

Evaluation Report for Category B, Subcategory 2.1,2.3,2.4,3.1,3.11,3.12 Application

Application Number: 2020-0611
Application: New End-Use Product: Product Chemistry, Application Rates, New Pests, New Site
Product: Ultim Fungicide
Registration Number: 34127
Active ingredient (a.i.): Copper (present as copper hydroxide)
PMRA Document Number : 3224161

Purpose of Application

The purpose of this application was to register a new seed treatment (USC 10) end-use product, Ultim Fungicide, for use against seed rot/pre-emergence damping off, post-emergence damping off, seedling blight and root rot (*Pythium* spp.) on corn (sweet, field and seed), spinach, and pea (dry and succulent).

Chemistry Assessment

Ultim Fungicide is formulated as a wettable powder containing elemental copper present as copper hydroxide at a concentration of 50%. This end-use product has a bulk density of 0.476-0.669 g/mL and pH of 7-9. The required chemistry data for Ultim Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

In rats, Ultim Fungicide is slightly acutely toxic by the oral route, but of low acute toxicity by the dermal route and moderately acutely toxic by the inhalation route. It is severely irritating to the eyes and mildly irritating to skin in rabbits. Ultim Fungicide is not a potential skin sensitizer in guinea pigs.

Occupational risk to individuals handling Ultim Fungicide is acceptable when the product is used according to label directions. Precautionary, personal protective equipment and directions for use statements on the product label aimed at mitigating user exposure are adequate to protect individuals from any potential risk due to occupational exposure.

Elemental copper (cupric ion) in copper-containing pesticides is not degraded; therefore, there are no degradates or metabolites of concern. There is no concern for dietary exposure and dietary risk from food and drinking water is acceptable.

Environmental Assessment

The PMRA reviewed new pollinator data and conducted a risk assessment for aquatic organisms, birds, mammals, and pollinators for Ultim Fungicide. The review of new pollinator data showed that copper, dosed as copper hydroxide, is practically non-toxic to adult and larval honeybees on an acute basis. The risk assessment found that environmental risks are acceptable when Ultim Fungicide is used according to the label.

Pollinators

A total of five new pollinator studies were submitted for review, addressing adult bee acute contact and oral toxicity, adult bee chronic toxicity, and bee larvae toxicity. The new data was reviewed and used to conduct a pollinator risk assessment according to the [Guidance for Assessing Pesticide Risks to Bees](#).

Ultim Fungicide containing copper hydroxide is not systemic. Therefore, pollinators are not expected to be exposed to residues of Ultim Fungicide in the pollen and nectar of plants grown from treated seed. Pollinators may be exposed to Ultim Fungicide contaminated dust generated from corn seeding equipment. Spinach and peas are planted with different seeding equipment that does not generate dust, thus, pollinators are not expected to be exposed to Ultim Fungicide residues in dust from seed-treated spinach or pea.

A conservative approach was taken to assess the risk to pollinators from dust generated from corn seed planting equipment. A foliar screening level risk assessment was conducted using the Ultim Fungicide corn seed treatment application rate (see Table 1). The screening level risk was not exceeded for acute adult or larval endpoints, or for the chronic larval endpoint. A screening level risk was identified for adult chronic exposure. Since the risk was based on a conservative foliar screen, and chronic dust-off exposure to adult pollinators is expected to be lower than exposure from direct foliar application the chronic risk to adult pollinators from the use of Ultim Fungicide as a seed treatment was determined to be acceptable.

Birds and Mammals

A conservative approach was taken to assess the risk to birds and mammals, as they may consume seeds treated with Ultim Fungicide. Bird and mammal toxicity endpoints used were from the re-evaluations for copper (PRVD2009-04 / RVD2010-05 and PRVD2016-04 / RVD2016-09) or from the US EPA RED (EPA 738-R-06-020; July 2006). The maximum proposed application rate for each seed type was used for the screening level risk assessment (RA).

Risk quotients (RQs) exceed the level of concern (LOC) for acute and chronic risk to all size classes of birds and mammals (Table 2). The potential for exposure to Ultim Fungicide treated seeds is likely much lower as seeds are not the only component of a bird or mammal's diet and not all seeds are equally palatable to all birds and mammals. As well, a small fraction of the applied treated seeds would be available for consumption due to the incorporation of seeds into the soil at planting and subsequent seed germination times (typically 3 to 7 days for corn, pea and spinach seeds in optimal conditions). In addition, the re-evaluation noted that animals repeatedly exposed to sublethal levels of copper may undergo enzymatic adaptation which allows them to cope with greater levels of exposure.

Label guidance, including hazard statements and the requirement to incorporate or clean up any

spilled or exposed seeds, are required to mitigate risk to birds and mammals from the seed treatment use of Ultim Fungicide.

Aquatic Organisms

A conservative approach was taken to assess the risks to aquatic organisms. The toxicity endpoints and risk assessment methods used for this risk assessment were the same as those used by the PMRA during the re-evaluation for copper. During the re-evaluation, the PMRA used the Biotic Ligand Model (BLM) to adjust the most sensitive toxicity values for freshwater invertebrates and fish, thus, a genus mean acute value (GMAV) was used for freshwater invertebrate and fish acute toxicity endpoints. The BLM was not applied to endpoints for freshwater plants and estuarine/marine organisms. The maximum application rate (0.323 kg Cu/ha) resulted in an expected environmental concentration (EEC) of 1.11 µg Cu/L.

RQs slightly exceeded the LOC for freshwater algae and estuarine/marine invertebrates (Table 3). The potential for exposure to Ultim Fungicide is likely much lower due to the conservative assumptions made by the model used to generate the EEC. The assumptions that led to a risk that exceeded the level of concern included:

- Using the minimum reported K_d in sandy soil
- Assuming that copper hydroxide immediately converts to dissolved copper in water
- Modelling assumed runoff to a static pond

However, under realistic field conditions, a higher range of K_d values are available depending on the soil type, copper is highly reactive in water and has a demonstrated affinity for binding to sediment and organic matter, and most water bodies of concern have inflows and outflows that move water in and out of a system. Therefore, the elevated concentrations that lead to a risk would likely not persist on a chronic basis.

Considering the RQs and conservative assumptions underlying the exposure estimates, the risk to aquatic organisms from the use of Ultim Fungicide is acceptable.

Table 1. Endpoints and Risk Assessment for Honeybee Exposed to Copper Hydroxide.

| Exposure | Endpoint value(s) (µg Cu/bee/day) | Estimated Dose ¹ (µg Cu/bee/day) | RQ | LOC exceeded? ² | PMRA# |
|-----------------------|---|--|-------|----------------------------|-------------------------|
| Adult – acute oral | 72 hr LD ₅₀ : 16 96 hr LD₅₀: 16 | 0.72 | 0.045 | No | 3101540 |
| Adult – acute contact | 72 hr LD ₅₀ : 42 96 hr LD₅₀: 35 | 0.06 | <0.01 | No | 3101539 |

| | | | | | |
|-----------------------------------|--|-------|-------------|-----|-------------------------|
| Adult – chronic | Survival: NOED: 0.28 LOED: 0.46 LD ₅₀ : 0.47 Survivor weight: NOED: ≥0.68 LOED: >0.68 ED ₅₀ : >0.68 | 0.72 | 2.56 | Yes | 3101542 |
| Larva – acute (single exposure) | 72 hr LD₅₀: 30 | 0.01 | 0.01 | No | 3101544 |
| Larva – chronic (repeat exposure) | 3-8 day larval survival: NOED: 13 LOED: 24 LD ₅₀ : 35 8-22 day pupal survival: NOED: 24 LOED: 49 LD ₅₀ : 35 3-22 day adult emergence: NOED: 13 LOED: 24 LD ₅₀ : 33 Weight at emergence: NOED: ≥49 LOED: >49 ED ₅₀ : >49 | 0.023 | 0.023 | No | 3101542 |

Most sensitive endpoints used in screening level risk assessment are in **bold**.

¹ Estimated dose = corn application rate [25 g Cu/ha] x adjustment factor. Adjustment factors are 2.4, 28.6, and 12.15 µg a.i./bee per kg a.i./ha for adult bee contact exposure, adult bee oral exposure, and larval exposure, respectively.

² LOC for bees is set at 0.4 for acute endpoints and 1.0 for chronic endpoints.

Table 2. Endpoints and Risk Assessment for Birds and Mammals Exposed to Copper Complexes Converted to Elemental Copper.

| Test Species | Exposure | Endpoint Value (mg Cu/kg bw/day) | RQs: Peas & Sweet corn | | | RQs: Spinach | | |
|----------------|-------------------------|----------------------------------|------------------------|-------------|------------|--------------|-------------|------------|
| | | | Small | Med | Large | Small | Med. | Large |
| Birds | | | | | | | | |
| Bobwhite quail | Acute Oral ¹ | LD ₅₀ : 98 | 42.5 | 33.4 | 9.7 | 131 | 103 | 30 |
| Bobwhite quail | Chronic ² | NOAEL: 58 | 7.2 | 5.6 | 1.6 | 22.2 | 17.4 | 5.1 |

| Mammals | | | | | | | | |
|----------------|-------------------------|------------------------|------|------|-----|------|------|------|
| Rat | Acute Oral ¹ | LD ₅₀ : 114 | 4.6 | 4.0 | 2.2 | 14.2 | 12.2 | 6.7 |
| Mink | Chronic ¹ | NOAEL: 11.7 | 20.3 | 17.5 | 9.6 | 62.8 | 54.0 | 29.7 |

Note a 22% absorption factor was used to adjust acute mammalian RQs as per PRVD2009-04 / RVD2010-05.

¹ Copper dosed as copper sulfate pentahydrate

² Copper dosed as copper oxychloride sulfate

Table 3. Endpoints and Risk Assessment for Aquatic Organisms Exposed to Copper Hydroxide.

| Organism | Endpoint | RQ ¹ | LOC Exceeded? |
|---|--|-----------------|---------------|
| Freshwater organisms | | | |
| Invertebrates (<i>Daphnia magna</i>) | GMAV LC ₅₀ /2 = 1.80 µg Cu/L | 0.62 | No |
| | NOEC = 1.11 µg Cu/L | 1.0 | No |
| Fish (Salmonids, <i>Onchorynchus</i>) | GMAV LC ₅₀ /10 = 2.91 µg Cu/L | 0.38 | No |
| | NOEC = 9.01 µg Cu/L | 0.12 | No |
| Amphibian (<i>Bufo boreas</i>) | GMAV LC ₅₀ /10 = 4.75 µg Cu/L | 0.23 | No |
| | NOEC = 14.7 µg Cu/L | 0.08 | No |
| Non-vascular plant (Green algae, <i>Selenastrum capricornutum</i>) | EC ₅₀ /2 = 1.55 µg Cu/L | 0.71 | No |
| | NOEC = 0.2 µg Cu/L | 5.55 | Yes |
| Vascular plant (Duckweed, <i>Lemna minor</i>) | LC ₅₀ /2 = 1150 µg Cu/L | <0.0 1 | No |
| | NOEC = 100 µg Cu/L | 0.01 | No |
| Estuarine/marine organisms | | | |
| Invertebrates (Mussel, <i>Mytilus</i>) | LC ₅₀ /2 = 3.25 µg Cu/L | 0.34 | No |
| | NOEC = 1.01 µg Cu/L | 1.10 | Yes |
| Fish (Summer flounder, <i>Paralichthys dentatus</i>) | LC ₅₀ /10 = 1.27 µg Cu/L | 0.87 | No |
| | NOEC = 3.92 µg Cu/L | 0.28 | No |
| Plants (Marine diatom, <i>Skeletonema costatum</i>) | LC ₅₀ /2 = 125 µg Cu/L | 0.01 | No |
| | NOEC = 124 µg Cu/L | 0.01 | No |

¹ RQs calculated based on an EEC of 1.11 µg Cu/L, corresponding to the maximum proposed Ultim Fungicide application rate of 323 g Cu/ha.

Value Assessment

To support claims against seed rot/pre-emergence damping off, post-emergence damping off, seedling blight and root rot (*Pythium* spp.) when Ultim Fungicide is applied as a seed treatment on corn, spinach and pea seed, the applicant submitted 10 suitable field efficacy trials conducted

in Wisconsin, Washington, Iowa and South Dakota, USA. When used with a seed coat, Ultim Fungicide was found to control these diseases.

Pythium spp. seed and seedling diseases can cause significant reductions in plant stand, vigour and crop yield. Ultim Fungicide will provide a new fungicidal mode of action with a low potential for the development of fungicide resistance for use against *Pythium* spp. diseases in conventionally- and organically-grown corn, spinach and pea crops.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of Ultim Fungicide.

References

A. List of Studies/Information Submitted by Registrant

PMRA

Document

| Number | Reference |
|---------|--|
| 3091612 | 2019, SafeGuard-ST: Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO: 4.6.1 |
| 3091613 | 2019, SafeGuard-ST: Acute Dermal Toxicity in Rats, DACO: 4.6.2 |
| 3091614 | 2019, SafeGuard-ST: Acute Inhalation Toxicity in Rats, DACO: 4.6.3 |
| 3091615 | 2020, SafeGuard-ST: Primary Eye Irritation in Rabbits, DACO: 4.6.4 |
| 3091616 | 2019, SafeGuard-ST: Primary Skin Irritation in Rabbits, DACO: 4.6.5 |
| 3091617 | 2019, SafeGuard-ST: Dermal Sensitization Test in Guinea Pigs - Buehler Method, DACO: 4.6.6 |
| 3091618 | 2020, Exposure (Occupational and/or Bystander) Summary for Ultim Fungicide Seed Treatment containing Copper Hydroxide, DACO: 5.2 |
| 3091587 | 2020, Value Summary Tables for Corn, DACO: 10.2.3.1 |
| 3091588 | 2020, Value Summary Tables for Peas, DACO: 10.2.3.1 |
| 3091589 | 2020, Value Summary Tables for Spinach, DACO: 10.2.3.1 |
| 3091592 | 2018, Corn Wisconsin (two trials) 2018 - Part A, DACO: 10.2.3.3(D) |
| 3091593 | 2018, Spinach Wisconsin (two trials) 2018, DACO: 10.2.3.3(D) |
| 3091594 | 2018, Field Peas Wisconsin (two trials) 2018 - Part A, DACO: 10.2.3.3(D) |
| 3091595 | 2018, Corn Wisconsin (two trials) 2018 - Part B, DACO: 10.2.3.3(D) |
| 3091596 | 2018, Field Pea Wisconsin (two trials) 2018 - Part B, DACO: 10.2.3.3(D) |
| 3091599 | 2019, ProBio SafeGuard Formulation & Registration Trials - Spinach, DACO: 10.2.3.3(D) |
| 3091600 | 2019, ProBio SafeGuard Formulation & Registration Trials - Spinach - Raw Data, DACO: 10.2.3.3(D) |
| 3091601 | 2019, Germaines Corn 2019 SD, DACO: 10.2.3.3(D) |
| 3091602 | 2019, Final Report for Germaines Seed Technology Pea Trial in Prosser, WA, DACO: 10.2.3.3(D) |
| 3091605 | 2019, Value Summary Tables for Seed Safety Testing Corn Pea and Spinach, DACO: 10.3.1 |

- 1441637 2006, United States Environmental Protection Agency. Reregistration Eligibility Decision (RED) for Coppers. EPA 738-R-06-020.
- 3091606 2020, Additional Product Chemistry for Ultim Fungicide, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.4,3.5.5,3.5.8
- 3091608 2019, Ultim: Product Identity And Composition, Description Of Materials Used To Produce The Product, Description of Formulation Process, Explanation of Certified Limits, Discussion Of The Formation Of Impurities, and Enforcement Analytical Method, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1 CBI
- 3091609 2019, SafeGuard-ST: Physical and Chemical Characteristics: Color, Physical State, Odor, pH, and Bulk Density, DACO: 3.5.1,3.5.2,3.5.3,3.5.6,3.5.7
- 3091610 2019, SafeGuard-ST Physical and Chemical Characteristics: Waivers for Flammability, Explodability, Miscibility, Dielectric breakdown voltage, DACO: 3.5.11,3.5.12,3.5.13,3.5.15
- 3091611 2019, SafeGuard-ST: Accelerated Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14
- 3101539 2019, Ultim-ST: Acute Contact Toxicity Test with the Honey Bee (*Apis mellifera*), DACO: 9.2.4.1
- 3101540 2019, Ultim-ST: Acute Oral Toxicity Test with the Honey Bee (*Apis mellifera*), DACO: 9.2.4.2
- 3101541 2020, Ultim-ST: Honey Bee (*Apis mellifera*) Larval Toxicity Test, Repeated Exposure, DACO: 9.2.4.3
- 3101542 2020, Ultim-ST: 10-Day Oral Toxicity Test with the Adult Honey Bee (*Apis mellifera*), DACO: 9.2.4.4
- 3101544 2020, Ultim-ST: Honey Bee (*Apis mellifera*) Larval Toxicity Test, Single Exposure, DACO: 9.2.4.3

B. Additional Information Considered

Published Information

| PMRA Document Number | Reference |
|-----------------------------|---|
| 3220327 | 2013, Carrie E. DeJaco and George O. Batzli, Palatability of plants to small mammals in nonnative grasslands of east-central Illinois. J. Mamm. 94(2):427-435. DACO 9.9 |
| 1441637 | 2006, United States Environmental Protection Agency. Reregistration Eligibility Decision (RED) for Coppers. EPA 738-R-06-020. |

ABBREVIATIONS

| | |
|------------------|---|
| a.i. | active ingredient |
| bw | body weight |
| Cu | copper |
| EC ₅₀ | effective concentration for 50% of test organisms |
| ED ₅₀ | effective dose for 50% of test organisms |
| EEC | estimated environmental concentration |
| g | gram(s) |
| GMAV | genus mean acute value |
| ha | hectare(s) |
| hr | hour(s) |
| kg | kilogram(s) |
| K _d | solids-water equilibrium partition coefficient |
| L | liter(s) |
| LC ₅₀ | lethal concentration for 50% of test organisms |
| LD ₅₀ | lethal Dose for 50% of test organisms |
| LOC | level of concern |
| LOED | lowest observed effective dose |
| mg | milligram(s) |
| NOAEL | no observed adverse effect level |
| NOEC | no observed effect concentration |
| NOED | no observed effect dose |
| PMRA | Pest Management Regulatory Agency |
| PRVD | Proposed Re-evaluation Decision |
| RED | Reregistration Eligibility Decision |
| RQ | risk quotient |
| RVD | Re-evaluation Decision |
| US EPA | United States Environmental Protection Agency |

µg micrograms

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