

# **FINAL REGISTRATION REPORT**

## **Part B**

### **Section 1: Identity**

### **Section 2: Physical and chemical properties**

### **Section 4: Further information**

Detailed summary of the risk assessment

**Product code: FF-075**

**Product name(s): EUSKATEL PRO**

**Chemical active substances:**

**Prothioconazole, 200 g/L**

**Azoxystrobin 150 g/L**

**Central Zone**

**Zonal Rapporteur Member State: Poland**

## **CORE ASSESSMENT**

(New Product Authorization)

Applicant: Rotam Agrochemical Europe Limited

Submission date: May 2021

MS Finalisation date: 12/2021, 08/2022

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## Version history

When	What
1 May 2021	New product application in accordance with Article 33 of Regulation (EC) No. 1107/2009
December 2021	zRMS evaluation
August 2022	Final version after commenting period

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**zRMS conclusion:**

Data gap: shelf-life study is on-going. Study report shall be submitted when finished. Based on accelerated storage results, one-year conditional registration of the product is possible and proposed.

Packaging: Based on accelerated storage results, proposed commercial packaging material – HDPE and HDPE/F are appropriate and accepted.

## **1 Section 1: Identity of the plant protection product**

### **1.1 Applicant (KCP 1.1)**

Name: ROTAM AGROCHEMICAL EUROPE

Address:

Hamilton House  
Mabledon Place  
London, WC1H 9BB  
United Kingdom

### **1.2 Producer of the plant protection product and of the active substances (KCP 1.2)**

#### **1.2.1 Producer(s) of the preparation**

Confidential information or data are provided separately (Part C).

#### **1.2.2 Producer(s) of the active substance(s)**

Confidential information or data are provided separately (Part C).

#### **1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)**

##### **1.2.3.1 Prothioconazole**

Prothioconazole

min. 980 g/kg (Rotam source)  
≥ 970 g/kg (Commission Directive 2008/44/EC)

Toluene

max. < 5 g/kg

Prothioconazole-desthio

max. < 0.5 g/kg

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### 1.2.3.2 Azoxystrobin

Azoxystrobin	min. 975 g/kg (Rotam source) ≥ 930 g/kg (Reg. (EU) No 703/2011)
Toluene	max. 2 g/kg
Z-isomer	max. 25 g/kg (Reg. (EU) No 703/2011) According to SANCO/11027/2011 Rev 3 from March 2015, Z-isomer is not indicated as the relevant impurity

### 1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: EUSKATEL PRO  
Company code number: 'FF-075 ~~SE~~'

### 1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

#### 1.4.1 Composition of the plant protection product (KCP 1.4.1)

The formulation 'FF-075 ~~SE~~' is a new formulation and was not considered as the representative formulation for Annex I listing of prothioconazole approval under Directive 91/414 EEC nor renewal of approval of azoxystrobin under Commission Implementing Regulation (EU) No 703/2011.

Confidential information or data are provided separately (Part C).

**Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)**

Active substance / variant	Declared content of the pure active substance / variant (g/L)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
Prothioconazole	200	188 – 212	204	<del>17.45</del> 17.48
Azoxystrobin	150	141 - 159	<del>154</del> 153.8	<del>13.17</del> 13.18

\* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

\*\* Based on the density of the formulation = 1.1669 g/ml

**Table 1.4-2: Safener and synergists**

N/A

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**Table 1.4-3: Relevant impurities**

Prothioconazole

Relevant impurity	Maximum content (g/kg)
Toluene	≤ 5 g/kg in the technical material ≤ 1 g/L in the formulation
Prothioconazole-desthio	≤ 0.5 g/kg in the technical material ≤ 0.1 g/L in the formulation

Azoxystrobin

Relevant impurity	Maximum content (g/kg)
Toluene	≤ 2 g/kg in the technical material ≤ 0.3 g/L in the formulation
Z-isomer	25 According to SANCO/11027/2011 Rev 3 from March 2015, Z-isomer is not indicated as the relevant impurity

#### 1.4.2 Information on the active substance(s) (KCP 1.4.2)

**Table 1.4-4: Information on active substance - Prothioconazole**

Type	Name/Code Number
ISO common name	Prothioconazole
CAS No.	178928-70-6
EC/List No.	605-841-2
CIPAC No.	745

**Table 1.4-5: Information on active substance – Azoxystrobin**

Type	Name/Code Number
ISO common name	Azoxystrobin
CAS No.	131860-33-8
EC/List No.	603-524-3
CIPAC No.	571

### **1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)**

CONFIDENTIAL information is provided separately (Part C).

### **1.5 Type and code of the plant protection product (KCP 1.5)**

Type: SC (Suspension concentrate) [Code: SC]

### **1.6 Function (KCP 1.6)**

Fungicide – disease control winter/ spring cereals and oil seed rape

## 2                    **Section 2: Physical, chemical and technical properties of the plant protection product**

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 thick off-white liquid, with a mild characteristic odour. It is not explosive and has no oxidising properties. The product is not flammable and has no flash point below its decomposition temperature of 97.5 °C. It is not self-heating. In aqueous solution, it has a pH value of 6.64 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were significantly changed. The stability data indicate a shelf life of at least ~~2 years~~ 1 year at ambient temperature when stored in white HDPE bottles with white, plastic, screw-top lids. Its technical characteristics are acceptable for a *Suspension concentrate* formulation.

The intended concentration of use is ~~2 to 20 g/L~~ 0.2 – 2% v/v

No tank mixes recommended

### **Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only**

Not classified for any physical hazards

### **Notifier Proposals for Risk and Safety Phrases (KCP 12)**

No additional risk or safety phrases required

P280 Wear protective gloves/protective clothing/eye protection/face protection.

### **Compliance with FAO specifications:**

The product FF-075 complies with FAO specifications.

At the time of the evaluation, there is no FAO specification for the formulation with prothioconazole and azoxystrobin

### **Formulation used for tests**

The tested formulation has the same composition as that declared in Part C



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**Table 2-1: Physical, chemical and technical properties of the plant protection product**

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	OPPTS 830.6303 OPPTS 830.6302 OPPTS 830.6304	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension Concentrate Batch No. 20200426001	Thick off-white (Munsell color Notation: 5Y, 8.5/2) liquid with mild characteristic odour at 25 °C	Y	Lu, J. (2021) – Study No. 2950	Accepted
Explosive properties (KCP 2.2.1)	UN Manual of Tests and Criteria rev. 7 - part I, section 11.5.1 (koenen test)	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension Concentrate Batch No. 20200426001	Not explosive by Koenen test.  Based on Article 14(2) of the CLP Regulation the mixture need not be classified as explosive as none of the substances in the mixture possesses explosive properties.  In addition there are no functional groups associated with explosive properties present in the formulation.	Y	Lu, J. (2021) – Study No. 2949	Accepted
Oxidizing properties (KCP 2.2.2)	UN Manual of Tests and Criteria rev. 7 - part III, section 34.4.2 (Test O.2)	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension Concentrate Batch No. 20200426001	Not oxidising.	Y	Lu, J. (2021) – Study No. 2949	Accepted
Flash point (KCP 2.3.1)	CIPAC MT 12.3	Prothioconazole 200 g/L +	No flash point was observed below the decomposition temperature of 97.5 °C	-	Lu, J. (2021) – Study No. 2950	Accepted

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Azoxystrobin 150 g/L Suspension Concentrate Batch No. 20200426001	As no flash point was measured at $\leq 60$ °C, the mixture does not meet the criteria for classification as a flammable liquid according to CLP.			
Flammability (KCP 2.3.2)	Test waiver	-	Based on Article 14(2) of the CLP Regulation the mixture need not be classified as flammable as none of the substances in the mixture possesses flammable properties.	-	-	Not applicable  Accepted  None of the coformulants possesses flammable properties.
Self-heating (KCP 2.3.3)	Test waiver	-	<del>Not required as in general, the phenomenon of self heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore liquids are not classified as self heating.</del>	-	-	Method A15 is applicable to liquids. None of the coformulants possesses flammable properties. Auto-flammability is not expected
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191 CIPAC MT 75.3	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension Concentrate Batch No. 20200426001	<del>0.019%</del> 0.020% (calculated as NaOH) at 25 °C pH (neat) = 8.32 at 25 °C	Y	Lu, J. (2021) – Study No. 2950	Accepted  Since pH value <10, alkalinity test was not obligatory

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																	
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension Concentrate Batch No. 20200426001	6.64 at 25 °C	Y	Lu, J. (2021) – Study No. 2950	Accepted																	
Viscosity (KCP 2.5.1)	OECD 114	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension Concentrate Batch No. 20200426001	<table><tr><th rowspan="2">Shear rate (RPM)</th><th colspan="2">Dynamic viscosity (mPa·s)</th></tr><tr><th>20 °C</th><th>40 °C</th></tr><tr><td>30</td><td>415</td><td>379</td></tr><tr><td>50</td><td>288</td><td>260</td></tr><tr><td>60</td><td>253</td><td>230</td></tr><tr><td>100</td><td>183</td><td>165</td></tr></table> <p>The test substance was considered non-Newtonian fluid as the viscosity varies with shear rate.</p>	Shear rate (RPM)	Dynamic viscosity (mPa·s)		20 °C	40 °C	30	415	379	50	288	260	60	253	230	100	183	165	Y	Lu, J. (2021) – Study No. 2950	Accepted
Shear rate (RPM)	Dynamic viscosity (mPa·s)																						
	20 °C	40 °C																					
30	415	379																					
50	288	260																					
60	253	230																					
100	183	165																					
Surface tension (KCP 2.5.2)	EC A5	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension Concentrate Batch No. 20200426001	49.7 mNm <sup>-1</sup> at 20°C at concentration of 1 g product per liter water;  42.3 mNm <sup>-1</sup> at 20°C at concentration of 20.0 mL product per liter water  As the surface tension is <60 mN/m, the formulation is considered surface active.	Y	Lu, J. (2021) – Study No. 2950	Accepted  Surface active																	
Relative density (KCP 2.6.1)	CIPAC MT 3.3.2	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension	1.1669 at 20°C	Y	Lu, J. (2021) – Study No. 2950	Accepted																	

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Concentrate Batch No. 20200426001				
Bulk density (KCP 2.6.2)	Test waiver	-	Not required for a liquid formulation	-	-	Not applicable
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension Concentrate Batch No. 20200426001	The test substance is stable on storage for 14 days at 54°C without any significant change in its active ingredient content (Degradation: Prothioconazole: 1.36%, Azoxystrobin: 2.63%), physico-chemical properties and the containers (white HDPE bottles with white, plastic, screw-top lids).  See table 2-2 for detailed results	Y	Lu, J. (2021) – Study No. 2951  Lu, J. (2021) – Study No. 2952	<b>Acceptable</b>  The formulation was not affected by accelerated temperature. A.s. and impurities content were within the limits and there was no significant change of physical-chemical properties after storage. Commercial packaging used didn't present any deformation, leakage etc.
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	See ambient temperature shelf life	-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	CIPAC MT 46.3	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension Concentrate Batch No. 20200426001	The test substance is stable on storage for 14 days at 54°C without any significant change in its active ingredient content (Degradation: Prothioconazole: 1.36%, Azoxystrobin: 2.63%), physico-chemical properties and the containers (white HDPE bottles with white, plastic, screw-top lids).  See table 2-2 for detailed results	Y	Lu, J. (2021) – Study No. 2951	<b>Accepted</b>

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments			
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension Concentrate Batch No. 20200426001	The test substance was stable on storage for 0 ± 2 °C for 7 days.	Y	Lu, J. (2021) – Study No. 2950	<b>Accepted</b>  The formulation was not affected by low temperature			
			Results after storage						
			Uniformity				No separated material or layer was observed		
			Suspensibility (CIPAC MT 184.1)				2.0 mL product per liter water	Prothioconazole	97.08%
								Azoxystrobin	97.07%
							20.0 mL product per liter water	Prothioconazole	97.52%
								Azoxystrobin	97.53%
			Wet sieve test CIPAC MT 185				Passing through 75 µm sieve		99.9%
Remains on 75 µm sieve		0.1%							
Ambient temperature shelf life (KCP 2.7.5)			Study ongoing			Data gap. Shelf-life study report shall be (around December 2023)  Based on the composition of the product and results of accelerated storage test, one-year conditional registration of the product is possible and proposed.			

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Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
Shelf life in months (if less than 2 years) (KCP 2.7.6)								Not submitted
Wettability (KCP 2.8.1)	Test waiver	-	Not required for a Suspension Concentrate (SC) formulation			-	-	Not applicable
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension Concentrate Batch No. 20200426001	2.0 mL product per liter water	Foam after 1 minute±10 seconds	11 mL	Y	Lu, J. (2021) – Study No. 2950	<b>Accepted</b>
				Foam after 12 minutes±10 seconds	2 mL			
			20.0 mL product per liter water	Foam after 1 minute±10 seconds	No foam			
				Foam after 12 minutes±10 seconds	No foam			
			The results are within acceptable limits					
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension Concentrate Batch No. 20200426001	2.0 mL product per liter water	Prothioconazole	96.29%	Y	Lu, J. (2021) – Study No. 2950	<b>Accepted</b>
				Azoxystrobin	96.13%			
			20.0 mL product per liter water	Prothioconazole	96.53%			
				Azoxystrobin	96.48%			
			The results are within acceptable limits					
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension	Prothioconazole	96.24%		Y	Lu, J. (2021) – Study No. 2950	<b>Accepted</b>
			Azoxystrobin	96.19%				
			The results are within acceptable limits					App. 5% v/v was tested

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Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments			
		Concentrate Batch No. 20200426001								
Dispersion stability (KCP 2.8.3.3)	Test waiver	-	Not required for a Suspension Concentrate (SC) formulation		-	-	Not required			
Degree of dissolution and dilution stability (KCP 2.8.4)	Test waiver	-	Not required for a Suspension Concentrate (SC) formulation		-	-	Not required			
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	Test waiver	-	Not required for a Suspension Concentrate (SC) formulation		-	-	Not required			
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension Concentrate Batch No. 20200426001	<table><tr><td>Passing through 75 µm sieve</td><td>99.9%</td></tr><tr><td>Retained on 75 µm sieve</td><td>0.1%</td></tr></table> The results are within acceptable limits	Passing through 75 µm sieve	99.9%	Retained on 75 µm sieve	0.1%	Y	Lu, J. (2021) – Study No. 2950	Accepted  Concentration tested above the highest intended
Passing through 75 µm sieve	99.9%									
Retained on 75 µm sieve	0.1%									
Dust content (KCP 2.8.5.2.1)	Test waiver	-	Not required for a Suspension Concentrate (SC) formulation		-	-				
Particle size of dust (KCP 2.8.5.2.2)	Test waiver	-	Not required for a Suspension Concentrate (SC) formulation		-	-				
Attrition (KCP 2.8.5.3)	Test waiver	-	Not required for a Suspension Concentrate (SC) formulation		-	-				
Hardness and integrity (KCP 2.8.5.4)	Test waiver	-	Not required for a Suspension Concentrate (SC) formulation		-	-				

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Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments				
Emulsifiability (KCP 2.8.6.1)	Test waiver	-	Not required for a Suspension Concentrate (SC) formulation		-	-	Not required				
Emulsion stability (KCP 2.8.6.2)	Test waiver	-	Not required for a Suspension Concentrate (SC) formulation		-	-	Not required				
Re-emulsifiability (KCP 2.8.6.3)	Test waiver	-	Not required for a Suspension Concentrate (SC) formulation		-	-	Not required				
Flowability (KCP 2.8.7.1)	Test waiver	-	Not required for a Suspension Concentrate (SC) formulation		-	-	Not required				
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension Concentrate Batch No. 20200426001	<table><tr><td>Residue</td><td>1.74%</td></tr><tr><td>Rinsed residue</td><td>0.15%</td></tr></table> <p>The results are within acceptable limits</p>		Residue	1.74%	Rinsed residue	0.15%	Y	Lu, J. (2021) – Study No. 2950	Accepted
Residue	1.74%										
Rinsed residue	0.15%										
Dustability following accelerated storage (KCP 2.8.7.3)	Test waiver	-	Not required for a Suspension Concentrate (SC) formulation		-	-					
Physical compatibility of tank mixes (KCP 2.9.1)	Test waiver	-	Not required as tank mixes are not recommended		-	-	Not applied for				
Chemical compatibility of tank mixes (KCP 2.9.2)	Test waiver	-	Not required as tank mixes are not recommended		-	-	Not applied for				
Adhesion to seeds (KCP 2.10.1)	Test waiver	-	N/A – the product is not for seed treatment		-	-	Not required				



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Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
Distribution to seed (KCP 2.10.2)	Test waiver	-	N/A – the product is not for seed treatment		-	-	Not required
Other/special studies (KCP 2.11)							
Effectiveness of cleaning procedures	Efficacy guideline 305	Prothioconazole 200 g/L + Azoxystrobin 150 g/L Suspension Concentrate Batch No. 20200426001	Prothioconazole	100% removed	Y	Lu, J. (2021) – Study No. 2950	Accepted
			Azoxystrobin	100% removed			
			The results are within acceptable limits				
Self-reactive mixtures	Test waiver	-	Not classified as self-reactive as there are no chemical groups present in the components associated with explosive or self-reactive properties		-	-	Not required
Pyrophoric liquids	Test waiver	-	The classification procedure for pyrophoric liquids need not be applied as experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the product is known to be stable at room temperature for prolonged periods of time (days)).		-	-	Not required
Mixtures which, in contact with water, emit flammable gases	Test waiver	-	The classification procedure need not be applied as the chemical structure of the components do not contain metals or metalloids.		-	-	Not required
Organic peroxides	Test waiver	-	Not required – the product does have components that contains the bivalent -O-O-		-	-	Not required
Corrosive to metals	NACE TM0169/G31-12a	Prothioconazole 200 g/L + Azoxystrobin	The corrosiveness was assessed by immersing metal coupons (aluminum, steel, copper and zinc) into the test substance and stored at 45 ± 1 °C 10 days. The study is		Y	Lu, J. (2021) – Study No. 2950	Accepted

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments								
		150 g/L Suspension Concentrate Batch No. 20200426001	<div>considered valid for assessing the corrosvitiy of the tested material to metals.</div> <table><tr><td>Aluminum</td><td>0.000 mm/year (Low corrosive)</td></tr><tr><td>Steel</td><td>0.000 mm/year (Low corrosive)</td></tr><tr><td>Copper</td><td>0.000 mm/year (Low corrosive)</td></tr><tr><td>Zinc</td><td>0.000 mm/year (Low corrosive)</td></tr></table> <div>No significant change was observed in active ingredients content, pH of a neat formulation and density of test substance exposed to metals after corrosiveness test</div> <div>In additon, the corrosion rate of the test substance &lt; 0.025 mm/year) and no pits were observed.</div>	Aluminum	0.000 mm/year (Low corrosive)	Steel	0.000 mm/year (Low corrosive)	Copper	0.000 mm/year (Low corrosive)	Zinc	0.000 mm/year (Low corrosive)			
Aluminum	0.000 mm/year (Low corrosive)													
Steel	0.000 mm/year (Low corrosive)													
Copper	0.000 mm/year (Low corrosive)													
Zinc	0.000 mm/year (Low corrosive)													

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**Table 2-2 Storage Stability after 14 days at 54 ° C - Lu, J. (2021) – Study No. 2951 and Lu, J. (2021) – Study No. 2952**

PARAMETERS	TEST RESULT					
	Before storage			After storage		
Active ingredient content ± uncertainty (HPLC-PDA)	Prothioconazole	195.6 ± 2.0 g/L (16.87 ± 0.17%, w/v)		Prothioconazole	193.1 ± 2.0 g/L (16.64 ± 0.17%, w/w)	
	Azoxystrobin	145.3 ± 1.0 g/L (12.53 ± 0.09%, w/v)		Azoxystrobin	141.5 ± 1.0 g/L (12.20 ± 0.09%, w/w)	
Relevant impurity content (UPLC-PDA)	Prothioconazole-desthio	0.0020 % (w/w)		Prothioconazole-desthio	0.0018 % (w/w) <sup>1</sup>	
	Toluene	Below detectable limit Below LOQ (0.0056% w/w)		Toluene	Below detectable limit Below LOQ (0.0056% w/w)	
Physical state (OPPTS 830.6303)	Thick liquid at 25 °C			Thick liquid at 25 °C		
Color (OPPTS 830.6302)	Off-white (Munsell color Notation: 5Y, 8.5/2)			Off-white (Munsell color Notation: 5Y 8.5/2)		
Odor (OPPTS 830.6304)	Mild characteristic odor			Mild characteristic odor		
Alkalinity (CIPAC MT 191)	0.019 0.020% (calculated as NaOH) at 25 °C			0.019% (calculated as NaOH) at 25 °C		
pH of a 1% aqueous dilution (CIPAC MT 75.3)	6.64 at 25 °C			6.62 at 25 °C		
pH of a neat formulation (CIPAC MT 75.3)	8.32 at 25 °C			8.26 at 25 °C		
Pourability (CIPAC MT 148.1)	Residue	1.74%		Residue	1.70%	
	Rinsed residue	0.15%		Rinsed residue	0.17%	
Spontaneity of dispersion (CIPAC MT 160)	Prothioconazole	96.24%		Prothioconazole	97%	
	Azoxystrobin	96.19%		Azoxystrobin	97%	
Wet sieve test (CIPAC MT 185)	Passing through 75 µm sieve		99.9%	Passing through 75 µm sieve		100.0%
	Retained on 75 µm sieve		0.1%	Retained on 75 µm sieve		0.0%
Persistent foam (CIPAC MT 47.3)	2.0 mL product per liter water	Foam after 1 min ± 10 seconds	11 mL	2.0 mL product per liter water	Foam after 1 min ± 10 seconds	11 mL
		Foam after 12 min ± 10 seconds	2 mL		Foam after 12 min ± 10 seconds	2 mL
	20.0 mL product per liter	Foam after 1 min ± 10 seconds	No foam	20.0 mL product per liter water	Foam after 1 min ± 10 seconds	No foam
		Foam after 12 min ± 10 seconds	No foam		Foam after 12 min ± 10 seconds	No foam

<sup>1</sup> Below limit of quantification of 0.0019 % (w/w)

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PARAMETERS	TEST RESULT					
	Before storage			After storage		
	water					
Suspensibility (CIPAC MT 184.1)	2.0 mL product per liter water	Prothioconazole	96%	2.0 mL product per liter water	Prothioconazole	97%
		Azoxystrobin	96%		Azoxystrobin	97%
	20.0 mL product per liter water	Prothioconazole	97%	20.0 mL product per liter water	Prothioconazole	97%
		Azoxystrobin	96%		Azoxystrobin	97%
Stability of packaging	The containers are stable without visual damages and significant weight loss (up to 0.1%).					

### 3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

## 4 Section 4: Further information on the plant protection product

### 4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

**Table 4.1-1: Packaging information for 0.03 to 1 litre high density polyethylene (HDPE) bottle**

Type	Description
Material:	High density polyethylene (HDPE)
Shape/size:	Outer diameter: 28 to 91 mm Height: 65 to 221 mm
Opening:	16 - 50 mm inner diameter
Closure:	HDPE screw cap
Seal:	aluminium foil
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-2: Packaging information for 1.2 to 1000 litre HDPE drum**

Type	Description
Material:	HDPE
Shape/size:	Length: 145 to 1200 mm Height: 177 to 1160 mm Width: 77 to 1000 mm
Opening:	42 - 150 mm inner diameter
Closure:	HDPE screw cap
Seal:	aluminium foil
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-3: Packaging information for 0.1 to 1 litre fluorinated HDPE bottle**

Type	Description
Material:	Fluorinated HDPE
Shape/size:	Outer diameter: 46.5 to 91 mm Height: 103 to 221 mm
Opening:	28 - 50 mm inner diameter
Closure:	aluminium foil
Seal:	HDPE screw cap
Manner of construction	extruded
UN/ADR	compliant

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**Table 4.1-4: Packaging information for 1.2 to 25 litre fluorinated HDPE drum**

Type	Description
Material:	Fluorinated HDPE
Shape/size:	Lenght:. 145 to 293 mm Height: 177 to 470 mm Width: 77 to 245 mm
Opening:	42 - 63 mm inner diameter
Closure:	aluminium foil
Seal:	HDPE screw cap
Manner of construction	extruded
UN/ADR	compliant

### **Compatibility**

No claims for compatibility are being made on the label.

## Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.  
MS to blacken authors of vertebrate studies in the version made available to third parties/public.

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1 KCP 2.3.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11	Jun Lu	2021	STUDY ON THE PHYSICO-CHEMICAL PROPERTIES OF Prothioconazole 200 g/L + Azoxystrobin 150 g/L SUSPENSION CONCENTRATE Rotam Agrochem International Co., Ltd. Study No.: 2950 RRL Global Services GLP Unpublished	N	Rotam

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.2.1 KCP 2.2.2	Jun Lu	2021	STUDY ON THE PHYSICO-CHEMICAL PROPERTIES OF Prothioconazole 200 g/L + Azoxystrobin 150 g/L SUSPENSION CONCENTRATE Rotam Agrochem International Co., Ltd. Study No.: 2949 RRL Global Services GLP Unpublished	N	Rotam
KCP 2.7.1/01	Jun Lu	2021	STUDY ON THE PHYSICO-CHEMICAL PROPERTIES OF PROTHIOCONAZOLE 200 G/L + AZOXYSTROBIN 150 G/L SUSPENSION CONCENTRATE AFTER ACCELERATED STORAGE AT 54°C FOR 14 DAYS Rotam Agrochem International Co., Ltd. Study No.: 2951 RRL Global Services GLP Unpublished	N	Rotam
KCP 2.7.1/02	Jun Lu	2021	DETERMINATION OF RELEVANT IMPURITIES IN PROTHIOCONAZOLE 200 g/L + AZOXYSTROBIN 150 g/L SUSPENSION CONCENTRATE Rotam Agrochem International Co., Ltd. Study No.: 2952 RRL Global Services GLP Unpublished	N	Rotam



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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Verte- brate study Y/N</b>	<b>Owner</b>
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

The following tables are to be completed by MS.

**List of data submitted by the applicant and not relied on**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Verte- brate study Y/N</b>	<b>Owner</b>
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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**List of data relied on and not submitted by the applicant but necessary for evaluation**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Verte- brate study Y/N</b>	<b>Owner</b>
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

## **Appendix 2    Additional data on the physical, chemical and technical properties of the active substance**

N/A