



Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.6, 3.11, 3.12 Application

Application Number: 2007-8778
Application: New end-use product guarantee, identity & proportion of formulants, new combination of technical grade active ingredients, and new pests and hosts.
Product: USF 2010 Fungicide
Registration Number: 29818
Active ingredients (a.i.): Tebuconazole & Trifloxystrobin
PMRA Document Number : 1930364

Purpose of Application

The purpose of this application is to register a new commercial end-use product, USF 2010 Fungicide, containing a new combination of actives, tebuconazole (65 g a.i./ha) and trifloxystrobin (65 g a.i./ha). This product was proposed for use on Use Site Category 13 and 14 (Terrestrial Feed and Food Crops).

Chemistry Assessment

USF 2010 Fungicide is a liquid suspension concentrate containing the actives tebuconazole and trifloxystrobin at a nominal concentration of 261 g/L each. This product also contains the preservatives 1,2-benzisothiazolin-3-one (at 0.048 %), 5-chloro-2-methyl-4-isothiazolin-3-one (at 0.001 %), and 2-methyl-4-isothiazolin-3-one (at 0.0004 %). This product has a density of 1.156 g/mL and a pH of 9.0 for a 10 % solution in water. The chemistry requirements for USF 2010 Fungicide have been completed.

Health Assessments

USF 2010 Fungicide is of low acute toxicity by the oral route ($2,000 \text{ mg/kg bw/d} < \text{LD}_{50} < 5,000 \text{ mg/kg bw/d}$) and by the dermal route ($\text{LD}_{50} > 4,000 \text{ mg/kg bw/d}$), and is of slight acute toxicity by the inhalation route ($\text{LC}_{50} > 1.676 \text{ mg/L}$) in rats. It is not irritating to the eyes (MAS = 0/110) and skin (MAS = 0/110) of rabbits. USF 2010 Fungicide is not a dermal sensitizer in guinea pigs.

The new end-use product, USF 2010 Fungicide, should not result in unacceptable exposure to the active ingredients, tebuconazole and trifloxystrobin. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

No new residue data were submitted to support the registration of the new end-use product USF 2010 Fungicide, containing two registered active ingredients tebuconazole and trifloxystrobin. Data on file support the use of tebuconazole and trifloxystrobin on wheat, barley, oats and soybean. The use of USF 2010 Fungicide will not result in the residues of tebuconazole and trifloxystrobin exceeding the established and recommended MRLs in these commodities. Therefore, the dietary exposure is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The PMRA has determined that the increase in rate of 3% tebuconazole per season does not represent an increase in risk to non-target organisms as the product's rate per application is decreasing by 48.5%. The 4% increase in rate of trifloxystrobin is unlikely to represent an increase in risk to non-target organisms as the hazard based environmental risk mitigation label statements as well as the buffer zones on the USF 2010 Fungicide label are driven by those required for the active ingredient tebuconazole. The PMRA does not anticipate that the registration of USF 2010 Fungicide will result in an unacceptable risk to terrestrial or aquatic non-target organisms.

Value Assessment

Twenty-eight efficacy trials conducted between 2002 and 2007 were submitted in support of this application. The rate for foliar applications on wheat, barley, oats, and soybean is 250 mL/ha (131 g a.i./ha). Up to two applications per season are permitted for all of the uses. All of the trials were conducted in Canada with the exception of the Asian soybean rust trial, which was conducted in Florida. Wheat and barley claims were supported by twelve and ten trials, respectively. Four trials from Ontario and Manitoba were submitted in support of oat claims. The two trials submitted in support of the frogeye leaf spot on soybean claim were conducted in Ontario. All of the claims were supported as proposed either directly by efficacy data supplied in this submission or by rationales and evidence derived from related submissions.

Conclusion

The PMRA has completed an assessment of available information for USF 2010 Fungicide and has found the information sufficient to support the registration.

References

PMRA Document Number	Reference
1521694	2007. USF 2010 SC fungicide - Control of foliar disease in wheat, barley, oat and soybeans. 277 pp.
1521697	2007, USF 2010 Folicar Fungicide, DACO: 3.1,3.1.1,3.1.2,3.1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.3.1,3.4.1,3.5,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI
1521698	2004, Product Chemistry of Stratego Max 500 SC Fungicide, BR 2332, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1,3.5,3.5.1,3.5.11,3.5.12,3.5.13,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI
1521699	2006, Product Chemistry of Absolute 500 SC Fungicide, BR 2535, DACO: 3.5.10,3.5.14 CBI
1521700	2005, Absolute 500 - Acute toxicity in the rat after oral administration. Laboratory report number: AT01966. Activity ID: TXTFY018. Study number: T8075349. DACO 4.6.1.
1521701	2005, Absolute 500 - Acute toxicity in the rat after dermal application. Laboratory report number AT01965. Study number: T0075350. DACO 4.6.2.
1521702	2005, Absolute 500 - Acute Inhalation Toxicity in Rats. Laboratory report number: AT01976. Study number: T3075335. DACO 4.6.3.
1521703	2005, Absolute 500 - Acute eye irritation on rabbits. Laboratory report number: AT01945. Study number: T0074450. DACO 4.6.4.
1521704	2005, Absolute 500 - Acute skin irritation/corrosion on rabbits. Laboratory report number: AT01949. Study number: T8074449. DACO 4.6.5.
1521705	2005, Absolute 500 - Study for the skin sensitization effect in guinea pig (Buehler patch test). Laboratory report number: AT01993. Study number: T 5074987. DACO 4.6.6.

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