



Evaluation Report for Category A, Subcategory 1.1 Application

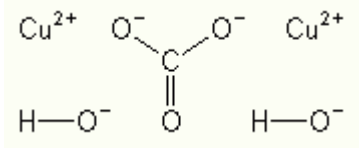
Application Number:	2010-1098	2008-5426
Product:	Arch Basic Copper Carbonate	Wolman µNB
Registration Number:	30569	30570
Active ingredients (a.i.):	copper, present as basic copper carbonate (CUV)	copper, present as basic copper carbonate (CUV) and tebuconazole (TEU)
Application:		New Active Ingredient
PMRA Document Number :		2203060

1.0 Purpose of Application

The purpose of this application was to register the technical active, Arch Basic Copper Carbonate, containing the technical grade active ingredient copper, present as basic copper carbonate, and the end-use product, Wolman µNB, containing the technical grade active ingredients copper, present as basic copper carbonate and tebuconazole as heavy duty wood preservative for lumber for above-ground, ground contact, and fresh-water uses. Copper, present as basic copper carbonate, in Arch Basic Copper Carbonate is in a solid, “micronized” particulate form dispersed in water. Copper, present as basic copper carbonate, is formulated with tebuconazole to form a copper azole-type wood preservative in Wolman µNB.

2.0 Chemistry Assessment

Identity of the Active Ingredient:

Active substance	Copper, present as basic copper carbonate
Function	Heavy duty wood preservative
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Not available
2. Chemical Abstracts Service (CAS)	[µ-[carbonato(2-)-κO:κO']]dihydroxydicopper
CAS number	12069-69-1
Molecular formula	CH ₂ Cu ₂ O ₅
Molecular weight	221.1
Structural formula	
Purity of the active ingredient	45.4 % copper, present as basic copper carbonate

Physical and Chemical Properties of the Technical Grade Active Ingredient—Arch Basic Copper Carbonate

Property	Result
Colour and physical state	Light green paste
Odour	Odourless
Melting range	No melting observed; chemical change at 206°C (wet dense grade) and 191°C (dry light grade)
Boiling point or range	Not applicable
Density	3.5 – 4.0 g/mL at 20°C
Vapour pressure	Not provided; product is a paste
Ultraviolet (UV)-visible spectrum	Not expected to absorb in UV/visible range
Solubility in water at 20°C	0.36 mg/L (wet dense grade) 0.22 mg/L (dry light grade)
Solubility in organic solvents	Not determined, since the product is only to be used in aqueous formulations
<i>n</i> -Octanol-water partition coefficient (K_{ow})	Not applicable, as the substance is an inorganic salt
Dissociation constant (pK_a)	Not applicable, as the substance is an inorganic salt that has no dissociable groups.
Stability (temperature, metal)	Stable to reducing agents (zinc).

Physical and Chemical Properties of the End-Use Product—Wolman µNB

Property	Result
Colour	Light green
Odour	Mild paint-like odour
Physical state	Liquid
Formulation type	Suspension
Guarantee	9.25% copper, present as basic copper carbonate 0.37% tebuconazole
Container material and description	Steel totes, 957 L Bulk tankers, 16 317 L
Density	1.152 g/mL at 20°C
pH of 1% dispersion in water	8.7
Oxidizing or reducing action	This product is a reducing agent but has minimal reactivity with other substances (e.g. reducing or fire extinguishing agents)
Storage stability	Stable for one year
Corrosion characteristics	Not corrosive to its carbon steel packaging over one year
Explosibility	Not expected to be explosive

Methods for Analysis of the Active Ingredient, Formulation and Residue Analysis

The methods provided for the analysis of the active ingredient and the impurities in Arch Basic Copper Carbonate have been validated and assessed to be acceptable. The methods provided for the analysis of the active ingredients in the formulation have been validated and assessed to be acceptable for use as enforcement analytical methods. Published standard methods were proposed for data generation and enforcement purposes in environmental media. Methods for residue analysis are summarized in Appendix I, Table 1.

3.0 Health Assessment

Toxicology Summary

Certain copper-containing pesticides were recently re-evaluated by the PMRA (PRVD 2009-04/RVD 2010-05). The re-evaluation was based largely upon the conclusions reached in the US EPA Reregistration Eligibility Decision (RED) for Coppers, published in July 2006, and updated in 2009. Although copper, present as basic copper carbonate was not registered in Canada at the time, it was included in the cluster of copper compounds which were addressed in the US EPA RED. The active component of toxicological concern with the majority of copper-containing pesticides is elemental copper (the cupric ion), and most copper compounds, including copper, present as basic copper carbonate, can be considered similar in terms of their toxicity. These recent re-evaluations were used as the basis for the current assessment. With the exception of the acute toxicity studies, which were conducted on Arch Basic Copper Carbonate and the end-use product, Wolman μ NB, the remainder of the toxicology discussion will refer to copper when present as the copper ion.

Arch Basic Copper Carbonate was moderately acutely toxic via the oral route of exposure and of low acute toxicity following dermal exposure 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. The end-use product, Wolman μ NB, was of slight acute toxicity in rats via the oral route of exposure. It was of low acute toxicity to rats via the dermal and inhalation routes of exposure. It was mildly irritating to the eyes of rabbits, but was not irritating to the skin. Wolman μ NB was not considered to be a dermal sensitizer when tested using the Buehler method in guinea pigs. Toxicity profiles of Wolman μ NB and Arch Basic Copper Carbonate are presented in Table 2 and 3, Appendix I.

Copper is a naturally occurring metal that occurs in many foods and in drinking water. Copper is also an essential element, with adverse effects in humans more likely to result from copper deficiency rather than excess.

Dietary exposure of laboratory animals to high levels of copper was associated with decreased food intake and body weight gains, irritation of the stomach, and increased copper concentrations in the liver. High levels of copper in the drinking water of mice suggested an effect on the immune system, a finding which has also been reported for other trace metals.

There was no evidence of copper being carcinogenic or resulting in any other systemic toxicity in animals having normal copper homeostasis. 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.

Based on the exposure considerations, and consistent with the approach taken by the US EPA, upon which the recent PMRA re-evaluation of copper pesticides was based, toxicological endpoints were not established for the proposed use as a heavy-duty wood preservative. Therefore, a qualitative risk assessment was conducted.

There was no evidence to suggest that copper has carcinogenic potential; therefore, no cancer risk assessment was necessary.

For tebuconazole, refer to the Regulatory Note REG 2006-11, *Tebuconazole* for a detailed assessment of the toxicological database.

Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the PMRA website. Incidents from Canada and the United States were searched and reviewed for copper, present as basic copper carbonate. As of May 2, 2012, there were no incident reports submitted for products containing copper, present as basic copper carbonate.

PCPA Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

A qualitative approach to the human health risk assessment was taken for copper, present as basic copper carbonate. Available information does not indicate that the young would be more sensitive to basic copper carbonate toxicity than the adult; consequently, there was no residual concern relating to risks to infants and children.

Occupational and Residential Risk Assessment

Workers can come in direct contact with Wolman μ NB while treating wood in commercial wood treatment facilities as well as while handling freshly treated wood. Occupational exposure to Wolman μ NB is characterized as long-term and is predominantly by the dermal and/inhalation routes. Since the treatment solution concentrations for copper and tebuconazole fit within the registered values, no new risk assessment was required for Wolman μ NB.

In summary, no systemic toxicological endpoints of concern were identified for dermal exposures to copper, present as basic copper carbonate, and no dermal, oral or inhalation endpoints of toxicological concern were established. As such, a quantitative chemical handler risk assessment for copper, present as basic copper carbonate was not required. Exposure to tebuconazole is not expected to result in unacceptable risk for chemical handlers provided the product is used according to the label directions. Similarly, exposure for sawmill workers and to individuals contacting treated wood in residential scenarios are not expected to result in risks of concern when Wolman μ NB is used according to label directions. However, a wood wipe study is required to confirm tebuconazole and copper transferable residue levels for the post-

application and residential exposure assessment, and to account for any changes the new copper active may have on the transferable residues of the two actives.

Determination of Acute Reference Dose

As Wolman μ NB is not proposed for use on food, a food residue assessment, an establishment of an Acute Reference Dose and Acceptable Daily Intake were not required.

4.0 Environmental Assessment

Copper, present as basic copper carbonate, is an inorganic form of copper. Copper is an element that occurs naturally in the environment and does not break down any further via hydrolysis, metabolism or any other degradation processes. The free cupric ion has a high sorption affinity for soil, sediments and organic matter, and copper applied to the surface is not expected to move readily into groundwater.

Copper is expected to pose a risk to aquatic organisms and terrestrial vascular plants. As such, mitigative measures must be taken to minimise adverse effects on plant populations and aquatic organisms. Risk is mitigated by precautionary label statements limiting exposure of aquatic systems to copper. A complete evaluation of copper's environmental fate and toxicity is available in Proposed Re-evaluation Decision PRVD2009-04, *Copper Pesticides*.

A laboratory study on the leaching of copper and tebuconazole from treated wood was submitted to support the registration of Wolman μ NB. When comparing specific uses, target retention rates and expected leaching rates to those for the registered uses of copper and tebuconazole, no additional environmental risk is expected from the use of this product. Therefore, a new environmental assessment was not required.

5.0 Value

There is a clear economic value to increasing the service life of wood through treatment with wood preservatives. The data submitted to register Wolman μ NB are adequate to demonstrate its efficacy for use as a heavy-duty wood preservative for the treatment of lumber intended for above-ground, ground contact and fresh water uses. The active ingredient copper, present as basic copper carbonate offers advantages over the current soluble copper actives used in the currently registered ACQ wood preservatives in that it is dispersed in water with no need for organic solvents. Data has also been provided showing that the micronized copper leaches less from the MCQ and MCA preservatives than the conventional ACQ and CA preservatives.

Mode of action

Copper has a well-established efficacy against decay fungi resulting in the non-specific denaturation of proteins and enzymes. Wolman μ NB is similar to the currently registered copper azole preservatives, with the major difference being that the copper active is in solid form rather than in solution. The biocidal efficacy and ability of the soluble copper ion to penetrate wood has been well established, and it appears as though the micronized copper particles are also capable of sufficiently penetrating the wood. Within the wood, the copper particles dissolve at a slow

rate that is sufficient to prevent fungi from decaying the wood. Tebuconazole, as co-biocide, acts to inhibit the enzyme 14- α demethylase, thereby interrupting the synthesis of ergosterol and disrupting cell wall development.

Effectiveness Against Pests

Data from two laboratory soil-block studies, one ground-contact soil bed trial, one soft rot test and one ground-contact field trial were submitted. The studies were found to have appropriate experimental designs and to consist of a large enough number of test rates to establish target retentions. The efficacy of Wolman μ NB was evaluated as weight loss due to decay in the soil block tests, and by visual observation of the wood condition in the soil bed, and field trials. These visual observations were made on an annual basis and recorded in a semi-quantitative manner. No commercial Canadian wood species were included in the trials, but detailed wood treatability data were provided that clearly demonstrated that the retention rates found to be effective in the field trials were able to be achieved in many Canadian wood species within the recommended treatment parameters.

Acceptable Efficacy Claims

For the proposed use as a heavy-duty wood preservative against decay fungi, the submitted data established an effective range of retention rates from 1.7 to 5.0 kg/m³ (see Table 4, Appendix I for details). The range of rates was determined by testing treatments of southern yellow pine in field tests at Hilo, Hawaii, United States.

Survey of Alternatives

The availability of copper, present as basic copper carbonate would provide an additional source and physical form of copper to copper azole wood preservatives. In addition, the micronized, dispersed copper in Wolman μ NB provides an improvement over the conventional copper azole preservatives in that it is dispersed in water, rather than dissolved in organic solvents, and has a lower copper leaching rate. The use of naturally durable wood such as western red cedar is an alternative to treated wood for residential applications, but its use and resistance to decay are limited.

The key options available for treatment of wood for residential uses are summarized in Appendix I, Table 5.

Compatibility with Current Management Practices Including Integrated Pest Management

The end-use product, Wolman μ NB, should be compatible with pressure treatment plants currently set up to treat with copper azole-type preservatives, but may require modifications to treatment cylinders that are set up to treat with other wood preservatives (e.g. CCA).

Information on the Occurrence or Possible Occurrence of the Development of Resistance

Copper-resistant fungi such as *Postia placenta* have been known to be problematic with wood preservative efficacy. However, the copper in Wolman μ NB is formulated with tebuconazole as

a co-biocide. It is unlikely that resistance will form to this combination of active ingredients as the secondary biocide will kill the copper resistant fungi, while fungi that may be resistant to the secondary biocides will be susceptible to the copper. Laboratory soil block studies that included copper-tolerant decay fungi have been provided, and it can also be assumed that copper tolerant fungi would have been present in at least some of the submitted foreign, long-term field studies, all of which demonstrated acceptable efficacy. Furthermore, Wolman μ NB is not expected to differ substantially from conventional copper azole preservatives which have been on the market for many years with no significant resistance issues being reported.

6.0 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the 1995 federal TSMP, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

The federal TSMP and PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, were taken into account during the re-evaluation of pesticides containing copper. The PMRA has reached the following conclusions.

- Copper does not bioaccumulate. The *n*-octanol–water partition coefficient ($\log K_{ow}$) is not applicable as copper is not soluble in water and octanol. The TSMP Track 1 cut-off criterion is ≥ 5.0 . Copper is persistent, but binds to soil particles and becomes biologically unavailable. Aerobic soil half-life is far above the TSMP Track 1 criterion of 182 days; therefore, copper is not a candidate for Track 1 classification.
- Based on a review of the available chemistry information, the technical product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive DIR98-04 or TSMP Track 1 substances as identified in Regulatory Directive DIR99-03, Appendix II.

No other impurities of toxicological concern as identified in Regulatory Directive DIR98-04, Section 2.13.4, or TSMP Track 1 substances as identified in Regulatory Directive DIR99-03, Appendix II, are expected to be present in the technical products of copper.

There were no identified environmental concerns with the formulants in the end-use product Wolman μ NB.

Formulant issues are being addressed through PMRA formulant initiatives and Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*, published on 31 May 2006.

7.0 Conclusion

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of the technical active, Arch Basic Copper Carbonate, containing the technical grade active ingredient copper, present as basic copper carbonate, and the end-use product, Wolman µNB, containing the technical grade active ingredients copper, present as basic copper carbonate and tebuconazole as heavy duty wood preservative for lumber for above-ground, ground contact, and fresh-water uses. Confirmatory wood wipe study will be required as a condition of registration.

List of Abbreviations

µg	micrograms
a.i.	active ingredient
AAS	atomic absorption spectroscopy
ACQ	alkaline copper quaternary
AES	atomic emission spectroscopy
AOAC	Association of Official Analytical Chemists
bw	body weight
°C	degree Celsius
CA	copper azole-type wood preservative
CAS	Chemical Abstracts Service
CCA	chromated copper arsenate
CU	copper
cm	centimetres
CUV	copper, present as basic copper carbonate
g	gram
hr	hour
ICP	inductively coupled plasma
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	<i>n</i> -octanol-water partition coefficient
L	litre
LC ₅₀	lethal concentration to 50%
LD ₅₀	lethal dose to 50%
m	metre(s)
MAS	maximum average score for 24, 48 and 72 hours
MCA	a copper azole-type of wood preservative in which the copper active is in a "micronized" particulate form that is dispersed in water, rather than dissolved in organic solvents.
MCQ	an ACQ-type of wood preservative in which the copper active is in a "micronized" particulate form that is dispersed in water, rather than dissolved in organic solvents.
MIS	maximum irritation score
mg	milligram(s)
mL	millilitre
MS	mass spectrometry
NIOSH	National Institute for Occupational Safety and Health

NZW New Zealand white
Pa Pascal
PCPA Pest Control Product Act
 pK_a dissociation constant
PMRA Pest Management Regulatory Agency
RED Reregistration Eligibility Decision
TEU tebuconazole
TGAI Technical Grade Active Ingredient
TSMP Toxic Substances Management Policy
US EPA United States Environmental Protection Agency
UV ultraviolet

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ	PMRA #
Animal	NIOSH Method 8005, NIOSH Method 8005, NIOSH Method 8310	copper	ICP-AES	1 µg Cu/100 g blood 0.20 µg Cu/g tissue 0.1 µg Cu/sample	1876677
Soil or sediment	AOAC Method 990.8	copper	ICP-AES	6 µg Cu/L	1876677
	US EPA Method 7210	copper	AAS	20 µg Cu/L	1876677
Water	US EPA Method 220.7	copper	ICP-MS	6 µg Cu/L	1876677
	US EPA Method 220.1	copper	AAS (direct aspiration)	20 µg Cu/L	1876677
	US EPA Method 220.2	copper	AAS (graphite furnace)	1.0 µg Cu/L	1876677

Table 2 Toxicity Profile of Wolman µNB

Study Type/Animal	Study Results	PMRA #
Acute oral toxicity Sprague Dawley rats	LD ₅₀ = 1750 mg/kg bw Slight toxicity	1677141
Acute dermal toxicity Sprague-Dawley rats	LD ₅₀ > 5050 mg/kg bw Low toxicity	1677142
Acute inhalation toxicity (nose-only) Sprague Dawley rats	LC ₅₀ > 2.09 mg/L Low toxicity	1677143
Dermal irritation NZW rabbits	MAS = 0, MIS = 0 Non-irritating	1677145
Eye irritation NZW rabbits	MAS = 14.3 MIS = 18, at 24 hr All scores zero by Day 17 Mildly irritating	1677144
Dermal sensitization (Buehler test) Hartley guinea pigs	Non-sensitizer	1677146

Table 3 Acute Toxicity Profile of Arch Copper Carbonate Technical

Study Type/Animal	Study Results	PMRA #
Acute oral toxicity Sprague Dawley rats	LD ₅₀ between 500 and 2000 mg/kg bw Moderate toxicity	1876675
Acute dermal toxicity Sprague Dawley rats	LD ₅₀ > 2000 mg/kg bw Low toxicity	1876675
Eye irritation New Zealand White rabbits	MAS = 14.8 MIS = 20 Mildly irritating	1876675
Dermal irritation New Zealand White rabbits	MAS = 0 MIS = 0 Non irritating	1876675
Dermal sensitization (Maximization) Hartley guinea pigs	Negative	1876675

Table 4 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Proposed label claim	Supported use claim	
Heavy duty wood preservative in the treatment of non-industrial wood products for above ground, ground contact, fresh water contact or treatable members out of water but subject to salt water splash. Treatment concentration: 0.3 - 3.0% Target Retention Rates: Not on label	Accepted as proposed	
	Target Retention Rates ((kg/m³):	
	Above Ground	1.7
	Ground Contact/Fresh Water Contact/Subject to Salt Water Splash	3.3
	Ground Contact (severe decay hazard)	5.0

Table 5. Alternative Wood Preservatives for the Treatment of Wood for Residential Uses

End-Use Product	PCP#	Actives	Registered Uses
Wolman NB	27132	Cuprous Oxide; Tebuconazole	Non-Industrial Wood; Above-Ground Ground Contact Fresh Water Contact
ACQ 2102	27130	Copper Ethanolamine Complexes; N-Alkyl (67% C12, 25% C14, 7% C16, 1% C18) Dimethyl Benzyl Ammonium Chloride	Non-Industrial Wood; Above-Ground Ground Contact
NW 100	27131	Cuprous Oxide; N-Alkyl (67% C12, 25% C14, 7% C16, 1% C18) Dimethyl Benzyl Ammonium Chloride	Non-Industrial Wood; Above-Ground Ground Contact
NW 100C	28634	Copper Ethanolamine Complexes	Non-Industrial Wood; Above-Ground Ground Contact

ACQ-C2 EU	28635	Copper Ethanolamine Complexes	Non-Industrial Wood; Above-Ground Ground Contact
Carboquat WP-50	28633	Didecyldimethyl Ammonium Carbonate	Non-Industrial Wood; Above-Ground Ground Contact

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA # Reference

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