Proposed Registration Decision PRD2024-03

Copper (Metallic) and V2 Net

(*publié aussi en français*)

8 March 2024

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

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Canada

ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2024-3E (print version)
H113-9/2024-3E-PDF (PDF version)

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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 Copper Flake Technical and V2 Net, containing the technical grade active ingredient copper (metallic), for antifouling protection of fish farm nets against organisms such as hydroids, barnacles, and mussels and for fish containment and protection in fresh, brackish, and marine waters.

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 V2 Net.

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. 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 Health

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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."

Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides section of the Canada.ca website.

Before making a final registration decision on copper (metallic) and V2 Net, 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 V2 Net, 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, copper (metallic) is referred to as "metallic copper" or as "metallic copper powder".

Copper (metallic) is a conventional active ingredient with antimicrobial properties. When a surface or material is embedded with copper, copper ionic species can be released, and when contacting an organism's cell membrane, it generates reactive oxygen species which causes cell death.

Throughout this document, the technical grade active ingredient is referred to as "copper (metallic)." The more general term "copper" is used when referring to the metal itself, as well as to alloys, or compounds that contain copper.

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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.

Potential exposure to copper (metallic) may occur through the diet (food and water) or when handling the product. 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.

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.

In laboratory animals, copper (metallic) was of high acute toxicity via the oral route, low acute toxicity via the dermal route, and moderate acute toxicity via the inhalation route. Copper (metallic) was slightly irritating to the eyes, not irritating to the skin, and not a dermal sensitizer.

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.

The end-use product, V2 Net, is considered to be of low acute toxicity by the oral, dermal, and inhalation routes, slightly irritating to the eyes, not 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.

Residues in drinking water and food

Dietary risks from food and drinking water are acceptable.

Copper leaching from V2 Net and taken up by fish grown in the aquaculture enclosures is not expected to exceed background concentrations in the fish or in any potential source of drinking 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.

Individuals engaged in recreational aquatic activities near the deployed V2 Nets are not expected to be exposed to levels of the active ingredient exceeding natural background concentrations. Consequently, the health risk to residents and the general public is acceptable.

Occupational risks from handling V2 Net

Occupational risks are acceptable when V2 Net is used according to the label directions, which include protective measures.

Workers handling V2 Net can come into direct contact with copper (metallic) through contact with the skin during deployment, retrieval, maintenance, and cleaning of the nets.

To protect workers from exposure to the end-use product, the precautionary label statements indicate that contact with eyes must be avoided and that gloves must be worn when handling. Precautionary and hygiene 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 (metallic) is introduced into the environment?

When copper (metallic) is used according to the label directions, the risks to the environment are acceptable.

When copper (metallic) is present as a component of the V2 Net netting material used in aquaculture nets, it will enter the aquatic environment when the netting material comes in contact with water. Once in the water, the copper (metallic) will be rapidly diluted within seconds. Copper (metallic) is a natural element and does not break down in the environment. Copper (metallic) will not move from the treatment area into the air and therefore is not expected to move to non-treated sites via air. Copper (metallic) may move to non-treatment sites by ocean currents at increasingly lower concentrations as it moves further away from the treatment site. Copper is an essential trace element that is physiologically and nutritionally required by plants, mammals, and aquatic organisms and is especially important for aquatic invertebrates like shrimp, crab, and lobster. The measurement of the potential for copper to accumulate in plant and animal tissues as a result of the very small amounts released from the V2 Net netting material is not possible. Copper is not expected to accumulate in plant and animal tissues.

When copper (metallic) is used in accordance with the label directions, the risks to non-target organisms are acceptable. Risk mitigation measures are outlined under the Measures to minimize risk section.

Value considerations

What is the value of V2 Net?

V2 net resists the growth of aquatic biofouling organisms and can be used in fresh, brackish, and marine waters.

V2 Net provides effective resistance against aquatic biofouling organisms such as hydroids, barnacles, and mussels. This allows for a reduction in the frequency of net cleaning and maintenance cycles. The reduction of net cleaning events can reduce certain fish diseases associated with frequent cleaning, such as proliferative gill disease (PGD).

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 Copper Flake Technical and V2 Net to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

The hazard signal words “WARNING – EYE IRRITANT” are required on the principal display panel of the labels for Copper Flake Technical and V2 Net label.

Environment

Label statements indicating that the V2 Net is not to come into contact with any source of water other than in accordance with the directions for use on the product label are required. Label statements informing users of the toxicity of the V2 Net to aquatic organisms are required.

Next steps

Before making a final registration decision on copper (metallic) and V2 Net, 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 (8 March 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 Health Canada makes its registration decision, it will publish a Registration Decision on copper (metallic) and V2 Net (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 V2 Net

1.0 The active ingredient, its properties and uses

1.1 Identity of the active ingredient

Active substance	Copper (metallic)
Function	Antifouling / Material Preservative
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Copper
2. Chemical Abstracts Service (CAS)	Copper
CAS number	7440-50-8
Molecular formula	Cu
Molecular weight	63.5
Structural formula	Cu
Purity of the active ingredient	95.75%

1.2 Physical and chemical properties of the active ingredient and end-use product

Technical product—Copper flake technical

Property	Result
Colour and physical state	Reddish-brown solid
Odour	None
Melting range	1083ºC
Boiling point or range	2595ºC
Specific gravity	4
Vapour pressure at 20°C	Negligible
Ultraviolet (UV)-visible spectrum	Not susceptible to photochemical degradation

Property	Result
Solubility in water at 20°C	1 mg/L
Solubility in organic solvents at 20°C	<1 mg/L
n-Octanol-water partition coefficient (K_{ow})	Not applicable; solid metal
Dissociation constant (pK_a)	Does not dissociate
Stability (temperature, metal)	Stable elemental metal; does not decompose

End-use Product—V2 Net

Property	Result
Colour	Metallic Brown
Odour	Odourless
Physical state	Solid
Formulation type	Solid
Label concentration	Copper (metallic) 14.0%
Container material and description	High-density polyethylene (HDPE) yarn knitted into a net ranging from 0.5 to 10 metric tons (500 to 10 000 kg)
Density	1.02–1.05 g/cm^3
pH of 1% dispersion in water	The product is solid
Oxidizing or reducing action	The product is solid
Storage stability	The product was stable when stored in Polyethylene Woven Bags packaging material for 14 days at 54ºC.
Corrosion characteristics	The product was not corrosive to the packaging material when stored in Polyethylene Woven Bags for 14 days at 54ºC.
Explodability	The product is solid

1.3 Directions for use

Copper (metallic) is an active ingredient that is used in the manufacturing process to embed copper (14%) into a HDPE yarn, which is then formed into nets to be used in fish farms.

1.4 Mode of action

The copper (metallic) embedded in the HDPE yarn delays growth of biofouling organisms on the net structures. When copper from copper (metallic) leaches into marine water in the presence of oxygen, the predominant form of copper is cupric ion, Cu^{2+}. Cupric ion acts to delay the settlement of the microscopic larvae of biofouling organisms within a micro-layer of water at the V2 Net surface by slowing the organisms' vital processes by inactivating enzymes, and by precipitating the organisms' cytoplasmic proteins as metallic proteinates.

2.0 Methods of analysis

2.1 Method for formulation analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.2 Methods for residue analysis

No methods are required to quantify residues of copper due to the limited dietary exposure from the proposed use.

3.0 Impact on human and animal health

3.1 Toxicology summary

A detailed review of toxicology information was conducted in support of the end-use product, V2 Net. Additional data for the currently registered technical grade active ingredient, Copper Flake Technical, was not required. Refer to PRVD2009-04 for additional details. The data package for V2 Net consisted of publicly available literature as well as waiver requests for primary skin irritation and dermal sensitization and was considered acceptable to assess the toxic effects that may result from exposure to copper.

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.

Waivers for V2 Net were granted for primary skin irritation and dermal sensitization based on information on file for the active ingredient, copper (metallic), and information on the other components of the end-use product.

V2 Net (14.0% copper (metallic)) is considered to be of low acute oral, dermal, and inhalation toxicity in individuals with normal homeostasis abilities. V2 Net is also considered to be moderately irritating to the eyes, non-irritating to the skin, and is not expected to be a dermal sensitizer.

3.2 Dermal absorption

No information was provided on the dermal absorption of copper (metallic).

3.3 Occupational, residential, and bystander exposure and risk assessment

3.3.1 Use description

V2 Net is proposed for use in fish farms as a method of fish containment and protection from predators, as well as an antifoulant for organisms such as hydroids, barnacles, and mussels on the net, in marine, brackish or fresh waters. The anticipated replacement time of the net is six years. Each production site will have its own set of nets that are deployed for the entire production cycle. Afterwards, they are removed, shipped to a net repair facility, washed/disinfected, repaired, tested, and stored until the next fish cycle. Time between production cycles is anywhere from four to twelve months.

3.3.2 Occupational exposure and risk assessment

3.3.2.1 Mixer, loader, and applicator exposure and risk assessment

Exposure to workers installing and retrieving V2 Net is expected to be short-term in duration and predominantly by the dermal route. 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 label are followed, which include personal protective equipment (PPE).

3.3.2.2 Postapplication exposure and risk assessment

Postapplication activities include typical activities related to aquaculture, such as underwater inspections of the nets for breakage, fouling assessment, mortality collection, bringing feed to the farms, assisting with lice treatments, if necessary, harvesting procedures, and net changes. 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 post-application exposure are acceptable.

3.3.3 Residential and bystander exposure and risk assessment

Bystander exposure is possible if individuals engage in aquatic activities near where the nets are deployed. However, the concentration of the active ingredient released from the netting is expected to be low and unlikely to exceed the natural concentration in the body of water. Consequently, the health risk due to exposure of individuals involved in aquatic- or work-related activities in the vicinity of the V2 Net is acceptable.

Similarly, individuals engaged in recreational aquatic activities in the vicinity of the V2 Net are expected to be exposed to very low levels of the active ingredient not exceeding background concentrations. Consequently, the health risk due to exposure from recreational aquatic activities is acceptable.

3.4 Dietary exposure risk assessment

3.4.1 Food

Based on the limited leaching of copper in the water from the nets in which the fish are penned, and that copper concentrations resulting from the use of V2 Net are not expected to exceed those in the immediate environment, no adverse effects are anticipated from the presence of copper residues on food.

Consequently, when V2 Net is used as directed by the label, the health risk is acceptable for the general population, including infants and children, and domestic animals.

3.4.2 Drinking water

Although the end-use product could be installed in potential sources of drinking water, the concentration of copper leached from the net is not expected to exceed the background concentration in the body of water. Consequently, the health risk due to exposure from drinking water is acceptable.

3.4.3 Acute and chronic dietary risks for sensitive subpopulations

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

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.

Copper (metallic) is considered to be of low toxicity by the dermal route. Although the end-use product could be installed in potential sources of drinking water, the concentration of copper leached from the net is not expected to exceed the background concentration in the body of water. Furthermore, non-occupational exposure will be low when V2 Net 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 copper (metallic). This includes all anticipated food exposure, drinking water exposure, and all other non-occupational exposures (incidental oral, 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 exposure to pesticides with a common mechanism of toxicity. Accordingly, assessments of potential common mechanisms of toxicity with other pesticides were undertaken for copper.

For the current evaluation, the PMRA did not identify information indicating that copper shares a common mechanism of toxicity with other registered pest control products. Therefore, there is no requirement for a cumulative health risk assessment at this time.

3.7 Maximum residue limits

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether dietary risks are acceptable from the consumption of foods treated with the pesticide when used according to the supported label directions. If acceptable, this means food containing that amount of residue is safe to eat, and maximum residue limits (MRLs) may be proposed. Maximum residue limits are the maximum amount of pesticide residue legally permitted to remain in/on food sold in Canada and are specified under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act.*

Copper leaching from V2 Net and taken up by fish grown in the aquaculture enclosures is not expected to exceed background concentrations in the fish or in any potential source of drinking water. Consequently, the specification of an MRL, under the *Pest Control Products Act*, will not be required for copper in fish.

3.8 Health incident reports

As of 21 July 2023, no human or domestic animal incidents involving copper (metallic) had been submitted to the PMRA.

4.0 Impact on the environment

The physical properties, chemical properties, ecotoxicology, and environmental fate characterization of copper (metallic) have been previously reviewed and reported in PRVD2009-04 and RVD2010-05.

It was determined that the maximum rate of release of copper into the environment from the V2 Net netting material was 18.8 µg/cm^2/day. This release rate is below the maximum daily release rate of 40 µg/cm^2/day that was determined to be acceptable (Regulatory Directive DIR94-03, *Registration of Antifouling Coatings*).

When used in accordance with label directions, the risks to non-target organisms from the use of copper (metallic) as an antifouling agent present in the V2 Net netting material are acceptable.

4.1 Environment incident reports

As of 21 July 2023, no environment incidents involving copper (metallic) had been reported to the PMRA.

5.0 Value

Copper-painted nets were once the industry standard for Canadian farmed salmon, but the industry is transitioning away from them due to the accumulation of copper sediment on the ocean floor. High-density polyethylene nets became a suitable alternative; however, HDPE nets require more frequent underwater in situ cleaning in order to maintain optimum water flow through the nets.

Frequent in situ cleaning can release accumulated biofouling organisms from the net and negatively impact the health and welfare of salmon. One prevalent disease affecting salmon farms is PGD, which has been linked to the direct mortality of salmon, as well as indirect mortalities from handling fish with compromised gills. This condition is exacerbated by frequent in situ net cleaning.

Submitted studies have shown that V2 Net generally has similar biofouling resistance as traditional nylon nets coated with a copper-based paint, and that V2 Net does not require as much biofouling maintenance (removal or cleaning) as unpainted nylon and HDPE nets. V2 Net generally has similar efficacy for biofouling resistance as traditional nylon nets dipped in copper-based paint.

V2 Net is effective against biofouling organisms and requires less in situ cleaning compared to HDPE nets. This in turn benefits the health and welfare of farmed salmon, as it may lead to decreases in the occurrence of PGD.

6.0 Pest Control Product Policy considerations

6.1 Toxic Substances Management Policy considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances, in other words, those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, copper was assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. Please refer to Appendix I, **Error! Reference source not found. Error! Reference source not found.**for further information on the TSMP assessment.

With respect to the bioaccumulation criterion, the bioconcentration factor (BCF) and bioaccumulation factor (BAF) ratios may have limited usefulness in predicting metal accumulation. BCF/BAF values were not reported in the draft screening assessment of copper compounds by Environment and Climate Change Canada (ECCC). Copper is an essential trace element that is physiologically and nutritionally required by plants, mammals, and aquatic organisms and is especially important for aquatic invertebrates like shrimp, crab, and lobster. The measurement of the potential for copper to accumulate in plant and animal tissues as a result of the very small amounts released from the V2 Net netting material is not possible. Copper is not anticipated to accumulate in plant and animal tissues. Additionally, ECCC reported an absence of copper biomagnification in field studies of food chains and terrestrial food webs.

The PMRA has reached the conclusion that copper does not meet all of the TSMP Track 1 criteria.

6.2 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use products are compared against Parts 1 and 3 of the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.[6] The list is used as described in the PMRA Science Policy Note SPN2020-01[7] and is based on existing policies and regulations, including the Toxic Substances Management Policy[1] and Formulants Policy[8], and taking into consideration the Ozone-depleting Substances and Halocarbon Alternatives Regulations, under the *Canadian Environmental Protection Act, 1999*, (substances designated under the Montreal Protocol).

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

6 SI/2005-114, last amended on June 4, 2020. See Justice Laws website, Consolidated Regulations, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*

7 PMRA's Science Policy Note SPN2020-01, *Policy on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under paragraph 43(5)(b) of the Pest Control Products Act*

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document*

Health Canada has reached the following conclusions:

- Copper and its end-use product, V2 Net, do not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

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 Copper Flake Technical and V2 Net, containing the technical grade active ingredient copper (metallic), for antifouling protection of fish farm nets against organisms such as hydroids, barnacles, and mussels and for fish containment and protection in fresh, brackish, and marine waters.

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

µg	microgram
°C	degrees centigrade
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CEPA	Canadian Environmental Protection Act
cm	centimetres
ECCC	Environment and Climate Change Canada
g	gram
HDPE	high-density polyethylene
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	*n*–octanol-water partition coefficient
L	litre
mg	milligram
MRL	maximum residue limit
NA	Not Available
PDG	proliferative gill disease
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PRVD	Proposed Re-evaluation Decision Document
RVD	Re-evaluation Decision Document
TSMP	Toxic Substances Management Policy
UV	ultraviolet

Appendix I Tables and figures

Table 1 Toxic Substances Management Policy considerations-Comparison to TSMP Track 1 Criteria for copper (metallic)

Toxic Substances Management Policy considerations-Comparison to TSMP Track 1 Criteria			
TSMP Track 1 Criteria	**TSMP Track 1 Criterion value**		**Active ingredient[1]**
CEPA toxic or CEPA toxic equivalent[2]	Yes		Yes
Predominantly anthropogenic[3]	Yes		Yes
Persistence[4]:	Soil	Half-life ≥ 182 days	Yes Half-life: Stable
	Water/Sediment Whole System	Half-life ≥ 182 days (water) ≥ 365 days (sediment)	Yes Half-life: Stable
	Air	Half-life ≥ 2 days or evidence of long range transport	Not determined
Bioaccumulation[5]	Log K_{OW} ≥ 5		NA[6]
	BCF ≥ 5000		NA[6]
	BAF ≥ 5000		NA[6]
Is the chemical a TSMP Track 1 substance. (all four criteria must be met)?			No, does not meet all TSMP Track 1 criteria.

[1] No major transformation products were detected in lab or field studies.

[2] All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (in other words, all other TSMP criteria are met).

[3] The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

[4] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment, or air) than the criterion for persistence is considered to be met.

[5] Field data (for example, BAFs) are preferred over laboratory data (for example, BCFs) which, in turn, are preferred over chemical properties (for example, log K_{ow}).

[6] Not Available. BCF/BAF values were not reported in the draft screening assessment of copper compounds by ECCC. Copper is an essential trace element that is physiologically and nutritionally required by plants, mammals, and aquatic organisms. The measurement of the potential for copper to accumulate in plant and animal tissues as a result of the very small amounts released from the V2 Net netting material is not possible. Additionally, ECCC reported an absence of copper biomagnification in field studies of food chains and terrestrial food webs.

References

PMRA Document Number **Reference**

A. List of studies/Information submitted by registrant

1.0 Chemistry

3153335 2020, Product Chemistry Summary for V2 Net, DACO: 3.0 CBI
3297092 2021, Validation of analytical method for copper in V2 Nets, DACO: 3.4.1 CBI
3297093 2021, Determination of accelerated storage stability of V2 Nets, DACO: 3.5.10 CBI

2.0 Human and animal health

1056934 2001, Acute Oral Toxicity in the Rat, DACO: 4.2.1
1056935 2001, Acute Dermal Toxicity (Limit Test) in the Rat, DACO: 4.2.2
1056936 2001, Acute Inhalation Toxicity (Nose Only) in the Rat, DACO: 4.2.3
1056937 2001, Acute Eye Irritation in the Rabbit, DACO: 4.2.4
1056938 2001, Acute Dermal Irritation in the Rabbit, DACO: 4.2.5
1056939 2001, Acute Eye Irritation in the Guinea Pig Magnusson and Kligman Maximisation Method, DACO: 4.2.6
3153336 2020, Acute Toxicity of V2 Nets and Request for Waiver, DACO: 4.1,4.6
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B. Additional information considered

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