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Registration Decision

RD2014-24

Cyflumetofen

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

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Registration Decision for Cyflumetofen

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Cyflumetofen Technical and Nealta Miticide, containing the technical grade active ingredient cyflumetofen, to control European red mite and two spotted spider mite and McDaniel spider mite on pome fruits, grapes, strawberries, and tomatoes.

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.

These products were first proposed for registration in the consultation document¹ Proposed Registration Decision PRD2014-10, *Cyflumetofen*. This Registration Decision² describes this stage of the PMRA's regulatory process for Cyflumetofen and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2014-10. This decision is consistent with the proposed registration decision stated in PRD2014-10.

For more details on the information presented in this Registration Decision, please refer to PRD2014-10, *Cyflumetofen* that contains a detailed evaluation of the information submitted in support of this registration.

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 acceptable³ 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 conditions of registration. The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *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".

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 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.

What Is Cyflumetofen?

Cyflumetofen is a compound in the benzoylacetone class of chemistry. It interferes with energy production within cells and acts as an acaricide on contact with spider mites. Foliar application of cyflumetofen formulated as Nealta Miticide provides control of European red mite, twospotted spider mite and McDaniel spider mite on pome fruits, grapes, strawberries and tomatoes.

Health Considerations

Can Approved Uses of Cyflumetofen Affect Human Health?

Nealta Miticide, containing cyflumetofen, is unlikely to affect your health when used according to label directions.

Potential exposure to cyflumetofen may occur through diet (food and water), when handling and applying the product, or when entering an area that has been treated with the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide-containing products are used, according to label directions.

In laboratory animals, the technical grade active ingredient cyflumetofen was of low acute toxicity by oral, dermal and inhalation routes of exposure. It was minimally irritating to the eyes and non-irritating to the skin. Cyflumetofen did cause an allergic skin reaction; consequently, the hazard statement "POTENTIAL SKIN SENSITIZER" is required on the label.

The acute toxicity of the end-use product, Nealta Miticide, was low via the oral, dermal and inhalation routes of exposure. Nealta Miticide was non-irritating to the eyes, minimally irritating to the skin, and did not cause an allergic skin reaction.

Cyflumetofen did not damage genetic material. There was evidence of testicular tumours and thyroid tumours in the rat; however, the endpoints selected for risk assessment are considered protective of these findings. There was no indication that cyflumetofen caused damage to the nervous system or immune system. Cyflumetofen did not cause effects on the ability to reproduce. Health effects in animals given repeated doses of cyflumetofen included effects on the adrenal glands, liver, kidneys, ovaries and testes.

When cyflumetofen was given to pregnant rabbits, a marginal shift in the normal pattern of bone growth was observed in fetuses at a dose which produced body weight and liver weight changes in the mothers. At the highest dose level, malformations of the paws were observed in fetuses; additional effects in the mothers included decreased food consumption and adrenal gland effects. When cyflumetofen was administered to pregnant or nursing rats, effects on the developing fetus (delayed bone ossification) and juvenile animal (slight delays in sexual maturation, adrenal gland effects) were observed at doses that were also toxic to the mothers, as evidenced by toxicity to the adrenal glands. These results indicate that the young do not appear to be more sensitive to cyflumetofen than the adult animal.

The risk assessment protects against the effects of cyflumetofen by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that the general population and children 1-2 years of age – the subpopulation that would ingest the most cyflumetofen relative to body weight – are expected to be exposed to less than 6.3% of the Acceptable Daily Intake. Based on these estimates, the chronic dietary risk from cyflumetofen is not of concern for all population subgroups. Cyflumetofen is not carcinogenic; therefore, a cancer dietary exposure assessment is not required.

The deterministic acute aggregate dietary intake estimate for females 13-49 years of age from exposure to cyflumetofen is 0.75% of the Acute Reference Dose. A single dose of cyflumetofen is not likely to cause acute health effects to any other population subgroup.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established Maximum Residue Limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout the United States of America using cyflumetofen on Citrus Fruits (Crop Group 10-revised), Pome Fruits (Crop Group 11-09), Tree Nuts (Crop Group 14-11), grapes, strawberries, and tomatoes were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of PRD2014-10.

Risks in Residential and Other Non-Occupational Environments

Potential residential exposure and risk for the general public (adults, youths and children) entering Nealta Miticide treated fields to pick their own fruit are considered acceptable.

Occupational Risks From Handling Nealta Miticide

Occupational risks are not of concern when Nealta Miticide is used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply – as well as field workers who re-enter freshly treated fields – can come in direct contact with Nealta Miticide residues on the skin. It is specified on the label that anyone mixing or loading Nealta Miticide and doing clean-up and repairs must wear a long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks, and that anyone applying the product must wear a long-sleeved shirt, pants and shoes plus socks. In addition, wear a suitable dust mask approved by NIOSH when handling. The label also specifies that workers do not enter treated fields for 12 hours after application. Taking into consideration these label requirements, health risks to agricultural workers are not of concern.

For bystanders, exposure is expected to be much less than that of field workers and can be considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens when Cyflumetofen is Introduced into the Environment?

Cyflumetofen is not persistent in terrestrial and aquatic environments. At the proposed use rates, cyflumetofen and its transformation products present a negligible risk to the majority of terrestrial and aquatic non-target organisms. However, a risk was identified for non-target terrestrial plants and amphibians.

Cyflumetofen enters the environment when used as an insecticide against mites on various crops. Cyflumetofen is not persistent in the terrestrial environment where biotransformation and hydrolysis in moist soils are the main routes of transformation. Cyflumetofen is not expected to volatilize, and leaching into groundwater is not a concern.

Cyflumetofen is not persistent in the aquatic environment. Once in water, it rapidly undergoes transformation by photolysis and hydrolysis at environmentally relevant pHs, and particularly alkaline pH. Cyflumetofen is also rapidly broken down by microbial activity in water and sediments, and it is not expected to bioaccumulate in fish tissue.

Many transformation products of cyflumetofen were identified in the abiotic transformation laboratory studies, and in the soil and aquatic biotransformation laboratory studies. Most major transformation products were further investigated. Generally, major transformation products having a large chemical structure similar to cyflumetofen, such as AB-1 and AB-1 dimers, tend to be immobile like the parent; while those with a small chemical structure (having a single benzene ring only), such as A-2, B-1 and B-3, tend to be mobile in soil.

Cyflumetofen can be applied by field sprayer or air-blast sprayer (late and early season). Non-target terrestrial and aquatic habitats may be exposed to the chemical as a result of spray drift or runoff. At the proposed use rates, cyflumetofen presents a negligible risk to terrestrial organisms such as earthworms, beneficial insects (bees and other beneficial arthropods), birds and small mammals. However, a risk to non-target terrestrial plants was identified. Cyflumetofen is not expected to pose a risk to freshwater or marine fish, invertebrates, or algae, but a risk was identified to amphibians. To minimize the risk resulting from off-field drift to sensitive non-target organisms, spray buffer zones will be required between the treated area and sensitive terrestrial and aquatic habitats downwind of the treatment area. No environmental risks were identified from exposure to the major transformation products of cyflumetofen.

Value Considerations

What Is the Value of Nealta Miticide?

Nealta Miticide provides control of European red mite, twospotted spider mite and McDaniel spider mite on pome fruits, grapes, strawberries, and tomatoes.

Nealta Miticide is applied using ground-based application equipment to the foliage of listed orchard, vineyard and field crops to control spider mites. It is effective against all life stages of spider mites and provides residual control. There are no other Group 25 acaricides registered in Canada, giving cyflumetofen particular value for resistance management.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Nealta Miticide to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

As users may come in direct contact with Nealta Miticide on the skin or through inhalation of spray mists, anyone mixing and loading Nealta Miticide and during clean-up and repairs, must wear a long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks.

Applicators must wear a long-sleeved shirt, long pants and shoes plus socks. In addition, they are required to wear a suitable dust mask approved by NIOSH when handling Nealta Miticide. The label also specifies that workers not enter treated fields for 12 hours after application. Moreover, a standard label statement to protect against spray drift to unintended areas during application is on the label. Taking into consideration these label statements, the number of applications, and the duration of exposure for workers, the health risks to these individuals are not of concern.

Environment

To reduce the exposure of terrestrial and aquatic habitats to cyflumetofen, the PMRA is proposing further risk reduction measures, which include:

- A hazard statement to inform the user that this product is toxic to non-target terrestrial plants and aquatic organisms;
- Guidance to reduce runoff from treated areas into aquatic areas; and
- Required spray buffer zones of up to five metres to protect sensitive terrestrial habitats, and up to three metres are required to protect sensitive aquatic habitats.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-10) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Requesting a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

⁵ per subsection 35(1) of the *Pest Control Products Act*.