European Commission

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

TRITICONAZOLE

Volume 3 – B.2 (PPP) – Premis 25 FS

Rapporteur Member State: Austria
Co-Rapporteur Member State: United Kingdom

Version History

When	What
2003/ September	Initial DAR, first version
2004/ September	Addendum 1
2005/January	Addendum rev. 2
2018/July	DRAR

Table of contents

B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT PREMIS 25 FS

Throughout this document the original DAR, is referred to as the DAR 2003 and this evaluation, is referred to as the RAR (Renewal assessment report). Studies that were evaluated in the DAR 2003 have not been re-evaluated and the results are presented in this report in **grey typeface**. New information (e.g. historical control data, additional experimental details) or new interpretation of the data has been taken into account or changes compared to the original DAR 2003 are written in **black typeface**.

Premis 25 FS was the representative formulation in the evaluation process for Annex I inclusion.
Premis 25 FS has a code number: BAS 595 01 F (former code EXP 80472 B). According to the GAP table the product should be used at a min concentration of 20% to max concentration of 100% (v/v). In order to assess the concentration dependent characteristics of the product, studies are performed correspondingly.

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1. APPEARANCE						
Physical state and colour **B.2.1/01**	Visual assessment and organoleptic determination	BAS 595 01 F 25 g/L	Bright orange-red, opaque liquid	EU agreed endpoint DAR 2003	Y	Uceda, L., Le Gren I., 2001
B.2.2. EXPLOSIVE AND OXIDIZING PROPERTIES						
Explosive properties **B.2.2/01**	EEC A.14 Thermal sensitivity test and shock test	BAS 595 01 F Batch No: OP960979	The formulation does not present a danger of explosion under the conditions of the test.	EU agreed endpoint DAR 2003	Y	Fillion, J., 1997
Oxidizing properties **B.2.2/02**	EEC A21	BAS 595 01 F, batch FD-140408-0021 25.8 g/L	BAS 595 01 F was found to be non-oxidising.	**Acceptable** No method for liquids was available at the first evaluation of triticonazole.	Y	Cowlyn, N., 2015 2014/1001867
B.2.3. FLAMMABILITY AND AUTO-FLAMMABILITY						
Flash point of the liquids formulations **B.2.3/01**	EEC A9	BAS 595 01 F, batch FD-140408-0021 25.8 g/L	No flashpoint was observed for BAS 595 01 F, the substance boils at approx. 102°C.	**Acceptable**	Y	Cowlyn, N., 2015 2014/1001867
Flammability of solid formulations **B.2.3/02**			Not relevant for liquid formulations			
Self-heating of formulation	EWG 16	BAS 595 01 F Batch No: OP960979	The preparation is auto-flammable with a self ignition temperature of 440 °C.	EU agreed endpoint DAR 2003	Y	Fillion, J., 1997

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.3/03						
B.2.4. ACIDITY/ALKALINITY AND PH VALUE						
pH of the neat aqueous formulation **B.2.4/01**	CIPAC MT 75.3	BAS 595 01 F FD-Batch No: 140408-0021 25.8 g/L	pH = 8.1 at 20 °C	**Acceptable** The study was conducted to comply with the requirements of Regulation 284/2013.	Y	Cowlyn, N., 2015 2014/1001868
pH of a 1 % dilution of the solid or non aqueous formulation **B.2.4/02**	CIPAC MT 75.3	BAS 595 01 F 25 g/L	pH = 7.5 at 22 °C	EU agreed endpoint DAR 2003	Y	Uceda, L., Le Gren I., 1997
		BAS 595 01 F FD-Batch No: 140408-0021 25.8 g/L	pH = 7.1 at 20 °C	**Acceptable**	Y	Cowlyn, N., 2015 2014/1001868
Acidity / Alkalinity **B.2.4/03**			Acidity/alkalinity not required because the pH value is >4 and <10			
B.2.5. VISCOSITY AND SURFACE TENSION						
Viscosity of the liquid formulation **B.2.5/01**	OECD 114 Rotational viscosimeter	BAS 595 01 F, batch FD-140408-0021 25.8 g/L	Pseudoplastic (non-Newtonian) in its flow behaviour. Under the specified test conditions, the measured viscosity range was 14.68 to 203.5 mPa.s at 20ºC 73 to 2240 mPa.s at 20ºC and 3.67 to 335 mPa.s at 40ºC 55 to 495 mPa.s at 40ºC	**Acceptable**	Y	Cowlyn, N., 2015 2014/1001867
Surface tension of the formulation **B.2.5/02**	EEC A5 Ring method	BAS 595 01 F, batch FD-140408-0021 25.8 g/L	The surface tension of the neat formulation was found to be 33.0 mN/m at 20°C	**Acceptable**	Y	Cowlyn, N., 2015 2014/1001867
B.2.6. RELATIVE DENSITY AND BULK DENSITY						
Relative density of the liquid formulation	EEC A3	BAS 595 01 F 25 g/L	1.068 at 20 °C	EU agreed endpoint DAR 2003	Y	Uceda, L., Le Gren I., 1997

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.6/01						
Bulk density (pour and tap) of powder or granules **B.2.6/02**			Not relevant for liquid formulations			
B.2.7. STORAGE STABILITY AND SHELF-LIFE: EFFECTS OF TEMPERATURE ON TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT						
Stability after accelerated storage (54°C during 14 days) B.2.7/01	CIPAC MT 46.3	BAS 595 01 F Batch: FD-140408-0021 25 g/L	No significant decrease in active substance content was observed following the 14 day storage period. No significant variation in the technical characteristics of the product was observed following the 14-day storage period. Results for individual parameters are presented in **Table B.2.12** below.	A new accelerated storage study has been performed to reflect a change in 'in-use' concentration (dilution 1:5). **Acceptable** The study is considered as additional information	Y	Cowlyn, N., 2014 2014/1001868
Effect of low temperature on stability of liquid formulation **B.2.7/02**	CIPAC MT 39.3	BAS 595 01 F Batch: FD-140408-0021 25 g/L	Following the 7 day storage at 0°C, the sample remained homogenous and no separation had occurred. Results for individual parameters are presented in **Table B.2.12** below.	A new low temperature study has been performed to reflect a change in 'in-use' concentration (dilution 1:5). **Acceptable** The study is considered as additional information	Y	Cowlyn, N., 2014 2014/1001869
Shelf life following storage at ambient temperature **B.2.7/03**		BAS 595 01 F 25 g/L	Stable after 2 years storage at ambient temperatures. No significant changes with respect to a.i. content, persistent foaming, pourability, wet sieve test and pH.	EU agreed endpoint DAR 2003	Y	Uceda, L., Le Gren I., 1999 (a)
B.2.8. TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT						
B.2.8.1. Wettability						
Wettability of solid formulation **B.2.8.1/01**			Not relevant for liquid formulations			
B.2.8.2. Persistence foaming						
Persistence of foaming of the diluted formulation **B.2.8.2/01**	CIPAC MT 47.3	BAS 595 01 F, batch FD-140408-0021 25.8 g/L	Initial: 63 mL Foam 10 seconds: 37 mL Foam 1 minute: <1 mL Foam	**Acceptable**	Y	Cowlyn, N., 2015 2014/1001868

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			3 minutes: <1 mL Foam 12 minutes: 0 mL Foam (mean of two results)			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8.3. Suspensibility						
Suspensibility of water dispersible formulation **B.2.8.3/01**	CIPAC MT 184	BAS 595 01 F, batch FD-140408-0021 25.8 g/L	16.7% v/v = 99% Neat = 101%	**Acceptable**	N	Cowlyn, N., 2015 2014/1001868
Spontaneity of dispersion of water dispersible formulation **B.2.8.3/02**	CIPAC MT 160	BAS 595 01 F 25 g/L	Spontaneity of dispersion (% w/w): 75 g/L: 90% 150 g/L: 85%	EU agreed endpoint DAR 2003	N	Uceda, L., Le Gren I., 1999 (b)
Dispersion stability of SE, OD or EG formulation **B.2.8.3/03**			Not relevant for FS formulation type			
B.2.8.4. Degree of dissolution and dilution stability						
Degree of dissolution of water soluble formulation **B.2.8.4/01**			Not relevant for FS formulation type			
Dilution stability of water soluble formulation **B.2.8.4/02**			Not relevant for FS formulation type			
B.2.8.5. Particle size distribution, dust content, attrition and mechanical stability						
B.2.8.5.1. Particle size distribution						
Wet sieve test of water dispersible formulation **B.2.8.5.1/01**	CIPAC MT 59.3	BAS 595 01 F 25 g/L	< 0.1% w/w retained on a 40µm sieve	EU agreed endpoint DAR 2003	Y	Uceda, L., Le Gren I., 1999 (a)
Size distribution of particles of powder or suspension concentrate formulation **B.2.8.5.1/02**			Not relevant for FS formulation type			
Nominal size range of granule			Not relevant for FS formulation type			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8.5.1/03						
B.2.8.5.2. Dust content						
Dust content of granular formulation **B.2.8.5.2/01**			Not relevant for FS formulation type			
B.2.8.5.3. Attrition						
Attrition characteristics of granules and tablets **B.2.8.5.3/01**			Not relevant for FS formulation type			
B.2.8.5.4. Hardness and integrity						
Hardness of tablets **B.2.8.5.4/01**			Not relevant for FS formulation type			
Integrity of tablets **B.2.8.5.4/02**			Not relevant for FS formulation type			
B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability						
Emulsifiability, emulsion stability and re-emulsifiability of formulation **B.2.8.6/01**			Not relevant for FS formulation type			
B.2.8.7. Flowability, pourability and dustability						
Flowability of granular formulation **B.2.8.7/01**			Not relevant for FS formulation type			
Pourability of suspensions **B.2.8.7/02**	CIPAC MT 148	BAS 595 01 F Batch: FD-140408-0021 25 g/L	Pourability: Residue: 1.2% Residue after rinsing: 0.11%	**Acceptable**	Y	Cowlyn, N., 2014 2014/1001868
Dustability of dustable powders after accelerated storage			Not relevant for FS formulation type			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8.7/03						
B.2.9. PHYSICAL AND CHEMICAL COMPATIBILITY WITH OTHER PRODUCTS INCLUDING PLANT PROTECTION PRODUCTS WITH WHICH ITS USE IS TO BE AUTHORISED						
Physical and chemical compatibility of tank mixtures **B.2.9/01**			Not applicable as the preparation is not intended to be mixed.			
B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS						
Distribution and adhesion to seeds **B.2.10/01**	CIPAC MT 147 (derived) Analytical assay using HPLC CIPAC MT 175	BAS 595 01 F 25 g/L	Adherence (n = 6) Recovery: 100.1% Standard deviation: 4.1% Seed-to-seed uniformity (n = 100) Mean value of absorbance: 0.313 Standard deviation: 0.06 Variation coefficient: 19.2%	EU agreed endpoint DAR 2003 (CIPAC MT 194 should be used according to the test methods communication.)	N	Le Gren, I., 2002
B.2.11. OTHER STUDIES						
	-	-	-	-	-	-

Table B.2.12: Storage Stability Data (2014/1001868 and 2014/1001869)

BAS 595 01 F, batch FD-140408-0021, 25.8 g/L

Parameter	Test Method	Initial	7 Days at 0 °C	2 Weeks at 54 °C
Triticonazole content (g/L)	HPLC-UV	26.0	-	25.8
Appearance	Visual	Red liquid	-	Red liquid
Packaging interactions	Visual	The packaging used was found not to distort or be permeated by the test substance.	-	The packaging used was found not to distort or be permeated by the test substance.
Weight change	Gravimetric	1144.65 1143.20	-	1144.30 (0.03% loss) 1142.85 (0.03% loss)
Persistent foaming	CIPAC MT 47.2 BAS 595 01 F in concentration 16.7% v/v was used	Initial: 63 mL Foam 10 seconds: 37 mL Foam 1 minute: <1 mL Foam 3 minutes: <1 mL Foam 12 minutes: 0 mL Foam (mean of two results)	-	Initial: 74 mL Foam 10 seconds: 47 mL Foam 1 minute: <1 mL Foam 3 minutes: <1 mL Foam 12 minutes: 0 mL Foam (mean of two results)
Wet Sieve	CIPAC MT 185	0.01 % retained on a 75 µm sieve	0.01 % retained on a 75 µm sieve	0.01 % retained on a 75 µm sieve
pH determination	CIPAC MT 75.3	pH of a 1% dilution = 7.1 pH of neat sample = 8.1	-	pH of a 1% dilution = 7.4 pH of neat sample = 8.5
Pourability	CIPAC MT 148	Residue = 1.2% Rinsed residue = 0.11%	- -	Residue = 1.2% Rinsed residue = 0.14%
Suspensibility	CIPAC MT 184 (HPLC analysis see Triticonazole_DRAR_16_Volume_3CP_Premis 25 FS)	16.7% v/v = 99% Neat = 101%	16.7% v/v = 98% Neat = 105%	16.7% v/v = 97% Neat = 100%

BAS 595 01 F is a flowable / suspension concentrate for seed treatment (FS) formulation containing 25 g/L triticonazole as active substance. It is a bright orange/red opaque liquid, with a relative density of 1.07 and a pH of 8.1-8.5 for the neat formulation and 7.1-7.5 for a 1% suspension in water. The product is not highly flammable, has an auto ignition temperature of 440°C and does not possess oxidising or explosive properties. BAS 595 01 F has good suspensibility and pourability characteristics, and does not produce excessive amounts of foam. The product has been demonstrated to be stable in studies at 54°C for 2 weeks, 0°C for 7 days and room temperature for 2 years, with no significant loss of active substance content. The packaging of the product remained free from any corrosion or degradation for the duration of the stability studies and the shelf life of the product is 24 months. A new accelerated storage study (54°C for 2 weeks) and a new low temperature study (7 days at 0°C) have been provided to support changes in the in-use concentrations. It was not deemed necessary to repeat the 2-year study, as there have been no changes to the product and the accelerated study adequately demonstrates that the in-use concentration changes do not affect the technical properties of the product. The technical properties of BAS 595 01 F indicate that no particular problems are expected when it is used as recommended and there are no implications for classification.

B.2.12. 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
KCP 2.1	Uceda L.G., Yslan F.J.	1997a	EXP80472B Determination of physico-chemical characteristics and storage stability Rhone-Poulenc Agro; Lyon; France C017038 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.1	Uceda L.G., Yslan F.J.	1997a	EXP80472B - Determination of physico-chemical characteristics and storage stability Rhone-Poulenc Agro; Lyon; France C017038 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.2	Fillion J.	1997a	Determination of the flash point, the auto-flammability and the explosion properties of EXP80472B Rhone-Poulenc Industrialisation; Decines Charpieu; France C017434 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.2	Fillion J.	1997a	Determination of the flash point, the auto-flammability and the explosion properties of EXP80472B Rhone-Poulenc Industrialisation; Decines Charpieu; France C017434 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.2/1	Fillion J.	1997 a	Determination of the flash point, the auto-flammability and the explosion properties of EXP80472B C017434 Rhone-Poulenc Industrialisation, Decines Charpieu, France yes Unpublished	No	Yes	New data for AIR3 renewal	BASF	No
KCP 2.2/2	Cowlyn N.	2015 a	BAS 595 01 F - Physico-chemical properties 2014/1001867 Huntingdon Life Sciences Ltd., Eye Suffolk IP23 7PX, United Kingdom yes Unpublished	No	Yes	New data for AIR3 renewal	BASF	No
KCP 2.3	Fillion J.	1997a	Determination of the flash point, the auto-flammability and the explosion properties of EXP80472B Rhone-Poulenc Industrialisation; Decines Charpieu; France C017434 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.3	Fillion J.	1997a	Determination of the flash point, the auto-flammability and the explosion properties of EXP80472B Rhone-Poulenc Industrialisation; Decines Charpieu; France C017434 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.3/1	Cowlyn N.	2015 a	BAS 595 01 F - Physico-chemical properties 2014/1001867 Huntingdon Life Sciences Ltd., Eye Suffolk IP23 7PX, United Kingdom yes	No	Yes	New data for AIR3 renewal	BASF	No

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
			Unpublished					
KCP 2.3/2	Fillion J.	1997 a	Determination of the flash point, the auto-flammability and the explosion properties of EXP80472B C017434 Rhone-Poulenc Industrialisation, Decines Charpieu, France yes Unpublished	No	N	Not applicable	BASF	No
KCP 2.4	Uceda L.G., Yslan F.J.	1997a	EXP80472B - Determination of physico-chemical characteristics and storage stability Rhone-Poulenc Agro; Lyon; France C017038 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.5	Uceda L., Le Gren I.	2001a	EXP80472B - Determination of dynamic viscosity and wet sieve retention before and after storage 7 days at 0 °C Aventis CropScience; Lyon; France C012263 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.5	Uceda L.G., Yslan F.J.	1997a	EXP80472B - Determination of physico-chemical characteristics and storage stability Rhone-Poulenc Agro; Lyon; France C017038 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.5/1	Cowlyn N.	2015 a	BAS 595 01 F - Physico-chemical properties 2014/1001867 Huntingdon Life Sciences Ltd., Eye Suffolk IP23 7PX, United Kingdom yes Unpublished	No	Yes	New data for AIR3 renewal	BASF	Yes
KCP 2.6	Uceda L.G., Yslan F.J.	1997a	EXP80472B - Determination of physico-chemical characteristics and storage stability Rhone-Poulenc Agro; Lyon; France C017038 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.7	Uceda L.G., Yslan F.J.	1997a	EXP80472B - Determination of physico-chemical characteristics and storage stability Rhone-Poulenc Agro; Lyon; France C017038 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.7	Uceda L.G., Yslan F.J.	1997a	EXP80472B - Determination of physico-chemical characteristics and storage stability Rhone-Poulenc Agro; Lyon; France C017038 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.7	Uceda L.G., Yslan F.J.	1997a	EXP80472B - Determination of physico-chemical characteristics and storage stability Rhone-Poulenc Agro; Lyon; France C017038 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.7	Uceda L., Le Gren I.	1999a	EXP80472B - Stability after 2 years storage at ambient temperature Rhone-Poulenc Agro; Lyon; France R004163 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.7/1	Cowlyn N.	2015 b	BAS 595 01 F, accelerated storage stability 2014/1001868	No	Yes	New data for AIR3	BASF	No

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
			Huntingdon Life Sciences Ltd., Eye Suffolk IP23 7PX, United Kingdom yes Unpublished			renewal		
KCP 2.7/2	Cowlyn N.	2015 c	BAS 595 01 F, low temp. stor. stab. 2014/1001869 Huntingdon Life Sciences Ltd., Eye Suffolk IP23 7PX, United Kingdom yes Unpublished	No	Yes	New data for AIR3 renewal	BASF	No
KCP 2.8.2	Uceda L., Le Gren I.	1999a	EXP80472B - Stability after 2 years storage at ambient temperature Rhone-Poulenc Agro; Lyon; France R004163 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.8.3	Uceda L., Le Gren I.	1999b	EXP 80472B - Determination of suspensibility and spontaneity of dispersion Rhone-Poulenc - Secteur Agro; Lyon; France R004480 No unpublished	N	N	Not applicable	BASF	Yes
KCP 2.8.3	Uceda L., Le Gren I.	1999b	EXP 80472B - Determination of suspensibility and spontaneity of dispersion Rhone-Poulenc - Secteur Agro; Lyon; France R004480 No unpublished	N	N	Not applicable	BASF	Yes
no KCP data point	Uceda L., Le Gren I.	1999a	EXP80472B - Stability after 2 years storage at ambient temperature Rhone-Poulenc Agro; Lyon; France R004163 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.8.7	Uceda L.G., Yslan F.J.	1997a	EXP80472B - Determination of physico-chemical characteristics and storage stability Rhone-Poulenc Agro; Lyon; France C017038 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.8.7	Uceda L., Le Gren I.	1999a	EXP80472B - Stability after 2 years storage at ambient temperature Rhone-Poulenc Agro; Lyon; France R004163 Yes unpublished	N	N	Not applicable	BASF	Yes
KCP 2.10	Le Gren I.	2002a	EXP 80472B - Seed treatment tests (loading, adherence and uniformity of distribution) - Interim report Aventis CropScience; Lyon; France C020785 No unpublished	N	N	Not applicable	BASF	Yes
KCP 2.10	Le Gren I.	2002a	EXP 80472B - Seed treatment tests (loading, adherence and uniformity of distribution) - Interim report Aventis CropScience; Lyon; France C020785 No unpublished	N	N	Not applicable	BASF	Yes
KCP 2.10	Le Gren I.	2002a	EXP 80472B - Seed treatment tests (loading, adherence and uniformity of distribution) - Interim report Aventis CropScience; Lyon; France C020785 No	N	N	Not applicable	BASF	Yes

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
			unpublished					