Registration Decision RD2012-25

Copper, present as Basic Copper Carbonate

(publié aussi en français)

1 August 2012

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0932 (print)
1925-0940 (online)

Catalogue number: H113-25/2012-25E (print version)
H113-25/2012-25E-PDF (PDF version)

Registration Decision for Copper, present as Basic Copper Carbonate

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Basic Copper Carbonate and MicroPro 200C-TS, containing the technical grade active ingredient copper, present as basic copper carbonate, for treating wood for above-ground, ground contact and fresh water contact uses.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2011-17, *Copper, present as Basic Copper Carbonate*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for copper, present as basic copper carbonate and summarizes the Agency's decision, the reasons for it and provides, in Appendix I, a summary of comments received during the consultation process as well as the PMRA's response to these comments. This decision is consistent with the proposed registration decision stated in PRD2011-17.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2011-17, *Copper, present as Basic Copper Carbonate* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act.*

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Copper, present as Basic Copper Carbonate?

Basic copper carbonate is a new, copper-based active ingredient for use in combination with other active ingredients, as a wood preservative. It must be combined with Carboquat, to form an ACQ-type of wood preservative. Basic copper carbonate differs from currently registered ACQ wood preservatives in that the copper is not dissolved but is in a solid form.

Health Considerations

Can Approved Uses of Copper, Present as Basic Copper Carbonate, Affect Human Health?

Copper, present as basic copper carbonate, is unlikely to affect your health when used according to label directions.

Potential exposure to copper, present as basic copper carbonate, may occur when handling and applying the product, or coming into contact with treated wood surfaces. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

In laboratory animals, copper, present as basic copper carbonate, was of slight acute toxicity via the oral and inhalation routes of exposure, and therefore the words "Caution – Poison" are required on the principle display panel of the label. It was of low toxicity following a single dermal exposure. Copper, present as basic copper carbonate, was minimally irritating to the eyes, not irritating to the skin, and did not cause an allergic skin reaction.

The end-use product MicroPro 200C-TS was of low acute toxicity via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the eyes and slightly irritating to the skin, and did not cause an allergic skin reaction.

The active component of toxicological concern with the majority of copper-containing pesticides is the copper ion, and most copper compounds, including basic copper carbonate, can therefore be considered similar in terms of their toxicity. Copper is a naturally occurring metal that occurs in many foods including organ meats, seafood, beans, nuts and whole grains, and in drinking water. Copper is also an essential element in maintaining normal health in humans, with adverse effects more likely to result from 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.

Residues in Food

As MicroPro 200C-TS is not proposed for use on food, a food residue assessment was not required.

Occupational Risks From Handling MicroPro 200C-TS

Occupational risks are not of concern when MicroPro 200C-TS is used according to the label directions, which include protective measures.

Workers can come in direct contact with MicroPro 200C-TS while treating wood in commercial wood treatment facilities as well as while handling treated wood. Therefore, the label specifies that workers wear full-face protection, chemical-resistant coveralls over long sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear when handling the concentrate or dilute solution, when opening treating cylinder doors and during cleaning, maintenance and repair activities on storage vessels or treating cylinders, and wear chemical-resistant coveralls over long sleeved shirt and long pants, goggles or face shield and chemical-resistant gloves when handling freshly treated wood. In addition, a closed system must be used when mixing/loading MicroPro 200C-TS. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for workers, risk to these individuals are not a concern.

Environmental Considerations

What Happens When Copper, Present as Basic Copper Carbonate, is Introduced Into the Environment?

Copper, present as basic copper carbonate is toxic to aquatic organisms and terrestrial plants, therefore, risk-reduction measures must be observed.

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 soil surface is not expected to move readily into groundwater. The copper ion is highly reactive, especially in aquatic environments. The form in which copper is found depends on the pH of the medium and the nature and concentration of other forms of copper present.

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.

Value Considerations

What is the value of the end-use product MicroPro 200C-TS?

MicroPro 200C-TS is a particulate copper source that must be added to Carboquat to form heavy duty wood preservatives for pressure treating lumber for above-ground, ground contact, and fresh water applications such as fence posts and boards, decks, docks, walkways and wood shingles.

In combination with Carboquat, MicroPro 200C-TS imparts to the treated wood an effective protection against decay fungi, extending the usable life of the wood. Wood treated with MicroPro 200C-TS is intended for above-ground, ground contact and fresh water contact uses. While similar to currently registered ACQ wood preservatives, the copper source of MicroPro 200C-TS is in a solid, particulate, "micronized" form rather than a dissolved form. This allows MicroPro 200C-TS to be dispersed in water rather than dissolving the copper in ammonia or ethanolamine. Due to the small size of the copper particles, MicroPro 200C-TS is able to penetrate wood species with reduced leaching relative to dissolved copper.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of MicroPro 200C-TS to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with MicroPro 200C-TS on the skin or through inhalation of spray mists, workers must wear full-face protection, chemical-resistant coveralls over long sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear when handling the concentrate or dilute solution, when opening treating cylinder doors and during cleaning, maintenance and repair activities on storage vessels or treating cylinders, and wear chemical-resistant coveralls over long sleeved shirt and long pants, goggles or face shield and chemical-resistant gloves when handling freshly treated wood. In addition, a closed system must be used when mixing/loading MicroPro 200C-TS.

Environment

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.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2011-17, *Copper, present as Basic Copper Carbonate* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act.*

Appendix I Comments and Responses

1. A comment was received requesting that the proposed regulatory decision should access the suitability for the registration of basic copper carbonate in a generic sense and should be inclusive of all prospective registration action pertaining to basic copper carbonate rather than specific for the products set forth in PRD2011-17.

Section 28(1) of the *Pest Control Product Act* states that the Minister shall consult the public and federal and provincial government departments and agencies before making a decision to grant or deny an application to register a pest control product that is or contains an unregistered active ingredient. Section 28 (3) of the *Pest Control Product Act* states that the consultation statement shall include a summary of any reports of the evaluation of the health and environmental risks and the value of the pest control product prepared or considered by the Minister. Therefore, a public consultation was required for the registration of the new active ingredient, copper, present as basic copper carbonate and its end-use product, MicroPro 200C-TS, and the consultation document (PRD2011-17) summarised the data and information submitted to support the registration of these products, in the context of the corresponding application only.

2. Comments were received concerning whether or not the Agency took particle size and the potential effects that nanoscale/sub-micron particles could have on the nature and behaviour of a product into consideration when making its decision.

The Agency requested and received information on the particle size distribution of the product, which was taken into consideration during the assessment. The Agency recognizes that particle size could have an impact on the properties of a product. As work on nanotechnology/nanomaterials and the appropriate data requirements are ongoing within Health Canada and at the International level, additional data may be required from registrants of nanoscale materials at a later date.

3. A comment was made as to a perceived inconsistency in the PRD. The specific concern was that MTZ was proposed for mixing with MicroPro 200C-TS referenced in Table 4, whereas the text in the PRD clearly stated that MicroPro 200C-TS was only for mixing with Carboquat.

It should be clarified that Table 4 contains both the use claims proposed by the applicant and those accepted for registration by the PMRA. The mixing of MTZ with MicroPro 200C-TS was a “Proposed label claim” in the left-hand column of the table, but was not supported for registration (right-hand column) under the current applications.

4. A question was posed regarding whether a dislodgeable residue study was considered in the registration decision

When conducting a risk assessment, the Agency takes into consideration the data requirements based on the use pattern and potential exposure. The requirement for a dislodgeable residue study was considered in the evaluation of MicroPro 200C-TS. However, no systemic toxicological endpoints of concern were identified for exposure to copper. As such, risk was addressed qualitatively for MicroPro 200C-TS and no concerns were identified.