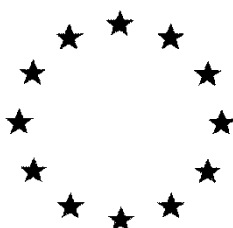


European Commission



**Draft (Renewal) Assessment Report prepared according to the Commission
Regulation (EU) N° 1107/2009**

TRITICONAZOLE

Volume 3 – B.3 (PPP) – Premis 25 FS

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B.3. DATA ON APPLICATION AND EFFICACY

B.3.1. FIELD OF USE ENVISAGED

Premis 25 Fs is used as a seed treatment in agriculture for the control of fungal diseases in cereals such as wheat, barley, triticale, rye and oat.

B.3.2. EFFECTS ON HARMFUL ORGANISMS

Triticonazole is used as a seed treatment in agriculture for the control of fungal diseases in cereals such as wheat, barley, triticale, rye and oat.

B.3.3. DETAILS OF INTENDED USE

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (day s) (l)	Remarks (m)
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applicatio ns (min)	Kg a.i./hl min max (g/hl)	Water l/ha min max	g a.i./ha min max (*) (g/ha)		
winter wheat TRZAW spring wheat TRZAS winter barley HORVX spring barley HORVS rye SECCW triticale TTLWI oats AVESA	BE, BG, CZ, EE, ES, FR, HU, IE, IT, LT, LV, PL, RO, UK	BAS 595 01 F	F	<i>Fusarium</i> spp (FUSASP), <i>Tilletia caries/Tilletia tritici</i> (TILLCA), <i>Ustilago nuda tritici</i> (USTINT), <i>Ustilago nuda</i> (USTINH), <i>Ustilago hordei</i> (USTIHO), <i>Ustilago avenae</i> (USTIAV), <i>Urocystis occulta</i> (UROCOC)	FS	25 g/L	Seed treatment (slurry). seed treatment machinery	BBCH 00/ Spring and autumn	a) 1 b) 1	N/A	N/A	Used undiluted or diluted with water at a max ratio of 1:5 (prod : water)	a) 12.5 g/ha (based on 5 g ai/100 kg seed, 250 kg seed/ha) b) 12.5 g/ha (based on 5 g ai/100 kg seed, 250 kg seed/ha)	N/A	Maximum seedling rate is 250 kg/ha

* For uses where the column „Remarks“ in marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).

- (a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
- (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated

- (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxyppr). In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).

- (j) Growth stage at 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

- (k) Indicate the minimum and maximum number of application possible under practical conditions of use

- (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)

- (m) PHI - minimum pre-harvest interval

B.3.4. APPLICATION RATE AND CONCENTRATION OF THE ACTIVE SUBSTANCE

Seed treatment use only. The application rate of Triticonazole is 12.5 g/ha (based on 5 g ai/100 kg seed and a maximum of 250 kg seed/ha).

B.3.5. METHOD OF APPLICATION

Premis (BAS 595 01 F) is applied as seed treatment (slurry) for cereals (pre-sowing).

B.3.6. NUMBER AND TIMING OF APPLICATIONS AND DURATION OF PROTECTION

The maximum number of applications is one. The application is done pre-sowing.

Triticonazole is used to control a range of seed and soil borne diseases such as *Tilletia* spp., *Ustilago* spp and *Fusarium* ssp. in cereals. Triticonazole is active as a contact and systemic fungicide. It shows apoplastic (upward) distribution inside the plant after penetration. When applied as a seed treatment, the product is slowly absorbed by the seedlings through the seed, teguments and the root.

Seed treatments are applied preventatively, and as such control disease at an early stage, by disinfecting infected seeds or protecting the germinating seed from pathogen attack from the soil. Seed treatment is the only effective method of controlling most seed and soil borne pathogens. The duration of protection afforded depends on the agronomic (disease pressure, soil type, etc.) and climatic conditions encountered. However, protection of the treated seed (by disinfection of existing soil and seed bore pathogens) should be effective enough to allow effective establishment and development of the crop.

B.3.7. NECESSARY WAITING PERIODS OR OTHER PRECAUTIONS TO AVOID PHYTOTOXIC EFFECTS ON SUCCEEDING CROPS

No minimum waiting period or limitation on required. Specific field trials have shown that even high rates of Triticonazole had no adverse effects on a range of succeeding crops; either as part of a normal crop rotation, or following a potential crop failure situation.

B.3.8. PROPOSED INSTRUCTIONS FOR USE

The product is applied to seed by specialist seed treatment application equipment which varies from Member State to Member State in scale and manufacturer. Most seed treatment products applied to cereals in the European Union are either on-farm or in usually larger-scale industrial plants or stations.

The product is applied to the seed usually in an enclosed space by means of equipment which ensures (after calibration) product is applied at the correct dose and evenly over the entire sample of seed. Application efficiency can usually be verified visually because of the use of a colorant in the formulation. Product does not need to be diluted, although water can be co-applied with the product without the need for pre-mixing. If dilution is required then up to 10 litres of water/t of treated seed are recommended (e.g. in Spain). In certain countries, dilution is not required and product is applied to the seed directly in its formulated concentration.

B.3.9. EFFECTIVENESS

Premis 25 FS (BAS 595 01 F) is used at rates of 5 g a.i./ha to control seed and soil borne diseases such as *Fusarium* sp., *Tilletia caries* and *Ustilago*. The tables below are a brief summary of results against three key diseases. Celest (Fludioxinil), which is widely authorized as cereal seed treatment in the EU, was used as reference product.

Premis 25 FS delivers nearly complete control of TILLCA and USTINH, and a mean of approx. 80% efficacy on *Fusarium* spp, which is similar to Celest.

Table 2.2.4.a: Efficacy of Premis 25 FS against *Tilletia caries* (TILLCA) on winter wheat (n = 13). Data from 2017.

Trial	EPPO Zone	Crop	Variety	Disease	Untreated	Premis25, 5g	Celest, 5g
					% infection	%efficacy	%efficacy
DEV-S-2017-DE-C02-A-06.0-DE-D11-C02	Central Maritime	TRZAW	JB ASANO	TILLCA	6.2	100.0	100.0
DEV-S-2017-DE-C14-A-05.0-DE-D04-S14	Central Maritime	TRZAW	JB ASANO 97%KF	TILLCA	45.0	100.0	100.0
DEV-S-2017-EX-C02-V-04.0-DE-VTF-518	Central Maritime	TRZAW	JB ASANO	TILLCA	9.8	100.0	99.6
DEV-S-2017-EX-C14-V-04.0-DE-VTF-516	Central Maritime	TRZAW	PATRAS	TILLCA	16.7	100.0	100.0
DEV-S-2017-EX-C14-V-04.0-DE-VTF-517	Central Maritime	TRZAW	PATRAS	TILLCA	17.7	100.0	100.0
DEV-S-2017-FR-C02-A-01.0-FR-FR4-417	South Maritime	TRZAW	JB ASANO	TILLCA	6.1	100.0	100.0
DEV-S-2017-FR-C02-A-01.0-FR-FRE-E08	South Maritime	TRZAW	PATRAS	TILLCA	29.2	100.0	100.0
DEV-S-2017-FR-C14-A-02.0-FR-FR7-701	South Maritime	TRZAW	PATRAS	TILLCA	41.3	100.0	100.0
DEV-S-2017-HU-C14-A-05.0-HU-HU0-AG1	Central South east	TRZAW	PATRAS	TILLCA	51.4	100.0	100.0
DEV-S-2017-HU-C14-A-05.0-HU-HU0-AG2	Central South east	TRZAW	PATRAS	TILLCA	45.0	100.0	100.0
DEV-S-2017-PL-C02-A-06.0-PL-PLC-025	Central North east	TRZAW	PATRAS	TILLCA	25.0	100.0	100.0
DEV-S-2017-PL-C14-A-05.0-PL-PLC-024	Central North east	TRZAW	JB ASANO	TILLCA	32.1	100.0	100.0
DEV-S-2017-PL-C14-A-05.0-PL-PLF-002	Central North east	TRZAW	JB ASANO	TILLCA	46.2	100.0	100.0
			Range	TILLCA	6,1 - 91,5	100 - 100	99,6 - 100
			Mean	TILLCA	28.6	100.0	100.0

Table 2.2.4.b: Efficacy of Premis 25 FS against *Ustilago nuda* (USTINH) on winter and spring barley (n = 9). Data from 2013-2017.

Trial	EPPO Zone	Crop	Variety	Disease	Untreated	Premis25, 5g	Celest, 5g
					% infection	%efficacy	%efficacy
DEV-S-2013-PL-C25-X-01.0-PL-PLC-080	Central North east	HORVS	BEATRIX	USTINH	26.3	83.5	-36.7
DEV-S-2013-PL-C25-X-01.0-PL-PLF-009	Central North east	HORVS	NADEK	USTINH	90.6	100.0	100.0
DEV-S-2013-UK-C25-A-01.0-UK-UK4-C38	Central Maritime	HORVS	CHALICE	USTINH	27.7	83.0	-28.9
DEV-S-2014-DE-C25-A-03.0-DE-D01-011	Central Maritime	HORVS	RIVIERA 91% KF	USTINH	15.0	100.0	6.7
DEV-S-2014-PL-C25-A-03.0-PL-PLF-002	Central North east	HORVS	NADEK	USTINH	5.0	100.0	95.8
DEV-S-2015-EX-C24-V-04.0-DE-VTF-519	Central Maritime	HORVS	STREIFERL	USTINH	11.8	100.0	89.9
DEV-S-2015-FR-C23-A-01.0-FR-FR3-317	South Mediterranean	HORVS	07KF335	USTINH	17.6	98.0	99.5
DEV-S-2017-ES-C50-A-06.0-ES-ESH-501	South Mediterranean	HORVW	SAFFRON	USTINH	21.6	100.0	9.2
DEV-S-2017-ES-C50-A-06.0-ES-ESH-502	South Mediterranean	HORVW	IGRI	USTINH	17.8	99.9	24.4
			Range	USTINH	5,0 - 90,6	83,5 - 100,0	-36,7 - 100
			Mean	USTINH	25.9	96.0	40.0

Table 2.2.4.c: Efficacy of Premis 25 FS against *Fusarium* spp (FUSASP) on winter and spring wheat (n = 12). Data from 2013-2017.

Trial	EPPO Zone	Crop	Variety	Disease	Untreated	Premis25, 5g	Celest, 5g
					% infection	%efficacy	%efficacy
DEV-S-2013-FR-C21-A-02.0-FR-FR3-303	South Mediterranean	TRZAW	ALIXAN	FUSASP	96.1	71.7	71.5
DEV-S-2013-PL-811-X-02.0-PL-PLC-060	Central North east	TRZAS	HEWILLA	FUSASP	12.5	84.0	76.0
DEV-S-2013-PL-811-X-02.0-PL-PLC-061	Central North east	TRZAS	ZURA	FUSASP	10.5	81.0	85.7
DEV-S-2013-PL-811-X-02.0-PL-PLD-001	Central North east	TRZAS	BOMBONA	FUSASP	35.5	83.1	81.7
DEV-S-2013-PL-811-X-02.0-PL-PLD-002	Central North east	TRZAS	KATODA	FUSASP	12.0	83.3	75.0
DEV-S-2013-PL-811-X-02.0-PL-PLF-001	Central North east	TRZAS	VINJETT	FUSASP	79.5	69.8	73.6
DEV-S-2013-PL-811-X-02.0-PL-PLF-002	Central North east	TRZAS	BOMBONA	FUSASP	79.5	73.6	73.6
DEV-S-2014-PL-C21-X-03.0-PL-PLC-014	Central North east	TRZAW	TURNIA	FUSASP	16.8	84.5	93.6
DEV-S-2017-IT-C13-A-06.0-IT-IT2-350	South Mediterranean	TRZAW	JULIE	FUSACU	15.0	77.8	100.0
DEV-S-2017-IT-C13-A-06.0-IT-IT2-351	South Mediterranean	TRZAW	JULIE	FUSACU	51.1	75.1	81.3
DEV-S-2017-PL-C13-A-06.0-PL-PLC-015	Central North east	TRZAW	JULIE	FUSACU	57.0	80.5	68.6
DEV-S-2017-PL-C13-A-06.0-PL-PLF-001	Central North east	TRZAW	TOBAK	FUSASP	79.5	90.6	96.9
			Range	FUSASP	10.5 - 96.1	69.8 - 90.6	68.6 - 100
			Mean	FUSASP	45.4	79.6	81.5

B.3.10. INFORMATION ON THE DEVELOPMENT OF RESISTANCE

Triticonazole is active as a contact and systemic fungicide seed treatment; target fungal pathogens are killed or suppressed. It shows an apoplastic (upwards) distribution inside the plant after penetration.

As with most of the methyl-triazol derivatives, triticonazole acts as a C-14 demethylation inhibitor in the sterol biosynthesis pathway found in most of the fungi except Oomycetes. When applied onto plants, triticonazole is effective against a broad range of fungi belonging to several groups of plant pathogens (Ascomycetes, Adelomycetes, Basidiomycetes) It is active as a contact and systemic fungicide. It shows an apoplastic (upward) distribution inside the plant after penetration. When applied as a seed treatment, the product is slowly absorbed by the seedlings through the seed, teguments and the root.

Information on Occurrence or Possible Occurrence of the Development of Resistance and Appropriate Management Strategies

Triticonazole should present the same cross-resistance patterns as other sterol demethylation inhibitor (DMI) fungicides. A resistance risk analysis was conducted in 2013. No reports on a reduced sensitivity to demethylation inhibitors (DMIs) for the target pathogens exist at the current time. There is no cross-resistance within the SBI-group, i.e. between morpholines and DMI fungicides. Likewise there is no cross resistance or a correlation in the sensitivity to SBI fungicides and other modes of action. Baseline data are not available. No monitoring data and no reports on field failure are available for the target pathogens. The FRAC (Fungicide resistance action committee) working group described the DMI-fungicides in general as medium-risk compounds. The pathogen risk is assessed as follows:

- Low risk pathogens: *Tilletia caries*, *Ustilago nuda*, *Pyrenophora graminea*
- Medium risk pathogens: *Microdochium* spp., *Fusarium* spp..

The combined resistance risk of *Pyrenophora graminea*, *Tilletia caries*, *Ustilago nuda* and DMIs is concluded to be low and that of *Microdochium* spp. and *Fusarium* spp. and DMIs to be medium. For common bunt (*Tilletia caries*) and loose smut (*Ustilago nuda*) resistance development would only have consequences if it developed in

a crop destined for seed production. Development of resistant isolates in a food crop would be inconsequential because the resistant propagules would be removed from the population at harvest. This further lowers the chances of resistance becoming a problem.

The objective of anti-resistance management strategies is the reduction of selection pressure to avoid or delay the occurrence of resistance. This can be achieved by good agricultural practice, which leads to less infection pressure (e.g. phytosanitary measurements, cultivation of less susceptible varieties, appropriate crop cultivation unfavourable for the target pathogens). Another important resistance management strategy is the restriction of use. By their very nature, cereal seed treatments are only applied once per season.

Since population size of pathogens is lower at disease onset than when already established in the field, selection pressure is less when using preventive applications rather than curative or eradicated spray schemes. A seed treatment is the most preventive application that can be made. This is - from a resistance management point of view - an optimal timing that is also an effective resistance management (van den Berg et al. 2013).

BASF is a member of the FRAC SBI Working Group and will promote effective anti-resistance management strategies.

Summary information on triticonazole

Triticonazole	
IUPAC name:	rac-(5 <i>E</i>)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)cyclopentanol
Chemical group:	Triazole
Mode of action:	Blocking of ergosterol biosynthesis leading to inhibition of growth and cell membrane disruption
Plant translocation:	Systemic, shows an apoplastic (upwards) distribution inside the plant after penetration.
Biological action: Harmful organism, plant growth regulator, etc.	Acts as a contact and systemic fungicide against seed and soil-borne diseases of cereals

B.3.11. ADVERSE EFFECTS ON TREATED CROPS

Triticonazole is very safe to treated seeds, as can be seen from the data on relative emergence and phytotoxicity to emerged plants presented below. Additional more than 20 years of commercial use have demonstrated that Triticonazole is safe to treated crops when used according to the label recommendation.

Table 2.2.6.a: Relative emergence (based on plant counts) of treated seeds compared to untreated control (n = 83).

Trial	EPPO Zone	Crop	Variety	Disease	Untreated	Premis25, 5g	Celest, 5g
					Emergence in %	Emergence in %	Emergence in %
Various	Various	n = 83	Range Mean	AUFLPF AUFLPF	100.0	78 - 193 106.5	76 - 195 109.2

Table 2.2.6.b: Phytotoxicity to emerged plants of treated seeds compared to untreated control (n = 53).

Trial	EPPO Zone	Crop	Variety	Disease	Untreated % PHYTOX	Premis25, 5g % PHYTOX	Celest, 5g % PHYTOX
Various	Various	n = 53	Mean	PHYTOX	0.0	0.0	0.1

B.3.12. OBSERVATIONS ON OTHER UNDESIRABLE OR UNINTENDED SIDE-EFFECTS

No reports of unintended effects have been reported.

B.3.13. REFERENCES RELIED ON

Data Point	Author (s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
-	-	-	-	-	-	-	-	-