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Registration Decision

RD2011-03

Thiencarbazone-methyl

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Registration Decision for Thiencarbazone-methyl

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 Thiencarbazone-methyl Technical Herbicide, Velocity Herbicide and AE1162464 WG63 Herbicide, containing the technical grade active ingredient thiencarbazone-methyl, to control weeds in corn and wheat (spring and durum).

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 PRD2010-28, *Thiencarbazone-methyl*. This Registration Decision² describes this stage of the PMRA's regulatory process for thiencarbazone-methyl and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2010-28, *Thiencarbazone-methyl*. This decision is consistent with the proposed registration decision stated in PRD2010-28, *Thiencarbazone-methyl*.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-28, *Thiencarbazone-methyl* 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 Thien carbazone-methyl?

Thien carbazone-methyl is the active ingredient in the herbicide end-use products Velocity Herbicide and AE1162464 WG63 Herbicide. Velocity Herbicide is used to control or suppress several grass and broadleaf weeds in wheat (spring and durum). AE1162464 WG63 Herbicide is used to control redroot pigweed and green foxtail and suppress lamb's quarters in field corn.

Thien carbazone-methyl inhibits the enzyme acetolactate synthase (ALS) in sensitive plants. Inhibition of this enzyme essentially starves the plants of essential amino acids, eventually leading to plant death.

Health Considerations

Can Approved Uses of Thien carbazone-methyl Affect Human Health?

Thien carbazone-methyl is unlikely to affect your health when used according to label directions.

The technical grade active ingredient thien carbazone-methyl was not acutely toxic. Consequently, no hazard statements are required on the technical product label.

The end-use product AE1162464 WG63 Herbicide was moderately irritating to the eye. Consequently, the statement "Warning – eye irritant" is required on the end-use product label. The end-use product Velocity Herbicide was mildly irritating to the skin and moderately irritating to the eye. As a result, the label statement "Warning – skin and eye irritant" is required on the end-use product label.

Thien carbazone-methyl was not genotoxic and there was no evidence of immunotoxicity or effects on the endocrine system. There was also no indication that thien carbazone-methyl caused damage to the nervous system and there were no effects on reproduction or fetal development. The first signs of toxicity in animals given daily doses of thien carbazone-methyl over longer periods of time were bladder and kidney effects. There was evidence of cancer in the urinary bladders of mice, but only at doses where distinct precursor urinary tract changes were previously noted. Although these tumours were considered to be of limited relevance to humans, they are taken into account in the risk assessment. When thien carbazone-methyl was given to pregnant animals, effects on the developing fetus were observed at doses that were toxic to the

mother, indicating that the fetus is not more sensitive to thiencazuron-methyl than the adult animal. The risk assessment protects against these effects by ensuring 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 chronic dietary intake estimates (food plus water) revealed that the general population and children (1 to 2 years old), the subpopulation which would ingest the most thiencazuron-methyl relative to body weight, are expected to be exposed to less than 0.1% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from thiencazuron-methyl is not of concern for all population sub-groups.

Animal studies revealed no acute health effects. Consequently, a single dose of thiencazuron-methyl is not likely to cause acute health effects in the general population (including infants and children).

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 Canada and the United States using thiencazuron-methyl on corn and wheat crops were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of Evaluation Report ERC2010-03, *Thiencazuron-methyl*.

Occupational Risks From Handling AE1162464 WG63 Herbicide and Velocity Herbicide

Occupational risks are not of concern when AE1162464 WG63 Herbicide and Velocity Herbicide are used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply AE1162464 WG63 Herbicide to corn or Velocity Herbicide to wheat and field workers entering freshly treated fields can come in direct contact with thiencazuron-methyl residues on the skin. Therefore, the labels specify that anyone mixing/loading and applying AE1162464 WG63 Herbicide or Velocity Herbicide must wear long sleeves, long pants and shoes plus socks. During mixing/loading, clean-up and equipment repair, chemical-resistant gloves must also be worn. The labels also require that workers do not enter treated fields for 12 hours after application. Consideration of these label statements, the number of applications and the expected exposure period for handlers and workers, indicated that the risks to these individuals are not a concern.

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 Thien carbazole-methyl Is Introduced Into the Environment?

Thien carbazole-methyl enters the environment when used as a herbicide on corn and wheat. In the terrestrial environment, thien carbazole-methyl undergoes biotransformation resulting in four major transformation products. Thien carbazole-methyl and three of the transformation products are slightly persistent in soil while one of the transformation products is persistent.

Thien carbazole-methyl and its transformation products weakly bind to soil particles and have potential for leaching to groundwater or for runoff to surface water.

In the aquatic environment, thien carbazole-methyl undergoes biotransformation resulting in five transformation products. Thien carbazole-methyl does not persist in aquatic systems. One of the transformation products is moderately persistent in water and sediment. Two of the transformation products are moderately persistent in water. One of the transformation products is not persistent in water and sediment while another is moderately persistent and is only formed under anaerobic conditions.

Based on its low volatility, thien carbazole-methyl residues are not expected in air.

Thien carbazole-methyl and its relevant transformation products pose negligible risk to earthworms, bees, birds, beneficial arthropods, small wild mammals, aquatic invertebrates, mollusks, amphibians or fish, when used as proposed.

Thien carbazole-methyl poses a risk to aquatic plants and algae and terrestrial plants. To minimise the risk from exposure via spray drift, buffer zones of 1 to 30 metres (depending on the end-use product and application equipment) are required to protect nearby plants.

Value Considerations

What Is the Value of Thien carbazole-methyl?

A single application of thien carbazole-methyl provides effective control of numerous grassy and broadleaved weeds, including wild oat and green foxtail, in wheat (spring and durum) and field corn. Thien carbazole-methyl is compatible with integrated weed management practices, conservation tillage and conventional crop production systems. As thien carbazole-methyl is applied after weed emergence, growers are able to assess whether the herbicide is suitable for the particular weed species present by ensuring the weeds present in the field correspond to the weeds on the label.

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 Velocity Herbicide and AE1162464 WG63 Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

As there is a concern with users coming into direct contact with AE1162464 WG63 Herbicide or Velocity Herbicide on the skin, anyone mixing, loading and applying AE1162464 WG63 Herbicide or Velocity Herbicide must wear long sleeves, long pants and shoes plus socks. During mixing/loading, clean up and equipment repair, chemical resistant gloves must also be worn. In addition, standard label statements to protect against drift during application were added to the label.

Environment

To minimise the risk to terrestrial plants, aquatic plants and algae from exposure to thien carbazole-methyl via spray drift, buffer zones of 1 to 30 metres (depending on the end-use product and application equipment) are required.

Other Information

The relevant test data on which the decision is based (as referenced in ERC2010-03, *Thien carbazole-methyl* and PRD2010-28, *Thien carbazole-methyl*) 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 (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

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