

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

Application Number: 2007-2340
Application: B.2.1 New/Changes to Product Chemistry – Guarantee
B.2.3 New/Changes to Product Chemistry – Identity of Formulants
B.2.4 – New/changes to Product Chemistry – Proportion of Formulants
Product: Micropel A285
Registration Number: 28330
Active ingredients (a.i.): Iodocarb (IPB)
PMRA Document Number: 1786389

Purpose of Application

Micropel LLC has submitted an application to register a new material preservative fungicide containing the active ingredient 3-iodo-2-propynyl butyl carbamate (Iodocarb), for use in extruded PVC film used in the manufacture of sealants and gaskets.

Chemistry Assessment

Micropel A285 is formulated as a solution containing 3-iodo-2-propynyl butyl carbamate at a minimum concentration of 15% w/w. This end-use product has a density of 1.04 - 1.06 g/cm³ and pH of 6.05. The chemistry requirements for Micropel A285 are complete.

Health Assessments

Micropel A285 is of low toxicity to rats via the oral (LD₅₀ > 5000 mg/kg bw), dermal (LD₅₀ > 5000 mg/kg bw), and inhalation routes (LC₅₀ > 2.07 mg/L). It is mildly irritating to the eye and slightly irritating to the skin of rabbits. It is considered to be dermal sensitizer in guinea pigs.

A health assessment has been conducted for Micropel A285. It is not expected that exposure of handlers and by-standers will increase over the exposure from currently registered products containing Iodocarb as the active ingredient.

Environmental Assessment

The use of Micropel A285 (15.5% of 3-iodo-2-propynyl butyl carbamate as TGAI) as a material preservative (fungicide) in extruded PVC film for sealants and gaskets is not expected to pose additional environmental concerns.

Value Assessment

Efficacy data was submitted to register Micropel A285 as a new material preservative. The active ingredient, Iodocarb is used at 15.5% to protect extruded PVC films for use in the manufacture of sealants and gaskets. After reviewing the data and rationales provided, this use was determined to be acceptable.

Conclusion

The PMRA has completed its assessment and has found the information adequate to support the registration of Micropel A285.

References

PMRA # Reference

Product Chemistry:

1013197 2004, Physical and Chemical Characteristics of Troy Bionyl A285. Storage Stability and Corrosion Characteristics, 650-66, DACO: 3.5.10,3.5.14 CBI
1013209 Applicant s Name and Office Address, DACO: 3.1.1 CBI
1013211 Formulating Plant s Name and Address, DACO: 3.1.2 CBI
1013212 Trade Name, DACO: 3.1.3 CBI
1013213 Description of Starting Materials, DACO: 3.2.1 CBI
1013214 Description of Formulation Process, DACO: 3.2.2 CBI
1013215 Discussion of the Impurities of Toxicological Concern, DACO: 3.2.3 CBI
1013216 Specifications, DACO: 3.3 CBI
1013217 2001, A Method for Determining the Percentage of 3-iodo-2-propynyl butyl carbamate in Polyphase Bionyl A285, MRID: 461880-01, DACO: 3.4.1 CBI
1013218 2003, Physical and Chemical Characteristics of Troy Bionyl A285, 650-65, , DACO: 3.5.1,3.5.11,3.5.12,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI
1065158 Specifications, DACO: 3.3 CBI
1603281 2008, Enforcement Analytical Method Addendum, DACO: 3.4.1

Health Evaluation

1013199 2003, Troy Bionyl A285 Acute Oral Toxicity Up and Down Procedure in Rats, 14144, DACO: 4.6.1
1013200 2003, Troy Bionyl A285 Acute Dermal Toxicity Study in Rats Limit Test, 14145, DACO: 4.6.2
1013201 2003, Troy Bionyl A285 Acute Inhalation Toxicity Test in Rats, 14146, DACO: 4.6.3
1013202 2003, Troy Bionyl A285 Primary Eye Irritation Study in Rabbits, 14147, DACO: 4.6.4
1013203 2003, Troy Bionyl A285 Primary Skin Irritation in Rabbits, 14148, DACO: 4.6.5
1013204 2003, Polyphase Bionyl A285 Dermal Sensitization Study in Guinea Pigs (Buehler Method), 13700, DACO: 4.6.6

Value and Efficacy:

1603282 Description of Pest Problem
1603285 Efficacy, Laboratory Report Addendum
1603283 Non-Safety Adverse Effects

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