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Proposed Registration Decision

PRD2010-28

# Thiencarbazon-méthyl

*(publié aussi en français)*

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# Overview

## Proposed Registration Decision for Thien carbazone-methyl

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

Thien carbazone-methyl (Registration Number 29068), Velocity Herbicide (Registration Number 29070) and AE1162464 WG63 Herbicide (Registration Number 29069) are conditionally registered in Canada. The detailed review for Thien carbazone-methyl Technical Herbicide, Velocity Herbicide and AE1162464 WG63 Herbicide can be found in Evaluation Report ERC2010-03, *Thien carbazone-methyl*. The current applications were submitted to convert Thien carbazone-methyl Technical Herbicide, Velocity Herbicide and AE1162464 WG63 Herbicide from conditional registration to full registration.

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 Thien carbazone-methyl Technical Herbicide, Velocity Herbicide and AE1162464 WG63 Herbicide.

## 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 acceptable<sup>1</sup> 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 value<sup>2</sup> when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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<sup>1</sup> "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

<sup>2</sup> "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."

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 (e.g. children) as well as organisms in the environment (e.g. 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 PMRA section of Health Canada's website at [healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra).

Before making a final registration decision on thien carbazone-methyl, the PMRA will consider all comments received from the public in response to this consultation document<sup>3</sup>. The PMRA will then publish a Registration Decision<sup>4</sup> on thien carbazone-methyl, 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.

## **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?**

Potential exposure to thien carbazone-methyl may occur through the diet (food and water) or 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 (such as 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.

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<sup>3</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>4</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

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 thien carbazone-methyl products are 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 thien carbazone-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 thien carbazone-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 thien carbazone-methyl is not of concern for all population sub-groups.

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

The *Food and Drugs Act (FDA)* 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 FDA purposes through the evaluation of scientific data under the *Pest Control Products Act (PCPA)*. 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 thien carbazon e-methyl on corn and wheat crops were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of ERC2010-03.

### **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 thien carbazon e-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 carbazon e-methyl Is Introduced Into the Environment?**

Thien carbazon e-methyl enters the environment when used as a herbicide on corn and wheat. In the terrestrial environment, thien carbazon e-methyl undergoes biotransformation resulting in four major transformation products. Thien carbazon e-methyl and three of the transformation products are slightly persistent in soil while one of the transformation products is persistent. Thien carbazon e-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 carbazone-methyl undergoes biotransformation resulting in five transformation products. Thien carbazone-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 carbazone-methyl residues are not expected in air.

Thien carbazone-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 carbazone-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 carbazone-methyl?**

A single application of thien carbazone-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 carbazone-methyl is compatible with integrated weed management practices, conservation tillage and conventional crop production systems. As thien carbazone-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 carbazone-methyl via spray drift, buffer zones of 1 to 30 metres (depending on the end-use product and application equipment) are required.

## **Next Steps**

Before making a final registration decision on thien carbazone-methyl, the PMRA will consider all 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 note that, to comply with Canada's international trade obligations, consultation on the proposed MRLs will also be conducted internationally via a notification to the World Trade Organization. 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 thien carbazone-methyl (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

## Thiencarbazone-methyl

### 1.0 The Active Ingredient, Its Properties and Uses

Please refer to ERC2010-03, *Thiencarbazone-methyl*, for a detailed review of the active ingredient, its properties and the uses of these products.

### 2.0 Methods of Analysis

Please refer to ERC2010-03, *Thiencarbazone-methyl*, for a detailed review of the methods of analysis of these products.

### 3.0 Impact on Human and Animal Health

Please refer to ERC2010-03, *Thiencarbazone-methyl*, for a detailed review of the impact on human and animal health of these products.

#### 3.1 Residues in Plant and Animal Foodstuffs

Freezer storage stability data was identified as a condition of registration as presented in ERC2010-03, *Thiencarbazone-methyl*.

Freezer storage stability data were submitted to the PMRA and deemed to be adequate. Residues of thiencarbazone-methyl (BYH 18636) and the metabolites BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside are stable during frozen storage for at least 24 months in corn kernel, corn forage, corn stover, soybean seed, lettuce head, potato tuber and tomato fruit.

#### 3.2 Occupational Exposure

The occupational exposure risk assessment presented in ERC2010-03, *Thiencarbazone-methyl* outlines the current endpoints and has both mixer/loader/applicator and a postapplication risk assessment. However, the occupational risk assessment did not use the Area Treated Per Day (ATPD) values currently supported by PMRA, so an updated risk assessment for ground and aerial application is presented below.

#### Mixer/Loader/Applicator Exposure and Risk Assessment

Individuals have potential for exposure to thiencarbazone-methyl during mixing, loading and application. Dermal and inhalation exposure estimates for workers applying AE1162464 WG63 Herbicide to corn and Velocity Herbicide to wheat were generated from the Pesticide Handlers Exposure Database (PHED), Version 1.1.

Exposure to workers mixing, loading and applying AE1162464 WG63 Herbicide or Velocity Herbicide is expected to be short-term in duration and to occur primarily by the dermal route. Exposure estimates were derived for mixer/loaders/applicators applying AE1162464 WG63 Herbicide to corn using groundboom application equipment and applying Velocity Herbicide to wheat using groundboom or aerial application equipment. The exposure estimates are based on mixers/loaders/applicators wearing long sleeves, long pants, shoes plus socks and chemical resistant gloves during mixing/loading, clean up and equipment repair.

Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day and the dermal absorption value. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 70 kg adult body weight.

Exposure estimates were compared to the toxicological end points (no observed adverse effects levels) to obtain the margin of exposure (MOE); the target MOE is 100.

#### **Exposure and Risk Estimates for Workers Mixing/Loading and Applying AE1162464 WG63 Herbicide to Corn**

Scenario	Exposure (µg/kg bw/day) <sup>a</sup>		MOE <sup>b</sup>		
	Dermal	Inhalation	Dermal	Inhalation	Combined
Farmer, groundboom	2.27	0.020	33 000	3 256 000	32 000
Custom Applicator, ground boom	7.65	0.080	10 000	968 000	10 000

<sup>a</sup> Exposure Estimates =  $\frac{\text{Exposure (µg/kg a.i. handled)} \times \text{Rate (kg a.i./ha)} \times \text{ATPD (ha)}}{\text{bw (70kg)}}$

<sup>b</sup> MOE =  $\frac{\text{NOAEL (74.5 mg/kg bw/day)}^5}{\text{Exposure estimate (mg/kg bw/day)}}$

<sup>5</sup> NOAEL of 74.5 mg/kg bw/day is based on calculi, haemorrhage, inflammatory changes and epithelial hyperplasia in the bladder in a 90-day feeding study in dogs with a 50% absorption factor applied to a NOAEL of 149 mg/kg bw/day.

## Exposure and Risk Estimates for Workers Mixing/Loading and Applying Velocity Herbicide to Wheat

Scenario	Exposure (µg/kg bw/day) <sup>a</sup>		MOE <sup>b</sup>		
	Dermal	Inhalation	Dermal	Inhalation	Combined
Farmer, groundboom	0.64	0.020	116 000	3 808 000	112 000
Custom Applicator, groundboom	2.16	0.066	34 000	1 132 000	33 000
Aerial Mix/load	1.46	0.046	51 000	1 630 000	49 000
Aerial Applicator	0.28	0.002	270 000	37 250 000	286 000

<sup>a</sup> Exposure Estimates =  $\frac{\text{Exposure (µg/kg a.i. handled)} \times \text{Rate (kg a.i./ha)} \times \text{ATPD (ha)}}{\text{bw (70kg)}}$

<sup>b</sup> MOE =  $\frac{\text{NOAEL (74.5 mg/kg bw/day)}^6}{\text{Exposure estimate (mg/kg bw/day)}}$

## Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers re-entering areas treated with AE1162464 WG63 Herbicide or Velocity Herbicide. Given the early crop stage of application, the only contact with treated foliage is expected to occur during early season scouting in low crop heights (i.e. crops with minimal foliage). Given the nature of activities performed, dermal contact with treated surfaces should be minimal. The duration of exposure is considered to be short-term, and the primary route of exposure for workers re-entering treated areas would be through dermal contact with treated foliage.

Dermal exposure to workers entering treated areas is estimated by coupling dislodgeable foliar residue values with activity-specific transfer coefficients. The activity transfer coefficient for wheat is based on data from hoeing in cotton and beans. The activity transfer coefficient for corn is based on data from scouting in sweet corn. Chemical-specific dislodgeable foliar residue data were not submitted. As such, a default dislodgeable foliar residue (DFR) value of 20% of the application rate was used in the exposure assessment.

Exposure estimates were compared to the toxicological end point to obtain the margin of exposure (MOE); the target MOE is 100.

<sup>6</sup> NOAEL of 74.5 mg/kg bw/day is based on calculi, haemorrhage, inflammatory changes and epithelial hyperplasia in the bladder in a 90-day feeding study in dogs with a 50% absorption factor applied to a NOAEL of 149 mg/kg bw/day.

## Postapplication Margin of Exposure on Corn and Wheat

Activity	Transfer Coefficient <sup>a</sup>	Exposure (mg/kg bw/day) <sup>b</sup>	Margin of Exposure <sup>c</sup>
Scouting in minimal foliage wheat	100	0.000114	654 000
Scouting in minimal foliage corn	400	0.000691	361 000

<sup>a</sup> Transfer coefficients are based on Agricultural Re-entry Task Force (ARTF) data. Bayer CropScience is a member of ARTF.

<sup>b</sup> Exposure Estimates:  $\text{DFR } (\mu\text{g}/\text{cm}^2) \times \text{transfer coefficient } (\text{cm}^2/\text{hr}) \times 8 \text{ hour/day worked} \times 100\% \text{ dermal absorption} / 70 \text{ kg body weight}$

<sup>c</sup>  $\text{MOE} = \frac{\text{NOAEL } (74.5 \text{ mg/kg bw/day})^7}{\text{Exposure estimate (mg/kg bw/day)}}$

## 4.0 Impact on the Environment

Please refer to ERC2010-03, *Thiencarbazone-methyl*, for a detailed review of the impact on the environment of these products.

## 5.0 Value

Please refer to ERC2010-03, *Thiencarbazone-methyl*, for a detailed review of the value of these products.

### 5.1 Efficacy on Pests and Crop Tolerance

Value data were identified as a condition of registration for the following tank mixes:

- Velocity + Refine DF + 2,4-D ester in spring wheat without Agral 90.
- Velocity + 2,4-D ester, Velocity + MCPA ester, Velocity + Infinity in durum wheat.

Twenty-one (21) trials were provided to address the conditions of registration for the above tank mixes.

### 5.2 Rotational Crops

Value data were identified as a condition of registration for the following rotational crops:

- chickpeas
- lentils
- timothy

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<sup>7</sup> NOAEL of 74.5 mg/kg bw/day is based on calculi, haemorrhage, inflammatory changes and epithelial hyperplasia in the bladder in a 90-day feeding study in dogs with a 50% absorption factor applied to a NOAEL of 149 mg/kg bw/day.

Twelve (12) trials were provided to address the condition of registration of the above rotational crop.

The conditions of registration for value have been met through the submission of trial data and scientific rationales.

## **6.0 Pest Control Product Policy Considerations**

Please refer to ERC2010-03, *Thiencarbazone-methyl*, for detailed information on the pest control policy considerations of these products.

## **7.0 Summary**

### **7.1 Human Health and Safety**

The toxicology database submitted for thiencarbazone-methyl is adequate to define the majority of toxic effects that may result from exposure to thiencarbazone-methyl. In subchronic and chronic studies on laboratory animals, the primary target was the bladder and kidney. Although there was no evidence of carcinogenicity in rats after longer-term dosing, 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. There was no evidence of increased susceptibility of the young in reproduction or developmental toxicity studies, and thiencarbazone-methyl was not considered to be a neurotoxicant. The risk assessment protects against the toxic effects noted above by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

The nature of the residue in cereals and animals is adequately understood. The residue definition for enforcement is thiencarbazone-methyl for cereals and thiencarbazone-methyl plus the metabolite BYH 18636-MMT in foods of animal origin. The proposed use of thiencarbazone-methyl on corn (field) and wheat does not constitute an unacceptable chronic dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed to recommend maximum residue limits to protect human health.

The freezer storage stability data identified in ERC2010-03, *Thiencarbazone-methyl* were submitted and deemed to be acceptable.

Mixer, loader applicators handling AE1162464 WG63 Herbicide or Velocity Herbicide and workers re-entering corn fields treated with AE1162464 WG63 Herbicide or wheat fields treated with Velocity Herbicide are not expected to be exposed to levels of thiencarbazone-methyl that will result in an unacceptable risk when the AE1162464 WG63 Herbicide and Velocity Herbicide are used according to label directions. The personal protective equipment on the product labels are adequate to protect workers.

## 7.2 Environmental Risk

The solubility of thien carbazone-methyl is moderate at environmentally relevant pH values and exhibits a pH-dependence in water. Thien carbazone-methyl is not expected to bioaccumulate in aquatic organisms, as the log  $K_{OW}$  value is less than 1.0 at environmentally relevant pH values.

Thien carbazone-methyl is not expected to persist in aerobic soil environments but may persist under anaerobic soil conditions. Thien carbazone-methyl is slightly persistent in aerobic aquatic environments but is not expected to persist under anaerobic aquatic conditions. Aerobic soil metabolism and anaerobic aquatic metabolism are the primary routes of transformation of thien carbazone-methyl in the environment. As thien carbazone-methyl residues are non persistent in aquatic systems, prolonged exposure of aquatic organisms to thien carbazone-methyl is unlikely under the proposed use pattern.

Hydrolysis and phototransformation are not expected to be important routes of transformation in the environment.

Thien carbazone-methyl weakly sorbs to soil and its adsorption positively correlates with soil organic matter. Thien carbazone-methyl is moderately to highly mobile and may readily move into surface water through runoff and/or leach into ground water, depending on the permeability and organic matter content of the soil.

Seven major transformation products were identified in the hydrolysis, aerobic and anaerobic soil metabolism, aerobic and anaerobic aquatic metabolism and terrestrial field dissipation studies.

### Risk Characterization:

Risk quotients were calculated using the highest proposed rate of 7.5 g a.i./ha.

Terrestrial organisms: No effects are expected on terrestrial invertebrates, birds or mammals. Risk quotients (EEC/toxicity endpoints) were less than 1 for all species tested.

Non-target terrestrial plants: Risk quotients exceed the level of concern for terrestrial non-target plants.

Aquatic organisms: No effects are expected on aquatic invertebrates, fish, mollusks, freshwater algae or crustaceans as risk quotients were less than 1.

Aquatic plants: Risk quotients exceed the level of concern for aquatic vascular plants.

Based on the risk identified to off-target sensitive habitats, buffer zones are required to protect freshwater and terrestrial habitats - see Measures to Minimize Risk in the Overview.

## **7.3 Value**

### **7.3.1 Velocity Herbicide**

The value data submitted in support of Velocity Herbicide are adequate to describe its efficacy for use in spring and durum wheat. A single post-emergence application of Velocity Herbicide provides control of many weeds in spring and durum wheat, including wild oats, barnyard grass and green foxtail. The submitted phytotoxicity and yield data demonstrate an adequate margin of safety of labelled crops to Velocity Herbicide. Velocity Herbicide also has a flexible re-cropping profile.

The data identified as a condition of registration in ERC2010-03, *Thiencarbazone-methyl*, were submitted and deemed to be acceptable.

### **7.3.2 AE1162464 WG63 Herbicide**

The value data submitted in support of AE1162464 WG63 Herbicide are adequate to describe its efficacy for use in field corn. A single post-emergence application of AE1162464 WG63 Herbicide provides control of redroot pigweed and green foxtail, and suppression of lamb's quarters, in field corn. The submitted phytotoxicity and yield data demonstrate an adequate margin of safety of labelled host crops to AE1162464 WG63 Herbicide.

The data identified as conditions of registration in ERC2010-03, *Thiencarbazone-methyl*, were submitted and deemed to be acceptable.

## **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 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.





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**Appendix I Tables and Figures**

Storage Stability	PMRA# 1798359
<p>Samples of corn kernel, corn forage, corn stover, soybean seed, lettuce head, potato tuber and tomato fruit spiked with thien carbazonemethyl (BYH 18636) and the metabolites BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside at approximately 0.2 ppm were stored at <math>\leq -18^{\circ}\text{C}</math> for a duration of 24 months.</p> <p>The results show that the residues of thien carbazonemethyl and the metabolites BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside were stable during frozen storage for at least 24 months in corn kernel, corn forage, corn stover, soybean seed, lettuce head, potato tuber and tomato fruit.</p>	



## References

### A. List of Studies/Information Submitted by Registrant

#### 1.0 Human and Animal Health

1798359                      2008, Storage stability of BYH18636 and its metabolites BYH18636-N-desmethyl and BYH18636-MMT-glucoside in plant matrices for 24 months, DACO: 7.3

#### 2.0 Value

PMRA 1792565              2009, BYH18636 herbicide (thiencarbazone-methyl) for grassy and broadleaf weed control in spring and durum wheat – Canadian value package, DACO:10, 10.3, 10.3.1, 10.3.2(A), 10.3.3.