

Evaluation Report for Category B, Subcategory 3.14 Application

Application Number: 2011-3647
Application: B.3.14 (Product labels – classifications)
Product: Insure Cereal Bulk
Registration Number: 30684
Active ingredients (a.i.): Metalaxyl, Pyraclostrobin, Triticonazole
PMRA Document Number: 2179377

Purpose of Application

The purpose of this application was to register a bulk manufacturing concentrate, Insure Cereal Bulk, that is a 100% repack of the new end-use product Insure Cereal.

Chemistry Assessment

Insure Cereal Bulk is formulated as a suspension containing pyraclostrobin at 17 g/L, triticonazole at 17 g/L and metalaxyl at 10 g/L. The manufacturing concentrate has a density between 1.06-1.08 g/cm³ and a pH between 6.0-8.0. The chemistry requirements for Insure Cereal Bulk are complete.

Health Assessments

Insure Cereal Bulk is of low oral (LD₅₀ > 2000 mg/kg bw), dermal (LD₅₀ > 5000 mg/kg bw) and inhalation (LC₅₀ > 5.8 mg/L) toxicity in the rat. It is not irritating (MAS (24-72 hours) = 0.0/110) to the eye or the skin (MAS (24-72 hours) = 0.0/8) of the rabbit. It is a dermal sensitizer in the mouse in the Local Lymph Node Assay.

Exposure assessments were not required for this application.

Environmental and Value Assessment

Environmental and value assessments were not required for this application.

Conclusion

The PMRA has completed an assessment of the available information and is able to support the registration of Insure Cereal Bulk.

References

2161043 2012, BASF response to Clarification Email, DACO: 3.5.10,3.5.14 CBI
2091848 2010, BAS 662 01 F - Acute Oral Toxicity Study in Rats, DACO: 4.6.1
2091852 2010, BAS 662 01 F - Acute Dermal Toxicity Study in Rats, DACO: 4.6.2
2091853 2010, BAS 662 01 F - Acute Inhalation Toxicity Study in Wistar Rats - 4-hour
Liquid Aerosol Exposure (head-nose only), DACO: 4.6.3
2091858 2010, BAS 662 XH F - Acute Eye Irritation / Corrosion in Rabbits, DACO: 4.6.4
2091860 2010, BAS 662 XH F - Acute Dermal Irritation / Corrosion in Rabbits, DACO:
4.6.5
2091861 2010, BAS 662 01 F - Murine Local Lymph Node Assay (LLNA), DACO: 4.6.6

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