Proposed Registration Decision PRD2024-11

Copper (Metallic), Intelligent Sink Trap

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Overview

Proposed registration decision for Copper (Metallic)

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of Intelligent Sink Trap, containing the technical grade active ingredient copper (metallic), to control the growth and disinfection of viruses inside a sink trap.

Copper (metallic) was first registered in 2004 and is registered as a broad-spectrum fungicide, algaecide, aquatic herbicide, molluscicide, and antimicrobial for use on indoor surfaces and materials. For details, see Proposed Re-evaluation Decision PRVD2009-04, *Copper Pesticides*, and Re-evaluation Decision RVD2010-05, *Copper Pesticides*.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

This Overview describes the key points of the evaluation, while the Science evaluation provides detailed technical information on the human health, environmental and value assessments of copper (metallic) and Intelligent Sink Trap.

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 individuals and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] 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 proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include precautionary measures on the product label to further reduce risk.

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). They also consider the unique characteristics of organisms in the environment.

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

2 "Value" as defined by subsection 2(1) of the *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."

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 Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Canada.ca.

Before making a final registration decision on copper (metallic) and Intelligent Sink Trap, Health Canada's PMRA will consider any written comments received from the public in response to this consultation document.[3] Health Canada will then publish a Registration Decision[4] on copper (metallic) and Intelligent Sink Trap, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

For more details on the information presented in this Overview, please refer to the Science evaluation of this consultation document.

What is copper (metallic)?

Copper is a naturally occurring, ubiquitous element in the environment. Copper is found in water and air and occurs naturally in various foods including organ meats, seafood, beans, nuts, and whole grains. In most foods, copper is bound to macromolecules rather than remaining as a free ion. For many animals, copper is essential for the homeostasis of life. The role of copper in maintaining normal health both in humans and animals has been recognized for many years.

Copper-containing pesticides are formulated using various forms of copper, which ultimately dissociates into the cupric ion, the active component. There are a number of pesticidal active ingredients containing copper registered in Canada. These include pesticides that are used in agriculture, such as cuprous oxide, copper sulfate pentahydrate, copper oxychloride, copper hydroxide and copper sulphate. There are also pesticides that have only antimicrobial uses, such as copper naphthenate, copper 8-quinolinolate, copper (metallic) and cupric oxide. In PRVD2009-04 *Proposed Re-evaluation Decision, Copper Pesticides*, copper (metallic) is referred to as "metallic copper" or as "metallic copper powder".

Copper is a metal that has well-known antimicrobial properties, although modes of action in viruses are debated. One commonly considered method is that copper generates reactive oxygen species (ROS), which increases oxidative stress. It is also thought that copper ions can bind to and interact with DNA. Both of these modes of action disrupt the viral genome.

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

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

Health considerations

Can approved uses of copper (metallic) affect human health?

Copper (metallic) is unlikely to affect human health when used according to label directions.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. 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. 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. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The end-use product, Intelligent Sink Trap, is a copper (metallic) ion generating device. Potential exposure to copper (metallic) may occur when handling the device. In laboratory animals, copper (metallic) was of slight acute toxicity via the oral route, low acute toxicity via the dermal route, moderate acute toxicity via the inhalation route, moderately irritating to the eye, mildly irritating to the skin and not a dermal sensitizer.

Copper is a naturally occurring metal that is present in many foods 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.

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.

Residues in drinking water and food

Dietary risks from food and drinking water are acceptable.

The Intelligent Sink Trap, is not proposed for food or feed uses. Dietary exposure, including drinking water, is not expected from the proposed use of copper (metallic) to reduce viruses in standing water. Consequently, health risks from dietary exposure are acceptable for all segments of the population, including infants, children, adults and seniors.

Risks in residential and other non-occupational environments

Estimated risk for residential and other non-occupational exposure is acceptable.

Professionals install the device under a sink, replacing the existing sink trap in hospitals, retirement homes, hotels, sport facilities, public washrooms, and restaurants. Based on the proposed use pattern, residents and the general public are not expected to have contact with metallic copper or copper ions generated by the device. Consequently, the health risk to residents and the general public is acceptable.

Occupational risks from handling Intelligent Sink Trap

Occupational risks are acceptable when Intelligent Sink Trap is used according to the label directions, which include protective measures.

After professionals install Intelligent Sink Trap under the sink, the device is controlled remotely. Workers do not come in contact with the device during normal operation. Precautionary statements on the label are considered adequate to protect individuals from occupational exposure.

The health risks to workers are acceptable when the precautionary statements on the label are observed.

Environmental considerations

What happens when copper ions generated from copper (metallic), in Intelligent Sink Trap are introduced into the environment?

Copper ions generated from metallic copper in the device, Intelligent Sink Trap, are used to disinfect standing water that collects in commercial sink traps. Disinfected sink trap water is expected to be released to aquatic environments via waste water. Metallic copper is a natural and ubiquitous element in the environment. The use of Intelligent Sink Trap is not expected to significantly contribute to the concentrations of copper in the environment relative to industrial sources (such as metal mining, pulp and paper mills, waste water from electric power generation) or piping and plumbing fixtures, and naturally occurring sources. Therefore, the environmental risks associated with the proposed use of Intelligent Sink Trap are acceptable.

Value considerations

What is the value of intelligent sink trap?

Intelligent Sink Trap is a copper ion-generating device capable of reducing viruses within the waste water that collects in sink traps.

The standing water which collects in sink traps can be contaminated with viruses. Aerosolized sink trap water may cause contamination of the surfaces surrounding the sink. The registration of Intelligent Sink Trap will offer a novel method of treating viruses in sink traps. When water stops running into the trap, a specific amount of copper ions are generated inside the standing waste water within the trap in order to reduce viruses.

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 Intelligent Sink Trap to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

To limit exposure, a label statement is required informing users not to separate the device from plumbing during normal operations.

Environment

None.

Next steps

Before making a final registration decision on copper (metallic) and Intelligent Sink Trap, Health Canada's PMRA will consider any written comments received from the public in response to this consultation document up to 45 days from the date of publication (19 December 2024) of this document. Please forward all comments to Publications (contact information on the cover page of this document). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada's response to these comments.

Other information

When the Health Canada makes its registration decision, it will publish a Registration Decision on copper (metallic) and Intelligent Sink Trap (based on the Science evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room. For more information, please contact the PMRA's Pest Management Information Service.

Science evaluation

Copper (metallic) and intelligent sink trap

1.0 The active ingredient, its properties and uses

1.1 Directions for use

This device can be installed as a replacement for existing sink p-traps. The device is intended for commercial use. These areas include hospitals, retirement homes, hotels, sport facilities, public washrooms, and restaurant settings. The device has one operational setting, with a maximum daily output of 60 mg of copper ions. The device will run for up to four uninterrupted cycles when the water stops flowing into the trap. After 24 hours without water flow, the device will run for another four uninterrupted cycles.

1.2 Mode of action

Copper is a naturally occurring antimicrobial material. There are multiple modes of action which may individually or cumulatively result in the inactivation of viruses. One considered method is through the reduction of copper, resulting in hydroxyl free radicals that induce oxidative stress. Another consideration is that copper ions can also bind and cross-link the strands of genome to damage DNA. The primary mechanism may vary across viruses.

2.0 Methods of analysis

2.1 Methods for residue analysis

No methods are required to quantify residues of copper as a quantitative dietary risk assessment is not required (see Section 3.4.1 for additional details).

3.0 Impact on human and animal health

3.1 Toxicology summary

A detailed review of toxicology information was conducted in support of the active ingredient metallic copper and the end-use product, Intelligent Sink Trap.

Additional data for the currently registered active ingredient, metallic copper, was not required. Metallic copper is considered to be of slight acute toxicity via the oral route, low acute toxicity via the dermal route, moderate acute toxicity via the inhalation route, moderately irritating to the eyes, mildly irritating to the skin, and not a dermal sensitizer.

The component of toxicological interest in copper-containing pesticides is elemental copper (cupric ion). Humans have homeostatic capabilities to regulate copper. There is no evidence of copper being carcinogenic or posing any other systemic toxicity in animals having normal copper homeostasis. Thus, toxicological endpoints were not established to quantify any potential risks from exposure to copper. Refer to PRVD2009-04 *Proposed Re-evaluation Decision, Copper Pesticides*, for additional details.

3.2 Occupational, residential and bystander exposure and risk assessment

3.2.1 Use description

Intelligent Sink Trap is proposed for use as a stand-alone commercial copper (metallic) ion generating device intended to reduce viruses in standing water inside the sink trap. An electrical current passes between copper electrodes releasing copper ions into the waste water. The device is installed by a professional under a sink, replacing the existing trap in hospitals, retirement homes, hotels, sport facilities, public washrooms, and restaurants. Once installed, the device is controlled remotely. At the termination of water flow, a 10-minute disinfection cycle is initiated followed by a 30-minute pause. The disinfection cycle is repeated four times. The approximate lifespan of the device is 8500 cycles, with a maximum output of 60 mg copper ions per day.

3.3 Occupational exposure and risk assessment

3.3.1 Mixer, loader, and applicator exposure and risk assessment

Intelligent Sink Trap is professionally installed and controlled remotely. There is no contact with the metallic copper or copper ions generated by the device during normal operation. When handled according to label directions, occupational exposure to Intelligent Sink Trap is characterized as short-term in duration and is expected to occur primarily by the dermal route during maintenance (repair) only. Precautionary statements on the end-use product label aimed at mitigating exposure are adequate to protect individuals from any risk due to occupational exposure. Overall, occupational risks to workers are acceptable when the precautionary statements on the labels are followed.

3.3.2 Postapplication exposure and risk assessment

Postapplication activities include monitoring the device remotely. Precautionary statements on the end-use product label aimed at mitigating exposure are adequate to protect workers from risk due to postapplication exposure. Consequently, the risks to workers due to postapplication exposure are acceptable.

3.3.3 Residential and bystander exposure and risk assessment

The device is installed professionally under the sink, in hospitals, retirement homes, hotels, sport facilities, public washrooms, and restaurants to reduce viruses inside the sink trap. Due to the proposed use pattern, bystander exposure to Intelligent Sink Trap is not expected to occur.

There is no contact with the metallic copper or copper ions (in treated water) generated by the device during normal operations. Residential/general public exposure is not expected.

Additionally, mitigating statements present on Intelligent Sink Trap label will minimize bystander and residential exposure.

Consequently, the health risks to bystanders and individuals in residential areas are considered acceptable.

3.4 Dietary exposure risk assessment

3.4.1 Food

Intelligent Sink Trap is not proposed for food or feed use. Consequently, dietary exposure to copper (metallic) from the proposed use is not of health concern.

3.4.2 Drinking water

Based on the proposed use pattern (see Section 3.2.1), exposure from drinking water is not expected. The label has the necessary mitigative measures to prevent contamination of drinking water from the proposed use of copper (metallic). Additionally, copper is naturally occurring in many foods and in drinking water. Health risks from residues of copper (metallic) in drinking water are acceptable.

3.4.3 Acute and chronic dietary risks for sensitive subpopulations

As noted above, when the end-use product is used as directed on the label, the health risk is acceptable for the general population, including infants and children.

3.5 Aggregate exposure and risk

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential exposure pathways is assessed. A major consideration is the likelihood of co-occurrence of exposures. Additionally, only exposures from routes that share common toxicological endpoints can be aggregated.

The end-use product is not proposed for food use and will not be applied near, or to, drinking water. Furthermore, non-occupational exposure will be low when Intelligent Sink Trap is used as directed on the label. When the end-use product is used as labelled, there is reasonable certainty that no harm will result from aggregate exposure of residues of metallic copper. This includes all anticipated dietary (food and drinking water) exposures and all other non-occupational exposures (dermal and inhalation) for which there is reliable information.

3.6 Cumulative assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative non-occupational exposure to pesticides with a common mechanism of toxicity, based on the likelihood that people may be exposed to more than one of these pesticides at the same time. Accordingly, assessments of potential common mechanisms of toxicity with other pesticides were undertaken for copper.

The mechanism of copper toxicity is well characterized. While exposure may co-occur to other copper-based pesticides, for the current evaluation, the PMRA did not identify information indicating that copper shares a common mechanism of toxicity with registered pest control products that are not copper-based. Therefore, there is no requirement for a cumulative health risk assessment at this time.

3.7 Maximum residue limits

The specification of a maximum residue limit for copper was not required for the proposed non-food use of the end-use product.

3.8 Health incident reports

As of May 2024, no human or domestic animal incidents involving metallic copper have been submitted to the PMRA.

4.0 Impact on the environment

Copper ions generated from metallic copper in the device, Intelligent Sink Trap, are considered for registration as non-conventional products according to PMRA Guidance Document, *Registration of Non-Conventional Pest Control Products (2023)*. The PMRA does not typically conduct an environmental risk assessment for Use-site Category 19 (Other Indoor Surfaces, Water, and Air). However, an exception was made for Intelligent Sink Trap because copper ions generated by this device can be released to aquatic environments via waste water given the proposed use.

Comprehensive reviews of copper as material preservative and pesticide are outlined in previous PMRA assessments (PRVD2009-04, PRVD2016-14, RVD2016-09). Further assessments are found in the Environment and Climate Change Canada draft screening assessment for copper and its compounds (ECCC 2019).

4.1 Fate and behaviour in the environment

Copper is a chemical element that is found in the free metallic state in nature. Copper does not break down through hydrolysis, photolysis or any other transformation processes, though it can transform to different chemical species in the environment. Metallic copper in Intelligent Sink Trap generates copper ions (Cu^{+}) to disinfect standing water found in commercial sink traps.

When Cu^{+} ions dissolve in water, they are oxidized to form Cu^{2+} ions, which bind to particulate matters including bacteria, viruses and fungi. Free copper ions have high sorption affinity to soil, sediments and organic matter. The forms in which copper is found depend on water chemistry, such as the pH or organic content.

4.2 Environmental risk characterization

Intelligent Sink Trap devices will be used as commercial disinfectants in hospitals, retirement homes, hotels, sport facilities, public washrooms and restaurant settings. Each device has one operational setting, with a maximum daily output of 60 mg of copper ions. The concentration of copper ions in disinfected standing water is estimated to be 1 mg/L. The industrial sectors (namely metal mining, pulp and paper mills, waste water from electric power generation), piping and plumbing fixtures, and naturally-occurring sources are expected to produce more significant exposures of copper when compared to antimicrobial uses. Thus, concentrations of 1 mg copper ion /L of disinfected standing water released from Intelligent Sink Traps would be a minimal contribution to the overall levels of copper found in waste water and in the environment. Moreover, any copper ions released to waste water will be further removed, where municipal waste water treatment plant (WWTP) processes are in place, prior to being released to the aquatic environment. Copper ions will be sorbed to activated sludge biomass with subsequent removal by clarification. Empirical monitoring data collected from 25 municipal WWTPs across Canada indicate the median removal value of copper from influent to final effluent was 75.3% (ECCC 2019). Given the limited release of copper ions expected from the commercial use of Intelligent Sink Trap and the expected waste water removal at municipal treatment facilities, risks to aquatic organisms are acceptable. No additional mitigation measures are required.

4.2.3 Environmental incident reports

As of May 2024, no environment incidents have been submitted to the PMRA.

5.0 Value

Viruses are present in the standing water in sink traps, which can serve as potential microbial reservoirs. Studies suggest that hospital-acquired infections can result from contaminated sink drains which has led to the development of self-cleaning traps. Some self-cleaning traps use a combination of heat and vibration but come at a greater cost and installation limitations. This device is unique as it uses copper ions and can be used to retrofit any existing sink.

Data from multiple laboratory studies was submitted to demonstrate the efficacy of Intelligent Sink Trap. These studies evaluated the efficacy of the device when four uninterrupted cycles are run in the presence of a representative hard-to-kill virus (Human Adenovirus Type 5) in the water within the sink trap. The studies demonstrated that the device is capable of reducing viruses by 2-log (99%).

A study confirming the maximum daily copper ion output of the device was submitted, where three devices were run multiple times in order to determine the average output per cycle. Based on this study, the maximum daily output was determined to be 60 mg of ionic copper.

The lifespan of the device was determined using an accelerated operational study, with the current set to allow for a constant copper ion deposition rate.

The results of the laboratory studies support claims that Intelligent Sink Trap reduces viruses in the standing waste water in the p-trap, provides a maximum daily output of 60 mg of copper ions, and has an approximate lifespan of 8500 treatment cycles.

6.0 Pest control product policy considerations

6.1 Toxic substances management policy considerations

For a review of the Pest Control Product Policy considerations such as the assessment of the active ingredient under the Toxic Substances Management Policy and the review of the Formulants and Contaminants of Health or Environmental concern, please refer to PRVD2009-04, *Proposed Re-evaluation Decision, Copper Pesticides*.

7.0 Proposed regulatory decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of Intelligent Sink Trap, containing the technical grade active ingredient copper (metallic), to control the growth and disinfection of viruses inside a sink trap.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

List of abbreviations

ECCC	Environment and Climate Change Canada
L	litre
mg	milligram
pH	measure of the acidity or basicity of an aqueous solution
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PRVD	Proposed Re-evaluation Decision
WWTP	Waste Water Treatment Plant

References

A. List of studies/Information submitted by registrant

1.0 Human and animal health

PMRA document number	Reference
3360103	2022, Certifications, DACO: 10.6
3360105	2022, Use description and Scenario, DACO: 5.2
3621535	2024, Response Letter to clarify Use Description Scenario, DACO: 5.2

2.0 Value

PMRA document number	Reference
3360088	2022, Mode of Action (TGAI) and Description of the product, DACO: 10.2,10.2.1
3360089	2022, Description of Pest Problem, DACO: 10.2.2
3444354	2023, Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Testing against Human Adenovirus Type 5 (AD-5) for efficacy of Intelligent Sink Trap Device, DACO: 10.2.3.2,10.2.3.3
3444358	2023, Copper measurement Report - Demonstrate output of copper at each device setting for power and duration and output of copper deposited per day., DACO: 10.2.3.2,10.2.3.3,10.2.3.4
3480797	2023, Report - Determine minimum lifespan of Intelligent Sink Trap device based on the maximum output., DACO: 10.6

B. Additional information considered

i) Published information

1.0 Environment

PMRA document number	Reference
3329083	2019, Environment and Climate Change Canada, Draft Screening Assessment: Copper and its Compounds, DACO: 9.9