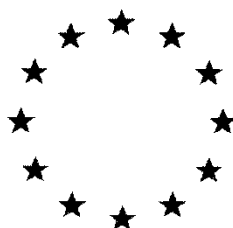


European Commission



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

BAS 750F (Mefentrifluconazole)

Volume 3 – B.4 (PPP) – BAS 750 01 F

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

Version History

When	What
April 2017	Initial DAR

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B.4. FURTHER INFORMATION

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

The applicant has provided the following information:

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

This dossier supports a safe use with two applications. The second application should be carried out latest at BBCH growth 69 (end of flowering). Under usual climatic conditions, these use directions correspond to a minimum preharvest interval of 35 - 42 DAT.

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

Because BAS 750 01 F 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:

The use of the target formulation BAS 750 01 F in cereals does not create any relevance with regard to worker re-entry. (The relevant assessment is provided in section CA7.2.3. The label should include the information that treated fields should not be re-entered before the spray has completely dried.)

Withholding period (in days) for animal feeding stuffs:

The withholding period for animal feeding stuff is fixed by the use recommendations with last application at BBCH growth stage 69. In order to avoid residues above the MRL values proposed for products of animal origin, a withholding period of 35 - 42 days (after application) for grains and 28 days for other plant parts to be used as feeding stuff is recommended.

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

This is not relevant here since a post-harvest treatment is not intended. The typical procedures for cereal harvesting are covered under “re-entry” (see CA/7.2.3).

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

No replant restriction is needed since no significant residues are expected for the uses supported in the present dossier (see section CA6.6).

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

Not applicable.

B.4.2. RECOMMENDED METHODS AND PRECAUTIONS

The applicant has stated the following:

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:

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

Where required the following personal protective equipment should be used:

Respiratory protection:

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

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).

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.

Information on storage

Segregate from foods and animal feeds.

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

Transport classification:

For Land transport

ADR

UN number UN3082

UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S. (contains TRIAZOLE DERIVATIVE, SOLVENT NAPHTHA)

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 TRIAZOLE DERIVATIVE, SOLVENT NAPHTHA)

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,
N.O.S. (contains TRIAZOLE DERIVATIVE, SOLVENT NAPHTHA)

Transport hazard class(es): 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 TRIAZOLE DERIVATIVE, SOLVENT NAPHTHA)

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 TRIAZOLE DERIVATIVE, SOLVENT NAPHTHA)

Transport hazard class(es): 9, EHSM

Packing group: III

Environmental hazards: yes

Special precautions for user: None known

Fire-fighting measures:

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

The following substances/groups of substances can be released in the event of a fire: carbon monoxide, Carbon dioxide, nitrogen oxides

Special protective equipment in case of fire and/or explosion:

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

Further information:

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

The applicant has provided the following information:

Personal precautions, protective equipment and emergency procedures:

First aid personnel should pay attention to their own safety. If the patient is likely to become unconscious, place and transport in stable sideways position (recovery position). Immediately 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.

Methods and materials for containment and cleaning up:

For small amounts:	Pick up with suitable absorbent material (e.g. sand, sawdust, general-purpose binder, kieselguhr).
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For large amounts:	Dike spillage. Pump off product.
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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. Wear suitable protective equipment.

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

The applicant has stated the following:

BAS 750 01 F is to be marketed in high-density polyethylene containers with an inner barrier, e.g., polyamide (PA/PE), with a minimum wall thickness of 0.7 mm. They are sealed by foil seals or by polyamide laminated PE-foam gaskets, protected by screw caps of polyethylene.

0,15 litre bottle	material:	PA/PE (Coex)
	shape/size:	Cylindrical / approx. 63 mm diameter x 92 mm
	opening:	42 mm inner diameter
	closure:	screw cap
	seal:	Induction sealed
0,25 litre bottle	material:	PA/PE (Coex)
	shape/size:	Cylindrical / approx. 63 mm diameter x 126 mm
	opening:	42 mm inner diameter
	closure:	screw cap
	seal:	Induction sealed
0.5 litre bottle	material:	PA/PE (Coex)
	shape/size:	Cylindrical / approx. 69 mm diameter x 185.5 mm
	opening:	42 mm inner diameter
	closure:	screw cap
	seal:	Induction sealed
1 litre bottle	material:	PA/PE (Coex)
	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: shape/size: opening: closure: seal:	PA/PE (Coex) Cylindrical / approx. 88.5 mm diameter x 234 mm 54 mm inner diameter screw cap gasket
3 litre container	material: shape/size: opening: closure: seal:	PA/PE (Coex) Rectangular / approx. 190 mm x 140 mm x 241 mm 54 mm inner diameter screw cap Induction sealed
5 litre container	material: shape/size: opening: closure: seal:	PA/PE (Coex) Rectangular / approx. 190 mm x 140 mm x 313 mm 54 mm inner diameter screw cap Induction sealed
5 litre eco-container	material: shape/size: opening: closure: seal:	PA/PE (Coex) Rectangular / approx. 185 mm x 136 mm x 313 mm 54 mm inner diameter screw cap gasket
10 litre container	material: shape/size: opening: closure: seal:	PA/PE (Coex) Rectangular / approx. 230 mm x 165 mm x 375 mm 54 mm inner diameter screw cap Induction sealed
10 litre eco-container	material: shape/size: opening: closure: seal:	PA/PE (Coex) Rectangular / approx. 230 mm x 187 mm x 358 mm 54 mm inner diameter screw cap gasket
50 litre container	material: shape/size: opening: closure: seal:	F-HDPE (fluorinated) Cylindrical / approx. 380 mm x 618 mm (d x h) 52 mm inner diameter screw cap + valve gasket

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 coex-material (PE/PA) with the intended product is verified.

Permeation: Rate of permeation: <0.008 g/lh; approved

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; approved

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.

After 52 weeks storage in PA/PE coextruded packs at ambient temperature, appearance were acceptable. No corrosion or other influence of the product on the original container were observed. Active content stability was within specification.

The 2 year study will be submitted directly after completion.

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

The applicant has provided the following information :

B.4.5.1. Neutralisation procedure

The pH of BAS 750 01 F is in a range between 6.5 and 6.8 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 750 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 Company 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 4.2/1	Wegkamp H.-G.	2015 a	Effectiveness of procedures for cleaning application equipment and protective clothing - BAS 750 01 F 2015/1173502 BASF SE,	No	No	Not applicable	BASF	Not applicable

			Limburgerhof, Germany Fed.Rep. no Unpublished					
KCP 4.3/1	Anonymou s	2016 b	Safety data sheet - BAS 750 01 F 2016/1052608 BASF SE, Ludwigshafen/ Rhein, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF	Not applicable
KCP 4.4/1	Maurer B.	2014 a	EU performance test of BAS 750 01 F, AGRO- packaging made of Coex- materials (HDPE with barrier layer) 2014/1132865 BASF SE, Ludwigshafen/ Rhein, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF	Not applicable
KCP 4.4/2	Maurer B.	2014 b	EU performance test of BAS 750 01 F, AGRO- packaging made of HDPE	No	No	Not applicable	BASF	Not applicable

			with flourinated barrier 2014/1132864 BASF SE, Ludwigshafen/ Rhein, Germany Fed.Rep. no Unpublished					
KCP 4.4/3	Kroehl T.	2015 a	Chemical and physical stability of formula BAS 750 01 F when stored for up to 3 years in PA/PE- coextruded packs - 52 week report 2015/1112122 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data for first Approval	BASF	Not applicable