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PRD2009-06

## Proposed Registration Decision

# Carfentrazone-ethyl

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# Overview

## Proposed Registration Decision for Carfentrazone-ethyl

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 Aim (Carfentrazone-ethyl) Technical Herbicide and Aim EC containing the technical grade active ingredient carfentrazone-ethyl to control weeds in numerous crops.

Aim (Carfentrazone-ethyl) Technical Herbicide (Registration Number 28572) and Aim EC (Registration Number 28573) are currently conditionally registered in Canada. The detailed review of these products can be found in Evaluation Report ERC2008-05 *Carfentrazone-ethyl*. The purpose of the current applications is to convert Aim (Carfentrazone-ethyl) Technical Herbicide and Aim EC from conditional 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 Aim (Carfentrazone-ethyl) Technical Herbicide and Aim EC.

## 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.

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,

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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."

please visit the Pesticides and Pest Management portion of Health Canada's website at [healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra).

Before making a final registration decision on carfentrazone-ethyl, 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 carfentrazone-ethyl, 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.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

## What Is Carfentrazone-ethyl?

Carfentrazone-ethyl is the active ingredient in Aim EC, a selective herbicide for use as a preplant burndown application in a fallow system or between the rows of a wide range of crops in a hooded sprayer application. Aim EC is also used as a harvest aid treatment to desiccate crops in order to facilitate harvest. One application of Aim EC applied as a broadcast treatment with ground application equipment will control several weeds.

## Health Considerations

### Can Approved Uses of Carfentrazone-ethyl Affect Human Health?

**Carfentrazone-ethyl is unlikely to affect health when used according to label directions.**

Exposure to carfentrazone-ethyl may occur through diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels at which 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 (e.g. 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 the 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 the carfentrazone-ethyl product according to label directions.

Aim EC caused eye and dermal irritation in rabbits. Consequently, the statement "CAUTION—EYE AND SKIN IRRITANT" is required on the product label.

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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*.

When tested in laboratory animals, carfentrazone-ethyl was not oncogenic, genotoxic or neurotoxic. Animal studies also demonstrated that carfentrazone-ethyl had no effects on reproductive toxicity, developmental toxicity, or teratogenicity. There was no evidence carfentrazone-ethyl affected the immune and endocrine systems. The toxicity data did not demonstrate an increased sensitivity of the young to the toxic potential of carfentrazone-ethyl when compared to the adult animals.

## **Residues in Water and Food**

### **Dietary risks from food and water are not of concern.**

The refined chronic dietary exposure from all carfentrazone-ethyl food uses for the total population, including infants and children, and all representative population subgroups ranged from 11.8% to 47.7% of the acceptable daily intake (ADI). Aggregate exposure from food and water is considered acceptable and below the level of concern. The use of carfentrazone-ethyl on crops does not constitute an unacceptable chronic dietary risk (i.e. in food and drinking water) to any segment of the population, including infants, children, adults and seniors.

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.

Supervised residue trials conducted throughout the United States using end-use products containing carfentrazone-ethyl at the proposed rate and exaggerated rates in or on numerous crops are sufficient to support the proposed maximum residue limits. The MRLs for this active ingredient can be found in the Science Evaluation of ERC2008-05.

## **Occupational Risks From Handling Aim EC**

### **Occupational risks are not of concern when Aim EC is used according to the proposed label directions, which include protective measures.**

Farmers and custom applicators who mix, load or apply Aim EC as well as field workers reentering recently treated fields can come in direct contact with carfentrazone-ethyl residues on the skin. Therefore, the label specifies that anyone mixing and loading Aim EC 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, long pants and shoes plus socks. Taking into consideration the label requirements, the expectation that occupational exposure is to be short-term for farmers and intermediate-term for custom applicators, and that the herbicide is applied only once per season, the risk to farmers, applicators or field workers is 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 Carfentrazone-ethyl Is Introduced Into the Environment?**

**Carfentrazone-ethyl poses a potential risk to terrestrial plants, therefore, risk-reduction measures must be observed.**

When carfentrazone-ethyl is applied for control of weeds in crops, some of the active ingredient finds its way into soil and water. Carfentrazone-ethyl, however, is rapidly broken down by soil microbes and by chemical reaction in water. Thus, it is not expected to persist in the environment. Its major transformation products will be present in soil and aquatic systems for a longer period of time. Laboratory studies indicate carfentrazone-ethyl and its transformation products are mobile in soil. However, there is no field evidence that the use of this herbicide will result in groundwater contamination, indicating that leaching in soil is offset by biotransformation processes. Therefore, potential for groundwater contamination would be low.

When carfentrazone-ethyl is used for weed control in crops, there is a potential that non-target plant species on land and in water may be exposed to the chemical as a result of spray drift or runoff. Some plant species are sensitive to carfentrazone-ethyl and would be adversely affected. To minimize the potential exposure, strips of land (buffer zones) between the agricultural field and the non-target terrestrial or aquatic areas will be left unsprayed. Carfentrazone-ethyl presents negligible risk to wild birds and mammals, bees and other arthropods as well as to aquatic organisms like fish, amphibians, invertebrates and plants. The width of these buffer zones will be specified on the product label.

## **Value Considerations**

### **What Is the Value of Aim EC?**

**Aim EC is used for control weeds in numerous crops.**

For the control of several broad leaf weeds, Aim EC may be applied in a fallow system or as a preplant burndown in succulent or dried legume vegetables, fruiting vegetables, cucurbit vegetables, cereal grains, oilseeds and potatoes.

Aim EC may be applied using hooded sprayers between the rows in root and tuber vegetables, bulb vegetables, leafy vegetables, brassica (cole) leafy vegetables, succulent or dried legume, fruiting vegetables, cucurbit vegetables, pome fruits, stone fruits and berries to control several broad leaf weeds.

Aim EC may be applied as a harvest aid treatment to dried shelled peas and beans, potatoes, soybeans, barley, millet, oats, sorghum, triticale and wheat.

Carfentrazone-ethyl is compatible with integrated weed management practices and with conservation tillage and conventional crop production systems. Carfentrazone-ethyl is applied after weed emergence; therefore, growers can better assess whether the herbicide is suitable for the particular weed species present. Carfentrazone-ethyl also provides control of both conventional and glyphosate tolerant volunteer canola.

During the initial value assessment, as presented in ERC2008-05, it was determined that confirmatory data are required to support the list of glyphosate tank mix partners that can be tank mixed with Aim EC in preplant burndown or fallow system applications.

The confirmatory data submitted have been determined to be adequate to satisfy the condition of registration by establishing the equivalence of Roundup Ultra Liquid Herbicide, Roundup Ultra Max Liquid Herbicide, Roundup Weathermax with Transorb 2 Technology Liquid Herbicide, Nufarm Credit Liquid Herbicide and Credit Plus Liquid Herbicide at 450–900 g acid equivalent/ha in tank mix with Aim EC at 8.76–17.52 g a.i./ha in preplant, burndown, hooded or fallow applications.

## **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 Aim EC 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 Aim EC on the skin or through inhalation of spray mists, anyone mixing and loading Aim EC must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes plus socks. Anyone applying the product must wear a long-sleeved shirt and long pants. In addition, standard label statements to protect against drift during application are on the label.

#### **Environment**

Mitigative measures are required to protect sensitive terrestrial and aquatic plant species from the use of carfentrazone-ethyl. These mitigative measures include precautionary statements on the label regarding environmental hazards and the directions for use as well as a 3 m buffer zone to protect sensitive plants from spray drift.



## **Next Steps**

Before making a final registration decision on carfentrazone-ethyl, 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 PMRA 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 carfentrazone-ethyl (based on the Science Evaluation of this consultation document and ERC2008-05). 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

## Carfentazone-ethyl

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

Please refer to ERC2008-05 *Carfentrazone-methyl* for a detailed evaluation of the properties and uses for carfentrazone-ethyl.

### 2.0 Methods of Analysis

Please refer to ERC2008-05 for a detailed evaluation of the methods of analysis for carfentrazone-ethyl.

### 3.0 Impact on Human and Animal Health

Please refer to ERC2008-05 for a detailed evaluation of the impact on human and animal health of carfentrazone-ethyl.

### 4.0 Impact on the Environment

Please refer to ERC2008-05 for a detailed evaluation of the impact on the environment of carfentrazone-ethyl.

### 5.0 Value

#### 5.1 Effectiveness Against Pests

Please refer to ERC2008-05 for a detailed evaluation of the efficacy of Aim EC.

##### 5.1.1 Acceptable Efficacy Claims for Herbicide Tankmixes

During the initial value assessment, as presented in ERC2008-05, it was noted that the submitted efficacy data to support the tank mix of Aim EC plus Roundup Ultra Liquid Herbicide or Roundup Ultra Max Liquid Herbicide or Roundup Weathermax with Transorb 2 Technology Liquid Herbicide or Nufarm Credit Liquid Herbicide or Credit Plus Liquid Herbicide as a preplant burndown application or in a fallow system did not indicate the product name for glyphosate products, i.e. only the term glyphosate was used in all reports. Therefore, confirmatory efficacy data were required to support all the glyphosate product tank-mix options listed above.

The confirmatory data consisted of reports from five (5) efficacy trials which were conducted in 2007 at locations in Ontario, Saskatchewan and Manitoba. The performance amongst the labelled glyphosate tank mix partners of Aim EC was found to be comparable from an efficacy standpoint.

The confirmatory data submitted have been determined to be adequate to satisfy the condition of registration by establishing the equivalence of Roundup Ultra Liquid Herbicide, Roundup Ultra Max Liquid Herbicide, Roundup Weathermax with Transorb 2 Technology Liquid Herbicide, Nufarm Credit Liquid Herbicide and Credit Plus Liquid Herbicide at 450–900 g acid equivalent/ha in tank mix with Aim EC at 8.76–17.52 g a.i./ha in preplant, burndown, hooded or fallow applications.

## **5.2 Phytotoxicity to Host Plants**

Please refer to ERC2008-05 for a detailed evaluation of the phytotoxicity to host plants of Aim EC.

## **5.3 Economics**

Please refer to ERC2008-05 for information on the economics of Aim EC.

## **5.4 Sustainability**

Please refer to ERC2008-05 for information on the sustainability of Aim EC.

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

Please refer to ERC2008-05 for information on the Pest Control Product Policy considerations of carfentrazone-ethyl.

## **7.0 Summary**

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

The toxicology database submitted for carfentrazone-ethyl is adequate to define the toxic effects that may result from human exposure. In short- and long-term toxicity studies in laboratory animals, carfentrazone-ethyl caused systemic toxicity at high dose levels and organ toxicity associated with metabolism and detoxification of orally administered carfentrazone-ethyl. Observed systemic toxicity at high doses included effects on food consumption, body weight and body-weight gain. Organ toxicity invariably involved the liver and the kidneys. One other notable observation was the effect of carfentrazone-ethyl on porphyrin metabolism, which resulted in increased urinary excretion of various porphyrin components. There was no evidence of other toxic effects, including carcinogenicity, mutagenicity, teratogenicity, neurotoxicity, reproductive toxicity or increased susceptibility of the young.

Farmers and custom applicators who mix, load or apply Aim EC and workers reentering treated fields are not expected to be exposed to levels of carfentrazone-ethyl that will result in an unacceptable risk when Aim EC is used according to label directions. The personal protective equipment on the product label is adequate to protect workers.

The nature of the residue in plants and animals is adequately understood. The residue definition for enforcement purposes in plant products is carfentrazone-ethyl and metabolite F8426-Cl-PAc and for risk assessment purposes, the residue definition in plants is carfentrazone-ethyl and metabolites F8426-Cl-PAc, 3-OH-F8426-Cl-PAc, 3-OH-F8426-BAc, F8426-BAc and Me-3-OH-F8426-BAc. The residue definition for enforcement and risk assessment in animal commodities is carfentrazone-ethyl and metabolite F8426-Cl-PAc.

The proposed use of carfentrazone-ethyl on crops does not constitute an unacceptable chronic dietary risk (in 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.

## **7.2 Environmental Risk**

Carfentrazone-ethyl is non-persistent in most soils and water systems, although its transformation products are more persistent than the parent compound. There is a potential that carfentrazone-ethyl may appear in surface water through runoff. The risk assessment of carfentrazone-ethyl indicates there is a potential for adverse effects on non-target terrestrial and aquatic plants. To reduce the effects of carfentrazone-ethyl in the environment, mitigation in the form of precautionary label statements and buffer zones are required. Carfentrazone-ethyl presents negligible risk to wild birds and mammals, bees and other arthropods as well as to aquatic organisms like fish, amphibians and invertebrates.

## **7.3 Value**

The data submitted to register Aim EC are adequate to describe its efficacy for use as a preplant burndown application for numerous crops in a fallow system, between the rows of a wide range of crops or as a harvest aid treatment. A single postemergence application of Aim EC provides control of several broadleaf weeds.

The confirmatory data submitted to address the conditional registration of Aim EC Herbicide when tankmixed with glyosate products have been determined adequate to satisfy the condition of registration by establishing the equivalence of Roundup Ultra Liquid Herbicide, Roundup Ultra Max Liquid Herbicide, Roundup Weathermax with Transorb 2 Technology Liquid Herbicide, Nufarm Credit Liquid Herbicide and Credit Plus Liquid Herbicide at 450–900 g acid equivalent/ha in tank mix with Aim EC at 8.76–17.52 g a.i./ha in preplant, burndown, hooded or fallow applications.

## 8.0 Proposed Regulatory Decision

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 Aim (Carfentrazone-ethyl) Technical Herbicide and Aim EC containing the technical grade active ingredient carfentrazone-ethyl to control weeds in numerous crops.

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.

## List of Abbreviations

a.i.	active ingredient
g	gram
ha	hectare(s)
MRL	maximum residue limit
PMRA	Pest Management Regulatory Agency



## References

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

#### 1.0 Value

**PMRA Document Number** 1510087

**Reference** 2007, 10.1 Summaries - Tank Mixes of Aim + Glyphosate Formulations, N/A, MRID: N/A, DACO: 10.1

**PMRA Document Number** 1510097

**Reference** 2007, 10.2.3.1 Summary, N/A, MRID: N/A, DACO: 10.2.3.1

**PMRA Document Number** 1510098

**Reference** 2007, Aim + Glyphosate Formulations - Summary Tables Efficacy Data, N/A, MRID: N/A, DACO: 10.2.3.1 CBI

**PMRA Document Number** 1510099

**Reference** 2007, Aim + Glyphosate Formulations - Frequency Distribution, N/A, MRID: N/A, DACO: 10.2.3.1