

Evaluation Report for Category B, Subcategory 3.8, 3.13 Application

Application Number: 2010-1664
Application: B.3.8 (Product labels - re-entry interval)
B.3.13 (Product labels - precautions)
Product: Heritage Maxx Fungicide
Registration Number: 28393
Active ingredients (a.i.): Azoxystrobin (AZY)
PMRA Document Number English PDF: 2051020

Purpose of Application

The purpose of this application was to amend the re-entry interval (REI), and the hazard signal words and symbol on the Heritage Maxx Fungicide label (Registration number 28393).

Chemistry, Environmental and Value Assessments

Chemistry, environmental and value assessments were not required for this application.

Health Assessments

A toxicology review of the previously submitted acute toxicity data with Heritage Maxx Fungicide and a new scientific rationale submitted by the applicant was conducted and did not support a change to the hazard signal words and symbol triggered by the acute oral toxicity study in rats. A re-visitation of the skin irritation study in rabbits indicated that Heritage Maxx Fungicide is slightly irritating to the skin, which does not warrant hazard signal words on the label.

There are no risks of concern with the proposed change in REI from 4 hours to ‘until sprays have dried’ on the label of Heritage MAXX Fungicide, in order to remain competitive with other similar products, provided that workers follow label directions and precautions, including the listed restrictions and personal protective equipment.

Conclusion

The PMRA has reviewed all available information and is able to support the revised re-entry (REI). However, the change to the hazard signal words and symbol could not be supported on the Heritage Maxx Fungicide label.

References

- 954442 2003, Azoxystrobin ME (95) (A13972A): Eye Irritation Study in the Rabbit, DACO: 4.6.4
- 954443 2003, Azoxystrobin ME (95) (A13972A): Skin Irritation Study in the Rabbit, DACO: 4.6.5
- 954444 2003, Azoxystrobin ME (95) (A13972A): Skin Sensitisation Study in the Guinea Pig, DACO: 4.6.6
- 954467 2003, Summary of Acute Toxicology Studies with Azoxystrobin ME (95) (A13972A), DACO: 4.1
- 954468 2003, Azoxystrobin ME (95): Acute Oral Toxicity Study in Rats, DACO: 4.6.1
- 954469 2003, Azoxystrobin ME (95) (A13972A): Acute Dermal Toxicity Study in the Rat, DACO: 4.6.2
- 954470 2003, Azoxystrobin ME (95) (A13972A): 4-Hour Acute Inhalation Toxicity Study in Rats, DACO: 4.6.3
- 1951016 2010, 4.8-1 Heritage MAXX Acute oral rationale, DACO: 4.8

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