

Evaluation Report for Category B, Subcategory 3.13 Application

Application Number: 2011-2687

Application: New or Changes to Product Labels - Precautions

Product: Fungitrol 940 Fungicide

Registration Number: 29904

Active ingredients (a.i.): 3-iodo-2-propynyl N-butylcarbamate

PMRA Document Number: 2109819

PMRA Document Number English PDF: 2124545

Purpose of Application

The purpose of this submission was to modify the toxicological statements on the label of the currently registered product, Fungitrol 940 Fungicide (Registration Number 29904). Fungitrol 940 Fungicide is a Commercial class product for use as a preservative in manufacturing paints, coatings, plastics and adhesives. At the time of the original registration, the acute toxicity data used in support of Fungitrol 940 Fungicide (which is a water-based product) were conducted using a similar product which was solvent-based (Fungitrol 440). With the current application, acute toxicity data, which are specific to the current product, were submitted in order to update the precautionary statements on the label. In addition, a submission was made to the US to register Fungitrol 940 Fungicide as a separate registration, as previously it was linked as an alternate formulation of Fungitrol 440.

Health Assessments

Fungitrol 940 Fungicide is of low acute oral toxicity in rats ($LD_{50} = 2658$ mg/kg bw), and of low acute dermal toxicity in rabbits ($LD_{50} > 5000$ mg/kg bw). It is slightly acutely toxic to rats via the inhalation route of exposure ($LC_{50} > 1.1$ mg/L). Fungitrol 940 Fungicide was mildly irritating to the eyes of rabbits but only slightly irritating to rabbit skin. Fungitrol 940 Fungicide was considered to be a dermal sensitizer based on the results of a local lymph node assay in mice.

The registered label was updated to reflect the personal protective equipment requirements associated with the revised acute toxicology profile and to align with the label amendments outlined in the Re-Evaluation Decision for 3-iodo-2-propynyl butyl carbamate (RVD2011-04).

A residue assessment was not required for this application.

Chemistry, Environmental and Value Assessments

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



Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Fungitrol 940 Fungicide, and has found the information sufficient to modify the toxicological statements.

References

PMRA Document	
Number	Reference
2073343	2011, Fungitrol 940:Acute Oral Toxicity in Rats - Up and Down Procedure, DACO: 4.6.1
2073345	2011, Acute Dermal Toxicity / LD50 in Rabbits, DACO: 4.6.2
2073347	2011, Acute Inhalation Toxicity Study of Fungitrol 940 Fungicide in Albino Rats, DACO: 4.6.3
2073350	2011, Fungitrol 940: Acute Eye Irritation in Rabbits, DACO: 4.6.4
2073351	2011, Fungitrol 940: Acute Dermal Irritation in Rabbits, DACO: 4.6.5
2073353	2011, Local Lymph Node Assay with Fungitrol 940 in Mice, DACO: 4.6.8

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