

Evaluation Report for Category B, Subcategory 2.3, 2.4, 3.12 Application

Application Number: 2013-4022
Application: New product chemistry – identity and proportion of formulants
New product label – new site or host
Product: Mergal BIT20W
Registration Number: 31465
Active ingredients (a.i.): 1,2-benzisothiazolin-3-one (BZZ)
PMRA Document Number: 2339116

Purpose of Application

The purpose of this application was to register Mergal BIT20W, a new material preservative (USC 18) containing 1,2-benzisothiazolin-3-one (BZZ) as the active ingredient.

Chemistry Assessment

Mergal BIT20W is formulated as a solution containing 1,2-benzisothiazolin-3-one at a nominal concentration of 19.18%. This end-use product has a density of 0.9818 g/mL and a pH of 5.35. With the exception of the storage stability and corrosion characteristic study which will be submitted once completed, the chemistry requirements for Mergal BIT20W are complete.

Health Assessments

Mergal BIT20W is considered to be of low acute toxicity via the oral and dermal routes, of slight acute toxicity via the inhalation route, corrosive to the eyes, moderately irritating to the skin, and not a dermal sensitizer.

The use of Mergal BIT20W is within the currently registered use patterns for 1,2-benzisothiazolin-3-one active ingredient. Therefore, exposure to Mergal BIT20W is not expected to increase over the exposure from the currently registered products.

Environmental Assessment

The Environmental Assessment Directorate has determined that the registration of the proposed new product does not represent an increase in risk to non-target organisms compared with other fully registered similar products.

Value Assessment

All approved label uses and rates were supported using precedent products Mergal BIT20W PCP#29360 and Mergal 753 PCP#30022.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of the new end-use product Mergal BIT20W.

References

PMRA Document Number	Reference
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2333963	2013, Mergal BIT20W Non-Safety Adverse Effects, DACO: 10.3.2
1164408	2005, Acute Oral Toxicity Up and Down Procedure in Rats., DACO: 4.6.1
1164409	2005, Acute Dermal Toxicity Study in Rats-Limit Test., DACO: 4.6.2
1164410	2005, Acute Inhalation Toxicity in Rats-Defined LC50., DACO: 4.6.3
1164411	2005, Primary Eye Irritation Study in Rabbits. , DACO: 4.6.4
1164412	2005, Primary Skin Irritation Study in Rabbits. , DACO: 4.6.5
1164413	2005, Dermal Sensitization Study in Guinea Pig (Buehler Method)., DACO: 4.6.6
2350028	2011, Primary Eye Irritation Study in Rabbits-Mergal BIT20W , DACO: 4.6.4
2350029	2011, Acute Oral Toxicity Up and Down Procedure in Rats , DACO: 4.6.1
2350031	2011, Mergal BIT20W Primary Skin Irritation Study in Rabbits , DACO: 4.6.5
2328981	2013, Cross Reference DACO 3.2, DACO: 3.2.1
2328983	2012, Enforcement Analytical Method Mergal BIT20W , DACO: 3.4.1
2328985	2013, Mergal BIT20W: DACOS 3.5.10, 3.5.14, DACO: 3.5.10
2328993	2013, DACOS 3.5.4, 3.5.5, 3.5.8, 3.5.12-3.5.15, DACO: 3.5.4
2329006	2013, DACOs 3.1.1 through 3.1.3 , DACO: 3.1.1 CBI
2333960	2013, Mergal BIT20W Establishing Certified Limits , DACO: 3.3.1 CBI
2430072	2014, DACO 3.2 - Mergal BIT20W Formulation Process, DACO: 3.2.2 CBI
2430073	2013, Mergal BIT20W: Analytical method for the Determination of 1,2-Benzisothiazol-3(2H)-one (BIT) by High Performance Liquid Chromatography, DACO: 3.4.1 CBI
2430075	2014, DACO 3.5 - Mergal BIT20W Physical Chemistry, DACO: 3.5 CBI
2430076	2011, Physical and Chemical Characteristics of BIT20W: Flammability, pH, Viscosity and Relative Density, DACO: 3.5.11, 3.5.6, 3.5.7 ,3.5.8 CBI
2430078	2010, Physical and Chemical Characteristics of BIT Paste: Oxidation/Reduction, DACO: 3.5.8 CBI
2430080	2014, Storage Stability and Corrosion Characteristics for Mergal BIT20W, DACO: 3.5.10,3.5.14

ISSN: 1911-8082

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