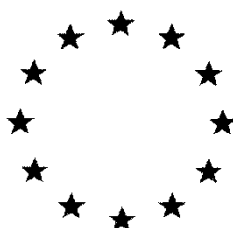


European Commission



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

Metconazole

Volume 3 – B.4 (PPP) – BAS 555 01 F

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

Version History

When	What
January 2004	Initial DAR Draft Assessment Report (DAR) – prepared in the context of the application for the first inclusion of the a.s. in Annex I to Council Directive 91/414/EEC. Various addenda were issued in August 2004, January and September 2005.
2018-01-31	Draft Renewal Assessment Report (DRAR) – prepared in the context of the application for renewal of approval of the a.s. according to Reg (EU) No EU 844/2012. <i>Note: The RAR is a stand-alone document containing the evaluations already displayed in the original DAR, as well as the new assessments. The revision of the initial DAR has been done in accordance with SANCO/10180/2013 rev.1 (March 2013), with changes to the original text – resulting from assessment of new studies (or reconsideration of old studies or studies that were not yet previously peer-reviewed) – being highlighted by means of yellow shading. However, for the renewal of the a.s., a new formulation is proposed as representative formulation. Data submitted on the formulation 'BAS 555 01 F' were therefore not evaluated in the initial DAR and are presented and evaluated in this document.</i>

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B.4. FURTHER INFORMATION

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

Pre-harvest interval

For oilseed rape the application is intended to meet a pre-harvest interval of 56 days. For cereals the application is intended to meet a pre-harvest minimum interval of 35 days or is based on the interval from the latest application at BBCH growth stage 69 to harvest at crop maturity.

Re-entry period for livestock to areas to be grazed

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

Re-entry period for man to treated crops

Re-entry assessments are given for the representative uses in the supplemental product dossiers. Re-entry is possible after the spray deposits on the crops have dried given the worker is wearing adequate work clothing (but no PPE).

Withholding period for animal feed stuffs

The withholding period for animal feeding stuff is given by the intended use (last application at BBCH growth stage 71 or 69 for oilseed rape and cereals, respectively). In order to avoid residues in products of animal origin above the MRLs, a withholding period of at least 56 or 35 days after the application for seeds or grains and for other plant parts to be used as feedstuffs is recommended, respectively.

Waiting period between application and crop sowing or planting the crop to be protected

No waiting period is necessary since metconazole is not intended in a pre-emergence use.

Waiting period between application and handling treated produce

This is not relevant here since a post-harvest treatment is not intended for oilseed rape and cereals.

Waiting period between last application and sowing or planting succeeding crops

Waiting periods before sowing or planting succeeding crops do not need to be defined at this point in time. No residues above the LOQ of the method can be expected in succeeding crops.

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

Not applicable

B.4.2. RECOMMENDED METHODS AND PRECAUTIONS

Handling and Storage

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.

Protection against fire and explosion:

Vapors may form ignitable mixture with air. Prevent electrostatic charge - sources of ignition should be kept well clear - fire extinguishers should be kept handy.

Conditions for safe storage, including any incompatibilities

Segregate from foods and animal feeds.

Further information on storage conditions: Keep away from heat. Protect from direct sunlight.

Storage stability:

Storage duration: 48 Months

Keep container dry.

Personal protective equipment

Respiratory protection:

Suitable respiratory protection for higher concentrations or long-term effect: Combination filter for gases/vapors of organic, inorganic, acid inorganic and alkaline compounds (e.g. EN 14387 Type ABEK).

Hand protection:

Suitable chemical resistant safety 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, protecting boots, chemical-protection suit (according to EN 14605 in case of splashes or EN ISO 13982 in case of dust).

General safety and hygiene measures

The statements on personal protective equipment in the instructions for use apply when handling crop-protection agents in final-consumer packing. Wearing of closed work clothing is recommended. Store work clothing separately. Keep away from food, drink and animal feeding stuffs.

Washing/cleaning of machinery and protective equipment

Report:	CP 4.2/1 Wegkamp H.-G., 2015a BAS 555 01 F: Effectiveness of procedures for cleaning application equipment and protective clothing 2015/1198590
Guidelines:	None
GLP:	no

BAS 555 01 F is a fungicide which can be used for example in wheat, durum and barley, against *Septoria spp.*, *Puccinia tritica.*, *R. secalis* and *Leptosphaeria maculans* in a maximum dose rate of 1.0 L/ha. The product must be applied in aqueous dispersion. The highest recommended concentration is 1.0 L Formulation/ha in a minimum of 110 L/ha water. The amount of 1.0 L formulation contains 90 g active ingredient (a.i.), at least in 110 L/ha. Regarding subsequent use of the spraying equipment, any carry-over would be insignificant according to the following calculation:

- 90 g active ingredient in 110 L water would result in 818.18 mg a.i. per liter as the maximum concentration.
- Any surplus spray mix must be diluted at a ratio of 1:10 with water, and sprayed onto the previously treated area, according to the use instructions. After that any remaining spray broth dilution would contain only 81.82 mg a.i. per liter water.
- If 3 % of the sprayers volume remain in the spraying equipment (an amount of usual relative volumes), this would be 30 L in a 1000 L sprayer. This remainder is diluted during the preparation of the next 1000 L spray broth. This corresponds to a concentration of 2.45 mg a.i. per liter. Only 0.3 % of the original concentrations of a.i. are left over in the new filling.

The calculation outlined above is based on ideal dilution. In reality some active ingredients tend to adhere preferentially to hydrophobic surfaces of seals or plastic tubing. But there is a large safety margin that plant damage can be excluded when the application equipment is subsequently used for crop treatment again.

Protective clothing for applicators of agrochemicals is usually made of cotton. The polar surface of the fiber presents little affinity to the non-polar active ingredients. Therefore, usual laundering with detergents will either suspend or dissolve any contamination efficiently.

In summary, common agricultural practice implying cleaning of application equipment with water will remove any remainders of BAS 555 01 F so efficiently that no plant damage can be caused when the equipment is used subsequently for the treatment of different crops. Protective clothing will be cleaned effectively when washed with usual laundry detergents.

B.4.3. EMERGENCY MEASURES IN CASE OF AN ACCIDENT

Report: CP 4.3/1
Anonymous, 2015b
Safety data sheet - Caramba 90
2015/1189718
Guidelines: EEC 1907/2006
GLP: no

Fire-Fighting Measures

Extinguishing media

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

Special hazards arising from the substance or mixture

Carbon monoxide, hydrogen chloride, carbon dioxide, nitrogen oxides, organochloric compounds. The substances/groups of substances mentioned can be released in case of fire.

Advice for fire-fighters

Special protective equipment: Wear self-contained breathing apparatus and chemical-protective clothing.

Further information:

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. In case of fire and/or explosion do not breathe fumes. Keep containers cool by spraying with water if exposed to fire.

Transport Information

Land transport

ADR

UN number	UN3082
UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (contains METCONAZOLE)
Transport hazard class(es):	9, EHSM
Packing group:	III
Environmental hazards:	yes
Special precautions for user:	Tunnel code: E

RID

UN number	UN3082
UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (contains METCONAZOLE)
Transport hazard class(es):	9, EHSM
Packing group:	III
Environmental hazards:	yes
Special precautions for user:	None known

Inland waterway transport

ADN

UN number	UN3082
UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

Transport hazard class(es):	N.O.S. (contains METCONAZOLE) 9, EHSM
Packing group:	III
Environmental hazards:	yes
Special precautions for user:	None known
Transport in inland waterway vessel:	Not evaluated

Sea transport**IMDG**

UN number:	UN 3082
UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (contains METCONAZOLE)
Transport hazard class(es):	9, EHSM
Packing group:	III
Environmental hazards:	yes
Marine pollutant:	YES
Special precautions for user:	None known

Air transport**IATA/ICAO**

UN number:	UN 3082
UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (contains METCONAZOLE)
Transport hazard class(es):	9, EHSM
Packing group:	III
Environmental hazards:	yes
Special precautions for user:	None known

First aid measures

Show container, label and/or safety data sheet to physician. Remove contaminated clothing.

If inhaled:

Keep patient calm, remove to fresh air, seek medical attention.

On skin contact:

Wash thoroughly with soap and water.

On contact with eyes:

Wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.

On ingestion:

Immediately rinse mouth and then drink 200-300 ml of water, seek medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms: The most important known symptoms and effects are described below.

- Eye contact causes irritation.
- Danger of serious damage to health by prolonged exposure if swallowed.
- Possible risk of harm to the unborn child.

Further important symptoms and effects are so far not known.

Indication of any immediate medical attention and special treatment needed

Treatment: Treat according to symptoms (decontamination, vital functions), no known specific antidote.

Accidental release measures

Personal precautions, protective equipment and emergency procedures

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

Environmental precautions

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

Methods and material for containment and cleaning up

For small amounts: Pick up with suitable absorbent material (e.g. sand, sawdust, general-purpose binder, kieselguhr).

For large amounts: Dike spillage. Pump off product.

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

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

BAS 555 01 F is to be marketed in blow moulded high-density polyethylene containers (HDPE). They are sealed by either a foil seals or a polyamide laminated PE-foam gasket, protected by a polyethylene screw cap

0,15 litre bottle:	material:	HDPE
	shape/size:	Cylindrical / approx. 63 mm diameter x 92 mm
	opening:	42 mm inner diameter
	closure:	screw cap
	seal:	HF-seal
0,25 litre bottle:	material:	HDPE
	shape/size:	Cylindrical / approx. 63 mm diameter x 126 mm
	opening:	42 mm inner diameter
	closure:	screw cap
	seal:	HF-seal
0.5 litre bottle:	material:	HDPE
	shape/size:	Cylindrical / approx. 69 mm diameter x 185.5 mm
	opening:	42 mm inner diameter
	closure:	screw cap
	seal:	HF-seal
1 litre bottle:	material:	HDPE
	shape/size:	Cylindrical / approx. 88.5 mm diameter x 234 mm
	opening:	42 mm inner diameter
	closure:	screw cap
	seal:	Induction sealed
1 litre eco-bottle:	material:	HDPE
	shape/size:	Cylindrical / approx. 88.5 mm diameter x 234 mm
	opening:	54 mm inner diameter
	closure:	screw cap
	seal:	gasket
5 litre container	material:	HDPE
	shape/size:	Rectangular / approx. 190 mm x 140 mm x 313 mm
	opening:	54 mm inner diameter
	closure:	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
10 litre container	material:	HDPE
	shape/size:	Rectangular / approx. 230 mm x 165 mm x 375 mm
	opening:	54 mm inner diameter
	closure:	Polyethylene screw cap
	seal:	Induction sealed
10 litre eco-container	material:	HDPE
	shape/size:	Rectangular / approx. 230 mm x 187 mm x 358 mm
	opening:	54 mm inner diameter
	closure:	screw cap
	seal:	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
Report:	CP 4.4/1	
	Schreiner B., 2003a	
	EU performance tests (Standard-PE-Bottle, 1 L, Spec.-No. 7755107)	
	2003/1014017	
Guidelines:	none	
GLP:	no	

Summary

The product BAS 555 01 F was tested for stability of packaging after storage at 40°C and ca. 15 % storage humidity (RH) for 8 weeks in original containers. The packaging material proved to be suitable for use with BAS 555 01 F.

Examined packaging:

Standard-PE-Bottle, 1 L, Spec: No. 7755107

Material: Lupolen 4261 A (High density Polyethylene)

Barrier: ---

Testing packaging: Original bottle, opening sealed with Alu/PE

Performed testsDrop Test (ADR 6.1.5.3)

Test performed at -20°C, n = 3

Height of drop: 1.20 m, density: 1.05 kg/L

Type of drop: perpendicular onto bottom; perpendicular onto top; dropped flat on side

Result: all bottles are tight

Approved: Yes

Leak Test (ADR 6.1.5.4)

n= 3

Result: all bottles are tight

Approved: Yes

Hydraulic (Hydrostatic) Test (ADR 6.1.5.5)

n= 3

applied internal (hydraulic) pressure of 100 kPa for 30 min.;

Result: all bottles are tight

Approved: Yes

Stacking Test (ADR 6.1.5.6)

not applicable (part of combination packaging)

Permeation (ADR 6.1.5.8)

Result: < 0.008 g/Lh

Approved: Yes

ADR 6.1.4.21

Packagings are supplied in UN-approved combination packs

The shelf life storage stability testing was carried out in HDPE bottles of 1 L volume (see Vol.3 CP-B.2). Due to the fact that this product is an EC formulation, i.e. it does not contain particles of solids (as in case of SC formulations), the data of the shelf life testing can be transferred to packages of higher volumes, e.g. 50 L containers as listed above.

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

B.4.5.1. Neutralisation procedure

The pH of BAS 555 01 F is in a range between 5.2 and 6.1 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 555 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

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Verteb rate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCP 4.2/1	Wegkamp H.-G.	2015 a	BAS 555 01 F: Effectiveness of procedures for cleaning application equipment and protective clothing 2015/1198590 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF	No, submitted for purpose of renewal
KCP 4.3/1	Anonymous	2015 b	Safety data sheet - Caramba 90 2015/1189718 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF	No, submitted for purpose of renewal

KCP 4.4/1	Schreiner B.	2003 a	EU performance tests (Standard-PE-Bottle, 1 L, Spec.-No. 775 5107) 2003/1014017 BASF AG, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF	No, submitted for purpose of renewal
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