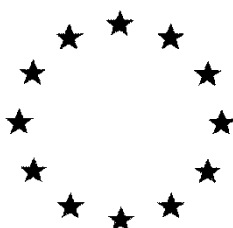


# ***European Commission***



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

**TRITICONAZOLE**

**Volume 3 – B.4 (PPP) – Premis 25 FS**

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

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## Version History

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

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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**.

## **B.4. FURTHER INFORMATION**

### **B.4.1. SAFETY INTERVALS AND OTHER PRECAUTIONS TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT**

#### **Pre-harvest interval (in days) for each relevant crop:**

Triticonazole is to be used for seed treatment in cereals only. The pre-harvest interval is covered by the application conditions and the growing period between sowing and harvest. Therefore, it is not necessary to lay down a pre-harvest interval in days.

The proposed pre harvest interval is F (ref. working doc. 7039/VI/95 EN, 1997).

#### **Re-entry period (in days) for livestock, to areas to be grazed:**

Because triticonazole is not intended to be used in areas to be grazed, no re-entry period for livestock has to be defined.

#### **Re-entry period (in hours or days) for man to crops, buildings or spaces treated:**

Triticonazole is used as seed treatment only. Therefore, no re-entry period can be set. However, a possible contact to treated seed is possible during sowing and a risk assessment on using of treated cereals grain for sowing by operators has been made in the supplemental product dossiers (M-CP 7.2).

#### **Withholding period (in days) for animal feeding stuffs:**

Treated cereals (grain and straw) may be used as fodder for livestock Due to the favorable residue situation in the cereal matrices of concern with residues consistently below LOQ no withholding period is needed.

#### **Waiting period (in days) between application and handling of treated products:**

Treated seed has to be handled during sowing using the recommended PPE (gloves). No waiting period has to be set. A risk assessment on using of treated cereals grain for sowing has been made in the supplemental product dossiers (M-CP 7.2).

#### **Waiting period (in days) between last application and sowing or planting succeeding crops:**

Neither the results from confined rotation crops study nor the results from field rotational crop studies give reason to assume the uptake of triticonazole after sowing of treated grain from soil. Therefore no waiting period for replanting is necessary.

#### **Information on specific conditions under which the preparation may or may not be used:**

Product may only be used in accordance with the registered label in the Member State where it is registered. The statutory conditions of use mean that the product can only be used as a seed treatment on the indicated crops.

### **B.4.2. RECOMMENDED METHODS AND PRECAUTIONS**

#### **Precautions for safe handling**

No special measures necessary if stored and handled correctly. Ensure thorough ventilation of stores and work areas. When using, do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift.

Where required the following PPE should be used:

Respiratory protection:	Not required.
Hand protection:	Suitable chemical resistant gloves (EN 374) also with prolonged, direct contact. (Recommended: protective index 6, corresponding > 480 minutes of permeation)

time according to EN 374): e.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) and other.

Eye protection: Safety glasses with side-shields (frame goggles) (e.g. EN 166)

Body protection: Body protection must be chosen depending on activity and possible exposure, e.g. apron, protective boots, chemical-protection suit (according to EN 14605 in case of splashes, or EN ISO 13982 in case of dust).

#### Information on storage

Product is stable under normal conditions of warehouse storage. Store in the original container; in a cool, dry and well-ventilated place; away from food, drink and animal feeding stuffs and out of the reach of children. Keep away from heat and protect from direct sunlight.

#### Transport classification:

Not classified as a dangerous good under international transport regulations.

#### Fire-fighting measures:

Suitable extinguishing media: water spray, carbon dioxide, foam or dry powder.

The following substances/groups of substances can be released in the event of a fire: carbon monoxide, hydrogen chloride, nitrogen oxides and organochloric compounds.

Wear a self-contained breathing apparatus and chemical-protective clothing.

In case of fire and/or explosion do not breathe fumes. Keep containers cool by spraying with water if exposed to fire. Collect contaminated extinguishing water separately, do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

#### Environmental precautions:

Do not discharge into the subsoil/soil. Do not discharge into drains / surface waters / groundwater.

### **B.4.3. EMERGENCY MEASURES IN CASE OF AN ACCIDENT**

#### Personal precautions, protective equipment and emergency procedures:

Do not breathe vapor/spray. Use personal protective clothing. Avoid contact with the skin, eyes and clothing.

In the event of an accident, the following first aid measures should be observed:

If inhaled:	Keep patient calm, remove to fresh air.
On skin contact:	After contact with skin, wash immediately with plenty of water and soap. If irritation develops, seek medical attention.
On contact with eyes:	Wash affected eyes for at least 15 minutes under running water with eyelids held open.
On ingestion:	Rinse mouth and then drink plenty of water.

#### Methods and materials for containment and cleaning up:

For small spillages of BAS 595 01 F pick up with suitable absorbent material (e.g. sand, sawdust, general-purpose binder, kieselgur).

For large spillages dike and pump off product.

Collect waste in suitable containers which can be labelled and sealed. Clean contaminated floors and objects thoroughly with water and detergents, observing environmental regulations. Dispose of absorbent material in accordance with regulations.

#### B.4.4. PACKAGING, COMPATIBILITY OF THE PLANT PROTECTION PRODUCT WITH PROPOSED PACKAGING MATERIALS

<b>Reference:</b>	<b>EXP80472B - Stability after 2 years storage at ambient temperature</b>
Author(s), year:	Uceda L., Le Gren I. 1999
Report/Doc. number:	R004163
Guideline(s):	EEC 94/37; EEC 91/414
GLP:	Yes

##### Conclusion

After 2 years storage in HDPE pack at ambient temperature, appearance were acceptable. The material proposed for use is known from experience to be very resistant to the influence of chemicals. The high barrier properties of the plastic prevent moisture to alter the product. No detrimental effects were noted after completion of the 2 year storage stability test. Active content stability was within specification.

BAS 595 01 F is to be marketed in standard-PE-bottles (HDPE). They are sealed by PE/ aluminium seals, protected by screw caps of polyethylene or polypropylene.

5 litre container	material:	HDPE
	shape/size:	rectangular / approx. 190 mm x 140 mm x 313 mm
	opening:	54 mm inner diameter
	closure:	polyethylene screw cap
	seal:	HF-seal
5 litre eco-container	material:	HDPE
	shape/size:	Rectangular / approx. 185 mm x 136 mm x 313 mm
	opening:	54 mm inner diameter
	closure:	screw cap
	seal:	Gasket
20 litre container	material:	HDPE
	shape/size:	rectangular / approx. 295 mm x 245 mm x 432 mm
	opening:	54 mm inner diameter
	closure:	polyethylene screw cap
	seal:	Polyethylene gasket
50 litre container	material:	HDPE
	shape/size:	Cylindrical / approx. 380 mm x 618 mm (d x h)
	opening:	52 mm inner diameter
	closure:	screw cap + valve
	seal:	Gasket
220 litre container	material:	HDPE
	shape/size:	cylindrical / approx. 585 mm diameter x 935 mm (dxh)
	opening:	54 mm inner diameter
	closure:	polyethylene screw cap
	seal:	Polyethylene gasket
1000 litre container	material:	HDPE
	shape/size:	rectangular / approx. 1000 mm x 1200 mm x 1160 mm
	opening:	54 mm inner diameter
	closure:	polyethylene screw cap
	seal:	Heat sealed

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<b>Reference:</b>	<b>BAS 595 01 F, EU performance test, Packagings made of HDPE</b>
Author(s), year:	Schreiner B., 2008a
Report/Doc. number:	2008/1010545
Guideline(s):	ADR/RID
GLP:	No

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The packaging complies with ADR/RID regulations having been tested using the test methods in accordance with ADR and appropriate to the pack type and material and classification of the contents and an appropriate UN certificate issued. They are labelled individually with all the use instructions.

The chemical compatibility from HDPE with the intended product is verified.

Permeation: Rate of permeation: <0.008 g/Lh (as required by ADR/RID 6.1.5.7)

#### **B.4.5. PROCEDURES FOR DESTRUCTION OR DECONTAMINATION OF THE PLANT PROTECTION PRODUCT AND ITS PACKAGING**

##### Waste treatment methods:

Must be sent to a suitable incineration plant, observing local regulations.

##### Contaminated packaging:

Contaminated packaging should be emptied as far as possible and disposed of in the same manner as the substance/product.

##### Disposal of product:

For purposes of disposal, combustion of BAS 595 01 F in a licensed incinerator is recommended. This method of disposal applies also to contaminated packages, which cannot be cleaned or reused.

Although it is possible to incinerate the product at lower temperatures, combustion at approximately 1100°C with a residence time of about 2 sec. is advised.

By doing so, i.e., operating the incinerator according to the conditions laid down in council directive 94/67/EEC resp. directive 2000/76/EC of the European Parliament, one will achieve complete combustion and minimize the formation of undesired by-products in the off-gases.

##### Disposal of packaging:

Users are requested to triple rinse empty primary packages as described in the ECPA "Guidelines for the rinsing of agrochemical containers", 1993.

Pressure rinsing or integrated pressure rinsing of the packaging material achieves a similar or even better result. The rinsed material must be added to the spray liquid.

To minimize waste of packages it is recommended that empty and rinsed containers be delivered to local container collection stations. If these do not exist, empty and rinsed containers must be rendered unusable and disposed of according to local regulations.

**B.4.5.1. Neutralisation procedure**

The pH of BAS 595 01 F is in a range between 7.0 and 7.6 in aqueous solution. Therefore, the proposal of a neutralization procedure is not considered to be necessary. Any spilled product and contaminated soil or water has to be absorbed and disposed according to the use instructions.

**B.4.5.2. Controlled incineration**

For purposes of disposal, combustion of BAS 595 01 F at a licensed incinerator is recommended. This method of disposal applies also to contaminated packages, which cannot be cleaned or reused.

Although it is possible to incinerate the product at lower temperatures, combustion at approximately 1100°C with a residence time of about 2 seconds is advised. By doing so, i.e. operating the incinerator according to the conditions laid down in council directive 94/67/EEC. resp. directive 2010/75/EU of the European Parliament, one will achieve complete combustion and minimize the formation of undesired by-products in the off-gases.



**B.4.6. REFERENCES RELIED ON**

*In every chapter (B.1, B.2, etc) in Volume 3 (PPP) the reference relied on heading should start with a cross reference to the corresponding heading in Volume 3 (AS) where it is indicated how the literature search was carried out and if this is considered acceptable. It is not considered necessary to duplicate that information in this volume. However if there are specific remarks related to the way PPPs were handled in the literature search these should be made in this volume. Relevant literature would be evaluated and assessed in the normal way within each section.*

*For (draft) renewal assessment reports the reference lists at the end of each section/chapter (sorted by data requirement) should include the newly submitted data relied upon as well as those original submitted tests and studies that are still considered relevant to support the application for renewal. However these studies should be clearly identified in the reference list as well as in the individual study sections. This could be done by consistent use of a statement for each study:*

*Previous evaluation: responded “N.A”. for NAS, “Submitted for the purpose of renewal”, or “In DAR (year)”, “In addendum to DAR (year)” or any other appropriate*

Data point(s) EU as of 2014)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Vertebrate study	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner	Previously submitted Y/N  If yes, old Data point
KCP 4.4	Timbers R. et al.	2001a	EXP 80472B - Packaging - Size: 1 litre- Premis 25 FS - Plastic container - Bouchon plastique - Plastic cap - Shipping case Rhone-Poulenc Agro; Lyon; France C019778 No, not subject to GLP regulations unpublished	N	N	Not applicable	BASF	Yes
KCP 4.4	Timbers R. et al.	2001b	EXP 80472B - Packaging - Size: 5 litres - Premis 25FS - EXP 80472B - Plastic container - Bouchon plastique - Plastic cap - Shipping case Rhone-Poulenc Agro; Lyon; France C019781 No, not subject to GLP regulations unpublished	N	N	Not applicable	BASF	Yes
KCP 4.4	Timbers R., German S.	2001a	EXP 80472B - Packaging - Size: 200 litres - Premis 25 FS EXP 80472 - Drum Rhone-Poulenc Agro; Lyon; France C019780 No, not subject to GLP regulations unpublished	N	N	Not applicable	BASF	Yes
KCP 4.4	Timbers R. et al.	2001c	EXP 80472B - Packaging - Size: 1000 litres - Premis 25 FS - EXP 80472B - Conteneur vrac liquide - Liquid semi- bulk container Rhone-Poulenc Agro; Lyon; France C019779 No, not subject to GLP regulations unpublished	N	N	Not applicable	BASF	Yes

Data point(s) EU as of 2014)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Vertebrate study	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner	Previously submitted Y/N  If yes, old Data point
KCP 4.4	Timbers R. et al.	2001a	EXP 80472B - Packaging - Size: 1 litre- Premis 25 FS - Plastic container - Bouchon plastique - Plastic cap - Shipping case Rhone-Poulenc Agro; Lyon; France C019778 No, not subject to GLP regulations unpublished	N	N	Not applicable	BASF	Yes
KCP 4.4	Timbers R. et al.	2001b	EXP 80472B - Packaging - Size: 5 litres - Premis 25FS - EXP 80472B - Plastic container - Bouchon plastique - Plastic cap - Shipping case Rhone-Poulenc Agro; Lyon; France C019781 No, not subject to GLP regulations unpublished	N	N	Not applicable	BASF	Yes
KCP 4.4	Timbers R., German S.	2001a	EXP 80472B - Packaging - Size: 200 litres - Premis 25 FS EXP 80472 - Drum Rhone-Poulenc Agro; Lyon; France C019780 No, not subject to GLP regulations unpublished	N	N	Not applicable	BASF	Yes
KCP 4.4	Timbers R. et al.	2001c	EXP 80472B - Packaging - Size: 1000 litres - Premis 25 FS - EXP 80472B - Conteneur vrac liquide - Liquid semi- bulk container Rhone-Poulenc Agro; Lyon; France C019779 No, not subject to GLP regulations unpublished	N	N	Not applicable	BASF	Yes
KCP 4.4	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 4.4/1	Schreiner B.	2010 a	BAS 595 01 F, EU-Performance- Test, Packagings made of HDPE 2008/1010545 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	Yes	New data for AIR3 renewal	BASF	No
KCP 4.5	Bascou J.P.	2002a	Triticonazole - Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions - Code: AE C632720 or RPA400727 Aventis CropScience; Lyon; France C018491 No, not subject to GLP regulations unpublished	N	N	Not applicable	BASF	Yes

