

Evaluation Report for Category B, Subcategory 3.13, 3.2, 3.7 Application

Application Number: 2012-2230
Application: B.3.13 – Product labels – Precautions
B.3.2 – Product labels – Application timing
B.3.7 – Product labels – Pre-grazing interval
Product: QUILT Fungicide
Registration Number: 28328
Active ingredients (a.i.): Azoxystrobin and Propiconazole
PMRA Document Number : **2236216**

Purpose of Application

The purpose of this application was to amend the QUILT Fungicide label by the addition of new application timing on wheat and barley, amend the pre-grazing interval for forage on cereals and to update the secondary and primary precautionary statements.

Chemistry and Environmental Assessment

Chemistry and environmental assessments were not required for this application.

Health Assessments

QUILT Fungicide is of slight toxicity to rats via the oral route (LD_{50} of 1750 mg/kg bw) and of low acute toxicity by the dermal ($LD_{50} > 5000$ mg/kg) and inhalation ($LC_{50} > 2.55$ mg/L) routes. It is moderately irritating to the eye and mildly irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

The use on cereals represents an expansion of use for propiconazole and azoxystrobin. A risk assessment was performed for workers entering treated fields. No risks of concern are expected when workers follow the label directions and wear the personal protection equipment identified on the label.

No new residue data were submitted in support of the addition of new application timing and frequency for barley and wheat and amendment of the pre-grazing interval for cereal forage on the registered label for QUILT Fungicide. Data on file support the amendments for QUILT Fungicide. The uses of QUILT Fungicide are not expected to increase the magnitude of azoxystrobin and propiconazole residues in/on wheat and barley. Therefore, the dietary exposure to azoxystrobin and propiconazole is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Value Assessment

The applicant submitted a rationale to support the changes to the use pattern for wheat and barley diseases. The reduced propiconazole rate of 62.5 g/ha is currently registered to suppress the diseases in question on the Tilt 250E label. The reduced rate of azoxystrobin to 38 g/ha has previously demonstrated a level of efficacy comparable to the registered rate in QUILT Fungicide (56 g/ha). The requested upper rate (1.0 L/ha) exceeds the currently registered rate of QUILT Fungicide for these diseases (0.75 L/ha). The new high rate is supported to provide consistent efficacy and to encompass rust control in the application.

The change in application timing to the two leaf stage is the same as the early timing recommendation registered on the Tilt 250E label. The addition of a second application falls within FRAC guidelines and is not expected to negatively affect efficacy.

The registrant has acknowledged that leaf tip burn may result when mixing QUILT Fungicide with certain herbicides and fertilizers. A phytotoxicity statement has been added to the product label to address phytotoxic effects associated with these types of tank mixes.

The registration of a lower rate of QUILT Fungicide gives the grower the option of applying less product to their crop leading to cost savings. The registration of a suppression claim informs the grower that the lower rate has a lower level of efficacy and is not recommended for high disease pressures. The option of applying QUILT Fungicide at an earlier growth stage gives the grower the opportunity to tank mix QUILT Fungicide with herbicides and fertilizers. This stage of application is also considered a preventative treatment, which may eliminate foliar diseases and maximize yield and quality. A second application extends the period of protection since the earlier timing may not address infection events later in the season.

Conclusion

The PMRA has completed an assessment of the available information and is able to support the addition of new application timing on wheat and barley, amend the pre-grazing interval for forage on cereals and to update the secondary and primary precautionary statements on the QUILT Fungicide label.

References

PMRA No.	References
2200693	2012, Summary - Toxicology Profile, DACO: 4.1
2200694	2007, CGA64250/Azoxystrobin SE (125/075) (A13705L) - Acute Oral Toxicity Up-and-Down Procedure in Rats, DACO: 4.6.1
2200695	2007, CGA64250/Azoxystrobin SE (125/075) (A13705L) - Acute Dermal Toxicity in Rats, DACO: 4.6.2
2200696	2007, CGA64250/Azoxystrobin SE (125/075) (A13705L) - Acute Inhalation Toxicity in Rats, DACO: 4.6.3
2200697	2006, Propiconazole/Azoxystrobin SE (125/075) (A13705L): Primary Eye Irritation Study In Rabbits, DACO: 4.6.4
2200698	2009, Azoxystrobin/Propiconazole SE (A13705W) Acute Eye Irritation Study in

- Rabbits, DACO: 4.6.4
- 2200699 2006, Propiconazole/Azoxystrobin SE (125/075) (A13705L): Primary Skin Irritation Study In Rabbits, DACO: 4.6.5
- 2200700 2009, Azoxystrobin/Propiconazole SE (A13705W) Acute Dermal Irritation Study in Rabbits, DACO: 4.6.5
- 2200701 2012, CGA64250/Azoxystrobin SE (125/075) (A13705L) - Dermal Sensitization Test - Buehler Method, DACO: 4.6.6
- 2200717 2012, Rationale to Support the Application of the rate range of 0.5-1.0 L/ha for QUILT Fungicide at a new timing of G.S. 12-23, DACO: 10.1,10.2.3.1,10.2.3.3,10.3.1,10.3.2

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