Evaluation Report for Category B, Subcategory 2.1, 2.3, & 2.4 Application

Application Number: 2006-5092
Application: B.2.1, New EP Product Chemistry-Guarantee
B.2.3, New EP Product Chemistry-Identity of Formulants
B.2.4, New EP Product Chemistry-Proportion of Formulants
Product: Fungitrol 11-50S Fungicide
Registration Number: 28993
Active ingredients (a.i.): Folpet
PMRA Document Number: 1575627

Purpose of Application

The purpose of this application is to register Fungitrol 11-50S Fungicide, a new commercial product containing the active ingredient folpet, for use as a material preservative in paints, coatings and caulking compounds.

Chemistry Assessment

Fungitrol 11-50S Fungicide is formulated as a solution containing folpet at a nominal concentration of 48%. This end-use product has a density of 1.14 g/cm^3 and pH of 8.9 for a 1% solution. The chemistry requirements for Fungitrol 11-50S Fungicide are complete.

Health Assessments

Fungitrol 11-50S Fungicide is of low toxicity to rats via the oral (LD50 >5000 mg/kg), dermal (LD50 >5000 mg/kg), is of moderate toxicity via the inhalation route (LC50 >0.171 mg/L). It is mildly irritating to the eye and minimally irritating to the skin of rabbits. It is a dermal sensitizer in guinea pigs.

Fungitrol 11-50S Fungicide is a solution formulation containing the active ingredient folpet for use in solvent-based paints and coatings. The value assessment indicates the acceptable use rate of 1.0 - 2.0% Fungitrol 11-50S Fungicide in paints and coatings which fits within the existing pattern of folpet containing material preservatives. No increase in exposure is expected but Personal Protective Equipment (PPE) are recommended based on the acute toxicity of the end use product.

Environmental Assessment

No environmental studies were required to support registration of Fungitrol 11-50S Fungicide as the proposed use is the same as for Fungitrol 11 Powder, and the proposed guarantee is less than that of the precedent product. However, the end use product contains petroleum distillates at 35.6% of the formulation. Therefore, the EP will require an environmental hazard statement for petroleum distillate products. The environmental assessment does not expect the registration of Fungitrol 11-50S Fungicide to pose an unacceptable risk to the environment, provided Environmental Hazard statements are included on the product label.

Value Assessment

Efficacy data were submitted for field trials from New Jersey, Florida, and Puerto Rico in which Fungitrol 11 was added at a range of concentrations to non-aqueous based paints. The paint samples were applied to wood panels, and subjected to the weather for a period of two years, during which time they were periodically rated for mold and mildew growth. The New Jersey field test representing a temperate climate comparable to much of Canada, found that 1.0 % Fungitrol 11 provided adequate protection against mold and mildew.

Fungitrol 11 is a pure active ingredient (96% Folpet), while Fungitrol 11-50S Fungicide(48% Folpet) contains half of the active and some formulants. Bridging data was provided, which compared the two products in paint films within a tropical chamber. Results indicate the two Fungitrol products, adjusted to the same concentration of active ingredient, performed similarly for over two weeks. As such, the formulation of Fungitrol 11-50S Fungicide is not expected to have any significant impact on efficacy, and Fungitrol 11-50S Fungicide should be effective at protecting paint films at concentrations of 2%.

The efficacy data from a laboratory trial evaluating Fungitrol 11-50S Fungicide in caulking material was provided, but found to be inadequate. The use of Fungitrol 11-50S Fungicide in caulks is not supported.

Conclusion

The Agency has completed an assessment of available information and has found the information sufficient to allow for full registration of Fungitrol 11-50S Fungicide for use on paint films at 1 to 2% concentration. However, the use of Fungitrol 11-50S Fungicide in caulks is not supported.

Reference List

List of Studies/Information Provided by Registrant

Chemistry Assessment

1290922 2002, 11-50S End Use Product Chemistry Data, DACO: 3.2 CBI
1290923 2003, Analytical Method, DACO: 3.4.1
1290924 2001, Fungitrol 11-50S Physico-Chemical Properties, RTS/032, DACO: 3.5
1290925 2006, Fungitrol 11-50S Fungicide EPA Registration Amendment, DACO: 3.7 CBI
1290927 2006, US EPA Response to Amended Application, DACO: 3.7
1421442 Establishing Certified Limits, DACO: 3.3.1
1436903 2007, N-[(trichlormethyl)thia]phthalimide, DACO: 3.5.10 CBI

Health Assessment

1290928 2001, Fungitrol 11-50S Acute Oral Toxicity Study in the Rat, 8045-001/T/290/2001, DACO: 4.6.1
1290929 2001, Fungitrol 11-50S Acute Dermal Toxicity in the Rat, 8046-001/T/320/2000, DACO: 4.6.2
1290930 2001, Acute (Four- Hour) Inhalation Study in Rats, RTS 031/012930, DACO: 4.6.3
1290932 2001, Acute Eye Irritation Study in the Rabbit, 8049-001/T/338/2000, DACO: 4.6.4
1290933 2001, Acute Dermal Irritation Study in the Rabbit, 8048-001/T/317/2000, DACO: 4.6.5
1290934 2001, Delayed Dermal Sensitization Study in the Guinea Pig, 8050-001/T/050/2001, DACO: 4.6.6

Value Assessment

1290918 1998, 1150S Efficacy Test Review (1998), DACO: 10.6

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