Health Canada Santé Canada

Evaluation Report for Category B, Subcategories 1.1, 1.3 Application

Application Number: 2019-5365
Application: Changes to TGAI Product Chemistry-New Source (site), same registrant; Specifications
Product: Arch Basic Copper Carbonate
Registration Number: 30569
Active ingredient (a.i.): copper, present as basic copper carbonate
PMRA Document Number: 3160440

Purpose of Application

The purpose of this application is to add a new source of technical active ingredient to the registered technical product, Arch Basic Copper Carbonate.

Chemistry Assessment

Common Name: Basic copper carbonate
IUPAC* Chemical Name: copper(II) carbonate hydroxide (2:1:2)
CAS† Chemical Name: [μ-[carbonato(2−)-κO:κO′]]dihydroxydicopper

* International Union of Pure and Applied Chemistry
† Chemical Abstracts Service

Arch Basic Copper Carbonate has the following properties:

Property	Result
Colour and physical state	Green paste
Nominal concentration	45.4% as copper
Odour	None
Density	3.5 – 4.0 g/mL
Vapour pressure	Negligible
pH	6-9 for 1% dilution
Solubility in water	0.36 mg/L
n-Octanol/water partition coefficient	Not applicable

The required chemistry data for Arch Basic Copper Carbonate have been provided, reviewed, and found to be acceptable.

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Health Assessments

Arch Basic Copper Carbonate was moderately acutely toxic via the oral route of exposure (LD_{50} between 500 and 2000 mg/kg bw) and of low acute toxicity following dermal exposure (LD_{50} > 2000 mg/kg bw) in rats. It was mildly irritating to the eyes but not irritating to the skin of rabbits, and was not a dermal sensitizer in guinea pigs when tested using the Maximization test method.

There was no evidence of copper being carcinogenic or resulting in any other systemic toxicity in animals having normal copper homoeostasis. Available studies in animals generally indicate that the main concern for reproductive and developmental effects is associated with copper deficiency rather than excess.

Humans have efficient mechanisms in place to regulate levels of copper in the body, and as such are generally protected from exposure to excess levels of copper; however, some less common genetic conditions in humans may cause abnormal copper metabolism.

Dietary and occupational exposure risk assessments were not required for this application.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Additional Information Being Requested

Since this technical product was manufactured only at pilot scale before registration, five-batch data representing commercial-scale production are required as post-market information after registration.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the registration of the new source of technical active ingredient for Arch Basic Copper Carbonate.

References

PMRA Document Number	Reference
3036330	2019, Basic Copper Carbonate Technical Grade (Wet) Production Process Description and Preliminary Analysis, DACO: 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.13, 2.13.1, 2.13.3 CBI
3057542	2019, Basic Copper Carbonate Technical Grade (WET), DACO: 2.11.1, 2.12.1, 2.13.1, 2.2