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RVD2008-03

Re-evaluation Decision

Metalaxyl and Metalaxyl-M

(publié aussi en français)

30 January 2008

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

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ISBN: 978-0-662-47716-7 (978-0-662-47717-4)
Catalogue number: H113-28/2008-3E (H113-28/2008-3E-PDF)

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Table of Contents

Overview	1
Re-evaluation Decision	1
What Does Health Canada Consider When Making a Re-evaluation Decision?	1
What Are Metalaxyl (the racemic mixture) and Metalaxyl-M (the R-enantiomer)?	2
Health Considerations	2
Environmental Considerations	4
Measures to Minimize Risk	4
What Additional Scientific Information Is Required?	5
Other Information	5
Appendix I Comment and Response	6
Appendix II Current Canadian Registered Products Containing Metalaxyl and Metalaxyl-M as of 1 January 2008	7
Appendix III Label Amendments for Products Containing Metalaxyl (racemic mixture) and Metalaxyl-M (R-enantiomer)	9
Appendix IV Revised Data Requirements	12

Overview

Re-evaluation Decision

After a re-evaluation of the fungicide metalaxyl (the racemic mixture) and metalaxyl-m (the R-enantiomer), Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the [Pest Control Products Act](#) and Regulations, is granting continued registration for the sale and use of products containing the racemic mixture and R-enantiomer in Canada.

An evaluation of available scientific information found that products containing the racemic mixture and R-enantiomer 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 racemic mixture and R-enantiomer 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 metalaxyl and metalaxyl-m was first presented in Proposed Re-evaluation Decision document [PRVD2007-10](#), *Re-evaluation of Metalaxyl and Metalaxyl-M*, a consultation document.¹ This Re-evaluation Decision document² describes this stage of PMRA's regulatory process for the re-evaluation of metalaxyl and metalaxyl-m 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. This decision is consistent with the proposed re-evaluation decision stated in PRVD2007-10. To comply with the decision, registrants of products containing metalaxyl and metalaxyl-m will be informed of the specific requirements affecting their product registration(s) and of 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.

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*.

Metalaxyl racemic mixture and R-enantiomer, two of the active ingredients in the current re-evaluation cycle, have 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. 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 re-evaluation 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 will propose a re-evaluation decision and appropriate risk-reduction measures for uses of an active ingredient in Canada. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy).

The USEPA re-evaluated the racemic mixture and R-enantiomer, and conclusions of this re-evaluation are published in a 1994 RED. In addition, an aggregate risk assessment was published in 2001 in the Federal Register.

What Are Metalaxyl (the racemic mixture) and Metalaxyl-M (the R-enantiomer)?

The racemic mixture and R-enantiomer are systemic fungicides used to control plant diseases caused by water-mould fungi (*Oomycetae*) in field and greenhouse food and feed crops (including seed treatment) as well as nursery outdoor and greenhouse non-food crops (including conifers, ornamentals and turf).

Appendix II lists all products containing the racemic mixture and R-enantiomer of metalaxyl that are registered under the authority of the *Pest Control Products Act*.

Health Considerations

Can Approved Uses of the Metalaxyl Racemic Mixture and R-enantiomer Affect Human Health?

Additional risk-reduction measure statements are required on the racemic mixture and R-enantiomer labels. The racemic mixture and R-enantiomer are not likely to affect human health when used according to revised label directions.

People could be exposed to the racemic mixture and R-enantiomer by consuming food and water, 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 (e.g. 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 the racemic mixture and R-enantiomer were unlikely to affect human health provided that risk-reduction measures were 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/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

The metalaxyl racemic mixture and R-enantiomer are currently registered in Canada for use on seed (alfalfa, barley, bean, beet, canola, chickpea, clover, forage grasses, turf grasses, lentil, oat, pea, rapeseed, rye, sainfoin, sorghum, sunflower, trefoil, vetch and wheat), non-bearing apple, bean, blueberry, carrot, cucumber, ginseng, grape, hop, lettuce, onion, potato, raspberry, strawberry, tobacco, ornamentals, conifers and turf. The racemic mixture and R-enantiomer could be used in other countries on crops that are imported into Canada.

In Canada, MRLs for metalaxyl and metalaxyl-m have been established for the following commodities:

- green onions and spinach at 10 ppm;
- asparagus at 7 ppm;
- citrus fruits, endives and lettuce at 5 ppm;
- avocados at 4 ppm;
- ginseng and dry onions at 3 ppm;
- blueberry, broccoli, cabbage, cauliflower and raisins at 2 ppm;
- apricot, cantaloupe, cherry, cucumber, grape, peach/nectarine, peppers, plum, soybean, squash, sugar beet molasses, tomato and watermelon at 1 ppm;
- almond, carrot, potato, radish and walnut at 0.5 ppm;
- strawberry at 0.4 ppm;
- beans, peanut, pea, raspberry and wheat at 0.2 ppm; and
- barley at 0.05 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 the Metalaxyl Racemic Mixture and R-enantiomer Are Introduced Into the Environment?

The racemic mixture and R-enantiomer are unlikely to affect non-target organisms when used according to revised label directions. Additional risk-reduction measures are required on the racemic mixture and R-enantiomer labels.

Non-target organisms (e.g. birds, mammals, insects, aquatic organisms and terrestrial plants) may be exposed to the racemic mixture and R-enantiomer in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the expected environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistrations of the metalaxyl racemic mixture and R-enantiomer were acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of the racemic mixture and R-enantiomer, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- To protect mixer/loader/applicators: additional protective equipment
- To protect workers re-entering treated sites: a restricted-entry interval

Environment

- To reduce potential surface and groundwater contamination: additional advisory label statements

Appendix III lists all required label amendments, including instructions related to basic hygiene practices.

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under section 12 of the *Pest Control Products Act*. The registrants of metalaxyl and metalaxyl-m must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter.

Appendix IV lists all data requirements.

Other Information

Any person may file a notice of objection³ regarding this decision on metalaxyl and metalaxyl-m 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 PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), 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 Comment and Response

1.0 Comment on data requirement:

One registrant requested clarification on the requirement for non-target terrestrial plant studies for seed treatment uses.

Response: Non-target terrestrial plant studies are not required for seed treatment uses.

Appendix II Current Canadian Registered Products Containing Metalaxyl and Metalaxyl-M as of 1 January 2008

Reg. No.	Marketing Class	Registrant	Product Name	Guarantee (% a.i.)	Formulation Type
METALAXYL PRODUCTS					
26644	Technical	Bayer CropScience Inc.	Gustafson Metalaxyl Technical	97	Dust
24262	Commercial	Bayer CropScience Inc.	Apron FL Seed Treatment	317 g/L (28.1%)	Suspension
26674	Commercial	Bayer CropScience Inc.	Allegiance FL Seed Treatment	317 g/L (28.1%)	Suspension
27564	Commercial	Bayer CropScience Inc.	Prosper FL Insecticide and Fungicide Seed Treatment	4 g/L (0.04%)	Suspension
27692	Commercial	Bayer CropScience Inc.	Raxil MD Fungicide	6.6 g/L (0.06%)	Suspension
METALAXYL-M PRODUCTS					
25372	Technical	Syngenta Crop Protection Canada Inc.	Metalaxyl-M Technical	97%	Liquid
25379	Commercial	Syngenta Crop Protection Canada Inc.	Ridomil Gold MZ 68WP	4%	Wettable powder
25384	Commercial	Syngenta Crop Protection Canada Inc.	Ridomil Gold 480EC	480 g/L (42.6%)	Emulsifiable concentrate
25419	Commercial	Syngenta Crop Protection Canada Inc.	Ridomil Gold MZ 68WP Water Soluble Bag	4%	Wettable powder
25585	Commercial	Syngenta Crop Protection Canada Inc.	Apron XL LS	33.3%	Suspension
25777	Commercial	Syngenta Crop Protection Canada Inc.	Dividend XL RTA Fungicide	0.27%	Suspension
25778	Commercial	Syngenta Crop Protection Canada Inc.	Dividend XL	1.38%	Suspension
26443	Commercial	Syngenta Crop Protection Canada Inc.	Ridomil Gold/Bravo Twin-Pak	480 g/L (42.6%)	Suspension
26612	Commercial	Syngenta Crop Protection Canada Inc.	Ridomil Gold 1G	1%	Granule
26637	Commercial	Syngenta Crop Protection Canada Inc.	Helix Liquid Seed Treatment	0.39%	Solution
26638	Commercial	Syngenta Crop Protection Canada Inc.	Helix Xtra Seed Treatment	0.39%	Solution

Reg. No.	Marketing Class	Registrant	Product Name	Guarantee (% a.i.)	Formulation Type
27055	Commercial	Syngenta Crop Protection Canada Inc.	Subdue MAXX	240 g/L (21.3%)	Emulsifiable concentrate
27071	Commercial	Syngenta Crop Protection Canada Inc.	Maxim XL Seed Treatment Fungicide	8.4%	Solution
27307	Commercial	Syngenta Crop Protection Canada Inc.	Helix Xtra Colourless Seed Treatment	0.39%	Solution
27312	Commercial	Syngenta Crop Protection Canada Inc.	Helix Colourless Seed Treatment	0.39%	Solution
27577	Commercial	Syngenta Crop Protection Canada Inc.	Apron MAXX RTA	1.10%	Ready-to-use liquid
27650	Commercial	Syngenta Crop Protection Canada Inc.	Tribune Seed Treatment Fungicide	0.51%	Ready-to-use liquid
28474	Commercial	Syngenta Crop Protection Canada Inc.	Ridomil Gold 480SL Fungicide	480 g/L (42.6%)	Solution
28817	Commercial	Syngenta Crop Protection Canada Inc.	Apron MAXX REC Seed Treatment Fungicide	3.46%	Suspension
28821	Commercial	Syngenta Crop Protection Canada Inc.	Cruises MAXX Beans Seed Treatment	1.70%	Suspension

Appendix III **Label Amendments for Products Containing Metalaxyl (racemic mixture) and Metalaxyl-M (R-enantiomer)**

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

The following statements must be included in the section entitled **DIRECTIONS FOR USE**.

Do not apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats.

Do not contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

The following statements must be included in the section entitled **DIRECTIONS FOR USE** for products used on field crops, except those having a granular formulation.

- for airblast application:

Do not apply during periods of dead calm. Avoid application of this product when winds are gusty. Do not direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. Do not apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

- for aerial application:

Do not apply during periods of dead calm. Avoid application of this product when winds are gusty. Do not apply when wind speed is greater than 16 km/h at flying height at the site of application. Do not apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification.

- for 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) classification.

- for all labels with field applications:

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

The following statements must be included in the section entitled **PRECAUTIONS**.

- for all end-use products:

Do not apply in a way that this product will contact workers or other persons, either directly or through drift. Only handlers (mixers, loaders and applicators) wearing personal protective equipment may be in the area being treated during application.

- for products with seed treatment uses:

Wear a suitable dust mask when bagging or sewing bags of treated seed or when transferring seed to a storage bin.

All bags containing treated seed for sale or use in Canada must be labelled or tagged as follows: "This seed has been treated with [product name] fungicide containing [metalaxyl or metalaxyl-m]. Use chemical-resistant gloves when handling treated seed.

- for all products with foliar application (conifers, ornamentals, grape, ginseng, lettuce, onion and potato):

Do not enter or allow worker entry into treated areas for 24 hours following application.

- for all products with soil drench application:

Do not enter or allow worker entry into treated areas for 12 hours following application.

- for all products with food and/or feed uses:

If this pest control product is to be used on a commodity that may be exported to the United States and you require information on acceptable residue levels in the United States, contact 1-866-375-4648 or www.croplife.ca.

The following statements must be included in the **ENVIRONMENTAL HAZARDS** section.

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

To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to, heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g. compacted or fine-textured soils such as clay).

Avoid application of this product when heavy rain is forecast.

The label amendments presented above 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 above label statements. Based on basic hygiene and for label consistency, chemical-resistant gloves must be added to the list of personal protective equipment for mixing, loading, application, clean-up and repair activities for end-use products having the granular formulation and applied by groundboom equipment.

Appendix IV Revised Data Requirements

The following data are required as a condition of continued registration under section 12 of the *Pest Control Products Act*. The registrants of metalaxyl-m (R-enantiomer) are required to provide these data within the timeline specified in the decision letter the PMRA will send.

- DACO 9.8.4: Terrestrial Vascular Plants–Seedling Emergence (USEPA OPPTS 850.4100 guideline) and Vegetative Vigour (USEPA OPPTS 850.4150 guideline). These studies must be conducted according to the appropriate OPPTS guidelines.