear Sir / Madam,

Bayer AG Crop Science Division (BAYER), Alfred-Nobel-Straße 50, 40789 Monheim am Rhein, Germany, herewith confirms that it has granted to **Nufarm Polska Sp. z o. o.**, ul. Grójecka 1/3, 02-019 Warszawa, Poland ("RECEIVING PARTY"), rights of access to the study reports listed in the attached reference list ("Study Reports"), which are owned by BAYER.

BAYER hereby agrees that **MINISTERSTWO ROLNICTWA I ROZWOJU WSI** (the Competent Registration Authority) may refer to the aforementioned Study Reports for the registration/application of the crop protection product **Joust** ("Purpose").

Product Name	Formulation Type	Content of active substance	Registration number
Joust	EC	250 g/L Prothioconazole	pending

RECEIVING PARTY may use the reference to the Study Reports solely to support its individual product risk assessments in relation to crop protection products for which they are either (a) the registration applicant or (b) the holder of a registration.

December 2, 2021

Dr. Karsten Strösch

Bayer AG  
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Supervisory Board:  
Norbert Winkelhahn

Registered Office:  
Leverkusen  
Local Court of Cologne  
HRB 46248

## **Appendix 4   Lists of data considered for national authorization**

The list has been provided as a separate document.