Bayer CropScience

Document Title

Summary of the fate and behaviour in the environment Prothioconazole FS 100 (100 g/L)

Data Requirements

EU Regulation 1107/2009 & EU Regulation 284/2013 Document MCP Section 9: Fate and behaviour in the environment

According to the guidance document, SANCO 10181/2013, for preparing dossiers for the approval of a chemical active substance

Date

2015-12-07

Author(s)

[redacted]

Bayer CropScience

[redacted]

[redacted]

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Version history

Date	Data points containing amendments or additions[1] and brief description	Document identifier and version number

[1] It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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CP 9 FATE AND BEHAVIOUR IN THE ENVIRONMENT

Introduction

A dossier on prothioconazole (CAS No. 178928-70-6) was submitted February 2002 by Bayer CropScience to the EU RMS United Kingdom for agricultural use as a fungicide. Prothioconazole was included into Annex I of the Council Directive 91/414/EEC by the Commission Directive 2008/44/EC published 4 April 2008, with an entry into force by 1 August 2008.

This Supplemental Dossier contains only detailed summaries of studies, which were not part of the dossier during the first Annex I inclusion of prothioconazole and were, therefore, not evaluated during the first EU review of this compound. In order to facilitate discrimination between new and old information, the new information is written in black letters whereas *grey letters describe the old information.*

All studies, which have been already submitted by Bayer CropScience for the first Annex I inclusion, are contained in the Monograph and its Addenda and are included in the Baseline dossier provided by Bayer CropScience. The summaries on the different endpoints were taken from the Monograph and its Addenda and supplemented with new information (new studies, references, further comments).

A synonymous name for prothioconazole used at several locations in this supplementary dossier is JAU 6476.

The representative formulation (spray use) submitted in the first Annex I listing process is no longer considered as a representative formulation for the renewal of approval of prothioconazole. One of the representative formulations used for the submission of the renewal of the approval of prothioconazole is the seed treatment formulation Prothioconazole FS 100 The summaries of formulation studies and the risk assessment will be presented in this Dossier.

In this Dossier only endpoints used for the risk assessment are presented. For an overview of all available endpoints for prothioconazole and its metabolites please refer to the respective section of the MCA document. In order to facilitate discrimination between new and information submitted during the Annex I inclusion process, the previously evaluated information is written in grey letters.

Use pattern considered in the environmental exposure and risk assessment

Table CP 9- 1: Intended application pattern

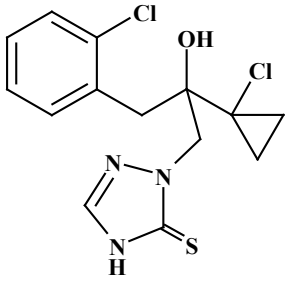
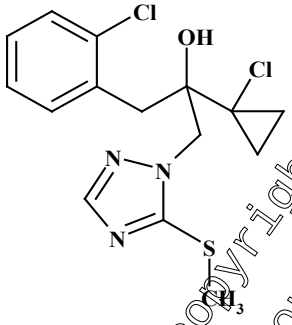
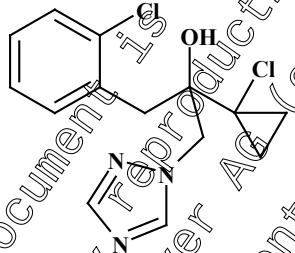
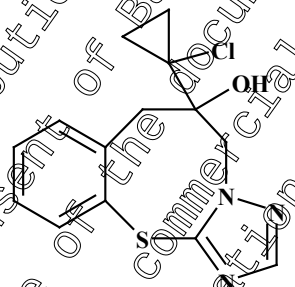
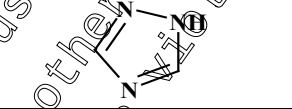
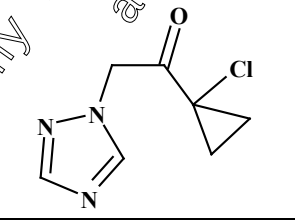
Crop	Timing of application	Number of applications	Max. application rate, individual treatment [g a.s./ha] Prothioconazole*
Wheat (spring, winter), Barley (spring, winter), Oat, Spelt, Triticale	Seed treatment BBCH 00	1	18

* Maximum label rate: 0.180 L prod./ha; seeding rate: 180 kg seeds/ha; 0.100 L product/100 kg seeds (i.e. 10 g a.s./100 kg seeds)

Compounds addressed in this document

In addition to the active substance prothioconazole, the degradation products summarised in Table 9- 2 were addressed in this document as they have to be considered for exposure assessments.

Table CP 9- 2: Active substance and degradation products addressed in this document

Compound / Codes	Chemical structure	Considered for
Prothioconazole (JAU 6476)		PEC_{soil} PEC_{gw} PEC_{sw} & PEC_{sed}
JAU 6476-S-methyl (M01)		PEC_{soil} PEC_{gw} PEC_{sw} & PEC_{sed}
JAU 6476-desthio (M04)		PEC_{soil} PEC_{gw} PEC_{sw} & PEC_{sed}
JAU 6476-thiazocine (M12)		PEC_{sw} & PEC_{sed}
1,2,4-triazole (M13)		PEC_{sw} & PEC_{sed}
JAU 6476-triazolylketone (M42)		PEC_{sw} & PEC_{sed}

A list of metabolites, which contains the structures, the synonyms and code numbers attributed to the compound prothioconazole, is presented in Document N3 of this dossier.

Definition of the residue for risk assessment

Justification for the residue definition for risk assessment is provided by MCA Section 7.

Table CP 9- 3: Definition of the residue for risk assessment

Compartment	Residue definition for risk assessment
Soil	Prothioconazole, JAU 6476-S-methyl *(M01)* and JAU 6476-desthio *(M04)*
Groundwater	Prothioconazole, JAU 6476-S-methyl *(M01)* and JAU 6476-desthio *(M04)*
Surface water	Prothioconazole, JAU 6476-S-methyl *(M01)*, JAU 6476-desthio *(M04)*, JAU 6476-thiazocine *(M12)*, 1,2,4-triazole *(M13)* and JAU 6476-triazolylketone *(M42)*
Sediment	Prothioconazole, JAU 6476-S-methyl *(M01)*, JAU 6476-desthio *(M04)*, JAU 6476-thiazocine *(M12)*, 1,2,4-triazole *(M13)* and JAU 6476-triazolylketone *(M42)*
Air	Prothioconazole and JAU 6476-desthio *(M04)*

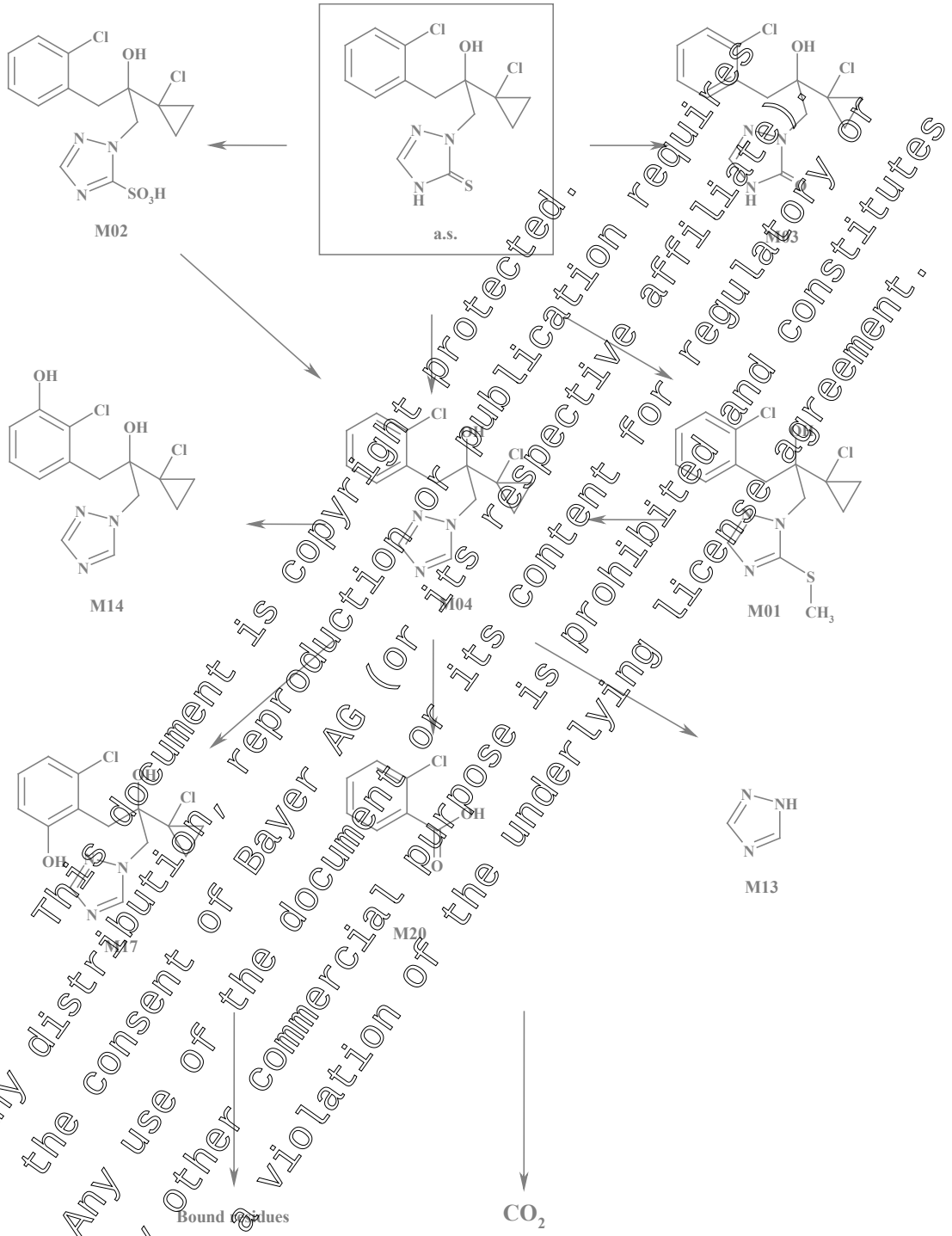
*Justification for the residue definition for risk assessment is provided in MCA Sec.7, Point 7.4.1

CP 9.1 Fate and behaviour in soil

For information on the fate and behaviour in soil please refer to MCA Section 7, data point 7.1.

The proposed degradation pathway of prothioconazole in soil is shown in Figure CP 9.1- 1.

Figure CP 9.1- 1: Proposed degradation pathway of prothioconazole in soil under laboratory conditions considering all routes of soil degradation and lysimeter studies.



a.s. = prothioconazole
M01 = JAU 6476-S-methyl
M02 = JAU 6476-sulfonic acid
M03 = JAU 6476-triazolinone
M04 = JAU 6476-desthio
M13 = 1,2,4-triazole
M14 = JAU 6476-desthio-3-hydroxy
M17 = JAU 6476-desthio-6-hydroxy
M20 = 2-chlorobenzoic acid

CP 9.1.1 Rate of degradation in soil

No specific studies with the formulation are required. For further information on the fate and behaviour in soil please refer to MCA Section 7, data points 7.1.1 and 7.1.2.

CP 9.1.1.1 Laboratory studies

For information on laboratory studies please refer to MCA Section 7, data point 7.1.2.1.

CP 9.1.1.2 Field studies

For information on field studies please refer to MCA Section 7, data point 7.1.2.2.

CP 9.1.1.2.1 Soil dissipation studies

For information on field dissipation studies please refer to MCA Section 7, data point 7.1.2.2.1.

CP 9.1.1.2.2 Soil accumulation studies

For information on field accumulation studies please refer to MCA Section 7, data point 7.1.2.2.2.

CP 9.1.2 Mobility in the soil

For information on mobility studies please refer to MCA Section 7, data point 7.1.4.

CP 9.1.2.1 Laboratory studies

For information on laboratory studies please refer to MCA Section 7, data point 7.1.4.1

CP 9.1.2.2 Lysimeter studies

For information on lysimeter studies please refer to MCA Section 7, data point 7.1.4.2.

CP 9.1.2.3 Field leaching studies

For information on field leaching studies please refer to MCA Section 7, data point 7.1.4.3.

CP 9.1.3 Estimation of concentrations in soil

New calculations were performed to reflect findings from new studies presented in the active substance dossier, section 7 "Fate and behaviour in the environment". In addition these calculations considered the most recent guidance documents for exposure calculations. Calculations of predicted environmental concentrations in soil (PEC_{soil}) are presented below.

Predicted environmental concentrations in soil (PEC_{soil})

Endpoints for PEC_{soil}

For deriving the respective end points please refer to MCA Section 7, data point 7.1.

Table CP 9.1.3- 1: Key modelling input parameters for prothioconazole and its metabolites

Compound	Worst case DT_{50} non-normalised [days]	Maximum occurrence in soil [%]	Molar mass [g/mol]	Molar mass correction factor
Prothioconazole	1.6	100	344.3	1
JAU 6476-S-methyl	280	14.2	358.3	1.0407
JAU 6476-desthio	63.4	56	312.2	0.9068

Report: KCP 9.1.3/03 [redacted] A, 2015, M-536053-01-1
Title: Prothioconazole (PTZ) and metabolites: PECsoil EUR - Use in cereals as spray application and as seed treatment in Europe
Report No.: EnSa-15-0492
Document No.: M-536053-01-1
Guideline(s): not applicable
Guideline deviation(s): not applicable
GLP/GEP: **no**

Methods and Materials: The predicted environmental concentrations in soil (PEC_{soil}) of prothioconazole and its metabolites were estimated based on a first tier approach using a Microsoft® Excel spreadsheet. A bulk density of 1.5 kg/L and a soil mixing depths of 5 cm were used as recommended by FOCUS (1997) and EU Commission (1995, 2000). The accumulation potential of prothioconazole and metabolites after long term use was also assessed, employing the mixing depth of 20 cm for the calculation of the background concentration.
Detailed application data used for simulation of PEC_{soil} were compiled in Table CP 9.1.3- 2.

Table CP 9.1.3- 2: Application pattern used for PEC_{soil} calculations of prothioconazole

Individual crop	FOCUS crop used for interception	Application				Amount reaching soil per season application [g a.s./ha]
		Rate per season [g a.s. /ha]	Interval [days]	Plant interception [%]	BBCH stage	
Winter & spring cereals (seed treatment), GAP	-	1 × 18	-	-	00	-
Winter cereals (seed treatment), simulation	Winter cereals	1 × 18	-	-	00	1 × 18.0
Spring cereals (seed treatment), simulation	Spring cereals	1 × 18	-	-	00	1 × 18.0

Substance Specific Parameters: The compound specific input parameters (end points for PEC_{soil} calculations) are summarized in Table CP 9.1.3- 1.

Findings: The maximum PEC_{soil} values for prothioconazole and its metabolites are summarised in Table CP 9.1.3- 3. The maximum, short-term and long-term PEC_{soil} values and the time weighted average values ($TWAC_{soil}$) are provided thereafter.

Table CP 9.1.3- 3: Maximum PEC_{soil} of prothioconazole and its metabolites for the uses assessed

	Prothioconazole	S-methyl	Desthio
Use Pattern	**PEC_{soil} [mg/kg]**	**PEC_{soil} [mg/kg]**	**PEC_{soil} [mg/kg]**
Winter and spring cereals Seed treatment	0.024	0.004	0.012

Table CP 9.1.3- 4: PEC_{soil} (actual) of prothioconazole and its metabolites

	Time [days]	Winter and spring cereals (seed treatment) 1×18 g a.s./ha, 0% interception		
		Prothioconazole	S-methyl	Desthio
		PEC_{soil} [mg/kg]	PEC_{soil} [mg/kg]	PEC_{soil} [mg/kg]
Initial	0	0.024	0.004	0.012
Short term	1	0.016	0.004	0.012
	2	0.010	0.004	0.012
	4	0.004	0.004	0.012
Long term	7	0.001	0.003	0.011
	14	<0.001	0.003	0.010
	21	<0.001	0.003	0.010
	28	<0.001	0.003	0.009
	42	<0.001	0.003	0.008
	50	<0.001	0.003	0.007
	100	<0.001	0.003	0.004

Table CP 9.1.3- 5: $TWAC_{soil}$ of prothioconazole and its metabolites

	Time [days]	Winter and spring cereals (seed treatment) 1×18 g a.s./ha, 0% interception		
		Prothioconazole	S-methyl	Desthio
		$TWAC_{soil}$ [mg/kg]	$TWAC_{soil}$ [mg/kg]	$TWAC_{soil}$ [mg/kg]
Initial	0	---	---	---
Short term	1	0.019	0.004	0.012
	2	0.016	0.004	0.012
	4	0.011	0.004	0.012
Long term	7	0.008	0.004	0.012
	14	0.004	0.003	0.011
	21	0.003	0.003	0.011
	28	0.002	0.003	0.011
	42	0.001	0.003	0.010
	50	0.001	0.003	0.009
	100	<0.001	0.003	0.007

Potential accumulation in soil:

The accumulation potential after long term use was also assessed. The results for a standard-mixing depth of 20 cm for an arable crop with tillage are presented in Table CP 9.1.3- 6.

Table CP 9.1.3- 6: PEC_{soil} of prothioconazoleand its metabolites taking the effect of accumulation into account (mixing (tillage) depth of 20 cm)

Use Pattern		Prothioconazole	S-methyl	Desthio
	PEC_{soil}	[mg/kg]	[mg/kg]	[mg/kg]
Winter and spring cereals (seed treatment), 1×18 g a.s./ha, 0% interception	plateau	<0.001	<0.001	<0.001
	total*	0.024	0.004	0.012

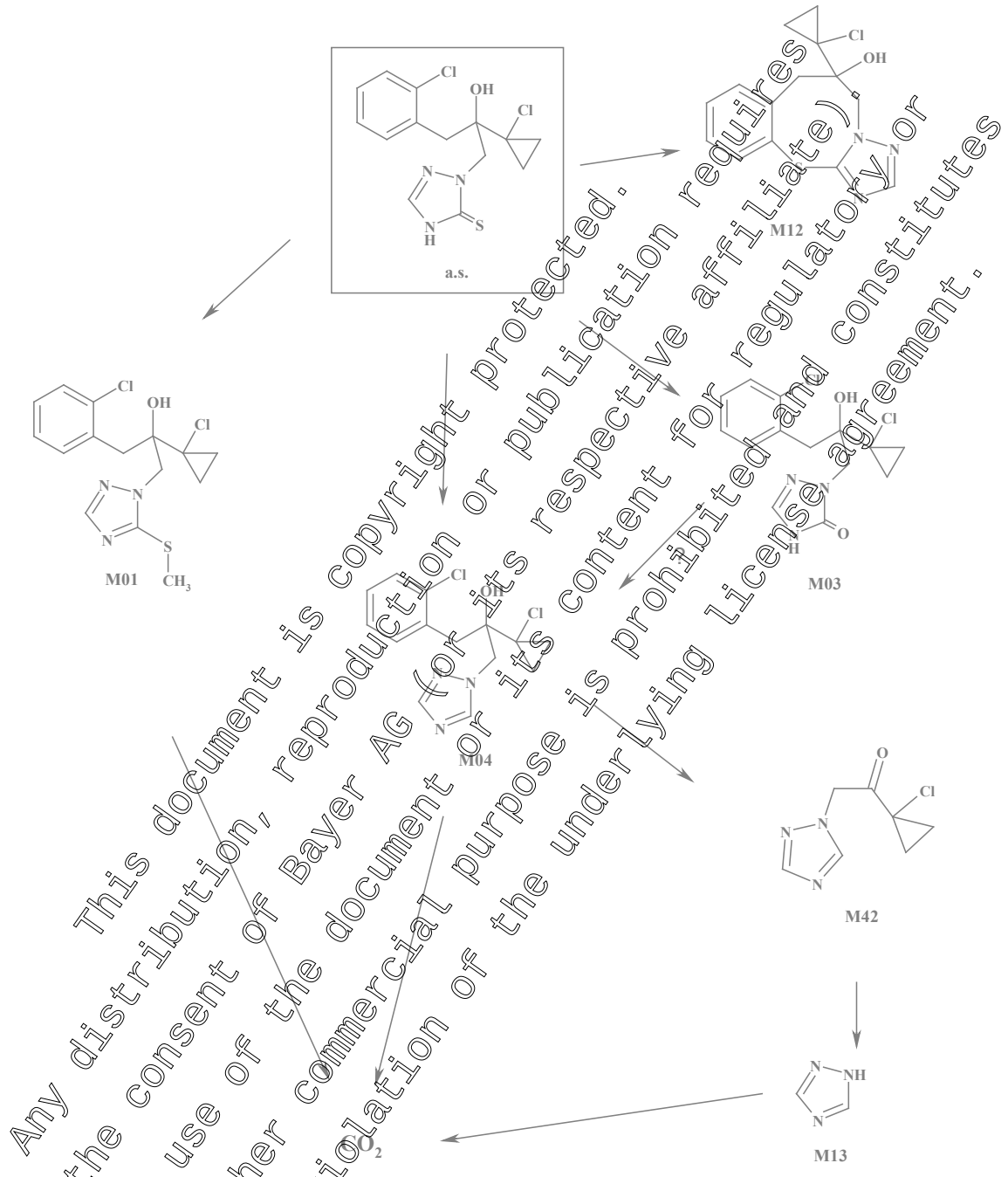
* total = plateau (background concentration after multi-year use) + max. PEC_{soil} (see Table CP 9.1.3- 3)

CP 9.2 Fate and behaviour in water and sediment

The proposed degradation pathway of prothioconazole in water and sediment is shown in Figure CP 9.2- 1.

Specific studies with the formulation have not been performed and are not required. For information on the fate and behaviour in water and sediment please refer to MCA Section 7, data point 7.2.

Figure CP 9.2- 1: **Proposed bio-degradation pathway of prothioconazole (JAU 6476-desthio) in water and sediment (major degradation products)**



CP 9.2.1 Aerobic mineralisation in surface water

For information on aerobic mineralisation in surface water studies please refer to MCA Section 7, data point 7.2.2.2.

CP 9.2.2 Water/sediment study

For information on water/sediment studies please refer to MCA Section 7, data point 7.2.2.3.

CP 9.2.3 Irradiated water/sediment study

For information on irradiated water/sediment studies please refer to MCA Section 7, data point 7.2.2.4.

CP 9.2.4 Estimation of concentrations in groundwater

Calculations were performed, to reflect findings from new studies presented in the active substance dossier, section 7 "Fate and behaviour in the environment". In addition these calculations consider the most recent guidance documents for exposure calculations.
Calculations of predicted environmental concentrations in groundwater (PEC_{gw}) are presented below.

Endpoints for PEC_{gw}

For deriving the respective end points please refer to MCA Section 7, data point 7.1.

Table CP 9.2.4.1- 1: Compound input parameters for prothioconazole and its metabolites

Parameter	Unit	Prothioconazole	S-methyl	Desthio
Common				
Molar Mass	[g/mol]	344.3	58.3	312.2
Solubility	[mg/L]	22.5	4.6	50.6
Vapour Pressure	[Pa]	1.00E-10	8.20E-06	1.00E-10
Freundlich Exponent		1.000	0.880	0.810
Plant Uptake Factor		0.0	0.0	0.0
Walker Exponent		0.7	0.7	0.7
PEARL Parameters				
Substance Code		PTZ	Smet	Des
DT_{50}	[days]	0.90	46.4	24.7
Molar Activ. Energy	[kJ/mol]	65.4	65.4	65.4
K_{om}	[mL/g]	1024.0	1465.0	332.7
PELMO Parameters				
Substance Code		AS	A1	B1
Rate Constant	[1/day]	0.77009	0.02806	0.01494
Q_{10}		2.58	2.58	2.58
K_{oc}	[mL/g]	1765.0	2526.0	573.5

Table CP 9.2.4.1- 2: Degradation pathway related parameters for prothioconazole and its metabolites

Degradation fraction from → to (FOCUS PEARL)	0.11 PTZ -> Smet 0.49 PTZ -> Des 1 Smet -> Des
Degradation rate from → to (FOCUS PELMO)	0.3773080 Active Substance -> A1 0.0847180 Active Substance -> B1 0.3080650 Active Substance -> <BR/CO_2 0.0280630 A1 -> B1 0.0149390 B1 -> <BR/CO_2

CP 9.2.4.1 Calculation of concentrations in groundwater

Predicted environmental concentrations in soil (PEC_{gw})

Report: KCP 9.2.4.1/02[redacted]; 2015; M-536056-01-1
Title: Prothioconazole (PTZ) and metabolites: PEC gw FOCUS PEARL, PELMO EUR - Use in cereals as spray application and as seed treatment in Europe
Report No.: EnSa-15-0491
Document No.: M-536056-01-1
Guideline(s): not applicable
Guideline deviation(s): not applicable
GLP/GEP: **no**

The predicted environmental concentrations in groundwater (PEC_{gw}) for prothioconazole and its metabolites were calculated using the simulation model FOCUS PEARL (version 4.4.4) and FOCUS PELMO (version 5.5.3). Crop interception was taken into account according to the BBCH growth stage, as recommended by FOCUS (2014). Application dates for the simulation runs were defined following the crop event dates of the respective crop and scenario as given by FOCUS (2000, 2009).

Detailed application data used for simulation of PEC_{gw} were compiled in the following table.

Table CP 9.2.4.1- 3: Application pattern used for PEC_{gw} calculations

Individual crop	FOCUS crop used for interception	Application				Amount reaching soil per season application [g a.s./ha]
		Rate per season [g a.s./ha]	Interval [days]	Plant interception [%]	BBCH stage	
Winter & spring cereals (seed treatment), GAP	-	1 × 18	-	-	00	-
Winter cereals (seed treatment), simulation	Winter cereals	1 × 18	-	0	00	1 × 18
Spring cereals (seed treatment), simulation	Spring cereals	1 × 18	-	0	00	1 × 18

For cereal applications, absolute dates were derived for the simulation runs. All application dates are summarised in the table below.

Table CP 9.2.4.1- 4: First application dates and related information for prothioconazole as used for the simulation runs

Individual crop	**Winter cereals**	**Spring cereals**
Repeat Interval for App. Events	Every Year	Every Year
Application Technique	Incorp. [4 cm]	Incorp. [4 cm]
Absolute / Relative to	Planting	Planting
Scenario	1st App. Date/(Julian day)	1st App. Date/(Julian day)
Chateaudun	20 Oct/(293)	20 Feb/(51)
Hamburg	12 Oct/(285)	10 Mar/(69)
Jokioinen	10 Sep/(253)	07 May/(127)
Kremsmuenster	25 Oct/(298)	10 Mar/(69)
Okehampton	07 Oct/(280)	25 Mar/(84)
Piacenza	25 Nov/(329)	-
Porto	15 Nov/(319)	20 Feb/(51)
Sevilla	15 Nov/(319)	-
Thiva	15 Nov/(319)	-

Findings: PEC_{GW} were evaluated as the 80th percentile of the mean annual leachate concentration at 1 m soil depth. FOCUS PEARL and PELMO PEC_{gw} results for prothioconazole and its metabolites after application to winter cereals and spring cereals are given in Table CP 9.2.4.1- 5

Table CP 9.2.4.1- 5: Winter & spring cereals: FOCUS PEARL & PELMO PEC_{gw} results of prothioconazole and its metabolites

Use Pattern	**Winter cereals (seed treatment), 1 × 18 g a.s./ha**			**Spring cereals (seed treatment), 1 × 18 g a.s./ha**		
	PTZ*	**S-methyl**	**Desthio**	**PTZ***	**S-methyl**	**Desthio**
FOCUS PEARL	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Kremsmuenster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Piacenza	<0.001	<0.001	<0.001	-	-	-
Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Sevilla	<0.001	<0.001	<0.001	-	-	-
Thiva	<0.001	<0.001	<0.001	-	-	-
FOCUS PELMO	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Kremsmuenster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Piacenza	<0.001	<0.001	<0.001	-	-	-
Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Sevilla	<0.001	<0.001	<0.001	-	-	-
Thiva	<0.001	<0.001	<0.001	-	-	-

* PTZ = prothioconazole

Conclusion: There are no concerns for groundwater from the use of prothioconazole in accordance with the use pattern for the representative formulation.

CP 9.2.4.2 Additional field tests

No additional field studies were performed or required due to low PEC_{gw} values calculated (see CP 9.2.4.1).

CP 9.2.5 Estimation of concentrations in surface water and sediment

Calculations were performed considering the most recent guidance documents for exposure calculations and taking into account the residue definition derived from the environmental fate studies on MCA Section 7.

Calculations of predicted environmental concentrations in surface water (PEC_{sw}) for prothioconazole and its metabolites are presented below.

Table CP 9.2.5- 1: Key modelling input parameters for prothioconazole and its metabolites at Steps 1/2 level PEC calculations

Parameter	Unit	Prothioconazole	JAU 6476-Desthio	JAU 6476-S-Methyl	1,2,4-Triazole	Thiazocine	Triazolylketone
Molar Mass	g/mol	344.26	312.2	358.3	69.1	307.8	185.7
Water Solubility	mg/L	22.5	50.6	4.6	100000	20	1000000
Koc	mL/g	1765	5725	2526	83	165	1
Degradation							
Soil	days	1.4	39.6	62.6	1000	1000	1000
Total System	days	14.2	55.6	80.7	1000	1000	1000
Water	days	1.2	20	10.4	1000	122.1	1000
Sediment	days	80.1	57	53.6	1000	1000	1000
Max Occurrence							
Water / Sediment	%	100	54.5	12.7	41.8	15.2	9.1
Soil	%	100	56.2	14.2	0.0001	0.0001	0.0001

Table CP 9.2.5- 2: Additional modelling input parameters for prothioconazole and its metabolites at Steps 3/4 level PEC calculations

Parameter	Unit	Prothioconazole	JAU 6476-desthio
SWASH code		PTZ	Des
General			
Molar mass	g/mol	344.3	312.2
Water solubility (temp.)	mg/L	22.5 (20 °C)	50.6 (20 °C)
Vapour pressure (temp.)	Pa	1E-10 (20 °C)	1E-10 (20 °C)
Crop processes			
Coefficient for uptake by plant (TSCF)	-	0	0
Wash-off factor	1/m	50	50
Sorption			
KOC	mL/g	1765.38	573.57
KOM	mL/g	1024	332.7
Freundlich exponent (1/n)	-	1	0.81
Transformation			
DT50 in soil	days	0.9	24.7
temperature	°C	20	20
moisture content (relative to)	%	-	
pF	log(cm)	2	2
formation fraction in soil	-		0.6
DT50 in water	days	14.2	55.6
temperature	°C	20	20
formation fraction in water	-		0.638
DT50 in sediment	days	1000	1000
temperature	°C	20	20
formation fraction in sediment	-		0.638
DT50 on canopy	days	10	4
Exponent for the effect of moisture			
PRZM and TOXSWA (Walker exp.)	-	0.7	0.7
MACRO (calibrated value)		0.49	0.49
Effect of temperature			
TOXSWA (molar activation energy)	kJ/mol	65.4	65.4
MACRO (effect of temperature)	1/K	0.0948	0.0948
PRZM (Q10)	-	2.58	2.58

Predicted environmental concentrations in water (PEC_{sw}) and sediment (PEC_{sed})

Report: KCP 9.2.5/08 [redacted]; 2015; M-536157-01-1
Title: Prothioconazole (PTZ) and metabolites: PECsw,sed FOCUS EUR - Use in winter and spring cereals in Europe
Report No.: EnSa-15-0840
Document No.: M-536157-01-1
Guideline(s): not applicable
Guideline deviation(s): not applicable
GLP/GEP: **no**

Materials and Methods: Predicted environmental concentrations in surface water and sediment (PEC_{sw} and PEC_{sed}) of prothioconazole and its metabolites have been calculated for the use in winter and spring cereals in Europe. The relevant entry paths can differ based on the intended application type, e.g., spray drift is not relevant for seed treatments.

At FOCUS Step 2 the application period was set to October to February for winter cereals and to March to May for spring cereals. Additioanlly, the use in Northern and Southern Europe was considered. Details of the application pattern used in the Step 2 calculations are summarised in Table CP 9.2.5- 3.

Table CP 9.2.5- 3: Application pattern used for $PEC_{sw,sed}$ calculations at FOCUS Steps 1&2

Crop	Rate [g a.s./ha]	Interval [days]	BBCH stage	FOCUS crop (crop group)	Season	Crop cover
Winter cereals, GAP & simulation	1 × 18	-	00	no drift (incorp or seed trtmt) (arable crops)	Autumn (Oct. - Feb.)	no interception
Spring cereals, GAP & simulation	1 × 18	-	00	no drift (incorp or seed trtmt) (arable crops)	Spring (Mar. - May)	no interception

In FOCUS Step 3, the application date for each scenario is determined by the Pesticide Application Timer (PAT), which is part of the FOCUS SW Scenarios. The user may only define an application time window. The actual application date is then set by the PAT in such a way that there are at least 10 mm of rainfall in the first 10 days after application, and at the same time less than 2 mm of rain per day in a five day period around the date of application. If no such date can be found within the application time window, the above rules are step-wise relaxed. Details of the parameters used in the Step 3 calculations are summarised in Table CP 9.2.5- 4.

Table CP 9.2.5- 4: Application dates of prothioconazole for the FOCUS Step 3 calculations

Parameter	Winter cereals		Spring cereals	
PAT start date rel./absolute Appl. method (appl. type) PAT window range	Emergence, -10 days Soil Incorp. (CAM 8 - incorp soil at one depth, 4 cm) 30		Emergence, -10 days Soil Incorp. (CAM 8 - incorp soil at one depth, 4 cm) 30	
Application Details	PAT Start/End Date (Julian Day)	Appl. Date	PAT Start/End Date (Julian Day)	Appl. Date
D1 Ditch/Stream	15-Sep/15-Oct (258/288)	15.Sep	25-Apr/25-May (115/145)	25.Apr
D2 Ditch/Stream	15-Oct/14-Nov (288/318)	15.Oct		
D3 Ditch	11-Nov/11-Dec (315/345)	14.Nov	22-Mar/21-Apr (81/111)	04.Apr
D4 Pond/Stream	12-Sep/12-Oct (255/285)	12.Sep	16-Apr/16-May (106/136)	18.Apr
D5 Pond/Stream	31-Oct/30-Nov (304/334)	27.Nov	05-Mar/04-Apr (64/94)	07.Mar
D6 Ditch	20-Nov/20-Dec (324/354)	06.Dec		
R1 Pond/Stream	02-Nov/02-Dec (306/336)	14.Nov		
R3 Stream	21-Nov/21-Dec (325/355)	21.Nov		
R4 Stream	31-Oct/30-Nov (304/334)	03.Nov	05-Mar/04-Apr (64/94)	05.Mar

Compound input parameters for the Steps 1&2 simulation runs are summarised in Table CP 9.2.5- 1 and for the Steps 3&4 simulation runs in Table CP 9.2.5- 2.

Findings: Steps 1&2: The maximum PEC_{sw}, PEC_{sed} and 21d-TWA_{SW} values for prothioconazole and its metabolites at Steps 1&2 are summarised in Table CP 9.2.5- 5.

Table CP 9.2.5- 5: Maximum PEC_{sw} and PEC_{sed} values and 21d-TWA_{SW} values for prothioconazole and its metabolites at Steps 1&2

Use pattern	Scenario	Prothioconazole			JAU 6476-desthio			JAU 6476-S-methyl		
		PEC_{sw} [µg/L]	21d-TWA [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	21d-TWA [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	21d-TWA [µg/L]	PEC_{sed} [µg/kg]
Winter cereals 1 × 18 g a.s./ha	Step 1	1.789	1.119	31.58	3.441	3.028	19.73	0.385	0.352	9.714
	Step 2									
	N-EU Single	0.124	0.026	2.179	0.937	0.723	5.372	0.110	0.082	2.769
	S-EU Single	0.099	0.021	1.743	0.749	0.578	4.298	0.088	0.066	2.216
Spring cereals 1 × 18 g a.s./ha	Step 1	1.789	1.119	31.58	3.441	3.028	19.73	0.385	0.352	9.714
	Step 2									
	N-EU Single	0.049	0.010	0.872	0.375	0.289	2.149	0.044	0.033	1.108
	S-EU Single	0.099	0.021	1.743	0.749	0.578	4.298	0.088	0.066	2.216

Table CP 9.2.5- 6: Maximum PEC_{sw} and PEC_{sed} values and 21d-TWA_{SW} values for prothioconazole and its metabolites at Steps 1&2 (contd.)

Use pattern	Scenario	1,2,4-triazole			Thiazocine			Triazolylketone		
		PEC_{sw} [µg/L]	21d-TWA [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	21d-TWA [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	21d-TWA [µg/L]	PEC_{sed} [µg/kg]
Winter cereals 1 × 18 g a.s./ha	Step 1	0.453	0.450	0.376	0.668	0.664	1.103	0.294	0.292	0.003
	Step 2									
	N-EU Single	0.031	0.031	0.026	0.046	0.044	0.076	0.020	0.020	<0.001
	S-EU Single	0.025	0.025	0.021	0.037	0.036	0.061	0.016	0.016	<0.001
Spring cereals 1 × 18 g a.s./ha	Step 1	0.453	0.450	0.376	0.668	0.664	1.103	0.294	0.292	0.003
	Step 2									
	N-EU Single	0.013	0.012	0.010	0.018	0.018	0.030	0.008	0.008	<0.001
	S-EU Single	0.025	0.025	0.021	0.037	0.036	0.061	0.016	0.016	<0.001

Step 3: The maximum PEC_{sw} and PEC_{sed} values of prothioconazole and its metabolite JAU 6476-desthio for relevant FOCUS Step 3 scenarios are given in the table below.

Table CP 9.2.5- 7: Winter cereals: Maximum PEC$_{sw}$ and PEC$_{sed}$ values for prothioconazole and its metabolite JAU 6476-desthio at Step 3

Use pattern	Winter cereals, 1 × 18 g a.s./ha				
		Prothioconazole		JAU 6476-desthio	
FOCUS scenario	Entry route*	PEC$_{sw}$ [µg/L]	PEC$_{sed}$ [µg/kg]	PEC$_{sw}$ [µg/L]	PEC$_{sed}$ [µg/kg]
D1 (Ditch)	D	<0.001	<0.001	<0.001	<0.001
D1 (Stream)	D	<0.001	<0.001	<0.001	<0.001
D2 (Ditch)	D	<0.001	<0.001	<0.001	<0.001
D2 (Stream)	D	<0.001	<0.001	<0.001	<0.001
D3 (Ditch)	D	<0.001	<0.001	<0.001	<0.001
D4 (Pond)	D	<0.001	<0.001	<0.001	<0.001
D4 (Stream)	D	<0.001	<0.001	<0.001	<0.001
D5 (Pond)	D	<0.001	<0.001	<0.001	<0.001
D5 (Stream)	D	<0.001	<0.001	<0.001	<0.001
D6 (Ditch)	D	<0.001	<0.001	<0.001	<0.001
R1 (Pond)	R	<0.001	<0.001	<0.001	<0.001
R1 (Stream)	R	<0.001	<0.001	<0.001	<0.001
R3 (Stream)	R	<0.001	<0.001	<0.001	<0.001
R4 (Stream)	R	<0.001	<0.001	<0.001	<0.001

* Entry route: letters D, and R correspond to the dominant entry path – drainage, and runoff.

Table CP 9.2.5- 8: Spring cereals: Maximum PEC$_{sw}$ and PEC$_{sed}$ values for prothioconazole and its metabolite JAU 6476-desthio at Step 3

Use pattern	Spring cereals, 1 × 18 g a.s./ha				
		Prothioconazole		JAU 6476-desthio	
FOCUS scenario	Entry route*	PEC$_{sw}$ [µg/L]	PEC$_{sed}$ [µg/kg]	PEC$_{sw}$ [µg/L]	PEC$_{sed}$ [µg/kg]
D1 (Ditch)	D	<0.001	<0.001	<0.001	<0.001
D1 (Stream)	D	<0.001	<0.001	<0.001	<0.001
D3 (Ditch)	D	<0.001	<0.001	<0.001	<0.001
D4 (Pond)	D	<0.001	<0.001	<0.001	<0.001
D4 (Stream)	D	<0.001	<0.001	<0.001	<0.001
D5 (Pond)	D	<0.001	<0.001	<0.001	<0.001
D5 (Stream)	D	<0.001	<0.001	<0.001	<0.001
R4 (Stream)	R	<0.001	<0.001	<0.001	<0.001

* Entry route: letters D, and R correspond to the dominant entry path – drainage, and runoff.

CP 9.3 Fate and behaviour in air

For information on the fate and behaviour in air please refer to MCA Section 7, data point 7.3.

CP 9.3.1 Route and rate of degradation in air and transport via air

For information on route and rate of degradation in air and transport via air please refer to MCA Section 7, data points 7.3.1 and 7.3.2.

Due to the low volatility and short half-life in air, no PEC calculations are required.

CP 9.4 Estimation of concentrations for other routes of exposure

There are no other routes of exposure if the product is used according to good agricultural practice. Therefore no further estimations are considered necessary.