

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.1, 3.12 Application

Application Number: 2009-5097
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
B.3.1 – New Product Labels-Application Rate Increase
B.3.12 - New Product Labels-New Site or Host
Product: Mergal 753
Registration Number: 30022
Active ingredients (a.i.): 1,2-Benzisothiazolin-3-one [BZZ]
PMRA Document Number English PDF: 2032497

Purpose of Application

The purpose of this application was to register a new commercial microbiocide , Mergal 753, as a material preservative for polymer emulsions, emulsion paints and coatings, mineral slurries and dispersions, lattices, metalworking fluids, adhesives, joint compounds and Exterior Insulated Finish Systems (EIFS) finish.

Chemistry Assessment

Mergal 753 is formulated as a solution containing 1,2-benzisothiazolin-3-one at a nominal concentration of 44.90% w/w. This end-use product has a density of 1.10-1.30 g/mL and a pH of 4.76. The chemistry requirements for Mergal 753 are complete.

Health Assessments

Mergal 753 is considered to be of slight acute toxicity via the oral route, and low acute toxicity via the dermal and inhalation routes in rats. Mergal 753 was extremely irritating to the eye and slightly irritating to the skin of rabbits, and is a dermal sensitizer.

A health assessment has been conducted for registration of a new commercial end-use product, Mergal 753, containing 44.9% 1,2-benzisothiazolin-3-one. This product is to be used as a material preservative for polymer emulsions, emulsion paints and coatings, mineral slurries and dispersions, lattices, metalworking fluids, adhesives, joint compounds and EIFS finish. Exposure to mixer/loader/ applicators and post-application workers was determined to be acceptable.

Environmental Assessment

An environmental risk assessment was not required as the accepted uses for this new EP are indoor and outdoor with minimal environment exposure. Therefore, applications of Mergal 753 according to product label are not expected to result in an increase in environmental risk.

Value Assessment

Laboratory studies were conducted to evaluate the ability of Mergal 753 to protect adhesives, joint compounds and wallpaper paste and EIFS finish. The studies were conducted with various materials and used bacterial inoculum simulating real-life contamination possibilities. The data demonstrated that Mergal 753 is effective against bacterial growth under representative use conditions. For other label uses, the applicant relied on a precedent, Mergal BIT20 (PCP# 29360).

Conclusion

The PMRA has completed an evaluation of the data provided to support Mergal 753 and has found the information sufficient for full registration.

References

- 1832325 2009, Formulating Plants Name and Address, DACO: 3.1.2 CBI
- 1832326 2009, Trade Name, DACO: 3.1.3
- 1832327 2009, Other Names, DACO: 3.1.4
- 1832329 2009, Description of Starting Materials, DACO: 3.2.1 CBI
- 1832330 2009, Description of Formulation Process Mergal 753, DACO: 3.2.2
- 1832331 2009, Certified Limits/Product Specifications-Mergal 753, DACO: 3.3.1
- 1832332 2009, A Tentative HPLC Method for the Determination of 1,2-benzisothiazolin-3-one (BIT) in BIT Products, DACO: 3.4.1 CBI
- 1832333 2009, Physical State of Mergal 753, DACO: 3.5.2
- 1832334 2009, Formulation Type-Mergal 753, DACO: 3.5.4
- 1832335 2009, Container Material and Description, DACO: 3.5.5
- 1832336 2009, Product Chemistry of Mergal 753, DACO: 3.5.6
- 1832338 2009, Description of Starting Materials Mergal 753, DACO: 3.5.8 CBI

1832340 2009, Storage Stability Mergal 753, DACO: 3.5.10

1832342 2009, Explodability-Mergal 753, DACO: 3.5.12

1832343 2009, Miscibility-Mergal 753, DACO: 3.5.13

1832347 2009, Dielectric Breakdown Voltage-Mergal 753, DACO: 3.5.15

1852715 2009, Mergal 753 Corrosion Characteristics, DACO: 3.5.10, 3.5.14

1909816 2010, Revised Description of Formulation Process-Mergal 753, DACO: 3.2.2 CBI

1909818 2010, Addendum Enforcement Analytical Method-Mergal 753, DACO: 3.4.1

1909820 2010, Mergal 753 Oxidizing or Reducing Action (Chemical Incompatibility), DACO: 3.5.8

1913202 2010, Analytical Method -Blank Formulation Chromatogram, DACO: 3.4.1

1597367 2008, BIT Technical: Analysis of Dioxins, Furans and [CBI Removed], DACO: 2.13.4

1870787 2010, Efficacy Mergal 753-Laboratory Trials, DACO: 10.2.3.2(E)

1878776 2008, Evaluation of Mergal BIT20, Mergal K10N, Mergal 753 and Polyphase 678 in An Adhesive Sample and Evaluation of Nine Preserved Adhesive Samples and One Latex Resin Emulsion Sample, DACO: 10.2.3.2(E)

1878777 2008, Evaluation of Mergal 192, Mergal 753, Mergal K12N, Mergal 758 and Mergal 723K in Four Wallpaper Paste Samples, DACO: 10.2.3.2(E)

1878778 2008, Evaluation of Mergal 174, Mergal 723K, Mergal 758, Mergal 753, Mergal K14 and Dowicil 75 in a Joint Compound Sample, DACO: 10.2.3.2(E)

1878779 2008, Comparison of Mergal 753, Mergal K12N, Mergal 758, Mergal 786 Mergal 142 and BioTech 036 in a Precipitated Calcium Carbonate Slurry Sample, DACO: 10.2.3.2(E)

1878780 2009, Evaluation of Mergal 174, Mergal 395, Mergal 753, Polyphase 663, and Mergal S90 in an EIFS Finish Sample and Evaluation of a Current Production Sample, DACO: 10.2.3.2(E)

1832366 2009, Non-Safety Adverse Effects Mergal 753, DACO: 10.3.2

1832349 2009, Acute Toxicology Profile, DACO: 4.1

1832350 2007, Acute Oral Toxicity Up and Down Procedure in Rats, DACO: 4.6.1

- 1832351 2007, Acute Dermal Toxicity Study in Rats-Limit Test, DACO: 4.6.2
- 1832352 2007, Acute Inhalation Toxicity Study in Rats-Limit Test, DACO: 4.6.3
- 1832353 2007, Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
- 1832354 2007, Primary Skin Irritation Study In Rabbits, DACO: 4.6.5
- 1832355 2007, Dermal Sensitization Study in Guinea Pigs (Buehler Method), DACO: 4.6.6
- 1878775 General correspondence on Mergal 753: Response to Girard Email of March 10, 2010

Additional information considered

- 1586244 2008, PRVD2008-13 Benzisothiazolin-3-one

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2011

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.