

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2009-4723
Application: New Source of Technical Grade Active Ingredient by a New Registrant
Product: Copper Hydroxide MUP
Registration Number: 30390
Active ingredients (a.i.): Copper Hydroxide
PMRA Document Number : 2139841

Purpose of Application

The purpose of this application was to register a new source of the active ingredient, copper hydroxide, by a different Registrant.

Chemistry Assessment

Accepted Name: Copper hydroxide
Chemical Name: Copper hydroxide (Cu(OH)₂)

Copper Hydroxide MUP has the following properties:

Property	Result
Colour and physical state	Blue-green powder
Nominal concentration	60.6 %
Odour	Odourless
Specific gravity	0.701 g/mL (bulk material)
Vapour pressure	Not applicable
pH	7.27 (1 % aqueous suspension)
Solubility in water	2.9 mg/L at 25 °C
n-Octanol/water partition coefficient	Not applicable

The chemistry requirements for Copper Hydroxide MUP are complete.

Health Assessments

No new toxicology data were submitted to support registration of a new source of Copper Hydroxide MUP. The change in the formulation was considered to be acceptable and no additional toxicology data are required. As well, elemental copper (cupric ion) in copper-containing pesticides

is not degraded, and there are therefore no degradates or metabolites of concern. The metabolism of copper is not expected to change in the proposed manufacturing product. Therefore, the dietary exposure is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No new environmental data were submitted to support registration of the new TGAI, Copper Hydroxide MUP and additional environmental data are not required. Estimated environmental concentrations of impurities are not expected to exceed background levels following the use of the product.

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 it can support the registration of Copper Hydroxide MUP.

References

- 1826126 2008, Manufacturing Summary, DACO: 2.11.1 CBI
- 1826139 2009, Copper Hydroxide-letter of intent-TGAI-14nov2009, DACO: 0.8
- 1891082 2010, Copper Hydroxide-letter of intent-TGAI-15april2010-clarification, DACO: 0.8,2.11.3,2.13.4,2.14
- 1826137 2009, Copper Hydroxide MUP: Preliminary Analysis and Enforcement Analytical Method, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
- 2024427 2011, Copper Hydroxide MUP: Preliminary Analysis and Enforcement Analytical Method, DACO: 2.13.4,4.8 CBI
- 1826128 2008, Physical and Chemical Characteristics of Copper Hydroxide MUP: Color, Physical State, Odor, Stability, Oxidation/Reduction, pH, UV/Visible Absorption, Melting Point, Bulk Density and Solubility, DACO: 2.14.1,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.1
- 1826133 2008, Boiling Point/ Boiling Range, DACO: 2.14.5.
- 1826134 2008, Vapour Pressure, DACO: 2.14.9
- 1826132 2008, Octanol Water Coefficient, DACO: 2.14.11
- 1891083 2007, COA - COPPER HYDROXIDE MUP 57%, DACO: 2.14.13 CBI

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