

Evaluation Report for Category D IMEP, Subcategory B.1.1 Application

Application Number: 2011-0958
Application: IMEP B.1.1 (Product Chemistry – new source same registrant)
Product: Nuosept BIT
Registration Number: 24412
Active ingredients (a.i.): 1,2-benzisothiazolin-3-one (BZZ)
PMRA Document Number English PDF: 2056218

Purpose of Application

The purpose of this application was to register an alternate source (site of manufacture) for the Importation for Manufacturing and Export Program (IMEP) technical Nuosept BIT (Registration number 24412).

Chemistry Assessment

Common Name: 1,2-benzisothiazolin-3-one
Chemical Name: 1,2-benzothiazol-3(2*H*)-one
 OR
 1,2-benzisothiazolin-3(2*H*)-one

Property	Result
Colour and physical state	White to off white powder
Nominal concentration	84 % (on a wet basis)
Odour	No discernible odour
Specific gravity	1.43 – 1.45
Vapour pressure	2.3×10^{-4} Pa at 25°C
pH	4.66 at 25°C (1% aqueous dispersion)
Solubility in water	1.15 g/L at 20 °C (pH 7)
n-Octanol/water partition coefficient	$\log K_{ow} = 1.19$ at 20 °C (pH 7)

The chemistry requirements for Nuosept BIT have been completed.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

Conclusion

The PMRA has reviewed all available information and has determined that the registration of the new source of Nuosept BIT is acceptable.

References

PMRADocument

Number	Reference
2024836	2010, Product Chemistry Series 830 Group A: Product Identity, Composition, and Analysis of [CBI REMOVED] BIT Technical, DACO: 2.11 CBI
2024837	2007, Five Batch Analysis of 1,2-benzisothiazol-3(2H)-one Technical from [CBI REMOVED] For Active Ingredient and,Impurities [CBI Removed], DACO: 2.13.3 CBI
2024838	2006, 1,2-Benzisothiazolin-3-one (BIT) Active Substance: Determination of Physico-chemical properties, DACO: 2.14
2030119	2007, Reverse Phase HPLC Analysis of BIT (Benzisothiazolone) Technical for Active Ingredient, DACO: 2.13.1 CBI
2030120	2007, Capillary GC Analysis of BIT for Water, DACO: 2.13.1 CBI
2030121	2007, Analysis for % [CBI Removed] in BIT Technical by Potentiometric Titration, DACO: 2.13.1 CBI
2030122	2007, Reverse Phase HPLC Analysis of Organic Impurities in BIT Technical, DACO: 2.13.1 CBI
2030123	2007, GLP Validation of CIS Analytical Test Method # 04-94-01 for the analysis of BIT Tech for Active Ingredient, DACO: 2.13.2 CBI
2030124	2007, GLP Validation of PC&B Analytical Test Method # 07-120-01 for Analysis of Sodium Chloride in BIT Technical, DACO: 2.13.2 CBI
2030125	2007, GLP Validation of PC&B Analytical Test Method # 07-118-01 for the Analysis of Water in BIT Technical Samples, DACO: 2.13.2 CBI
2030127	2007, GLP Validation of PC&B Analytical Test Method # 07-116-01 for Analysis of Impurities in 1,2-benzisothiazol-3(2H)-one (B IT), DACO: 2.13.2 CBI

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