



Health
Canada Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Proposed Re-evaluation Decision

PRVD2018-18

Copper (present as cuprous thiocyanate) and Its Associated End- use Products

Consultation Document

(publié aussi en français)

17 October 2018

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. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
hc.pmra.publications-arla.sc@canada.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
hc.pmra.info-arla.sc@canada.ca

Canada 

ISSN: 1925-0959 (print)
1925-0967 (online)

Catalogue number: H113-27/2018-18E (print)
H113-27/2018-18E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2018

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Table of Contents

Proposed Re-evaluation Decision	1
Outcome of Science Evaluation	1
Proposed Regulatory Decision for Copper thiocyanate	1
International Context	2
Next Steps.....	2
Science Evaluation.....	3
1.0 Introduction.....	3
2.0 Technical Grade Active Ingredient.....	3
2.1 Identity	3
2.2 Physical and Chemical Properties	4
3.0 Human Health Assessment	4
3.1 Toxicology Summary.....	4
3.2 Dietary Exposure and Risk Assessment.....	5
3.3 Occupational Exposure and Risk Assessment	6
3.3.1 Mixer/Loader/Applicator Exposure and Risk.....	6
3.3.2 Postapplication Exposure and Risk.....	6
3.4 Non-Occupational Exposure and Risk Assessment	6
3.4.1 Residential and Bystander Exposure and Risk	7
3.5 Aggregate Exposure and Risk Assessment	7
3.6 Cumulative Assessment	7
4.0 Environmental Assessment.....	7
4.1 Aquatic Environmental Fate and Effects on Non-Target Species.....	8
4.2 Environmental Risk Assessment.....	8
5.0 Value Assessment	10
6.0 Pest Control Product Policy Considerations.....	10
6.1 Toxic Substances Management Policy Considerations.....	10
6.2 Formulants and Contaminants of Health or Environmental Concern	10
7.0 Incident Reports	11
8.0 Conclusion of Science Evaluation	11
List of Abbreviations	13
Appendix I Registered Products Containing Copper Thiocyanate in Canada ¹	15
Appendix II Label Amendments for End-Use Products Containing Copper Thiocyanate	17
References.....	21

Proposed Re-evaluation Decision

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Copper (present as cuprous thiocyanate; also known as copper thiocyanate) is used in antifouling paint applied to boats. It can be used on aluminum, fiberglass, wood, steel and lead hulls below the true waterline in fresh, salt and brackish water and can be applied using brush, roller, and/or spray equipment. It is registered for both commercial and domestic uses.

This document presents the proposed regulatory decision for the re-evaluation of copper thiocyanate including the proposed risk mitigation measures to further protect human health and the environment, as well as the science evaluation on which the proposed decision was based. All products containing copper thiocyanate registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period, during which the public including the pesticide manufacturers and stakeholders may submit written comments and additional information to the PMRA. The final re-evaluation decision will be published taking into consideration the comments and information received.

Outcome of Science Evaluation

Antifouling paints based on copper thiocyanate have acceptable value in that they are the only ones registered in Canada for use on aluminum boats, and they provide protection against fouling organisms in fresh, salt, and brackish waters at a lower copper concentration than what is found in other copper-based antifouling paints.

With respect to human health, risks are acceptable due to the low toxicity of copper thiocyanate and the low potential for exposure expected when the product is applied according to the label directions.

Aquatic environments are expected to be exposed to copper leachates from boats treated with copper thiocyanate based paint. When used as directed, potential risk to the aquatic environment from copper thiocyanate based antifouling paints is acceptable.

Proposed Regulatory Decision for Copper thiocyanate

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, Health Canada is proposing that products containing copper thiocyanate are acceptable for continued registration in Canada, provided that required label updates are made to meet the current labelling standard.

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. As a result of the re-evaluation of copper thiocyanate, further updates for product labels are being proposed (see Appendix II).

Human Health

- Label updates to meet current standards for antifouling paint use, i.e., additional label statements for toxicology, additional personal protective equipment (PPE) and additional directions for use.

Environment

- Label updates to meet current standards for antifouling paint use, i.e., environmental hazards, storage, and disposal are proposed for both commercial and domestic end-use products.

International Context

Copper thiocyanate is currently acceptable for use as a pesticide in other Organisation for Economic Co-operation and Development (OECD) member countries, including Australia, the United States, and the European Union. No decision by an OECD-member country to prohibit all uses of copper thiocyanate for health or environmental reasons has been identified.

Next Steps

The public including the registrants and stakeholders are encouraged to submit comments during the 90-day public consultation period¹ upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of re-evaluation decision document,² which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

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*.

Science Evaluation


1.0 Introduction

Copper thiocyanate is used in antifouling paint applied to boats. Copper thiocyanate acts to inhibit the growth of fouling organisms on surfaces due to the copper ions released, which are believed to inhibit vital processes by inactivating essential enzymes and precipitating cytoplasmic proteins. The copper thiocyanate products currently registered under the authority of the *Pest Control Products Act* as of 26 July 2018 are listed in Appendix I.

Following the re-evaluation announcement for copper thiocyanate, the registrant indicated support to continue registration of all uses included on the labels of copper thiocyanate end-use products.

2.0 Technical Grade Active Ingredient

2.1 Identity

Common name	Cuprous thiocyanate
Function	Material preservative
Chemical Family	Copper
Chemical name	
1 International Union of Pure and Applied Chemistry (IUPAC)	Copper(I) thiocyanate
2 Chemical Abstracts Service (CAS)	Thiocyanic acid, copper(1+) salt (1:1)
CAS Registry Number	1111-67-7
Molecular Formula	CNSCu
Structural Formula	
Molecular Weight	121.63
Purity of the Technical Grade Active Ingredient	52% as copper
Registration Number	25546

2.2 Physical and Chemical Properties

Property	Result
Vapour pressure	Negligible as product is a solid
Ultraviolet/visible spectrum	Not expected to absorb at $\lambda > 300$ nm
Solubility in water	0.1 mg / 100 g
n-Octanol/water partition coefficient	$\log K_{ow} = 0.5$
Dissociation constant	1.6×10^{-11}

3.0 Human Health Assessment

Based on the registered use pattern, exposure to copper thiocyanate can occur when working as a commercial loader/applicator, handling the product in a residential setting, or as a bystander during application. Two key factors are considered when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Continued registration is only supported for uses that are determined as having acceptable risks.

3.1 Toxicology Summary

With the exception of the acute toxicity data, the assessment was based primarily on a literature review of copper and thiocyanate moieties. The active component of toxicological concern with the majority of copper-containing pesticides is the cupric ion, and most copper compounds can therefore be treated similarly in terms of their toxicity. Copper thiocyanate is of low acute toxicity via the oral and dermal routes and is classified as slightly toxic via the inhalation route. It is not irritating to the skin or eyes and is not a dermal sensitizer.

Given the low toxicity profile of copper thiocyanate, no toxicological endpoints have been established for conducting a quantitative risk assessment. Consequently, Health Canada has followed a qualitative approach to assess the potential risks to copper thiocyanate.

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

Copper homeostasis is maintained in humans with effective regulatory mechanisms which allow the body control over excessive amounts of copper by either decreasing absorption or increasing elimination of the metal under normal circumstances. Since copper homeostasis prevents excessive accumulation of copper in the body, acute and chronic copper toxicity are rare. However, copper toxicity resulting from disturbed homeostasis contributes to different

symptoms and disease conditions, such as hepatic and neurological disorders, which are most often linked to the redox-active transition metal role of copper, as it can initiate oxidative damage.

Thiocyanate is a natural component of the human diet. Sources of dietary thiocyanate exposure include cassava, cruciferous vegetables, bamboo shoots, and almond. It is also present in milk, and dietary intake can be as high as 0.14 mg/kg bw per day. The human body also forms thiocyanate in the detoxification pathway of cyanide, and it is readily excreted in urine (half-life approximately 3 days). There is no evidence of carcinogenic activity with thiocyanate.

The most sensitive toxic endpoint reported for thiocyanate is its influence on thyroid function through the competitive inhibition of iodide anion uptake by the thyroid, and iodine status modifies the sensitivity of the thyroid to the toxicity of thiocyanates. The reported effect of thiocyanate on thyroid-function observed in rats is at 53 mg/kg bw/day (2240 ppm potassium thiocyanate administered in diet for 11.5 months). Reproductive performance of the dams was not affected by treatment with approximately 22 mg thiocyanate (SCN)/kg bw/day in rats or 33 mg SCN/kg bw/d in pigs. In subchronic exposure conditions in rats, a NOEL of 15.2 mg SCN/kg bw/day (using ammonium thiocyanate) has been reported. No effects on thyroid function have been observed at levels of 100 and 500 mg/kg bw/day of the test-substance. It has been reported that toxicity often occurs at plasma thiocyanate concentrations above 120 mg/L. In human studies, goiters due to the consumption of thiocyanate were more likely to occur when iodine levels were low, and were reversed with iodine supplementation. In humans, a low level of thiocyanate exposure is not likely to induce negative effects on thyroid function in healthy individuals. No significant effects on thyroid function (thyronine, triiodothyronine, and thyroid stimulating hormone) resulted from the human consumption of 8 mg of thiocyanate in milk daily for 12 weeks, although serum and urinary thiocyanate levels increased. A dietary contribution of thiocyanate from directly consuming thiocyanate rich foods, such as Brassica is known to contribute 14.7 mg/d on average. In one study with human subjects, feeding milk with 19 mg/L of thiocyanate was without effect on thyroid metabolism at least over the month of the experiment. It was reported that the clinically significant reduction in iodine uptake is likely to require a dose of 200–400 mg of thiocyanate.

Thiocyanate toxicity depends largely on the dose, in that high acute doses could lead to cyanide formation and subsequent cyanide toxicity. Since thiocyanate is rapidly eliminated in the urine, tolerance to thiocyanate is greater when the intake is gradual. However, renal insufficiency limiting the excretion of thiocyanate and low iodine levels together with high systemic availability of thiocyanate may lead to adverse effects.

3.2 Dietary Exposure and Risk Assessment

Copper thiocyanate is not registered for use on any food commodity and is not expected to contaminate drinking water sources when used according to label directions. The dietary risk is acceptable for all populations. No additional mitigation measures are proposed.

3.3 Occupational Exposure and Risk Assessment

The commercial class copper thiocyanate end-use product currently registered for use in Canada is applied using brush, roller, and/or spray equipment. When spraying, a thinning agent is to be mixed with the antifouling paint. The antifouling paint containing copper thiocyanate can be used to coat aluminum, fiberglass, wood, steel, and lead boat hulls, and related submerged surfaces that are susceptible to biological fouling from organisms such as barnacles, mussels, sponges, and algae in fresh, salt, and brackish waters. Because toxicological endpoints were not established by Health Canada, a qualitative exposure assessment was conducted for the workers handling the antifouling paint.

Workers can be exposed to copper thiocyanate through mixing, loading, applying, clean-up and maintenance activities, when coming in contact with a treated surface prior to it drying, or when removing old antifouling paints containing copper thiocyanate from boats.

3.3.1 Mixer/Loader/Applicator Exposure and Risk

When mixing, loading and applying copper thiocyanate, as well as during clean-up and maintenance activities, worker exposure is primarily by the dermal and inhalation routes. However, non-dietary oral and incidental ocular exposure is also possible. Amendments to the precautionary label statements are required to reflect current Canadian practices (Appendix II).

3.3.2 Postapplication Exposure and Risk

Worker postapplication exposure by the dermal route is possible from accidental contact with a treated surface prior to its drying. However, the low toxicity profile of copper thiocyanate is such that the potential risk due to incidental dermal exposure is acceptable.

There is also the potential for postapplication exposure when removing old antifouling paints containing copper thiocyanate from vessels. Worker exposure is primarily dermal and inhalation but non-dietary oral and ocular exposure is also possible. Amendments to the precautionary label statements are required to reflect current Canadian practices (Appendix II).

3.4 Non-Occupational Exposure and Risk Assessment

One domestic class copper thiocyanate end-use product is registered in Canada as an antifouling paint for use on aluminum, fiberglass, wood, steel and lead boat hulls, and related submerged surfaces that are susceptible to biological fouling from organisms such as barnacles, mussels, sponges, and algae in fresh, salt, and brackish waters. The application of the domestic class end-use product is limited to brush and roller. Because toxicological endpoints were not established by Health Canada, a qualitative exposure assessment was conducted for the residential users handling the end-use product.

Residential users can be exposed to copper thiocyanate when mixing, loading, and applying the product, as well as during clean-up and maintenance activities. Individuals can also be exposed by accidental contact with wet paint on the vessel during the post application drying period and when removing old antifouling coatings by sanding.

3.4.1 Residential and Bystander Exposure and Risk

When mixing, loading and applying copper thiocyanate, user exposure is primarily by the dermal route. The current label for the domestic class product requires the use of chemical resistant gloves, goggles and footwear, and chemical resistant clothing including hood or hat at all times during handling and application. Individuals are also expected to wear appropriate respiratory protection (for example, dust masks) when removing old antifouling coatings. Given the current use pattern, low toxicity profile of copper thiocyanate, and mitigative measures already on the label, the potential risk to human health due to exposure of the residential user is acceptable.

Bystander exposure may occur while spray painting with the commercial product, as well when removing old antifouling paint coatings from vessels by sand blasting or sanding. Exposure to the spray and particles/dust generated during the removal of coats of old antifouling paints is primarily by inhalation and by the dermal route. However, given the low toxicity profile of copper thiocyanate the potential risk to human health due to exposure of bystanders is acceptable.

3.5 Aggregate Exposure and Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources from all known or plausible exposure routes (oral, dermal and inhalation). Based on the registered use pattern for copper thiocyanate, aggregate exposure is not expected to be of concern.

3.6 Cumulative Assessment

The *Pest Control Products Act* requires that Health Canada consider the cumulative exposure to pesticides with a common mechanism of toxicity. While copper thiocyanate may share a common moiety with other copper-based active ingredients, the potential health risks from cumulative exposure to copper from copper-based pest control products are acceptable given that copper is an essential element in mammalian nutrition and humans have efficient mechanisms in place to regulate levels of copper in the body.

4.0 Environmental Assessment

Since the active component of concern with the majority of copper-containing pesticides is elemental copper (the cupric ion, Cu^{2+}), and most copper compounds can be considered similar in terms of their toxicity and behaviour, the ecological exposure and risk assessment of copper thiocyanate is based on the environmental re-evaluation of other copper-containing antifouling paints published by Health Canada in 2016 (PRVD2016-14), as well as the United States Environmental Protection Agency's (USEPA) 2017 Risk Assessment of Copper-Based Antifoulant Coating/Paint and the 2017 Copper Compounds Proposed Interim Registration Review Decision found at www.regulations.gov (Docket Number: EPA-HQ-OPP-2010-0212).

American and Canadian end-use product formulations and use patterns were compared. Currently registered American product formulations (ready-to-use paint and spray can) and guarantees (3.71–45% a.i.) encompassed those registered in Canada (ready-to-use paint,

11.88% a.i.) as did the use sites and application methods. Target application rates indicated on American end-use product labels are similar to target Canadian application rates. Based on this comparison, Health Canada determined that the 2017 USEPA assessment and the assessment previously completed by Health Canada (PRVD2016-14) for other copper-based antifouling coatings were an adequate basis for the re-evaluation of copper-thiocyanate based paints in Canada.

4.1 Aquatic Environmental Fate and Effects on Non-Target Species

The fate and effects of copper in the aquatic environment were previously discussed for other copper pesticides and are applicable to the current re-evaluation. As in PRVD2016-14, refer to PRVD2009-04 for details.

4.2 Environmental Risk Assessment

Based on the current label use pattern of copper thiocyanate, aquatic environments are expected to be exposed to copper leachates from treated boats. Health Canada considered the potential risks to aquatic organisms from the use of copper thiocyanate based antifouling coatings on both commercial and recreational boats.

Commercial Boats

Based on the current use pattern of copper thiocyanate end-use products in Canada, Health Canada's previous assessment of copper-based antifouling paints on commercial vessels (50–350 m size in length) is considered applicable to copper thiocyanate based antifouling coatings. Similar to other copper-based antifouling coatings, the potential environmental risk from the use of copper thiocyanate on large commercial vessels is acceptable. Refer to PRVD2016-14 for details.

Recreational Boats

Recreational antifouling uses were represented by copper thiocyanate antifouling paint applied to recreational vessels (less than 50 m) moored in a recreational coastal marina. Estimated environmental concentrations of freely dissolved copper generated by the USEPA using the Marine Antifoulant Model to Predict Environmental Concentrations Model, version 3 (USEPA 2017) were considered. This model considered characteristics specific to copper, including leaching rate, as well as characteristics specific to American recreational coastal marinas, including boat density, marina design, and water characteristics (based on evaluation of recreational marinas and coastal waters within American jurisdiction).

Using estimated environmental concentrations generated by the USEPA, Health Canada conducted a screening-level risk assessment. For the screening-level exposure characterization (dissolved copper), the USEPA applied the following assumptions:

- 100% of boats in the recreational marina were treated with a freshly painted copper antifouling coating;

- All boats were placed into the marina during the same two-week period and were all leaching at the same rate;
- Copper would leach at a rate of 50 µg/cm²/day; and
- The recreational coastal marina design resulted in poor water exchange (flush volume and rate).

With these assumptions, the estimated environmental concentrations of dissolved copper for acute and chronic assessments were 56 µg/L and 45 µg/L, respectively. Risk quotients (RQs) were calculated by Health Canada based on the most sensitive aquatic endpoints for copper (PRVD2016-14). The most sensitive species were freshwater green algae, freshwater daphnia, and the marine mussel. Based on the estimated dissolved copper concentration in a recreational coastal marina, all screening-level RQs (2–35) exceeded the level of concern of 1, with the exception of exposure to duckweed.

Health Canada calculated refined estimated environmental concentrations using a leach rate of 40 µg/cm²/day, which is the maximum leach rate acceptable for antifouling coatings in Canada. Acute and chronic dissolved copper estimated environmental concentrations of 16.0 µg/L and 12.9 µg/L, respectively, can be expected within a well-designed saltwater recreational marina when 100% of boats are treated with a copper-based antifouling coating and are leaching at 40 µg/cm²/day. Based on the refined estimated environmental concentrations, RQs were then calculated by Health Canada. In this case, the level of concern was exceeded for all aquatic species with the exception of acute freshwater fish exposure and exposure to duckweed. Acute freshwater RQs ranged from 5 (green algae) to 4 (daphnia), and chronic freshwater RQs ranged from 10 (daphnia) to 1 (salmonids). Acute marine RQs for the mussel and summer flounder were 1, and chronic marine RQs ranged from 4 (mussel) to 3 (summer flounder).

Based on (1) the conservative assumptions used in the recreational exposure assessment (for example, 100% of boats are treated and the timing of return to service), (2) the calculation of freshwater RQs using copper EECs generated for a saltwater environment, and (3) combined with the environmental fate characteristics of copper (for example, copper ions are highly reactive in aquatic environments, bind tightly to sediment/organic matter, and are thus not always bioavailable) and the Canadian use pattern of copper thiocyanate, Health Canada concluded that any potential risk identified to the aquatic environment from copper thiocyanate based antifouling paint use on recreational boats is acceptable.

Health Canada's current approach to copper-based antifouling coatings relied on the USEPA's dissolved copper exposure assessments (2010 and 2017) to calculate RQs following use on both commercial and recreational vessels within coastal marinas. Overall, considering the conservatism in both the USEPA's exposure assessments and Health Canada's RQ calculations, and combined with the environmental fate of copper and the Canadian use pattern of copper thiocyanate, potential risks to aquatic organisms identified from copper thiocyanate antifouling paint use on both commercial and recreational vessels are acceptable.

Health Canada has established a Canadian leach rate cap for antifouling coatings (40 µg/cm²/day), and no further risk mitigation measures are proposed.

Label updates to meet current standards for antifouling coating use, environmental hazards, storage, and disposal are proposed for both commercial and domestic end-use products (Appendix I).

5.0 Value Assessment

Copper thiocyanate is one of only a handful of active ingredients currently registered in Canada for antifouling coatings. Other actives with the same use pattern include cuprous oxide and metallic copper; however, antifouling paints containing these actives have label directions specifically prohibiting their use on aluminum surfaces. As such, antifouling paints based on copper thiocyanate have acceptable value in that they are the only ones registered in Canada for use on aluminum boats. As well, copper thiocyanate has acceptable value in providing protection against fouling organisms (such as barnacles, mussels, sponges, and algae) in fresh, salt, and brackish waters.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

In accordance with the Health Canada Regulatory Directive DIR99-03,³ the assessment of copper against Track 1 criteria of Toxic Substances Management Policy under *Canadian Environmental Protection Act* was conducted. Health Canada has reached the conclusion that:

- Copper does not meet all Track 1 criteria, and is not considered a Track 1 substance

6.2 Formulants and Contaminants of Health or Environmental Concern

During the re-evaluation process, contaminants in the technical grade active ingredients were compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.⁴ The list is used as described in the Health Canada Notice of Intent NOI2005-01⁵ and is based on existing policies and regulations including: DIR99-03 and DIR2006-02,⁶ and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). Health Canada has reached the following conclusion:

³ DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy.

⁴ *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

⁵ NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

⁶ DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

- Copper thiocyanate technical grade active ingredient products do not contain contaminants of health or environmental concern.

7.0 Incident Reports

As of 25 May 2018, no human, domestic animal or environment incidents involving copper thiocyanate have been submitted to Health Canada.

8.0 Conclusion of Science Evaluation

With respect to human health, risks are acceptable due to the low toxicity of copper thiocyanate and the low potential for exposure expected when the product is applied according to the label directions.

Aquatic environments are expected to be exposed to copper leachates from boats treated with copper thiocyanate based paint. When used as directed, potential risk to the aquatic environment from copper thiocyanate-based antifouling paints are acceptable.

Antifouling paints based on copper thiocyanate have acceptable value in that they are the only ones registered in Canada for use on aluminum boats, and they provide protection against fouling organisms in fresh, salt, and brackish waters at a lower copper concentration than what is found in other copper-based antifouling paints.

List of Abbreviations

bw	body weight
d	day
g	gram(s)
kg	kilogram(s)
L	litre
mg	milligram(s)
NOEL	no observable effect level
OECD	Organisation for Economic Co-operation and Development
PMRA	Pest Management Regulatory Agency
ppm	parts per million
RQ	Risk Quotient
RVD	re-evaluation decision
SCN	thiocyanate
$\mu\text{g}/\text{cm}^2/\text{day}$	Microgram per square centimetre per day
USEPA	United States Environmental Protection Agency

Appendix I Registered Products Containing Copper Thiocyanate in Canada¹

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
25544	Domestic	International Paint LLC	Tri-Lux II Antifouling Series	Solution	11.88%
25545	Commercial	International Paint LLC	Tri-Lux II A/F Series	Suspension	11.88%
25546	Technical Active	Bardylke Chemicals Ltd.	Cuprous Thiocyanate Technical	Solid	52%

¹ As of 26 July 2018.

Appendix II Label Amendments for End-Use Products Containing Copper Thiocyanate

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

Human Health

For commercial end-use product

- i) The following statement must be included in a section entitled **TOXICOLOGY INFORMATION**.

“Treat symptomatically.”

- ii) The following statements must be included in a section entitled **PRECAUTIONS**.

“Wear a long-sleeved shirt, long pants, shoes and socks, chemical-resistant gloves, goggles, a chemical-resistant hat that covers the neck (e.g., Sou’Wester) during mixing/loading, application, clean-up and repair, or when removing old antifouling paint coatings. In addition, wear a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides during application. Wear a NIOSH-approved N95 filtering facepiece respirator (dust mask) that is properly fit tested when removing old antifouling paint coatings.”

“Remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”

“Remove clothing/personal protective equipment immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.”

“Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product’s concentrate. Do not reuse them.”

“For cleaning/maintaining personal protective equipment, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry.”

-
- iii) The following statements must be included in a section entitled **DIRECTIONS FOR USE**.

“**DO NOT** apply this product in a way that will contact workers or bystanders, either directly or through drift. Only protected handlers may be in the treatment area during application.”

“**DO NOT** contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.”

For the domestic end-use product

- i) The following statement must be included in a section entitled **TOXICOLOGY INFORMATION**.

“Treat symptomatically.”

Environment

For commercial end-use product

- i) The following statements must be included in a section entitled **DIRECTIONS FOR USE**:

“**DO NOT** contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.”

“**DO NOT** apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), or estuarine/marine habitats.”

“**DO NOT** discharge effluent containing this product or the biocide produced into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters unless the effluent has been detoxified.”

“Prevent paint chips or dust caused by removing paint from entering water. **DO NOT** place the painted parts in water after painting until the paint is fully cured (see dry times on the label).”

- ii) The following statement must be included in a section entitled **ENVIRONMENTAL HAZARDS**.

“Toxic to aquatic organisms.”

- iii) The following statement must be included in a section entitled **STORAGE**:

“To prevent contamination, store this product away from food or feed.”

For domestic end-use product

- i) The following statement must be included in a section entitled **DIRECTIONS FOR USE**:

“Prevent paint chips or dust caused by removing paint from entering water. **DO NOT** place the painted parts in water after painting until the paint is fully cured (see dry times on the label).”

- ii) The following statement must be included in a section entitled **ENVIRONMENTAL HAZARDS**:

“Toxic to aquatic organisms.”

- iii) The following statement must be included in a section entitled **STORAGE**:

“Prevent contamination. Store this product away from food or feed.”

- iv) The following statement must be included in a section entitled **DISPOSAL**:

“**DO NOT** reuse the empty containers. Dispose in household garbage. Unused or partially used products should be disposed at provincially or municipally designated hazardous waste disposal sites.”

References

A. Information Considered in the Chemistry Assessment

i) List of Studies/Information Submitted by Registrants

PMRA Document Number	Reference
1548919	Chemistry data used to support a Technical class product., DACO: 2.99
2724368	2012, 5 Batch Analysis of Cuprous Thiocyanate, DACO: 2.13.3,2.13.4
2724370	2012, 5 Batch Analysis of Cuprous Thiocyanate Appendix One: Analysis Data, DACO: 2.13.3,2.13.4
2724371	2014, 5 Batch Analysis of Cuprous Thiocyanate Appendix Two, DACO: 2.13.3,2.13.4
2730997	2017, Manufacturing Methods for CuSCN, DACO: 2.11.1
2778760	2016, Confidential_SpecificationPT21_CUSCN, DACO: 0.1.6003

B. Information Considered in the Human Health Assessment

i) List of Studies/Information Submitted by Registrants

PMRA Document Number	Reference
1261858	2005, The <i>In Vitro</i> Percutaneous Absorption of Copper in Two Paint Test Preparations Through Human Skin - Dermal Delivery.
1261859	2005, The <i>In Vitro</i> Percutaneous Absorption of Copper in Two Paint Test Preparations Through Human Skin An Expert Report.
1261860	2005, The <i>In Vitro</i> Percutaneous Absorption of Copper in Two Paint Test Preparations Through Human Skin.
965057	90-Day oral toxicity study with ammonium thiocyanate by daily gavage in the rat.
1137317	An Exposure and Risk Assessment for Copper (EPA -440/4-81-015;68-01-3857) (Cuprous Thiocyanate).
1261866	Copper Thiocyanate - Risk Characterization for the Use of the Active Substance in Biocidal Product.
1172270	Determination of Exposure to Copper During Commercial Application of Anti-fouling Paint to Ship Hulls & Appendices 1-3, Report, G. McCutcheon, 95.11.07 (95682;C3671/2;2.001;2.002;2.003;2.004;2.005;2.006;2.007;RI 16/95/TX) SUBN. #92-1047/93-1446/88-1372 (Copper Thiocyanate).

- 965065 Effects of Prolonged Cyanide and Thiocyanate Feeding in Rats.
- 965058 Evaluation of reproduction toxicity of CuSCN.
- 965062 Sodium Cyanide (CAS No. 143-33-9) Administered in Drinking Water to F344/N Rats and B6C3F1 Mice. United States Department of Health and Human Services; National Toxicology Program Toxicity Report Series Number 37 NIH Publication 94-3386. November 1993.

ii) **Additional Information Considered**

Published Information

PMRA Document Number	Reference
2835074	Altamir Benedito de Sousa and Silvana Lima Górnica, 2014. Toxicokinetic aspects of thiocyanate after oral exposure to cyanide in female Wistar rats in different physiological states. <i>Drug Chem Toxicol</i> , 2014; 37(1): 63–68.
2835064	Altamir Benedito de Sousa, Paulo César Maiorka, Ivair Donizete Goncalves, Lilian Rose Marques de Sá, Silvana Lima Górnica, 2007. Evaluation of effects of prenatal exposure to the cyanide and thiocyanate in wistar rats. <i>Reproductive Toxicology</i> 23 (2007) 568–577.
2850729	EU Antifouling Copper Task Force, 2016. Evaluation of active substance, assessment report- Copper Thiocyanate.
2862093	European Chemical Agency (ECHA). 9 December 2015. <i>Biocidal products committee (BPC) opinion on the application for approval of the active substance: copper thiocyanate (ECHA/BPC/079/2015)</i> . Available from https://echa.europa.eu/documents/10162/ed0c6e30-cc08-4d08-8ba6-45ab60cc1624 (accessed 2 October 2017).
2862091	European Commission (EC). 13 November 2012. <i>HEEG opinion on the paper by Linke et al. 2007 on occupational exposure during application and removal of antifouling paints</i> . Available from https://echa.europa.eu/documents/10162/19680902/heeg_opinion_15_paper_by_links_et_al_2007_on_occupational_exposure_en.pdf/15b06061-3552-4485-b77a-eb26c9331b8a (accessed 2 October 2017).
2862092	European Commission (EC). January 2016. <i>Regulation (EU) no 528/2012 concerning the making available on the market and use of biocidal products: evaluation of active substance: assessment report: copper thiocyanate: product-type 21</i> . Available from http://dissemination.echa.europa.eu/Biocides/ActiveSubstances/1277-21/1277-21_Assessment_Report.pdf (accessed 2 October 2017).

- 2862094 Garrod, A.N.I., Guiver, R., and Rimmer, D.A. 2000. Potential exposure of amateurs (consumers) through painting wood preservatives and antifoulant preparations. *Ann. Occup. Hyg.* 44(6): 421-426.
- 2835123 Gorter RW, Butorac M, Cobian EP, 2004. Examination of the cutaneous absorption of copper after the use of copper-containing ointments. *Am J Ther.* 2004 Nov-Dec; 11(6):453-8.
- 2862095 Hughson, G.W. and Aitken, R.J. 2004. Determination of dermal exposures during mixing, spraying, and wiping activities. *Ann. Occup. Hyg.* 48(3): 245-255.
- 2835122 Hyejung Han & Hoonjeong Kwon, 2009. Estimated Dietary Intake of Thiocyanate from Brassicaceae Family in Korean Diet. *Journal of Toxicology and Environmental Health, Part A*, 72: 1380–1387, 2009.
- 2835124 Jurij J. Hostynek, Frank Dreher, Howard I. Maibach, 2006. Human stratum corneum penetration by copper: In vivo study after occlusive and semi-occlusive application of the metal as powder. *J. Food and Chemical Toxicology* 44 (2006) 1539-1543.
- 2835065 Ling Yong, Yibaina Wang, Dajin Yang, Zhaoping Liu, Grant Abernethy, Jianwen Li, 2017. Investigation of concentration of thiocyanate ion in raw cow's milk from China, New Zealand and the Netherlands. *Food Chemistry* 215 (2017) 61–66.
- 2862096 Links, I. *et al.* 2007. Occupational exposure during application and removal of antifouling paints. *Ann. Occup. Hyg.* 51(2): 207-218.
- 2835120 Lisa M. Gaetke, Hannah S. Chow-Johnson, and Ching K. Chow, 2014. Copper: Toxicological relevance and mechanisms. *Arch Toxicol.* 2014 November ; 88(11): 1929–1938.
- 2835081 Marie-Emilie Willemin & Annie Lumen, 2017. Thiocyanate: a review and evaluation of the kinetics and the modes of action for thyroid hormone perturbations. *Critical Reviews in Toxicology*, 47:7, 537-563.
- 2850728 United States Environmental Protection Agency, 2009. Reregistration Eligibility Decision (RED) for Coppers.

C. Information Considered in the Environmental Assessment

i) Additional Information Considered

Published Information

PMRA Document Number	Reference
1719804	PMRA, 2009. PRVD2009-04: Copper Pesticides, Proposed Re-evaluation Decision. February 2009.

-
- 2638212 PMRA, 2016. PRVD2016-14: Copper Pesticides Environmental Assessment of Wood Preservatives, Material Preservatives, and Antifouling Uses. May 2016.
- 2685868 PMRA, 2016. RVD2016-09: Copper Pesticides Environmental Assessment of Wood Preservative, Material Preservative and Antifouling Uses. October 2016.
- 2880087 US EPA, 2010. Copper Compounds Subject to Registration Review. EPA-HQ-OPP-2010-0212-0012. Sept 22nd, 2010.
- 2880088 US EPA, 2010. Registration Review: Preliminary Problem Formulation for Ecological Risk, Environmental Fate, and Endangered Species Assessments for Coppers. EPA-HQ-OPP-2010-0212-0009. Sept 13th, 2010.
- 2880086 US EPA, 2017. Copper Compounds: Proposed Interim Registration Review Decision, Case Nos. 0636, 0649, 4025, 4026. EPA-HQ-OPP-2010-0212-0061. Sept 22nd, 2017.
- 2880085 US EPA, 2017. Risk Assessment of Copper-Based Antifoulant Coating (Revised June 2017). EPA-HQ-OPP-2010-0212-0064. Sept 22nd, 2017.
- 2880084 US EPA. 2017. Draft Guidance on Conducting an Ecological Exposure Assessment for Antifoulant Coatings and Paints – Saltwater Marinas. EPA-HQ-OPP-2010-0212-0065. August, 2017.