

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2008-5907
Application: New Source of Active Ingredient by a New Registrant
Product: Basic Copper 53 Technical
Registration Number: 29859
Active ingredients (a.i.): Copper as element (Present as Basic Copper Sulfate)
PMRA Document Number English PDF: 1943082

Purpose of Application

The purpose of this application is to register a new technical source of copper as element (present as basic copper sulfate). The source technical used to determine chemical equivalence was Registration No. 18180.

Chemistry Assessment

Common Name: Basic Copper Sulphate
 IUPAC Chemical Name: Cupric Sulfate-Tricupric Hydroxide
 Chemical Name: Basic Copper Sulfate, Copper Hydroxide Sulfate

Basic Copper 53 Technical has the following properties:

Property	Result
Colour and physical state	Green solid
Nominal concentration	Copper (present as basic copper sulfate) at 53.4%
Odour	None
Density	0.678 g/mL
Vapour pressure	N/A as the product is a solid
pH	7.13
Solubility in water	107 ppm (25°C)
n-Octanol/water partition coefficient	N/A as the product is an inorganic compound and this property is not required.

The chemistry requirements for Basic Copper 53 Technical have been completed.

Health Assessments

No new toxicology or residue data was submitted or requested to support registration of Basic Copper 53 Technical. An impurity measured not found in the old source was identified and consultation by the health evaluation division was requested. A search of other similar products currently registered by the PMRA indicates that similar measurable levels of this impurity have been reviewed and registered previously. The small amounts of the impurity in this product are not expected to add appreciably to background levels following use. Subsequently the health risks associated with the presence of this impurity is not likely to increase based on the use of this product. The applicant is, nevertheless, encouraged to refine their processes to reduce the levels of the identified impurity in this product.

Environmental Assessments

No new environmental data were submitted to support registration of the new TGAI, Basic Copper 53 Technical. Although the proposed TGAI contains an impurity not present in the precedent source, an environmental assessment was not required because the estimated environmental concentration is not expected to exceed background levels following use of the product. The environment risk profile of Basic Copper 53 Technical is expected to be similar to that of the precedent technical source. Additional data and assessments were not required.

Value Assessment

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

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that Basic Copper 53 Technical is eligible for full registration.

References

7.1.1 Studies/Information Provided by Applicant/Registrant

PMRA

Document

Number	Reference
1688336	2008, DACO 2 Chemistry Requirements for the Registration of a Technical Grade of Active Ingredients (TGAI) for Basic Copper 53, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
1688337	2008, Manufacturing Summary, DACO: 2.11.1 CBI
1688339	2008, OPPTS Product Properties Test Guidelines: Product Identity and Composition, Description of Materials Used to Produce the Product. Description of Production Process, Discussion of Formation of Impurities, and Certified Limits for Basic Copper 53 Man

- 1688341 2008, Basic Copper 53: Preliminary Analysis and Enforcement Analytical Method, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
- 1688344 2008, Physical and Chemical Characteristics of Basic Copper 53: Color, Physical State, Odor, Stability, Oxidation/Reduction, pH, UV/Visible Absorption, Melting Point, Bulk Density and Solubility, DACO: 2.14.1,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2
- 1688345 2008, Dissociation Constant of Basic Copper 53, DACO: 2.14.10 CBI
- 1688346 2008, Octanol-Water Coefficient of Basic Copper 53, DACO: 2.14.11 CBI
- 1688347 2008, Vapour Pressure of Basic Copper 53, DACO: 2.14.9 CBI
- 1688348 2008, Sample(s) of Analytical Standards and ROC, DACO: 2.15 CBI
- 1688349 2008, Boiling Point/Boiling Range, DACO: 2.14.5 CBI
- 1817468 2009, Copper Basic 53-letter of intent-TGAI-27oct2009, DACO: 0.8
- 1817469 2009, Basic Copper 53- Preliminary Analysis and Enforcement Analytical Method, DACO: 2.13.1,2.13.3 CBI

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