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Proposed Registration Decision

PRD2015-12

Copper (present as Copper Octanoate)

(publié aussi en français)

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Overview

Proposed Registration Decision for Copper (present as Copper Octanoate)

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of two technical grade active ingredients – Cueva TGAI and Cueva RTU TGAI – and eight end-use products – Cueva Commercial, Cueva Concentrate, Cueva Ready-to-Spray, Cueva RTU, Cueva RTU with Pull'N Spray Applicator, Cueva RTU with Quickpump Applicator, Cueva RTU with Wand Applicator, and Cueva RTU with Quick Connect Sprayer – containing the technical grade active ingredient copper (present as copper octanoate) to control or suppress various fungal and bacterial diseases on turf, nuts, as well as ornamentals, and a variety of fruit and vegetables in both the field and greenhouse.

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

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 Cueva TGAI and Cueva RTU TGAI and Cueva Commercial, Cueva Concentrate, Cueva Ready-to-Spray, Cueva RTU, Cueva RTU with Pull'N Spray Applicator, Cueva RTU with Quickpump Applicator, Cueva RTU with Wand Applicator, and Cueva RTU with Quick Connect Sprayer.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable¹ 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 value² when used according to the label directions. Conditions of registration may include special 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) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the

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.”

nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on copper (present as copper octanoate), the PMRA will consider any comments received from the public in response to this consultation document.³ The PMRA will then publish a Registration Decision⁴ on copper (present as copper octanoate), which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA'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 (present as Copper Octanoate)?

Copper (present as copper octanoate) is a fatty acid salt (soap) that combines copper and octanoic acid. It is a contact fungicide and bactericide that can be applied to foliage to control or suppress various plant diseases on a broad range of agricultural and ornamental crops and turfgrass. It is a new active ingredient in eight end-use products for commercial and domestic use.

Health Considerations

Can Approved Uses of Copper (present as Copper Octanoate) Affect Human Health?

Copper (present as copper octanoate) is unlikely to affect human health when used according to label directions.

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

In laboratory animals, copper (present as copper octanoate) was of low acute toxicity via the oral, dermal and inhalation routes of exposure. Copper (present as copper octanoate) was also minimally irritating to the eyes, non-irritating to the skin, and not a dermal sensitizer.

The toxicology profiles of the end-use products are no different than copper (present as copper octanoate).

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*.

The active component of toxicological concern with the majority of copper-containing pesticides is the copper ion, and most copper compounds, including copper (present as copper octanoate), can therefore be considered similar in terms of their toxicity. Copper is a naturally occurring metal that occurs in many foods including organ meats, seafood, beans, nuts and whole grains, and in drinking water. Copper is also an essential element in maintaining normal health in humans, with adverse effects more likely to result from copper deficiency rather than excess. Humans have efficient mechanisms in place to regulate copper in the body, and as such are readily able to clear excess copper from the body before harm is caused.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Based on the ubiquitous nature of copper and the currently registered use patterns of various forms of copper on the proposed commodities, the use of copper (present as copper octanoate) is not expected to appreciably increase food residue levels of copper beyond the maximum residue limit (MRL) of 50 ppm specified for copper on all food commodities.

Risks in Residential and Other Non-Occupational Environments

Risk to residential users of domestic end-use products is not expected to be of concern due to the low toxicity of copper (present as copper octanoate) and the low potential for exposure expected when the products are applied according to label directions.

Occupational Risks from Handling the Commercial end-use products Containing Copper (present as Copper Octanoate)

Occupational risks are not of concern when the end-use products containing copper (present as copper octanoate) are used according to the proposed label directions, which include protective measures.

Workers can come in direct contact with the commercial end-use products containing copper (present as copper octanoate) when handling the product, or come into contact with treated crops when entering treated areas before sprays have dried. The label has adequate precautionary measures including the requirement of personal protective equipment and precautionary and hygiene statements to minimize exposure. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for workers, risks to these individuals are not a concern.

Environmental Considerations

What Happens When Copper (present as Copper Octanoate) Is Introduced Into the Environment?

When used according to label directions, copper (present as copper octanoate) does not pose an unacceptable risk to the environment.

Copper (present as copper octanoate) enters the environment when used for the control of fungal diseases on a variety of agricultural crops, ornamental plants and on turf. Minimal environmental exposure is expected from the use of copper (present as copper octanoate) in greenhouses. Once in the environment, copper (present as copper octanoate) dissociates into copper and fatty acids. Fatty acids occur naturally in the environment and degrade rapidly in the presence of microorganisms in both aquatic and terrestrial environments. Copper is an element that also occurs naturally in the environment, but it does not break down. The non-metallic copper is highly reactive, especially in aquatic environments. The form in which copper is found depends on characteristics of its surrounding and the nature and concentration of other forms of copper present. The free non-metallic copper has a high sorption affinity for soil, sediments and organic matter, and copper applied to the surface is not expected to move readily into groundwater. Environmental concentrations can reflect naturally occurring and other sources of copper besides pesticides.

The use of copper (present as copper octanoate) is not expected to significantly increase environmental exposure to either copper or fatty acids. The environmental risks to non-target organisms have been previously assessed for environmental concentrations exceeding those for copper (present as copper octanoate) uses (Re-evaluation Decision (RVD) 2010-05: *Copper Pesticides*, Re-evaluation Decision Document (RRD) 2004-26: *Soap Salts*). At label rates, the use of copper (present as copper octanoate) presents a negligible risk to pollinators and aquatic vascular plants, but could pose a risk to birds, small wild mammals and aquatic organisms (freshwater and estuarine/marine invertebrates, fish and algae) if they are exposed to high enough concentrations. To minimize exposure to non-target organisms, spray buffer zones are specified on the label of the commercial product to protect freshwater and marine habitats adjacent to treated areas. Hazard statements are also specified on all product labels for birds, small wild mammals and aquatic organisms.

Value Considerations

What Is the Value of Cueva Commercial and the domestic products: Cueva Concentrate, Cueva Ready-To-Spray, Cueva RTU, Cueva RTU with Pull'n Spray Applicator, Cueva RTU with QuickPump Applicator, Cueva RTU with Wand Applicator and Cueva RTU with Quick Connect Sprayer?

Products containing copper (present as copper octanoate) control or suppress various diseases on many crops when used according to label directions. They are additional pest management tools useful in commercial or non-commercial sites, or for conventional or organic crop production.

The range of Cueva products containing copper (present as copper octanoate) consists of one commercial class and seven domestic class products. They are intended for managing various plant diseases on fruit crops, vegetable crops, and ornamental plants in the greenhouse and outdoors as well as on turf and tree nuts. The domestic class products may be applied through various types of spray attachments, including a standard garden hose.

The registration of copper (present as copper octanoate) products will provide growers with another broad spectrum fungicide/bactericide for both conventional and organic production as well as provide homeowners additional options for plant disease management in non-commercial settings. The registration of this active in Canada will address some of the pest management needs identified by growers. Copper (present as copper octanoate) has value in pest resistance management because it is considered to have a low risk of resistance development and could be used in an integrated pest management program.

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 labels of the end-use products containing copper (present as copper octanoate) to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Although the toxicological profiles of the commercial and domestic products raise no hazards of concern, the end-use product labels include a number of mitigation statements aimed at minimizing human exposure. The following statements are included on the commercial product label: "Mixers, loaders, applicators, and other handlers must wear long-sleeved shirt, long pants and shoes plus socks" and "DO NOT apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during

application.” In addition, the commercial product label requires a restricted-entry interval of four hours to allow sprays to dry and requires that the product not be applied within one day of crop harvest. For the domestic end-use products, unnecessary exposures are to be minimized by including the statement, “DO NOT allow adults, children or pets to enter the treated area until sprays have dried” on all labels.

Environment

To mitigate potential exposure of aquatic organisms through spray-drift, spray buffer zones of 1-50 metres are required on the commercial product label to protect sensitive aquatic habitats. As well, hazard statements indicating toxicity to birds, small wild mammals and aquatic organism are required on product labels.

Next Steps

Before making a final registration decision on copper (present as copper octanoate), the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency’s response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on copper (present as copper octanoate) (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 (located in Ottawa).

Science Evaluation

Copper (present as copper octanoate)

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance

Function Fungicide

Chemical name

1. International Union of Pure and Applied Chemistry (IUPAC) Copper dioctanoate

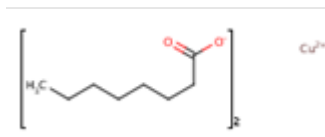
2. Chemical Abstracts Service (CAS) Octanoic acid, copper (2+) salt (2:1)

CAS number 20543-04-8

Molecular formula $\text{CuC}_{16}\text{H}_{30}\text{O}_4$

Molecular weight 349.95

Structural formula



Purity of Cueva RTU TGAI 11.52% as copper

Purity of Cueva TGAI 11.92% as copper

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Products

Technical Product – Cueva TGAI

Property	Result
Colour and physical state	Blue opaque, slightly viscous liquid
Odour	A soapy/fatty odour
Melting range	N/A
Boiling point or range	102°C
Density at 20°C	1.02 – 1.08 g/mL
Vapour pressure at 20°C	Negligible as the product is a salt

Property	Result
Ultraviolet (UV)-visible spectrum	Absorbs in visible range
Solubility in water at 20°C	Partially soluble / emulsifiable
Solubility in organic solvents at 20°C	Soluble in water miscible solvents
<i>n</i> -Octanol-water partition coefficient (K_{ow})	N/A
Dissociation constant (pK_a)	N/A
Stability (temperature, metal)	Stable at 54°C for 14 days
* These properties represent the formulated product, as the technical grade active ingredient does not exist in a pure form.	

Technical Product – Cueva RTU Technical

Property	Result
Colour and physical state	Pale blue liquid
Odour	Typical odour of fatty acid compounds
Melting range	N/A
Boiling point or range	~100°C
Density at 20°C	0.97 – 1.05 g/mL
Vapour pressure at 20°C	Negligible as the product is a salt
Ultraviolet (UV)-visible spectrum	Absorbs in visible range
Solubility in water at 20°C	Fully miscible
Solubility in organic solvents at 20°C	Similar to the miscibility of water in various organic solvents
<i>n</i> -Octanol-water partition coefficient (K_{ow})	N/A
Dissociation constant (pK_a)	N/A
Stability (temperature, metal)	Stable for 2 weeks at 54°C or for 2 months at 40°C
* These properties represent the formulated product, as the technical grade active ingredient does not exist in a pure form.	

End-Use Products – Cueva Commercial / Cueva Concentrate / Cueva Ready-to-Spray

Property	Result
Colour	Blue
Odour	A soapy / fatty odour
Physical state	Opaque, slightly viscous liquid
Formulation type	SN (solution)
Guarantee	1.80% as copper

Property	Result
Container material and description	plastic flask, can, drum, tote, bottle, 1 – 1000 L (Cueva Commercial) plastic flask, can, drum, bottle, 0.1 – 10 L (Cueva Concentrate) plastic bottle, 100 mL – 6 L (Cueva Ready-to-Spray)
Density	1.02 – 1.08 g/mL
pH	6.50 ± 0.32
Oxidizing or reducing action	No oxidizing or reducing properties are to be expected.
Storage stability	Stable for 4 years 8 months when stored in high density polyethylene (HDPE) bottles at ambient temperature.
Corrosion characteristics	No corrosion to HDPE bottles was observed during the storage period of 4 years and 8 months.
Explodability	The product is not expected to be explosive.

End-Use Products – Cueva RTU / Cueva RTU with Pull'n Spray Applicator / Cueva RTU with Quick Pump Applicator / Cueva RTU with Wand Applicator / Cueva RTU with Quick Connect Sprayer

Property	Result
Colour	Pale blue
Odour	Typical odour of fatty acids
Physical state	Liquid
Formulation type	SN (solution)
Guarantee	0.0178% as copper
Container material and description	HDPE and PET bottles, 100 mL to 1 L (Cueva RTU) HDPE and PET bottles, 1-6 L (Cueva RTU with Pull'n Spray Applicator, Cueva RTU with Quick Pump Applicator, Cueva RTU with Wand Applicator, Cueva with Quick Connect Sprayer)
Density at 20°C	0.97 – 1.03 g/mL
pH of 1% dispersion in water	5.75 ± 0.50
Oxidizing or reducing action	The product is neither an oxidizing nor a reducing agent.
Storage stability	The product is stable for six years stored in HDPE bottles at room temperature.
Corrosion characteristics	No corrosion to HDPE bottles was observed during two-year storage at room temperature.
Explodability	The product is not expected to be explosive.

1.3 Directions for Use

All Cueva products may be used as a foliar application to various food and ornamental crops. Cueva Commercial may be applied as a 0.5-2% solution, at rates between 470-940 L/ha, which delivers 42-338 g Cu²⁺/ha.

All other Cueva products may be applied as a 0.5-2% solution at 1000 L/ha or 1L/10m². All other Cueva products may be applied at the same rates as the rate for Cueva Commercial.

1.4 Mode of Action

Copper (present as copper octanoate) is a fatty acid salt (soap) that combines copper and octanoic acid. It degrades in the environment into cupric ions (Cu²⁺) and organic octanoic acid. The released cupric ions alter cellular proteins in susceptible fungi which inhibit fungal spore germination and growth. Octanoic acid is used by microorganisms as a food source.

The attachment of octanoic acid to copper reduces its solubility and phytotoxicity. In fixed-copper fungicides such as copper (present as copper octanoate), cupric ions are slowly released on the plant when in contact with water. The fungicidal and bactericidal properties of fixed-copper fungicides result from the release of cupric ions.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and impurities in the technical products have been validated and assessed to be acceptable for the determinations.

2.2 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.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Certain copper-containing pesticides were recently re-evaluated by the PMRA (Proposed Re-evaluation Decision PRVD2009-04, *Copper Pesticides* and Re-evaluation Decision RVD2010-05, *Copper Pesticides*). The re-evaluation was based largely upon the conclusions reached in the USEPA Reregistration Eligibility Decision for Coppers, published in July 2006, and updated in 2009. Copper (present as copper octanoate) was included in the cluster of copper compounds that were addressed in the USEPA Reregistration Eligibility Decision. The active component of toxicological concern with the majority of copper-containing pesticides is elemental copper (the cupric ion), and most copper compounds, including copper (present as copper octanoate), can be considered similar in terms of their toxicity.

These recent re-evaluations were used as the basis for the current assessment. With the exception of the acute toxicity studies, which were conducted on copper (present as copper octanoate), the remainder of the toxicology discussion will refer to copper when present as the copper ion.

The submitted toxicology studies were on Cueva Concentrate containing 10% w/w copper (copper present as copper octanoate at 1.8% w/w), which is the highest level of active ingredient that is ever made for this bundle of products, and it is identical to the technical grade active ingredient Cueva TGAI. Cueva RTU TGAI has a lower concentration of copper (0.51% w/w) than Cueva Concentrate. Therefore, the toxicity studies conducted on Cueva Concentrate are applicable to the technical grade active ingredients. The same studies are cited for the end-use products because the other end-use products are formulated similarly to Cueva Concentrate containing a similar concentration of copper, and those formulated with Cueva RTU TGAI containing significantly lower levels of copper (0.0178% w/w).

In laboratory animals, copper (present as copper octanoate) was of low acute toxicity via the oral, dermal and inhalation routes of exposure. Copper (present as copper octanoate) was minimally irritating to the eyes, non-irritating to the skin, and not a dermal sensitizer. The toxicology profiles of the end-use products are no different than copper (present as copper octanoate). Results of the toxicology studies conducted on laboratory animals with copper (present as copper octanoate) are summarized in Appendix I, Table 1.

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 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 rather than excess. Humans have efficient homeostatic mechanisms in place to regulate levels of copper in the body, and as such are generally protected from exposure to levels of excess copper.

Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Health Canada website. Copper (present as copper octanoate) is a new active ingredient pending registration for use in Canada. As a result, no incident reports involving this active ingredient are present in the PMRA database. The database was searched for incident reports involving any form of copper. As of 20 May 2014, there were nine human and nine domestic animal incident reports.

The symptoms reported in seven human incidents (all minor) were determined to have some degree of association with the reported exposure. Overall, skin effects like erythema, irritation or paresthesia were commonly described in these incidents. A few incidents described eye effects like tearing, irritation or red eye. In most incidents, exposure to the pesticide occurred during product application activities.

In six domestic animal incidents (mainly minor), the effects experienced by the animal were determined to be related to the reported pesticide exposure. Dogs were commonly affected in these incidents. In most of these incidents, the animal was able to gain access to a pesticide bag or powder containing copper and ingested an unknown amount of the product. Gastrointestinal effects like vomiting were reported in most incidents.

The above incident reporting information involving copper was incorporated into the evaluation of copper (present as copper octanoate).

3.2 Occupational and Bystander Risk Assessment

3.2.1 Dermal Absorption

Due to the partial solubility of copper (present as copper octanoate) in water, dermal absorption from the proposed use of the end-use products is expected to be minimal.

3.2.2 Use Description

The EPs are proposed for managing bacterial and fungal disease in turf, outdoor and greenhouse ornamentals, and agricultural and greenhouse food crops. Only one of the proposed end-use products, Cueva Commercial, is for commercial application, which is to be applied as a 0.5–2% solution using ground application equipment at a rate of 470–940/ha.

The domestic class products are either ready-to-use, packaged in various delivery systems, or sold as a concentrate that requires dilution with water prior to spray application.

3.2.3 Mixer, Loader, and Applicator Exposure and Risk

Workers can be exposed to copper (present as copper octanoate) when mixing, loading and applying Cueva Commercial primarily by the dermal route.

The application rates of copper (present as copper octanoate) are similar to those for currently registered copper-based commercial (agriculture) and domestic products. Based on the toxicological profile of Cueva Commercial (in other words, low toxicity by the oral, dermal and inhalation routes, minimally irritating to eyes, non-irritating to skin, and not a skin sensitizer), there is no toxicological concern from the occupational exposure expected from the proposed uses. Occupational exposure is not expected to result in unacceptable risk when workers follow label directions. The product label has the necessary exposure reduction statements, including the wearing of personal protective equipment (PPE) to protect workers.

3.2.4 Postapplication Exposure and Risk

Based on the use pattern, postapplication dermal exposure may occur from entry of workers, or other individuals, to treated areas where sprays have not dried such as turf, agricultural crops and greenhouses. To minimize exposure of postapplication workers to residues of freshly applied product, a restricted-entry interval of four hours is required to ensure sprays have dried before re-entry.

3.2.5 Residential and Bystander Exposure and Risk

As the application of Cueva Commercial involves only authorized personnel, bystander exposure is expected to be minimal and not of concern when the end-use product is used according to the label directions. Residential exposure is also likely to be minimal when the label directions are followed for Cueva Commercial, which include instructions for applicators to limit spray drift to neighbouring properties.

The proposed uses of the domestic class products are not likely to result in exposure levels of toxicological concern. Most of the domestic end-use products are ready-to-use products containing a low concentration of the active ingredient, and the domestic labels have adequate exposure mitigation measures to protect homeowners from the proposed uses. Postapplication dermal exposure is possible when adults or children enter the treated site, and hand to mouth contact (oral) exposure is also possible for children playing on freshly sprayed lawns and turf. To minimize postapplication exposure, the domestic product labels instruct users to prevent re-entry to freshly treated sites until all sprays have completely dried.

3.3 Food Residues Exposure Assessment

3.3.1 Food and Drinking Water

Dietary exposure to copper may occur through consumption of crops treated with copper (present as copper octanoate); however, it is not expected to be of concern. The main source of copper for infants, children, and adults, regardless of age, is the diet. Copper is typically present in a variety of mineral rich foods such as vegetables (potato and legumes), nuts (peanuts and pecans), grains (wheat and rye), fruits (peach and raisins), and chocolate in levels ranging from 0.3 to 3.9 ppm. A single day's diet may contain 10 mg or more of copper. The daily recommended allowance of copper required to meet an adult's nutritional needs ranges from 2-3 mg/day.

Plants tend to control levels of endogenous copper and can resist the accumulation and translocation of copper to stems, leaves and seeds. Positively charged copper ions also adsorb or bind readily to organic matter in soil which further reduces their availability to crops, and copper salts applied to plant surfaces can wash off by rain or irrigation water. Based on these considerations, along with a pre-harvest interval (PHI) of one day stipulated on the end-use product labels, the proposed application of copper (present as copper octanoate) at maximum label rates is unlikely to increase residue levels of copper beyond the currently established MRL of 50 ppm allowed for copper on food commodities. Consequently, the use of Cueva TGAI and

Cueva RTU TGAI in their associated end-use products is not expected to result in unacceptable dietary risks when the products are used according to label directions.

Copper is a natural element found in the earth's crust. Consequently, most of the world's surface water and ground water used for drinking purposes contains copper. Although the actual amount varies from region to region, the amount of copper in water is extremely low in almost all cases. Naturally occurring copper in drinking water is safe for human consumption, even in rare instances where it is at levels high enough to add a metallic taste to the water.

Based on the proposed use pattern of direct application to terrestrial and greenhouse sites, it is not anticipated that levels of copper would increase from that naturally present in drinking water supplies or reservoirs.

3.3.2 Maximum Residue Limits

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as an MRL under the *Pest Control Products Act* for the purposes of adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

PMRA has determined that the currently specified MRL of 50 ppm for copper is considered adequate to cover residues of copper from copper (present as copper octanoate) in/on these commodities as a result of the use of the new active ingredient. Residues of copper from copper (present as copper octanoate) in terrestrial food crops at the established MRL will not pose an unacceptable risk.

4.0 Impact on the Environment

Copper (present as copper octanoate) is a C8 fatty acid of copper. Ecotoxicity data on the toxicity of copper (present as copper octanoate) and other forms of copper were submitted to support the registration of the EPs. These submitted data were compared to historical data used in previous Canadian risk assessments for copper and fatty acids and were found to be representative of the historical data. In addition, the proposed use pattern falls within the currently registered use pattern for copper products and fatty acids and, therefore, no increase in environmental exposure is expected. Given the above, recently conducted risk assessments were used as the basis for determining the potential risks posed by copper (present as copper octanoate). An evaluation of copper pesticides is available in Re-evaluation Decision RVD2010-05 (revised), *Copper Pesticides*. A review of soap salts (fatty acids) C8-18 is available in *Re-evaluation Decision Document 2004-26: Soap Salts* (RRD2004-26). No additional data requirements were identified. Spray buffer zones are specified on the commercial product label to protect freshwater and marine habitats adjacent to treated areas. Hazard statements are also specified on all product labels for birds, small wild mammals and aquatic organisms.

5.0 Value

5.1 Consideration of Benefits

The registration of Cueva products in Canada would provide several benefits to Canadian growers. They have value as a broad-spectrum fungicide/bactericide in organic production, which has a limited number of available tools for managing plant diseases. Canadian growers have identified the need for copper and copper hydroxide-based products to manage bacterial diseases on various crops. Copper (present as copper octanoate) is a viable option for treatment of these same diseases.

While there are a number of fungicides/bactericides registered on the majority of the uses supported for the Cueva products, there are some uses where copper (present as copper octanoate) products are one of the few alternatives. Copper (present as copper octanoate) products provide additional plant disease management options for both conventional and organic growers. It can be an important tool in an Integrated Pest Management (IPM) program when used in rotation with registered alternatives and in conjunction with other elements such as resistant varieties, cultural controls, and predictive models. The use of copper (present as copper octanoate) products may also contribute to risk reduction. When applied according to label directions, some uses have lower seasonal rates than other fixed copper fungicides. Copper (present as copper octanoate) also has value in resistance management. It has a multi-site mode of action that is considered by the Fungicide Resistance Action Committee as having a low risk for pest resistance development.

5.2 Effectiveness Against Pests

The applicant provided one value information package on Cueva Commercial to support the registration of eight end-use products. Therefore, the uses that are supported for Cueva Commercial are also supported for the other Cueva products.

Value assessment was conducted using results of efficacy trials, use history, published information and scientific rationales. Where possible, extrapolations were accepted between crops and pests. For host-specific pathogens, such as powdery mildew and rust, the conclusions were based on trial data for most crops. If efficacy was demonstrated on at least three species under one genus of pathogen, a claim for the entire genus was supported (for example, *Erysiphe* spp.). Extrapolations were supported if crops were affected by the same pathogen and the disease was manifested in the same way. In some cases, a crop group claim was amended depending on the pathogens that were supported by value information.

5.2.1 Cueva Commercial

The control or suppression of various plant diseases on the following crops or crop groups were supported: root and tuber vegetables, pome and stone fruits, small fruits, Brassica leafy vegetables, parsley, cranberry, tree nuts, turf, greenhouse and outdoor ornamentals, as well as bulb vegetables, fruiting vegetables, cucurbits, and legumes in the greenhouse and field.

A total of 163 trials on the various crops were provided to support the registration of the Cueva products. Use history information from the European Union and the United States were also considered as well as published information such as extension guidelines. Trial data from other countries and non-border US states were accepted based on the long history of use of copper products as a plant disease management tool.

Claims for control were supported based on commercially acceptable levels of disease reduction and comparable performance to a commercial standard. For example, Cueva Commercial provided 94-99% control of late blight of celery under heavy disease pressure. This level of disease reduction was comparable to the commercial standards.

The level of disease management was deemed to be suppression if the average level of disease reduction fell between 60-80% control but was still of value to the user. For example, Cueva Commercial provided 37-59% reduction in black rot incidence on cabbage and 36-56% control in disease severity under moderate disease pressure. The average head weight of treated cabbage was also lower than the inoculated control. However, in other crops, Cueva Commercial has demonstrated good control of other pathovars of the pathogen that also causes black rot. In consideration of the weight of evidence submitted, suppression of the disease was supported.

All of the proposed uses were supported; some claims were amended to express a different level of control (suppression), to identify specific crops affected by the disease, or to modify the use pattern.

Please refer to Appendix 1, Table 2 for the summary of supported uses.

5.2.2 Cueva Concentrate

The same crops and diseases were proposed for Cueva Concentrate as in Cueva Commercial.

Cueva Concentrate and Cueva Commercial are considered biologically equivalent since they have the same guarantee (100 g copper (present as copper octanoate)/L; metallic copper equivalent: 1.8%), and their use directions are similar. Although Cueva Concentrate has a slightly higher maximum spray volume (1000 L/ha) compared to Cueva Commercial (940 L/ha), this is not expected to impact the amount of copper delivered per hectare.

Based on the similarity of these products, the supported claims for Cueva Commercial are extrapolated to Cueva Concentrate.

5.2.3 Cueva Ready-To-Spray

Cueva Ready-to-Spray and Cueva Commercial are considered biologically equivalent. Both products have the same guarantee and their use directions are comparable.

Cueva Ready-To-Spray is sold as a concentrated product that is designed to be applied with a standard garden hose. The hose can be attached to the hose-end sprayer attachment on the concentrated product, which will then automatically mix the concentrate with water from the hose to apply the properly diluted spray solution to the target area. The application rate is 1 L solution/10 m², which delivers an amount of copper similar to that delivered with Cueva Commercial.

The same uses proposed on the Cueva Commercial label were requested for Cueva Ready-To-Spray. These uses were extrapolated from the supported claims for Cueva Commercial because they are biologically equivalent.

5.2.4 Cueva RTU

Cueva RTU with Pull'n Spray Applicator

Cueva RTU with QuickPump Applicator

Cueva RTU with Wand Applicator

Cueva RTU with Quick Connect Sprayer

Side-by-side treatments in nine efficacy trials on potato, celery, tomato, cucumber, and zucchini showed that Cueva RTU and Cueva Commercial consistently provided comparable control of plant diseases under moderate to high disease pressure.

Cueva RTU and Cueva Commercial are considered as biologically equivalent. The use directions for these products are comparable since the amount of copper delivered to crops using Cueva RTU is within the amount delivered when Cueva Commercial is used.

Based on research trial results and scientific rationales, the uses for Cueva RTU are supported based on extrapolation from supported uses of Cueva Commercial. This conclusion applies to the other four Cueva RTU products with different types of applicators since these products have the same formulation and are applied at the same rates.

5.3 Non-Safety Adverse Effects

No adverse effects resulted from copper (present as copper octanoate) applications in the vast majority of trials.

No phytotoxicity symptoms were noted on: bean, cabbage, celery, crape myrtle, cucumber, currant, dandelion, hollyhock, Kentucky bluegrass, pear, pea, potato, strawberry, tomato, and zucchini.

Phytotoxicity was observed in some trials on peach, grape, basil, cilantro and dill.

In studies where phytotoxicity occurred, damage was generally considered acceptable, or was not limited to copper (present as copper octanoate) treatments. Copper toxicity is a well-known phenomenon in agriculture, especially under slow drying conditions. To mitigate the risk for phytotoxicity, a precautionary statement will be included on the label. Substantial phytotoxic reactions from Cueva Commercial applied at 0.5-2% solution are not anticipated. Precautionary statements on grapes and apples (excerpted from the US label) as well as ornamentals and stone fruits, will be added to the label.

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 [those that meet all four criteria outlined in the policy: in other words, 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*].

As indicated in PRVD2009-04 and Proposed Acceptability for Continuing Registration PACR2004-04, *Re-evaluation of Soap Salts*, pesticides containing copper or salts of fatty acids (soap salts) were assessed in accordance with the PMRA Regulatory Directive DIR99-03⁵ and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Copper is not a candidate for Track 1 classification.
- Soap salts do not meet all Track 1 criteria, and are not considered a Track 1 substance.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*⁶. The list is used as described in the PMRA Notice of Intent NOI2005-01⁷ and is based on existing policies and regulations including: DIR99-03; and DIR2006-02⁸, and taking into consideration the

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

⁶ *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) 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, SI/2008-67 (2008-06-25) 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.*

⁷ NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

⁸ DIR2006-02, *PMRA Formulants Policy.*

Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

- Copper (present as copper octanoate) does not contain any formulants of health or environmental concern identified in the Canada Gazette.
- No other impurities of toxicological concern as identified in Regulatory Directive DIR98-041⁹, Section 2.13.4, or TSMP Track 1 substances as identified in Regulatory Directive DIR99-03, Appendix II, are expected to be present in the technical products of copper (present as copper octanoate).

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 Summary

7.1 Human Health and Safety

Copper is a naturally occurring metal that is present in water and air, and occurs naturally in various foods, including organ meats, seafood, beans, nuts and whole grains. Copper is an essential element in maintaining normal health in humans, and subsequently, adverse effects are more likely due to copper deficiency rather than excess. In addition, humans have efficient homeostatic mechanisms in place to regulate total body burden of copper. It is unlikely that exposure to copper (present as copper octanoate) as a result of the proposed use pattern would result in systemic toxicity.

Worker, bystander and residential exposures to copper (present as copper octanoate) as a result of the proposed use patterns are not expected to result in unacceptable risk when the commercial and domestic end-use products are used according to label directions.

Dietary exposure to copper, present in the form of copper (present as copper octanoate), from the use of the proposed end-use products is not expected to result in unacceptable dietary risks when the products are used according to label directions. It is expected that residues that may result from this use pattern will be covered by the 50 ppm MRL specified by the PMRA for copper on all food commodities.

7.2 Environmental Risk

Copper (present as copper octanoate) is a copper salt of fatty acids. Fatty acid degradation by soil microorganisms is rapid. Copper is an element that occurs naturally in the environment and does not break down any further via hydrolysis, metabolism or any other degradation processes. It can exist in various organic and inorganic forms, including the cupric ion (Cu²⁺), cuprous ion (Cu⁺),

⁹ DIR98-04, Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product.

inorganic complexes, organic complexes and minerals. The copper ion is highly reactive, especially in aquatic environments. The form in which copper is found depends on physicochemical characteristics of the medium and the nature and concentration of other forms of copper present. The free cupric ion has a high sorption affinity for soil, sediments and organic matter, and copper applied to the surface is not expected to move readily into groundwater.

The use of copper (present as copper octanoate) is not expected to significantly increase environmental exposure to both copper and fatty acids. The environmental risks to non-target organisms have been previously assessed for environmental concentrations exceeding those for copper (present as copper octanoate) uses (RVD2010-05, RRD2004-26). At label rates, the use of copper (present as copper octanoate) presents a negligible risk to pollinators and aquatic vascular plants, but could pose a risk to birds, small wild mammals and aquatic organisms (freshwater and estuarine/marine invertebrates, fish and algae) if they are exposed to high enough concentrations. Spray buffer zones are specified on the commercial product label to protect freshwater and marine habitats adjacent to treated areas. Hazard statements are also specified on all product labels for birds, small wild mammals and aquatic organisms.

7.3 Value

The information provided to register copper (present as copper octanoate) containing products were adequate to demonstrate their value in pest management for various crops. The Cueva products demonstrated acceptable efficacy and have value as pest management tools in conventional and organic crop production, in non-commercial settings, and in managing pest resistance development. Products containing copper (present as copper octanoate) will address grower-identified pest management priorities for other copper active ingredients.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of two technical grade active ingredients, Cueva TGAI and Cueva RTU TGAI, and eight end use products, Cueva Commercial, Cueva Concentrate, Cueva Ready-to-Spray, Cueva RTU, Cueva RTU with Pull'N Spray Applicator, Cueva RTU with Quickpump Applicator, Cueva RTU with Wand Applicator, and Cueva RTU with Quick Connect Sprayer, containing the technical grade active ingredient copper (present as copper octanoate), to control or suppress various fungal and bacterial diseases on turf, nuts, as well as ornamentals, a variety of fruit, and vegetables in both the field and greenhouse.

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

List of Abbreviations

°C	degrees Celcius
♀	female
♂	male
µm	micrometre
bw	body weight
CAS	Chemical Abstracts Service
g	gram
ha	hectare(s)
HDPE	high density polyethylene
hrs	hours
IPM	integrated pest management
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	<i>n</i> -octanol-water partition coefficient
L	litre
LC ₅₀	lethal concentration 50%
LD ₅₀	lethal dose to 50%
mg	milligram
mL	millilitre
MAS	maximum average score for 24, 48 and 72 hours
MIS	maximum irritation score
MRL	maximum residue limit
N/A	not applicable
PET	polyethylene terephthalate
PHI	pre-harvest interval
pKa	dissociation constant
PMRA	Pest Management Regulatory Agency
PRVD	proposed re-evaluation decision
PPE	personal protective equipment
ppm	parts per million
RVD	Re-evaluation Decision
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet
w/w	weight per weight

Appendix I Tables and Figures

Table 1 Acute Toxicity Profile of Cueva Concentrate (Code Name: Neu1140f, Containing Copper (Present as Copper Octanoate) at 10% w/w (Copper Present as Copper Octanoate at 1.8% w/w)

Study/References	Species/Strain doses	Result	Target Organ/Significant Effects/Comments
Acute oral toxicity 2141241	Rat/Wistar strain 5 rats/sex/dose by gavage 2000 mg/kg bw	LD ₅₀ ♂ & ♀: > 2000 mg/kg bw	No mortality or treatment-related effects. No gross abnormalities were noted at necropsy. Low acute oral toxicity
Acute dermal toxicity 2141243	Rat/Wistar strain 5 rats/sex/dose 2000 mg/kg bw applied for 24 hrs	LD ₅₀ ♂ & ♀: > 2000 mg/kg bw	No mortality or treatment-related effects. No gross abnormalities were noted at necropsy. Low acute dermal toxicity
Acute inhalation toxicity (nose-only exposure) 2141244	Rat/Sprague-Dawley 5 rats/sex/dose Gravimetric chamber concentration of 2.0 mg/L, mass median aerodynamic diameter of 2.8 µm, and exposure period of 4 hrs	LC ₅₀ ♂ & ♀ > 2.0 mg/L	No mortality. Four males and four females showed abnormal respiration and one of these males was hypoactive until Day 2 of the study. Animals lost or failed to gain body weight by Day 1, but gained weight thereafter. Day 14. Necropsy findings were normal. Low acute inhalation toxicity
Acute inhalation toxicity (nose-only exposure) 2141245	Rat/Sprague-Dawley 5 rats/sex/dose Gravimetric chamber concentration of 0.38 mg/L, mass median	LC ₅₀ ♂ & ♀ > 0.38 mg/L The highest technical achievable concentration was low.	No mortality or treatment-related effects. No change in bodyweight gain. Day 14. Necropsy findings were normal. Low acute inhalation toxicity

Study/ References	Species/ Strain doses	Result	Target Organ/Significant Effects/Comments
	aerodynamic diameter of less than 3.0 µm, and exposure period of 4 hrs		
Eye irritation 2141248	Rabbit/New Zealand White 3 rabbits (♂) A single dose of 0.1 mL of the test substance was instilled into one eye of each rabbit and left unwashed. Ocular irritation was scored at 1, 24, 48 and 72 hrs post-instillation.	MAS ^a = 1.33/110 MIS ^b = 9.3/110 (1hr)	No corneal opacity or iritis. Conjunctival irritation observed in treated eyes was resolved by 48 hrs after exposure. Minimally irritating to the eye (Based on the MAS)
Dermal irritation 2141247	Rabbit/New Zealand White 3 rabbits (♂) 0.5 mL of the test substance was applied to one intact dose site per animal for 4 hour exposure using a semi-occlusive dressing	MAS ^a = 0/8 MIS ^b = 1.33/8	There was very slight erythema in all animals, which were resolved within 24 – 48 hrs after exposure. Slight oedema was observed in one animal at 1 hour after exposure, which resolved within 24 hrs. Non-irritating to the skin

Study/ References	Species/ Strain doses	Result	Target Organ/Significant Effects/Comments
<p>Dermal Sensitization (Maximization -test)</p> <p>2141249</p>	<p>Albino Guinea pig/Himalayan strain</p> <p>Treatment group: 20 (females)</p> <p>Naïve control: 10 (females)</p> <p>Treatment group animals were intradermally injected with a 0.5% concentration of the test substance (Day 1) and epidermally exposed to the undiluted test substance (Day 8) for induction.</p> <p>The control animals were similarly treated, but with vehicle only.</p> <p>All the animals were challenged 14 days after the last induction exposure with a 50% test substance concentration and vehicle.</p>	<p>Negative</p>	<p>Skin reactions (grade 1) were observed in one experimental and one control animal in response to the 50% test substance concentration after 24 hour-exposure only at challenge.</p> <p>Historical positive control validation study validates the test system of this study.</p> <p>Non-sensitizer</p>

^a MAS = Maximum Average Score for 24, 48 and 72 hrs

^b MIS = Maximum Irritation Score (average)

Table 2 List of Supported Uses

Proposed Claim			Supported claim ¹
Crop	Disease	Use Pattern	
Turf (lawns, golf course turf, lawn bowling greens)	powdery mildew	0.5-2.0% solution; 4.7-9.4 L solution/100 m ² ; 15 apps at 10-day intervals	<i>Erysiphe graminis.</i>
Greenhouse and outdoor ornamental shrubs and flowering plants (such as rose, hollyhock, hydrangea, crape myrtle)	black spot	1.0% solution; 470-940 L solution/ha; 10 apps at 5-10 day intervals	On rose*: <i>Diplocarpon rosae.</i>
	powdery mildew	0.8% solution; 470-940 L solution/ha; 10 apps at 5-10 day intervals	<i>Podosphaera pannosa</i> var. <i>rosae</i> ; <i>Erysiphe</i> spp.
	leaf spots	0.5-2.0% solution; 470-940 L solution/ha; 10 apps at 5-10 day intervals	On crape myrtle*: <i>Cercospora lythracearum</i> (Suppression)
			Suppression of corynespora leaf spot: <i>Corynespora cassiicola</i>
	rust		<i>Phragmidium mucronatum</i> , <i>Puccinia malvacearum.</i>
	bacterial blight		<i>Pseudomonas syringae</i>
	fire blight		<i>Erwinia amylovora</i>
coryneum blight	<i>Thyrostroma carpophilum</i>		
Crop Group 1: Root and Tuber Vegetables (garden beet, celeriac, potato, sugar beet)	early blight	0.5-2.0% solution; 470-940 L solution/ha; 15 apps at 5-10 day intervals	On potato*: <i>Alternaria solani.</i>
	late blight		On potato*: <i>Phytophthora infestans</i>
	septoria		septoria leaf spot on potato*: <i>Septoria lycopersici</i>

Proposed Claim			Supported claim ¹
Crop	Disease	Use Pattern	
	septoria (late) blight		On celeriac *: <i>Septoria apiicola</i>
	cercospora leaf spot		On beet and sugar beet:* <i>Cercospora beticola</i>
Crop Group 3: Bulb Vegetables (chives, garlic, leek, onion, shallot)	downy mildew		<i>Peronospora destructor</i>
	botrytis	0.5-2.0% solution; 470-940 L solution/ha; 15 apps at 5-10 day intervals	botrytis leaf blight: (<i>Botrytis squamosa</i>) botrytis neck rot (B. allii).
	bacterial neck		Bacterial neck is replaced with soft rot: <i>Erwinia carotovora</i> subsp. <i>carotovora</i> .
Celery (greenhouse and field)	cercospora (early) blight	0.5-2.0% solution; 470-940 L solution/ha; 15 apps at 5-10 day intervals	On celery: <i>Cercospora apii</i>
	septoria (late) blight		On celery: <i>Septoria apiicola</i>
Crop Group 5: Brassica Leafy Vegetables (bok choy, broccoli, Brussels sprouts, cabbage, cauliflower, kale, kohlrabi, mustard, pakchoi)	black rot	0.5-2.0% solution; 470-940 L solution/ha; 15 apps at 5-10 day intervals	Suppression: <i>Xanthomonas campestris</i> pv. <i>campestris</i>
Crop Group 6: Legumes (greenhouse and field; bean, pea, soybean)	ascochyta blight		<i>Ascochyta pisi</i> .
	bacterial blights	0.5-2.0% solution; 470-940 L solution/ha; 15 apps at 5-10 day intervals	Bacterial blights replaced with: halo blight: <i>Pseudomonas syringae</i> pv. <i>phaseolicola</i> , common blight: <i>Xanthomonas campestris</i> pv. <i>phaseoli</i> brown spot: <i>Pseudomonas syringae</i> pv. <i>syringae</i>

Proposed Claim			Supported claim ¹
Crop	Disease	Use Pattern	
	powdery mildew		<i>Erysiphe</i> spp.
	rust		<i>Uromyces appendiculatus</i> .
Crop Group 8: fruiting vegetables (greenhouse and field; eggplant, peppers, tomatoes)	early blight	0.5-2.0% solution; 470-940 L solution/ha; 15 apps at 5-10 day intervals	<i>Alternaria solani</i>
	late blight		<i>Phytophthora infestans</i>
	septoria		septoria leaf spot.: <i>Septoria lycopersici</i>
	bacterial speck		<i>Pseudomonas syringae</i> pv. <i>tomato</i>
	bacterial/leaf spot		<i>Xanthomonas campestris</i> pv. <i>vesicatoria</i>
	bacterial canker		<i>Clavibacter michiganensis</i> pv. <i>michiganensis</i>
Crop Group 9: Cucurbits (greenhouse and field; cucumbers, cantaloupe, melon, squash, pumpkin, zucchini)	powdery mildew	0.5-2.0% solution; 470-940 L solution/ha; 15 apps at 5-10 day intervals	<i>Podosphaera xanthii</i> , <i>Erysiphe cichoracearum</i>
	downy mildew		<i>Pseudoperonospora cubensis</i>
	alternaria		alternaria leaf blight.: <i>Alternaria cucumerina</i>
	anthracnose		<i>Colletotrichum orbiculare</i>
	angular leaf spot (bacterial)		<i>Pseudomonas syringae</i> pv. <i>orbiculare</i>
	bacterial wilt		<i>Erwinia tracheiphila</i>
	septoria leaf spot		<i>Septoria cucurbitacearum</i>
Crop Group 11: pome fruit trees (apple, pear, quince)	fire blight	0.5-2.0% solution; 470-940 L solution/ha; 10 apps at 5-10 day intervals	<i>Erwinia amylovora</i>
	scab		<i>Venturia inaequalis</i>
Crop Group 12: stone fruit trees (apricot, cherry, nectarine, peach, plum, necta-plum)	peach leaf curl	0.5-2.0% solution; 470-940 L solution/ha; 5 apps (peaches), 10 apps (nectarines) or 15 apps at 5-10 day	<i>Taphrina deformans</i>
	bacterial spot		<i>Xanthomonas campestris</i> pv. <i>pruni</i>
	coryneum blight		<i>Thyostroma carpophilum</i>
	bacterial		<i>Pseudomonas</i>

Proposed Claim			Supported claim ¹
Crop	Disease	Use Pattern	
	canker	intervals	<i>syringae</i> pv. <i>syringae</i> , <i>morsprunum</i>
	brown rot		<i>Monilinia fructicola</i>
	leaf and fruit spot		leaf spot: <i>Blumeriella jaapii</i>
Crop Group 13: small fruits (blackberry, blueberry, currant, gooseberry, grape, raspberry, strawberry)	powdery mildew	0.5-2.0% solution; 470-940 L solution/ha; 15 apps at 7-10 day intervals	On grape*: <i>Uncinula</i> (=Erysiphe) <i>necator</i> On strawberry*: <i>Podosphaera aphanis</i>
	downy mildew		On grape*: <i>Plasmopara viticola</i>
	rust		On currant* and gooseberry*: <i>Cronartium ribicola</i>
	bacterial blight		Supported on raspberry, blackberry and blueberry: <i>Pseudomonas syringae</i> pv. <i>syringae</i>
cranberry	leaf and twig blight	0.5-2.0% solution; 470-940 L solution/ha; 15 apps at 7-10 day intervals	<i>Phomopsis/Diaporthe vaccinii</i>
walnut	bacterial blight	0.5-2.0% solution; 470-940 L solution/ha; 15 apps at 5-10 day intervals	<i>Xanthomonas campestris</i> pv. <i>juglandis</i>
filbert, hazelnut	bacterial blight	0.5-2.0% solution; 470-940 L solution/ha; 15 apps at 5-10 day intervals	<i>Xanthomonas campestris</i> pv. <i>corylina</i>
	eastern filbert blight		<i>Anisogramma anomola</i>
Parsley	leaf spot	0.5-2.0% solution; 470-940 L solution/ha; 15 apps at 5-10 day intervals	septoria leaf spot: <i>Septoria petroselini</i>

*In a crop group, the disease (pathogen) is specific to that crop.

¹ Supported claim indicates “control” unless otherwise noted.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

- 2272408 2013, Cueva RTU TGAI Chemistry Binder, DACO: 2.1, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12, 2.12.1, 2.13.1, 2.13.2, 2.13.4, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI
- 2272410 2011, C of As Neu1140 RTU Premix, DACO: 2.13.3 CBI
- 2272412 2012, NEU010-120021 5 Batch Analysis, DACO: 2.13.3 CBI
- 2272413 2012, Accelerated (2 week, 54 deg C) Storage Stability of Cueva RTU TGAI, DACO: 2.14.14 CBI
- 2272415 2012, Accelerated (2 month, 40 deg C) Storage Stability of Cueva RTU TGAI, DACO: 2.14.14 CBI
- 2275977 2013, Cueva RTU TGAI Chemistry Binder, DACO: 2.1, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12, 2.12.1, 2.13.1, 2.13.2, 2.13.4, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI
- 2378325 2013, Binder 2, DACO: 2.0, 2.1, 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12, 2.12.1, 2.13, 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.14, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI
- 2378326 2013, CAS Registry Lookup Results, DACO: 2.6 CBI
- 2378327 2013, 5-batch Analysis CMR Cueva RTU TGAI, DACO: 2.13.3 CBI
- 2378328 2012, Density of Cueva RTU TGAI, DACO: 2.14.6 CBI
- 2378329 2012, Cueva RTU TGAI 2 week storage, DACO: 2.14.14 CBI
- 2378331 2012, Cueva RTU TGAI 2 month storage, DACO: 2.14.14 CBI
- 2141237 Packaging Information, DACO: 3.5.5,5.1,5.2,5.3,5.4,5.5, Document K,IIIA 4.1.1 CBI
- 2272457 2013, Binder 2 Chemistry Package, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.1, 3.2.2, 3.2.3, 3.4, 3.4.1, 3.4.2, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
- 2272458 Scotts Ecosense Disease Control Batch 1, DACO: 3.4.1 CBI
- 2272459 Scotts Ecosense Disease Control Batch 2, DACO: 3.4.1 CBI
- 2272460 Scotts Ecosense Disease Control Batch 3,4,5, DACO: 3.4.1 CBI
- 2272461 2002, Storage Stability of NEU1140 RTU, DACO: 3.5.10 CBI
- 2275970 2013, Binder 2 Chemistry Package, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.1, 3.2.2, 3.2.3, 3.4, 3.4.1, 3.4.2, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
- 2378444 2010, Cueva RTU 5-batch analysis, DACO: 3.3.1 CBI
- 2378445 2013, NEU1140F RTU Density, DACO: 3.5.6 CBI
- 2378446 2013, NEU1140F RTU pH, DACO: 3.5.7 CBI
- 2378447 1996, NEU1140F RTU Viscosity, DACO: 3.5.9 CBI
- 2378449 2013, Corrosion Characteristics of NEU1140F, DACO: 3.5.14 CBI

- 2141179 2011, Part B Section 2, DACO: 2.13.4, 2.14.14, 3.4.1, 3.4.2, 3.5.10, 3.6,3.7, 5.14, 5.5, 5.7, 7.2.1, 7.2.2, 7.2.3, 7.2.4, 7.2.5, 7.8, 8.2.2.4, 8.2.3.3.3, 8.2.3.6, 8.2.4.6, 8.6, IIIA 5.1.1, IIIA 5.1.2, IIIA 5.1.3, IIIA 5.1.4, IIIA 5.1.5, IIIA 5.2.1, IIIA 5.2.2, IIIA 5.2.3, IIIA 5.2.4
- 2141180 Confidential Data, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.3.2, 3.5.12, 3.5.8, 4.8, IIIA 1.2.3, IIIA 1.4.1, IIIA 1.4.2, IIIA 1.4.4, IIIA 1.4.5.1, IIIA 1.4.5.2, IIIA 2.2.1, IIIA 2.2.2, IIIA 7.9.1, IIIA 7.9.2 CBI
- 2141187 1996, Produktionsprozess Neu 1140F, DACO: 2.11.3, 3.2.2, Document K, IIIA 1.4.5.1 CBI
- 2141211 Amended Odor of Neu 1140 F Copper Soap, DACO: 2.14.1, 2.14.2, 2.14.3,3.5.1, 3.5.2, 3.5.3, Document K,IIIA 2.1 CBI
- 2141212 Colour of Neu 1140 F Copper Soap, DACO: 2.14.1, 2.14.2, 2.14.3, 3.5.1, 3.5.2, 3.5.3, Document K, IIIA 2.1 CBI
- 2141226 1999, Determination of The Surface Tension of an Aqueous Solution of NEU 1140F, DACO: 2.16, 3.7, Document K, IIIA 2.5.3 CBI
- 2141227 1994, Density of Neuf 1140 F, DACO: 2.14.6,3.5.6,Document K,IIIA 2.6.1
- 2141228 1999, Determination of Density (Liquid) of NEU 1140F, DACO: 2.14.6, 3.5.6, Document K, IIIA 2.6.1 CBI
- 2141229 2010, Density of NEU1140F, DACO: 2.14.6, 3.5.6, Document K, IIIA 2.6.1 CBI
- 2141230 2011, NEU 1140F Chemical Physical Properties and 0 deg and 54 deg C Storage Stability, DACO: 2.14.14, 3.5.10, Document K,IIIA 2.7.1 CBI
- 2141231 2002, Storage Stability of Neu 1140 Concentrate, DACO: 2.14.14, 3.5.10, Document K, IIIA 2.7.5 CBI
- 2169476 2011, 5 Batch Analysis of Cueva TGAI, DACO: 2.13.3 CBI
- 2272497 Batch Data, DACO: 2.13.3 CBI
- 2291587 1991, Product: C895 Fatty Acid, DACO: 2.11.2 CBI
- 2291588 2003, Certificate of Analysis, DACO: 2.11.2 CBI
- 2378375 2013, Binder 2, DACO: 2.0, 2.1, 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12, 2.12.1, 2.13, 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.14, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 C
- 2378377 2013, CAS Registry Lookup Results, DACO: 2.6 CBI
- 2378378 2013, 5-batch Analysis CMR Cueva TGAI, DACO: 2.13.3 CBI
- 2378379 1996, accelerated storage 14 days NEU1140F, DACO: 2.14.13 CBI
- 2378380 1996, low temperature stability NEU1140F, DACO: 2.14.13 CBI
- 2378381 2000, Storage Stability NEU1140F, DACO: 2.14.14 CBI
- 2141213 2010, Oxidizing and Explosive Properties of the Formulation NEU 1140 F, DACO: 3.5.12, Document K, IIIA 2.2.1 CBI
- 2141214 1995, Determination of the Flash-Point of NEU 1140 F, DACO: 3.5.11, Document K,IIIA 2.3.1 CBI
- 2141215 1995, Auto Ignition Temperature NEU 1140 F, DACO: 3.5.11,Document K,IIIA 2.3.3 CBI
- 2141217 1999, Determination of the pH of an aqueous dispersion of NEU 1140 F, DACO: 3.5.7,Document K,IIIA 2.4.2 CBI
- 2141219 1994, pH of of NEU 1140, DACO: 3.5.7,Document K,IIIA 2.4.2 CBI
- 2141222 2010, pH of of NEU 1140F, DACO: 3.5.7,Document K,IIIA 2.4.2 CBI
- 2141223 2010, pH of of NEU 1140F, DACO: 3.5.7,Document K,IIIA 2.4.2 CBI

- 2141225 2000, Determination of Viscosity of NEU 1140F, DACO: 3.5.9, Document K, IIIA 2.5.2 CBI
- 2141237 Packaging Information, DACO: 3.5.5, 5.2, Document K, IIIA 4.1.1 CBI
- 2169384 Trade Name and Other Names, DACO: 3.1.3, 3.1.4
- 2196354 Waiver Request, DACO: 3.5.13, 3.5.15 CBI
- 2378402 2013, 5-batch Analysis CMR Cueva TGAI, DACO: 3.3.1 CBI
- 2378404 2010, NEU1140F Density, DACO: 3.5.6 CBI
- 2378405 2010, NEU1140F pH, DACO: 3.5.7 CBI
- 2378408 1996, NEU1140F Viscosity, DACO: 3.5.9 CBI
- 2378411 1996, Corrosion Characteristics of NEU1140F, DACO: 3.5.14 CBI

2.0 Human and Animal Health

- 2141175 1998, Plant Metabolism and Environmental Fate Waiver Argumentation, DACO: 4.4.1, 4.4.2, 4.4.3, 4.4.4, 4.5.1, 4.5.2, 4.5.3, 4.5.4, 4.5.5, 4.5.7, 4.5.9, 6.1 (OECD), 6.3, 8.1 (OECD), 8.2.2.1, 8.2.2.2, 8.2.2.3, 8.2.2.4, 8.2.3.1, 8.2.3.2, 8.2.3.3.1, 8.2.3.3.2, 8.2.3.3.3, 8.2.4.1, 8.2.4.2, 8.3.2
- 2141174 2011, Part B Section 4, DACO: 5.2, 5.6, 6.1, 6.1 (OECD), 6.2, 6.3, 6.4, 7.1, 7.3, 7.4.1, 7.4.2, 7.4.3, 7.4.4, 7.4.5, 7.4.6, 7.5, 7.6, 7.7, 7.8, 8.4.1, 8.6, IIIA 8.1.1, IIIA 8.1.2, IIIA 8.10.1, IIIA 8.10.2, IIIA 8.10.3, IIIA 8.11, IIIA 8.2, IIIA 8.3.1, IIIA 8.3.2, IIIA 8.3.3, IIIA 8.3.4
- 2141250 1999, English Translation: Effects of NEU 1140 F on predatory mites (*Typhlodromus pyri*) in field application and obtaining a residue sample - (wine grapes, Germany 1998), DACO: 7.4.1, 7.4.2, 7.4.6, Document K, IIIA 8.3.1
- 2141251 1999, English Translation: Effects of NEU 1140 F on predatory mites (*Typhlodromus pyri*) in field application and obtaining a residue sample - (wine grapes, Germany 1998), DACO: 7.4.1, 7.4.2, 7.4.6, Document K, IIIA 8.3.1
- 2141252 1998, English Translation: Effects of NEU 1140 F on predatory mites (*Typhlodromus pyri*) in field application and obtaining a residue sample - (wine grapes, Germany 1998), DACO: 7.4.1, 7.4.2, 7.4.6, Document K, IIIA 8.3.1
- 2141258 1998, Residue Analysis of Copper in Grapes, DACO: 7.4.1, 7.4.2, 7.4.6, Document K, IIIA 8.3.1
- 2141259 1998, Residue Analysis of Copper in Grapes - 1st Amendment, DACO: 7.4.1, 7.4.2, 7.4.6, Document K, IIIA 8.3.1
- 2141260 1999, Residue Analysis of Copper in Grapes - 2nd Amendment, DACO: 7.4.1, 7.4.2, 7.4.6, Document K, IIIA 8.3.1
- 2141234 2011, Operator Exposure According to Uniform Principles for Operator Protection (BBA 1992) and Revised UK Predictive Operator Exposure Model (UK POEM) Predictive exposure Modelling for Pesticide Registration Purposes (NL POEM), DACO: 10.2.2, 5.2, Document K
- 2169416 2012, Exposure - Request for Waiver, DACO: 5.1, 5.10, 5.11, 5.12, 5.13, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9
- 2293341 2013, Binder 3 - DACO 5.2, DACO: 5.2
- 2141241 1995, Assessment of Acute Oral Toxicity with Neu 1140 F in Rat, DACO: 4.2.1, 4.6.1, Document K, IIIA 7.1.1.
- 2141243 1995, Assessment of Dermal Toxicity with Neu 1140 F in the Rat, DACO: 4.2.2, 4.6.2, Document K, IIIA 7.1.2.

- 2141245 1996, Acute Inhalation Toxicity Neu 1140 F, DACO: 4.2.3, 4.6.3, Document K, IIIA 7.1.3.
- 2141244 2011, Acute Inhalation Toxicity Study in Rats, DACO: 4.2.3, 4.6.3, Document K, IIIA 7.1.3
- 2141246 1996, Determination of Main Ingredients in Combination with the Study Inhalation Toxicity, DACO: 4.2.3, 4.6.3, Document K, IIIA 7.1.3.
- 2141247 1995, Primary Skin Irritation/Corrosion Study with Neu 1140 F in the Rabbit, DACO: 4.2.5, 4.6.5, Document K, IIIA 7.1.4.
- 2141248 1995, Acute Eye Irritation/Corrosion Study with Neu 1140 F in the Rabbit, DACO: 4.2.4, 4.6.4, Document K, IIIA 7.1.5.
- 2141249 1996, Assessment of Contact Hypersensitivity to Neu 1140 F in Albino Guinea Pig, DACO: 4.2.6, 4.6.6, Document K, IIIA 7.1.6.
- 2169482 Acute Inhalation DER, DACO: 12.5.4.
- 2169483 Acute Tox DER, DACO: 12.5.4.

3.0 Environment

- 2141142 Reduced Risk Rationale, DACO: 0.17 (OECD)
- 2141175 1998, Plant Metabolism and Environmental Fate Waiver Argumentaion, DACO: 4.4.1, 4.4.2, 4.4.3, 4.4.4, 4.5.1, 4.5.2, 4.5.3, 4.5.4, 4.5.5, 4.5.7, 4.5.9, 4.6, 4.6.1, 4.6.2, 4.6.3, 4.6.4, 4.6.5, 4.6.6, 6.1, 6.1 (OECD), 6.3, 8.1, 8.1 (OECD), 8.2.2.1, 8.2.2.2, 8.2.2.3, 8.2.2.4, 8.2.3.1, 8.2.3.2, 8.2.3.3.1, 8.2.3.3.2, 8.2.3.3.3, 8.2.4.1, 8.2.4.2, 8.3.1, 8.3.2, 8.4.1
- 2141176 2011, Part B Section 5, DACO: 8.1 (OECD), 8.2.3.4.2, 8.2.3.4.4, 8.2.3.6, 8.2.4.3, 8.2.4.4, 8.2.4.5, 8.2.4.6, 8.3.2.1, 8.3.2.2, 8.3.2.3, 8.3.3.1, 8.3.3.2, 8.3.3.3, 8.3.4, 8.5, 8.5.2, 8.6, IIIA 9.1.1, IIIA 9.1.2, IIIA 9.10.1, IIIA 9.10.2, IIIA 9.2.1, IIIA 9.2.2, IIIA 9.2.3, IIIA 9.2.4, IIIA 9.2.5, IIIA 9.3.1, IIIA 9.3.2, IIIA 9.3.3, IIIA 9.3.4, IIIA 9.3.5, IIIA 9.4.1, IIIA 9.4.2, IIIA 9.4.3, IIIA 9.5.1, IIIA 9.5.2, IIIA 9.5.3, IIIA 9.6.1, IIIA 9.6.2, IIIA 9.6.3, IIIA 9.6.4, IIIA 9.7.1, IIIA 9.7.2, IIIA 9.7.3, IIIA 9.7.4, IIIA 9.7.5, IIIA 9.7.6, IIIA 9.8.1, IIIA 9.8.2, IIIA 9.8.3, IIIA 9.8
- 2141178 2011, Part B Section 6, DACO: 9.1,9.1 (OECD), 9.2.1, 9.2.8, 9.2.9, 9.3.1, 9.3.2, 9.3.5, 9.3.6, 9.4.6, 9.4.7, 9.5.1, 9.5.4, 9.5.5, 9.6.1, 9.6.4, 9.6.5, 9.6.6, 9.7.2, 9.8.1, 9.8.2, 9.8.3, 9.8.6, 9.8.7, 9.9, IIIA 10.1.1, IIIA 10.1.2, IIIA 10.1.3, IIIA 10.1.4.1, IIIA 10.1.4.2, IIIA 10.1.5, IIIA 10.1.6, IIIA 10.1.7, IIIA 10.1.8, IIIA 10.1.9, IIIA 10.10.1, IIIA 10.10.2, IIIA 10.11.1, IIIA 10.11.2, IIIA 10.11.3, IIIA 10.11.4, IIIA 10.11.5, IIIA 10.2.1.1, IIIA 10.2.1.10, IIIA 10.2.1.11, IIIA 10.2.1.2, IIIA 10.2.1.3, IIIA 10.2.1.4, IIIA 10.2.1.5, IIIA 10.2.1.6, IIIA 10.2.1.7, IIIA 10.2.1.8, IIIA 10.2.1.11, IIIA 10.2.1.2, IIIA 10.2.1.3, IIIA 10.2.1.4, IIIA 10.2.1.5,
- 2141179 2011, Part B Section 2, DACO: 2.13.4, 2.14.14, 3.4.1, 3.4.2, 3.5.10, 3.6,3.7, 5.1, 5.14, 5.2, 5.3, 5.4, 5.5, 5.7, 7.1, 7.2.1, 7.2.2, 7.2.3, 7.2.4, 7.2.5, 7.4.1, 7.4.2, 7.8, 8.1, 8.2.2.4, 8.2.3.1, 8.2.3.3.3, 8.2.3.6, 8.2.4.1, 8.2.4.6, 8.3.1, 8.3.2, 8.4.1, 8.6, IIIA 5.1.1, IIIA 5.1.2, IIIA 5.1.3, IIIA 5.1.4, IIIA 5.1.5, IIIA 5.2.1, IIIA 5.2.2, IIIA 5.2.3, IIIA 5.2.4, IIIA 5.2.5, IIIA 5.3.1, IIIA 5.3.2, IIIA 5.4, IIIA 5.5, IIIA 5.6, IIIA 5.7, IIIA 5.8, IIIA 5.9 CBI
- 2141191 1996, Neuf 1140F Acute Toxicity Fish Study, DACO: 9.3.1, 9.5.1, 9.5.4, 9.6.1, 9.8.1, Document K, IIIA 10.2.2.1

- 2141192 Copper Soap Project Using Good Laboratory Practices, DACO: 9.3.1, 9.3.2,9.5.1, 9.6.1, 9.8.1, Document K, IIIA 10.2.2.2
- 2141193 1999, Fresh Water Algae Growth Inhibition Test with Neu 1140 F, DACO: 9.3.1, 9.5.1, 9.6.1, 9.8.1, 9.8.2, 9.8.3, Document K, IIIA 10.2.2.3
- 2141194 1999, Rainbow Trout, Juvenile Growth Test - 28 Days with Neu 1140 F, DACO: 9.3.1, 9.5.1, 9.5.4, 9.6.1, 9.8.1, Document K, IIIA 10.2.5.1
- 2141195 1999, Report Amendment 1 - Rainbow Trout, Juvenile Growth Test - 28 Days with Neu 1140 F, DACO: 9.3.1, 9.5.1, 9.5.4, 9.6.1, 9.8.1, Document K, IIIA 10.2.5.1
- 2141196 1999, Daphnia magna Reproduction Test with Neu 1140 F (Semi-Static), DACO: 9.3.1, 9.3.5, 9.5.1, 9.6.1, 9.8.1, Document K, IIIA 10.2.6.1
- 2141197 1995, Assessment of Side Effects of Neu 1140 F to the Honey Bee, DACO: 9.2.8, 9.3.1, 9.5.1, 9.6.1, 9.8.1, Document K, IIIA 10.4.2.1
- 2141198 1996, Assessment of Side Effects of Neu 1140 F on Aphid Parasitoid, DACO: 9.2.8, 9.3.1, 9.5.1, 9.6.1, 9.8.1, Document K, IIIA 10.5.1
- 2141199 1996, Assessment of Side Effects of Neu 1140 F on Green Lacewing, DACO: 9.2.8, 9.3.1, 9.5.1, 9.6.1, 9.8.1, Document K, IIIA 10.5.1
- 2141200 1995, Assessment of Side Effects of Neu 1140 F on Ground Beetle, DACO: 9.2.8, 9.3.1, 9.5.1, 9.6.1, 9.8.1, Document K, IIIA 10.5.1
- 2141201 1996, Assessment of Side Effects of Neu 1140 F on Predatory Mite, DACO: 9.2.8, 9.3.1, 9.5.1, 9.6.1, 9.8.1, Document K, IIIA 10.5.1
- 2141202 1999, Neu 1140 F: Acute Toxicity to the Aphid Parasitoid, DACO: 9.2.8,9.3.1,9.5.1,9.6.1,9.8.1,Document K,IIIA 10.5.2
- 2141204 1995, English Translation: Effects of NEU 1140 F on predatory mites (Typhlodromus pyri) in field application and obtaining a residue sample - (wine grapes, Germany 1998), DACO: 9.2.9,9.3.1,9.5.1,9.6.1,9.8.1,Document K,IIIA 10.5.4
- 2141205 1998, English Translation: Effects of NEU 1140 F on predatory mites (Typhlodromus pyri) in field application and obtaining a residue sample - (wine grapes, Germany 1998), DACO: 9.2.9,9.3.1,9.5.1,9.6.1,9.8.1,Document K,IIIA 10.5.4
- 2141209 1996, Acute Toxicity of Neu 1140 F on Earthworms, DACO: 9.2.8,9.3.1,9.5.1,9.6.1,9.8.1,Document K,IIIA 10.6.2
- 2141232 1999, Wet Sieving of Suspension Concentrate of Neu 1140 F, DACO: 8.1,8.2.3.1,8.2.3.6,8.2.4.1,8.3.1,8.3.2,8.4.1,Document K,IIIA 2.8.5.2 CBI
- 2141251 1999, English Translation: Effects of NEU 1140 F on predatory mites (Typhlodromus pyri) in field application and obtaining a residue sample - (wine grapes, Germany 1998), DACO: 7.4.1,7.4.2,7.4.6,Document K,IIIA 8.3.1
- 2141261 2010, Chemical Physical Properties of Copper Octanoate, DACO: 8.1,8.2.3.1,8.2.3.4.2,8.2.4.1,8.3.1,8.3.2,8.4.1,Document K,IIIA 9.1.1 CBI
- 2141262 2008, Report of the ad-hoc expert group on pesticides in organic food production, DACO: 8.1,8.2.3.1,8.2.3.4.2,8.2.4.1,8.3.1,8.3.2,8.4.1,Document K,IIIA 9.1.1
- 2169481 Acute Daphnia DER, DACO: 12.5.4
- 2169484 Acute Trout DER, DACO: 12.5.4

2169485	Acute Earthworm DER, DACO: 12.5.4
2169486	Acute Envirottox DER, DACO: 12.5.4
2196342	Waiver Request, DACO: 9.3.1,9.5.1,9.5.2.2,9.6.1,9.8.1
2196343	Waiver Request, DACO: 9.3.1,9.5.1,9.6.1,9.8.1,9.8.4,9.8.5

4.0 Value

2141177	2011, Part B Section 1, DACO: 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.3, 10.6, 2.1, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.14.1, 2.14.2, 2.14.3, 2.16, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.3.2, 3.5.1, 3.5.14, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.7, 5.11, 5.13, 5.14, 5.2, 5.6, 5.7, 5.9, 8.2.1 (OECD), 8.4.1, 8.5.2, 8.6, IIIA 1.1, IIIA 1.2.1, IIIA 1.2.2, IIIA 1.2.3, IIIA 1.3, IIIA 1.4.1, IIIA 1.4.2, IIIA 1.4.3.1, IIIA 1.4.4, IIIA 1.4.5.1, IIIA 1.4.5.2, IIIA 1.5, IIIA 1.6, IIIA 1.7, IIIA 11.1, IIIA 11.2, IIIA 11.3, IIIA 11.4, IIIA 11.5, IIIA 11.6, III CBI
2141343	2011, Efficacy Summary, DACO: 10.1 (OECD)
2141344	2011, Value Binder, DACO: 10.1 (OECD), 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.1, 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.6,5.2, IIIA 3.1, IIIA 3.2, IIIA 3.3.1, IIIA 3.3.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.5
2141410	Efficacy Data and Information Detailed summary, DACO: 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.2.3.4, 10.3.1, 10.3.2, 10.3.3, 10.4, 10.5.2, 10.5.3, 10.5.4, 10.6, Document K, IIIA 6.1.1, IIIA 6.1.2, IIIA 6.1.3, IIIA 6.1.4.1, IIIA 6.1.4.2, IIIA 6.1.4.3, IIIA 6.2.1, IIIA 6.2.2, IIIA 6.2.3, IIIA 6.2.4, IIIA 6.2.5, IIIA 6.2.6, IIIA 6.2.7, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.2, IIIA 6.4.3, IIIA 6.5, IIIA 6.6, IIIA 6.7
2141411	KIIIA1-6.1.3-01, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141412	KIIIA1-6.1.3-02_A-2, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141413	KIIIA1-6.1.3-03_A-3, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141414	KIIIA1-6.1.3-04_A-4, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141415	KIIIA1-6.1.3-05_A-5, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141416	KIIIA1-6.1.3-06_A-6, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141417	KIIIA1-6.1.3-07_A-7, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141418	KIIIA1-6.1.3-08_A-8, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141421	KIIIA1-6.1.3-09_R-1, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141422	KIIIA1-6.1.3-10_R-2, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141423	KIIIA1-6.1.3-11_R-3, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141424	KIIIA1-6.1.3-13_R-5, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141425	KIIIA1-6.1.3-14_R-6, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141426	KIIIA1-6.1.3-15_R-7, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141427	KIIIA1-6.1.3-16_R-8, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141428	KIIIA1-6.1.3-17_R-9, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141429	KIIIA1-6.1.3-18_R-10, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141430	KIIIA1-6.1.3-19_R-11, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141431	KIIIA1-6.1.3-20_R-12, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141433	KIIIA1-6.1.3-21_R-13, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141434	KIIIA1-6.1.3-22_R-14, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141435	KIIIA1-6.1.3-23_R-15, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141436	KIIIA1-6.1.3-24_R-16, DACO: 10.2.3.4, Document K, IIIA 6.1.3

-
- 2141437 KIII A1-6.1.3-25_R-17, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141438 KIII A1-6.1.3-26_R-18, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141439 KIII A1-6.1.3-27_R-19, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141440 KIII A1-6.1.3-28_R-20, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141442 KIII A1-6.1.3-29_R-21, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141443 KIII A1-6.1.3-30_R-22, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141444 KIII A1-6.1.3-31_R-23, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141445 KIII A1-6.1.3-32_R-24, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141446 KIII A1-6.1.3-33_R-25, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141447 KIII A1-6.1.3-34_R-26, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141448 KIII A1-6.1.3-35_R-27, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141449 KIII A1-6.1.3-36_T-1, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141450 KIII A1-6.1.3-37_T-2, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141451 KIII A1-6.1.3-38_T-3, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141452 KIII A1-6.1.3-39_T-4., DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141453 KIII A1-6.1.3-40_T-5, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141454 KIII A1-6.1.3-41_T-6, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141457 KIII A1-6.1.3-42_T-7, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141458 KIII A1-6.1.3-43_P-1, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141459 KIII A1-6.1.3-44_P-2, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141460 KIII A1-6.1.3-45_P-3, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141463 KIII A1-6.1.3-46_P-4, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141464 KIII A1-6.1.3-47_P-5, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141465 KIII A1-6.1.3-48_P-6, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141466 KIII A1-6.1.3-49_G-1, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141467 KIII A1-6.1.3-50_G-2, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141468 KIII A1-6.1.3-51_G-3, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141469 KIII A1-6.1.3-52_G-4, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141470 KIII A1-6.1.3-53_G-5, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141471 KIII A1-6.1.3-54_G-6, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141472 KIII A1-6.1.3-55_G-7, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141473 KIII A1-6.1.3-56_G-8, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141474 KIII A1-6.1.3-57_G-9, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141477 KIII A1-6.1.3-58_G-10, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141478 KIII A1-6.1.3-59_G11, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141479 KIII A1-6.1.3-60_G-12, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141480 KIII A1-6.1.3-61_G-13, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141483 Meagher PEI Potato, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141484 Meagher PEI Potato, DACO: 10.2.3.4, Document K, IIIA 6.1.3
2141485 2011, Environmental Fate of Copper Octanoate, DACO: 10.3.2, Document K, IIIA 6.1.4.1
2141486 BIOLOGICAL ASSESSMENT DOSSIER for NEU 1140 F, DACO: 10.2.3.1, 10.3.1, Document K, IIIA 6.6
2321269 2013, Value Binder - Addendum, DACO: 10.1, 10.2, 10.2.3, 10.2.3.1, 10.2.3.3(A), 10.3, 10.3.1, 10.3.2
2321270 2011, US Copper Hydroxide label, DACO: 10.2.3.1
2321271 2013, EFFICACY SUMMARY, DACO: 10.2.3.1
-

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- 2321273 2013, Use History, DACO: 10.2.3.1
- 2321275 1999, Efficacy of NEU1140F in comparison to chemical standards Delan and Sapro, DACO: 10.2.3.3
- 2321276 1999, Efficacy of NEU1140F in comparison to chemical standards Delan and Sapro, DACO: 10.2.3.3
- 2321278 1999, Efficacy of NEU1140F in comparison to chemical standards Delan and Sapro, DACO: 10.2.3.3
- 2321280 2013, Efficacy of NEU1140F against *Diplocarpon rosae* on *Rosa spec.*, DACO: 10.2.3.3
- 2321283 2013, Peach leaf curl on peaches, DACO: 10.2.3.3
- 2321284 2013, Trial Report NEU_F0104neu,2004, Neustadt - Additional Comments, DACO: 10.2.3.3
- 2321286 1999, Copper Soap Trial - Peas - 1999, DACO: 10.2.3.3
- 2321287 1998, Copper Soap Trial - Peas, DACO: 10.2.3.3
- 2321288 2001, Copper Soap Trial - French beans - Halo blight, DACO: 10.2.3.3
- 2321289 1999, Copper Soap Trial - Tomatoes, DACO: 10.2.3.3
- 2321290 1997, Copper Soap Trial - Cucumber, DACO: 10.2.3.3
- 2321291 1997, Copper Soap Trial - Cucumber, DACO: 10.2.3.3
- 2321292 1997, Copper Soap Trial - Cucumber, DACO: 10.2.3.3
- 2321293 2012, Certis, tomato Speck Control, DACO: 10.2.3.3
- 2321294 2011, Certis, tomato Speck Control, DACO: 10.2.3.3
- 2321295 2012, Evaluation of fungicides allowed for organic production on foliar diseases of tomato, DACO: 10.2.3.3
- 2321296 2011, Evaluation of plant defense activators and bactericides for the control of black rot on cabbage, DACO: 10.2.3.3
- 2321297 2011, Control of Peach Leaf Curl (*Taphrina deformans*) with Cueva on Necta-Plums, DACO: 10.2.3.3
- 2321298 2011, Evaluation of CX-9090, DACO: 10.2.3.3
- 2321299 2012, Evaluate Efficacy of CS-10440 for control of strawberry diseases, DACO: 10.2.3.3
- 2321301 2012, Comparison of Copper Bactericides for Efficacy Against Bacterial Spot on Peach and Plum, DACO: 10.2.3.3
- 2321303 2011, Management of Bacterial spot on Peach with Novel Bactericides, DACO: 10.2.3.3
- 2321304 2011, Comparison of efficacy of contact and systemic acting copper formulations for control of apple scab, DACO: 10.2.3.3
- 2321305 2011, Organic and synthetic fungicides compared for control of leaf spot diseases and powdery mildew on crapemyrtle and hydrangea, DACO: 10.2.3.3
- 2321306 2012, 2012 Peach Leaf Curl Trial, DACO: 10.2.3.3
- 2321307 2007, Control of late blight in organic potato production: evaluation of copper-free preparations under field, growth changer and laboratory conditions, DACO: 10.2.3.3
- 2321308 2013, DACO 10.3.1 Adverse Effects on use Site Summary, DACO: 10.3.1
- 2321311 2013, Cueva safety on Sweet Basil (*Ocimum basicilum*) grown under Greenhouse conditions, DACO: 10.3.2
- 2322331 2013, Cueva Mode of Action, DACO: 10.2.1
- 2346361 2013, Use History Table, DACO: 10.2.3.1
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