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Registration Decision

RD2014-26

Chlorantraniliprole

(publié aussi en français)

21 August 2014

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

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Canada 

ISSN: 1925-0932 (print)
1925-0940 (online)

Catalogue number: H113-25/2014-26E (print version)
H113-25/2014-26E-PDF (PDF version)

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Registration Decision for Chlorantraniliprole

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 Rynaxypyr Technical Insecticide and DuPont Altriset Termiticide, containing the technical grade active ingredient chlorantraniliprole, to control subterranean termites in various sites.

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 PRD2013-08, *Chlorantraniliprole*. This Registration Decision² describes this stage of the PMRA's regulatory process for chlorantraniliprole and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2013-08. This decision is consistent with the proposed registration decision stated in PRD2013-08.

For more details on the information presented in this Registration Decision, please refer to PRD2013-08, which 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 Chlorantraniliprole?

Chlorantraniliprole, the active ingredient in DuPont Altriset Termiticide, controls subterranean termites in structures, the surrounding soil, in non-edible fruit and nut bearing trees, and in other listed locations. It is also found in commercial class insecticides registered to control insect pests in agricultural crops and turf. Chlorantraniliprole kills insects by overstimulating their muscles, causing paralysis and eventually death.

Health Considerations

Can Approved Uses of Chlorantraniliprole Affect Human Health?

DuPont Altriset Termiticide containing chlorantraniliprole is unlikely to affect your health when used according to label directions.

Potential exposure to chlorantraniliprole in DuPont Altriset Termiticide may occur when handling and applying 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 those uses where 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 using pesticide-containing products according to label directions.

In laboratory animals, DuPont Altriset Termiticide was of low acute toxicity via the oral, dermal and inhalation routes of exposure. It was non-irritating to the skin and was minimally irritating to the eyes, and did not cause an allergic skin reaction.

The toxicological database for chlorantraniliprole indicates a low overall level of toxicity. Health effects in animals given repeated doses of chlorantraniliprole included effects on the liver and the adrenal gland; findings were considered largely adaptive in nature or observed at doses at, or approaching, the limit dose of toxicity testing. There was no evidence of carcinogenicity, reproductive toxicity, neurotoxicity or immunotoxicity. When chlorantraniliprole was given to pregnant animals, there was no indication that it affects the developing fetus.

The risk assessment protects against these effects 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

Based on the use pattern of DuPont Altriset Termiticide, a dietary risk assessment was not required.

Risks in Residential and Other Non-Occupational Environments

Residential risks are not of concern when DuPont Altriset Termiticide is used according to the label directions.

It is unlikely that individuals, residing in homes treated with DuPont Altriset Termiticide, will contact treated surfaces or inhale vapours when the product is applied according to the label directions. Subsequently, risk to these individuals is considered negligible.

Occupational Risks from Handling DuPont Altriset Termiticide

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

Pest control operators mixing, loading and/or applying DuPont Altriset Termiticide can come into direct contact with chlorantraniliprole on the skin or through inhalation. Therefore, the label specifies anyone mixing, loading or applying DuPont Altriset Termiticide must wear long-sleeved shirt, long pants and chemical resistant gloves during mixing, loading, application, clean up and repair.

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

Environmental Considerations

What Happens When Chlorantraniliprole is Introduced into the Environment?

Chlorantraniliprole enters the environment when used as a termiticide in buildings, posts, poles, landscape ornamentation, signs, and non-edible fruit and nut trees; in the surrounding soil under firewood, stumps, felled tree material and other cellulose materials; and as an insecticide on various agricultural crops. Please refer to the Evaluation Report ERC2008-03, *Chlorantraniliprole* for detailed information on agricultural uses of chlorantraniliprole and the associated environmental risk.

Chlorantraniliprole is persistent and mobile in soil and moderately persistent in the aquatic environment. The major breakdown product, (2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethyl-4(3H)-quinazolinone (IN-EQW78), is more persistent than chlorantraniliprole in the soil and aquatic environment. Chlorantraniliprole is expected to leach through the soil profile beyond 60 cm; therefore, it has the potential to reach groundwater. In surface waters, chlorantraniliprole will partition to sediment and is expected to accumulate in aquatic systems.

The risk to the environment was assessed for chlorantraniliprole based on the product label of the end-use product, DuPont Altriset Termiticide. Use of chlorantraniliprole according to approved product labels is expected to present negligible risk to wild mammals, birds, earthworms, terrestrial plants, bees, fish, algae and aquatic plants, non-target terrestrial arthropods and aquatic invertebrates.

Value Considerations

What Is the Value of DuPont Altriset Termiticide?

DuPont Altriset Termiticide controls subterranean termites in structures either as a pre-construction or post-construction treatment. The product may also be applied to control termites in other locations listed on the label such as poles, non-bearing fruit and nut trees, the surrounding soil under firewood and under logs. Subterranean termites cause extensive damage to structures, such as homes, which can result in expensive repairs. There are very few active ingredients registered to control subterranean termites. DuPont Altriset Termiticide is a valuable addition to termite management programs and will contribute to resistance management, as it is a new mode of action for use against subterranean termites. DuPont Altriset Termiticide can be used in conjunction with other pest management practices such as wood preservatives and physical barriers.

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 DuPont Altriset Termiticide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with chlorantraniliprole on the skin or through inhalation of spray mists, anyone mixing, loading and applying DuPont Altriset Termiticide must wear a long-sleeved shirt, long pants and chemical resistant gloves during mixing, loading, application, cleanup and repair.

Environment

To address potential concerns related to toxicity to aquatic organisms, carryover, runoff, and leaching, environmental hazard label statements are required for DuPont Altriset Termiticide.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2013-08) 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 As per subsection 35(1) of the *Pest Control Products Act*.