

## Evaluation Report for Category B, Subcategory 1.2 Application

**Application Number:** 2006-0458  
**Application:** B.1.2  
**Product:** Mergal BIT Paste  
**Registration Number:**  
**Active ingredients (a.i.):** 1,2-benzisothiazolin-3-one (BZZ)  
**PMRA Document Number:** 1771055

### Background

The original source of 1,2-benzisothiazolin-3-one technical grade active ingredient, “Proxel CRL Microbiostat Solution” (Reg. 11822) was first registered in 1973.

### Purpose of Application

The purpose of this application is to register a new technical source of 1,2-benzisothiazolin-3-one.

### Chemistry Assessment

Common Name: 1,2-benzisothiazolin-3-one  
Chemical Name: 1,2-benzisothiazol-3(2H)-one

Mergal BIT Paste has the following properties:

Property	Result
Colour and physical state	Off-white paste
Nominal concentration	72.00%
Odour	None
Density	0.58 – 0.71 g/cm <sup>3</sup>
Vapour pressure	0.15 mPa
pH	4.25 for a 1% solution
Solubility in water	1.1 mg/mL
n-Octanol/water partition coefficient	log K <sub>ow</sub> = 1.40

The chemistry requirements for Mergal BIT Paste have been completed.

### **Health Assessments**

A health assessment is not required for this technical grade active ingredient product.

### **Environmental Assessment**

An environmental assessment is not required for this technical grade active ingredient product.

### **Value Assessment**

A value assessment is not required for technical grade active ingredient products.

### **Conclusion**

The PMRA has completed its evaluation of the subject application and has determined that Mergal BIT Paste is eligible for full registration.

## References

### 7.1.1 Studies/Information Provided by Applicant/Registrant

- 1135353 2006, Product Chemistry Requirements Mergal BIT Paste, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
- 1135354 Manufacturing Summary, Materials Used to Produce the Product-XBINX, Detailed Production Process Description, Discussion of Formation of Impurities - Mergal BIT Paste, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
- 1135355 Establishing Certified Limits - Mergal BIT Paste, DACO: 2.12.1 CBI
- 1135356 1988, Assay of XBINX, Method 19-137 - Mergal BIT Paste, DACO: 2.13.1 CBI
- 1135357 XBINX Assay by Spectrophotometry - Method 19-020593, DACO: 2.13.2 CBI
- 1135358 2005, Batch Data - (5 Batch Analysis). Certificate of Analysis. Confidential Attachment. Preliminary Analysis, DACO: 2.13.3 CBI
- 1135359 1994, Physical and Chemical Properties of 1,2-Benzisothiazol-3 (2H)-one (BIT) and information on Manufacturing Use Product see - Mergal BIT Paste, Physical and Chemical Characteristics: Colour, Odor, Oxidation/Reduction, Flammability, pH, and Density/Bulk
- 1135360 UV/Visible Absorption Spectra, DACO: 2.14.12 CBI
- 1135361 Samples of Analytical Standards provided upon request, DACO: 2.15 CBI
- 1135363 Impurities of Toxicological Concern - Not applicable, DACO: 2.13.4 CBI
- 1326709 2006, Addendum to Product Chemistry Mergal Paste, DACO: 2.11.2 CBI
- 1326711 2006, Documentation for Canadian Registration, DACO: 2.11.3 CBI
- 1326712 2006, Batch Data-Mergal BIT Paste, DACO: 2.13.3 CBI
- 1326713 2006, Chemical & Physical Properties, DACO: 2.14 CBI
- 1485021 2007, Detailed Process Description, DACO: 2.11.3 CBI
- 1485022 2005, Preliminary Analysis, DACO: 2.13.3 CBI
- 1568440 2008, Description of Starting Materials Amendment, DACO: 2.11.2 CBI
- 1568441 2008, Batch Data Amendment, DACO: 2.13.3
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- 1597367 2008, BIT Technical: Analysis of [CBI REMOVED], DACO: 2.13.4

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