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revised

Re-evaluation Decision

Propyzamide

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
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

Canada 

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Re-evaluation Decision

After a re-evaluation of the herbicide propyzamide, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing propyzamide for sale and use in Canada.

An evaluation of available scientific information found that products containing propyzamide do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of propyzamide uses, new risk-reduction measures must be included on the labels of all products. Additional data are being requested as a result of this re-evaluation.

The regulatory approach for the re-evaluation of propyzamide was first presented in Proposed Re-evaluation Decision PRVD2008-20, *Propyzamide*, a consultation document.¹ This Re-evaluation Decision² describes this stage of PMRA's regulatory process for the re-evaluation of propyzamide as well as summarizes the Agency's decision and the reasons for it. Appendix I summarizes the comments received during the consultation process and provides the PMRA's response to these comments. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-20. To comply with this decision, registrants of products containing propyzamide will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Propyzamide, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents.

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*.

For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of propyzamide. In this decision, the PMRA took into account the Canadian use pattern and issues (for example the federal Toxic Substances Management Policy).

The USEPA re-evaluated propyzamide and published its conclusions in a 1995 RED and in a 2002 Tolerance Reassessment Eligibility Decision (TRED) document.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2008-20, *Propyzamide*.

What Is Propyzamide?

Propyzamide is a herbicide used to control weeds in: established ornamentals (i.e. iris, peony, ground covers [except *Vinca minor*] and coniferous trees and shrubs); ornamental nursery stock (container-grown coniferous trees and shrubs, in British Columbia only); established grass pastures or grass/legume (alfalfa, trefoil) pastures; alfalfa and trefoil grown for seed; apples, pears, lowbush blueberries, lettuce (direct seeded or transplanted) and strawberries (in the Maritimes and British Columbia only).

Propyzamide is applied in outdoor areas by farm workers and professional applicators using a groundboom sprayer or a low-pressure handwand sprayer.

Health Considerations

Can Approved Uses of Propyzamide Affect Human Health?

Propyzamide is unlikely to affect your health when used according to the revised label directions.

People could be exposed to propyzamide by consuming food and water, by working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: 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 (for example children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that propyzamide is unlikely to affect human health provided that risk-reduction measures are implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of 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*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Propyzamide is currently registered in Canada for use on alfalfa, apples, lowbush blueberries, lettuce, pears, strawberries and trefoil and could be used in other countries on crops that are imported into Canada. An MRL for propyzamide and its metabolites containing the 3,5-dichlorobenzoyl moiety and calculated as 3,5-dichloro-N-(1,1-dimethyl-2-propynyl) benzamide has been established for lettuce at 1 ppm.

Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Propyzamide Is Introduced Into the Environment?

Propyzamide is unlikely to affect non-target organisms when used according to the revised label directions.

Non-target organisms (for example birds, mammals, insects, aquatic organisms and terrestrial plants) could be exposed to propyzamide in the environment. To assess the ecological effects of propyzamide, the USEPA used expected environmental concentrations and maximum expected residues immediately after application and compared them to the lethal concentration to 50% (LC₅₀) for the various species.

The USEPA concluded that the reregistration of propyzamide was acceptable provided additional risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are also required. Furthermore, to protect terrestrial plants from spray drift the PMRA will require terrestrial buffer zones for propyzamide.

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. As a result of the re-evaluation of propyzamide, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect mixers/loaders/applicators
- A restricted-entry interval to protect workers from prematurely re-entering treated sites
- A plantback interval to ensure minimal residues in rotational crops

Environment

- Additional advisory label statements for the protection of surface water and groundwater sources
- Buffer zones to protect non-target, sensitive terrestrial habitats

Appendix II lists the required label amendments.

What Additional Scientific Information Is Requested?

See Appendix III.

Other Information

Any person may file a notice of objection³ regarding this decision on propyzamide within 60 days from the date of publication of this Re-evaluation 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 Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

³ As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1.0 Comments on the Buffer Zones

1.1 Comment

Propyzamide is an important herbicide used in the Atlantic region to control weeds and grasses in low-bush blueberry fields. For small fields surrounded by woodland, proposed buffer zones will render these [small] fields useless.

Response

It should be recognized that buffer zones are required only if sensitive habitats are downwind from the point of application. Buffer zones are not required when sensitive habitats are upwind from the application area and, if necessary, a previously unsprayed area could be sprayed at another time under favourable meteorological conditions.

For field sprayer application, buffer zones can be reduced by using drift reducing spray shields. When using a spray boom fitted with a full shield (i.e. a shroud, curtain) that extends to the crop canopy or ground, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy or ground, the labelled buffer zone can be reduced by 30%.

Also, the PMRA has released Regulatory Proposal PRO2005-06, *Agricultural Buffer Zone Strategy Proposal*, for stakeholder comments outlining buffer zone reduction strategies based on meteorological and equipment factors. The PMRA is currently working on finalizing this policy which will allow applicators more flexibility when applying pesticides.

1.2 Comment

Examples of sensitive terrestrial habitats include registered use patterns. For example, established pastures are registered use-pattern and grasslands are included as a sensitive terrestrial habitat. There is a need for clarification of instructions in regard to sensitive habitats.

Response

The PMRA does not consider pastures or livestock grazing lands to be included under the definition of sensitive habitats for grasslands. These have been identified as forage lands, which are often treated with herbicides to maintain desirable forage species. The PMRA is in the process of developing a best management practices booklet for agricultural spraying practices that will further clarify definitions of sensitive habitats and when and how to observe buffer zones around them.

Appendix II Label Amendments for Products Containing Propyzamide

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following statements must be included in the **PRECAUTIONS** section:

Wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks during mixing, loading and application. In addition, wear a chemical-resistant apron when cleaning equipment, mixing or loading.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 24 hours.

It is recommended that this product not be applied in a way that will contact workers or other persons, either directly or through drift. Only handlers wearing personal protective equipment may be in the area during application.

II) The following statements must be included in the **DIRECTIONS FOR USE** section:

Rotational crops: Observe a plantback interval of 30 days for leafy vegetables (except Brassica vegetables), 90 days for root and tuber vegetables and 360 days for all other crops.

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

Buffer zones:

Use of the following spray methods or equipment DO NOT require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands).

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:
		Terrestrial habitat
Field sprayer*	Established grass pastures, established grass/legume (alfalfa, trefoil) pastures, alfalfa grown for seed, trefoil grown for seed, strawberries, lettuce, established ornamentals	5
	Lowbush blueberries, apples, pears	10

* For field sprayer application, buffer zones can be reduced by using drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

III) The following statements must be included in the **ENVIRONMENTAL HAZARDS** section:

TOXIC to non-target terrestrial plants. Observe buffer zones specified under **DIRECTIONS FOR USE**.

DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), estuarine/marine habitats.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g. sandy soil) and/or the depth to the water table is shallow.

To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

Appendix III Additional Data

I) For the PMRA to refine occupational risk:

- DACO 4.3.5 Short-term Dermal (21/28-day)
- DACO 4.3.7 Short-term Inhalation (21/28-day)
- DACO 5.8 Dermal absorption study (in vivo)

II) For the PMRA to confirm aquatic buffer zones:

- DACO 9.3.3 Non-target Freshwater Invertebrate; *Daphnia sp.* Chronic (Life-Cycle)
- DACO 9.8.2 Fresh Water Algae (*Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom)
- DACO 9.8.5 Non-target Plants – Aquatic Vascular Plants (*Lemna gibba*)

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number 1564292

Reference Technical Chemistry for KRB-DCE-1. Kerb 50-W Active Ingredient Specifications, Analysis of Kerb Wet Cake, Test Method 1-4, 2-5, and 203-2., DACO: 2.99.

PMRA Document Number 1564367

Reference Technical Chemistry file KRB-DCE-1., DACO: 2.1, 2.10, 2.11.1, 2.12.2, 2.13.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9.

PMRA Document Number 1564287

Reference Technical Chemistry for KRB-DCE-1. Response to Outstanding Product Chemistry Requirements, Appearance Samples, Propyzamide (Pure) Spectral Data, Aqueous Solubility Conducted in Germany, Solubility in Organic Solvents., DACO: 2.14.

PMRA Document Number 1564275

Reference 1994, Technical Chemistry for KRB-DCE-1. Submitted for the purpose of verifying the change in the production site of Kerb.