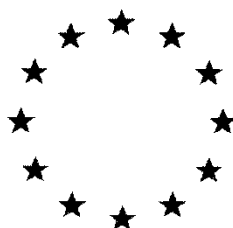


European Commission



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

BAS 750F (Mefentrifluconazole)

Volume 3 – B.3 (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.3. DATA ON APPLICATION AND EFFICACY

This Draft Assessment Report has been drafted by the Rapporteur Member State based on the information submitted by the applicant at Document M-CP, Section 3. No formal BAD was submitted. This application for this new active has been assessed in line with SANCO/10054/2013 rev 3 which requires only a limited consideration of Efficacy. The applicant states that trials were conducted to the appropriate EPPO standards, and in accordance with GEP, this will be examined at the product authorisation stage. A detailed consideration of efficacy will occur in the subsequent product authorisation process when a full biological assessment dossier will be required.

B.3.1. FIELD OF USE ENVISAGED

BAS 750 01F is intended as a fungicide for use in agriculture. Application of BAS 750 01F will be as a foliar spray.

B.3.2. EFFECTS ON HARMFUL ORGANISMS

As a most representative major crop/pest combination for Europe, the control of *Septoria tritici* (*Zymoseptoria tritici*, *Mycosphaerella graminis*) in wheat is described. Efficacy evaluation for further uses of products containing BAS 750 in cereals and other crops are stated to be currently under development or evaluation and will be addressed with the individual biological assessment dossiers for the corresponding product evaluations.

B.3.3. DETAILS OF INTENDED USE**Summary of intended uses**

GAP rev. 01, date: 2016-02-03

PPP (product name/code) **BAS 750 01 F**
 active substance **BAS 750 F**

Formulation type:
 Conc. of as: **EC (emulsifiable concentrate)**
100 g/L

safener **n.a.**
 synergist **n.a.**

Conc. of safener: **n.a.**
 Conc. of synergist: **n.a.**

Applicant: **BASF Agro B.V. Arnhem (NL) Zürich Branch**
 Zone(s): **Northern / Central / Southern EU**

professional use ☒
 non-professional use ☐

Verified by MS: **y/n**

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 | 12 | 13 | 14 |
|-------------|--------------------|--------------------------------------------------------------------|--------------------|---------------------------------------------------------------------------------------------------------------|----------------|------------------------------------------|----------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-------------------------|---------------|----------|
| Use- No. | Member state(s) | Crop or situation (crop destination / purpose of crop) | F G or I* | Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) | Application | | | Application rate | | | PHI (days) | Remarks: |
| | | | | | Method Kind | Timing / stage of crop & season | Growth Max. number of (min. interval between) applications a) per use b) per crop/ season | L product / ha a) max. rate per appl. b) max. total rate per crop/season | g as/ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min / max | | |
| 1 | EU28 | Cereals | F | <i>Septoria tritici</i> – <i>SEPTTR</i> further control claims are currently under evaluation | Foliar spray | BBCH 30-69 | a) 2 (14) b) 2 (14) | a) 1.5 L/ha b) 3.0 L/ha | 150 g as/ha 300 g as/ha | 100 - 300 | 35 | |

*Outdoor or field use (F), glasshouse application (G) or indoor application (I)

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

Application rate is 1.5 l product/ha. It is expected that this will be the maximum rate across the CMS as this is the dose required to control a difficult to control disease like *Septoria tritici* (SEPTTR). Lower doses may be appropriate against other less difficult to control diseases however this would need to be established at the product authorisation stage. A maximum of 2 applications per crop is proposed.

B.3.5. METHOD OF APPLICATION

BAS 750 F containing products are used as foliar sprays, and can be applied through all conventional sprayers providing they are in good working order and have been calibrated to manufacturer instructions.

The proposed application timings are at growth stages from BBCH 30 to BBCH 69 in a spray volume of between 100 and 300 l/ha.

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

The applicant states that BAS 750 01 F can provide control for up to six weeks after each application when applied before the start of disease attack.

| | |
|------------------------------------------------------------------------|-------------------------------------------------------|
| Maximum number of applications and their timings: | max. two applications with a min. interval of 14 days |
| Growth stages of crops or plants to be protected: | BBCH 30-69 |
| Duration of protection afforded by each application: | up to six weeks |
| Duration of protection afforded by the maximum number of applications: | up to twelve weeks |

This information will be assessed at the product authorisation stage.

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

BAS 750 F is stated to be highly selective fungicide with no herbicide activity. The applicant also states that no waiting periods or limitations for any succeeding crops are required. These will need to be considered at product authorisation stage.

B.3.8. PROPOSED INSTRUCTIONS FOR USE

BAS 750 01 F is a fungicide which is stated by the applicant to have both protectant and curative properties for disease control in cereal crops.

Time of application

The applicant provided the following general advice: For cereal disease control, apply BAS 750 01 F at the start of disease attack. A maximum of two applications can be made, starting from beginning of stem elongation (BBCH 30) until end of flowering (latest application at BBCH 69). The described application window can be more limited in specific countries or for specific uses. The recommended spray interval is 14-28 days depending on disease pressure and the general spray program strategy.

Please refer to point 3.3 (details of intended use – GAP table) for full use instructions.

B.3.9. EFFECTIVENESS

The applicant states that full biological assessment dossiers will be submitted to support the product authorisations of mefentrifluconazole containing products in Europe. For the Annex I submission however, the most challenging target is considered to be *Septoria tritici* on winter wheat requiring the highest dose of active substance.

The field trials data supporting effectiveness against this target comprise 59 trials conducted over 2 years, in 2014 and 2015. The trials were undertaken by Official and/or Officially Recognised Organisations, all of which follow EPPO guidelines. Trials were conducted in the following Member States: United Kingdom, Ireland, Germany, Denmark, Sweden, Czech Republic, France, Spain, Italy, Bulgaria, Hungary, Lithuania, Poland, Romania and Slovakia. These are representative of the following EPPO zones according to EPPO Standard PP1/241 (1): Maritime, Mediterranean, North-East and South-East climatic zones.

Results presented in Table 3.1 show that BAS 750 01 F provided strong activity irrespective of the period of assessment or the climatic zone considered. With 1.5 l/ha, BAS 750 01 F showed in all circumstances better performance than the reference product (containing 200 g prothioconazole/l). At the higher rate, BAS 750 01 F gave also a longer period of control, for example, data from the Maritime zone at T1 + 5-6 weeks, demonstrate that BAS 750 01 F is more efficient at 1.5 l/ha, providing a mean of 84% control compared to 79% efficacy at the 1 l/ha rate. Reduced dose rates of 1.0 l/ha or 0.75 l/ha showed lower efficacy. Minimum effective dose will need to be confirmed at the product authorisation stage.

In comparison with standards, BAS 750 01 F produced 1.4 to 8.6 dT/ha more yield than the reference product (Table 3.3).

Table 3.1: Summary data showing performance of mefentrifluconazole against *Septoria tritici* in winter wheat

| Crop | Target | Situation | Formulation type / application method | Number of applications | Time after application | Summary of Control achieved [by zone] | | | | | |
|-----------------|-------------------------|-----------|---------------------------------------|------------------------|------------------------|------------------------------------------|-------------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| | | | | | | Zone trials conducted | Untreated (infestation level) | BAS 750 01 F | | | PROLINE |
| | | | | | | | | 0.75 l/ha (75 g a.i./ha) | 1.0 l/ha (100 g a.i./ha) | 1.5 l/ha (150 g a.i./ha) | 0.8 l/ha (200 g a.i./ha) |
| Cereals (wheat) | <i>Septoria tritici</i> | out-door | EC 100 g/l foliar spray | 1 | 3-4 weeks | Ma (mean 24 trials) | 41% | 73% | 78% | 80% | 65% |
| | | | | | | Me (mean 4 trials) | 29% | 32% | 46% | 47% | 46% |
| | | | | | | NE (mean 5 trials) | 31% | 77% | 82% | 83% | 74% |
| | | | | | | SE (mean 8 trials) | 33% | 53% | 61% | 67% | 56% |
| | | | | | 5-6 weeks | Ma (mean 26 trials) | 46% | 75% | 79% | 84% | 62% |
| | | | | | | Me (mean 1 trials) | 51% | 61% | 72% | 69% | 59% |
| | | | | | | NE (mean 7 trials) | 31% | 74% | 81% | 86% | 80% |
| | | | | | | SE (mean 9 trials) | 34% | 60% | 69% | 77% | 65% |
| | | | | 2 | 2-4 weeks | Ma (mean 10 trials) | 54% | 87% | 91% | 92% | 73% |
| | | | | | | Me (mean 3 trials) | 21% | 68% | 78% | 76% | 77% |
| | | | | | 5-6 weeks | Ma (mean 8 trials) | 83% | 91% | 94% | 96% | 79% |
| | | | | | | Me (mean 2 trials) | 16% | 89% | 93% | 91% | 97% |

Ma: Maritime EPPO climatic zone, Me: Mediterranean EPPO climatic zone

NE: North-East EPPO climatic zone zone, SE: South-East EPPO climatic zone

Table 3.3: Summary data of yield (dT/ha)

| Crop | Situation | Formulation type/application method | Summary of Yield [by zone] | | | |
|--------------------|-----------|-------------------------------------|----------------------------|-----------|------------------------------------------|-------------------------------------|
| | | | Zone trials conducted | Untreated | BAS 750 01 F 1,5 l/ha (150 gai/ha) | PROLINE 0,8 l/ha (200 gai/ha) |
| | | | | | | |
| Cereals (wheat) | Outdoor | EC 100 g/l foliar spray | All (mean 45 trials) | 73.9 | 91.3 | 87.7 |
| | | | Ma (mean 24 trials) | 78.6 | 100.2 | 96.0 |
| | | | Me (mean 4 trials) | 65.4 | 73.8 | 71.4 |
| | | | NE (mean 5 trials) | 81.6 | 100.8 | 95.4 |
| | | | SE (mean 8 trials) | 63.4 | 73.0 | 71.2 |

B.3.10. INFORMATION ON THE DEVELOPMENT OF RESISTANCE

This is more fully addressed in the BAS 750 CA Section 3. The performance of BAS 750 01F across a range of current field populations of *S tritici* has been assessed and can be judged relative to a range of existing alternative DMI fungicides. Resistance management will be required and should be addressed at product authorisation.

B.3.11. ADVERSE EFFECTS ON TREATED CROPS

The applicant states that BAS 750 01 F showed excellent crop safety on a broad range of commercially grown crops (Table 3.2). A total of 53 efficacy trials were evaluated for crop injury. No phytotoxicity symptoms were observed in 52 trials, whilst negligible and transient symptoms (1-2 %) were observed in a single trial with the highest dose rates tested (1.0/1.5 l/ha). These symptoms were stated to have quickly disappeared and had no impact on yield. This information will need to be validated at the product authorisation stage.

Table 3.2: Crop varieties included in trials assessed for phytotoxicity

| Crop | Climatic zone | Number of trials | Varieties |
|-------|---------------|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Wheat | Ma | 30 | AKTEUR (2), ALANA (1), ALCHEMY (1), ALTIGO(1), AUBUSSON (2), CLAIRE (1), CORDIALE (1), DINOSOR (5), FEDERER (1), GENIUS (1), JB ASANO (2), JB DIEGO (1), JULIUS (1), KINGDOM (1), LINUS (1), MARIBOSS (2), PAKITO (2), RIBAND (3), SANTIAGO (1) |
| | Me | 6 | CEZANNE (1), DON JOSE (1), HYXO (1), MIRADOUX (1), SOLEHIO (1), SOLLARIO (1) |
| | NE | 7 | MUSZELKA (1), NARIDANA (1), PRINCEPS (3), SKAGEN (1), TURNIA (1) |
| | SE | 10 | ALACRIS (1), ENOLA (1), GK ELET (3), GLOSSA (1), JAFFET (1), QUEBON (1), SADOVOI (1), VENISTAR (1) |

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

The applicant states that no following crop or adjacent crop restrictions or warnings are necessary. Data presented in Vol 3CP Section 9.11 indicate that BAS 750 01F had low levels of activity against a range of non target plants (pre emergence NOER \geq 1500 ml product/ha

and a vegetative vigour ERC50 of ≥ 1500 ml product/ha). Taking into account the further reduction in exposure due to crop interception and off target drift the risk to succeeding and adjacent crops would appear to be low. This will need to be considered at the product authorisation stage.

B.3.13. 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 |
|------------|---------------------------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------------------|---------------------------------------------|-------|
| KCP 3 | Kienle M. Strobel D. | 2016 a | Uptake of Revysol® (Mefentrifluconazole) with BAS 750 01 F in wheat BASF SE, Limburgerhof, Germany Fed.Rep. 2016/1270660 no Unpublished | No | Yes | Data for first Approval | BASF |
| KCP 3.8/1 | Lefrancois C., McKeown B. | 2015 a | Efficacy Data and Information for Approval of new active Substance BAS 750 F - Confidential 2015/1260812 BASF Agro B.V. Arnhem (NL) - Zuerich Branch, Zuerich, Switzerland no Unpublished | No | No | Not applicable | BASF |