Registration Decision RD2018-01

Tioxazafen and MON 102133 SC Nematicide Seed Treatment

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Registration Decision Statement[1] for Tioxazafen

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of MON 102100 Technical and MON 102133 SC Nematicide Seed Treatment, containing the technical grade active ingredient tioxazafen, to suppress certain soil-inhabiting nematodes in field corn and soybeans.

This decision is consistent with the Proposed Registration Decision PRD2017-10, *Tioxazafen and MON 102133 SC Nematicide Seed Treatment* which contains a detailed evaluation of the information submitted in support of this registration. The evaluation found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment. See Appendix I for a summary of comments received during the consultation process as well as the PMRA's response to these comments.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2017-10, *Tioxazafen and MON 102133 SC Nematicide Seed Treatment* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[2] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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1 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

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

Appendix I Comments and Responses

1. **Comment**

Commenter indicated two statements on the end-use product label appear to be contradictory and therefore should be amended.

Under Section 8 (Application Instructions and Use Limitations), the sub-section on the Crop Rotation section of the label, the current statement is:

"Crops listed on this label (i.e., field corn and soybean NOT treated with Tioxazafen) may be replanted at any time. For all other crops, a 30 day plant-back interval must be observed."

The commenter proposes to delete the phrase "(i.e., field corn and soybean NOT treated with Tioxazafen)" from the Section 8 statement as this appears to contradict a statement under Section 5 (Environmental Precautions).

Response

Based on the results of the crop rotation study during which quantifiable residues (combined tioxazafen + benzamidine; residue definition) were found in the rotational crop commodities of lettuce leaves and radish tops, the following crop rotation statement was put on the end use product label:

"Crops listed on this label (i.e. field corn and soybean NOT treated with Tioxazafen) may be planted at any time. All other crops may be planted after 30 days."

The commenter indicated the crop rotation statement appeared to be contradictory to the label statements under Section 5 (Environmental Precautions) which is: "**Tioxazafen is persistent and may carryover. It is recommended that any products containing tioxazafen not be used in areas where they were used during the previous season."**

As such, deletion of the phrase "(i.e. field corn and soybean NOT treated with Tioxazafen)." from the crop rotation statement in Section 8 can be supported from the food residues perspective.

2. **Comment**

Commenter provided a rationale to support deleting the following label statement from the end use product label which appears under both Section 5 (Environmental Precautions) and Section 8 (Application Instructions and Use Limitation) of the label:

“Tioxazafen is persistent and may carryover. It is recommended that any products containing tioxazafen not be used in areas where they were used during the previous season.”

Response

A comment was received requesting to reconsider the presence of a carryover statement on the product label, as only the Manitoba field trial data was considered in determining persistence. The commenter stated that the following should also be considered when determining if the carryover statement is required: there is limited crop/plant uptake of tioxazafen from soil, the environmental fate characteristics show that tioxazafen sorbs strongly to soil, is a non-leacher, and does not move toward groundwater and the calculated soil accumulated concentration modeling indicates that environmental risk thresholds from potential exposure to tioxazafen are not exceeded for continuous annual product use (based on toxicity to earthworm).

The use of an advisory label statement to inform users of the potential for carryover of the active ingredient and to recommend limiting the use of a product to every other year is based on its observed persistence in soil under field conditions. The advisory label statement is not based on mobility, the potential for uptake by plants, or environmental risk. The statement is added to labels for all pesticides when 30% or more of the applied parent compound remains after one season of use in a terrestrial field dissipation study.

Several field dissipation studies were provided, but only two studies were conducted in ecoregions relevant to Canada (Illinois and Manitoba; Level II ecoregions 8.2, and 9.2, respectively). As indicated in PRD2017-10, >30% carryover was observed at the site in Manitoba (39-41% was measured 349-388 days after it was applied), and no carryover was observed at the site in Illinois. The presence of carryover in one of the two Canadian-relevant field studies is an indication that carryover can be expected under some conditions of use in Canada. Considering the Canadian ecological diversity (encompassing fifteen ecoregions), the absence of carryover at a single site (one ecoregion) cannot be considered sufficient data to remove the advisory label statement.

Therefore the label statement:

“Tioxazafen is persistent and may carryover. It is recommended that any products containing tioxazafen not be used in areas where they were used during the previous season.”

will remain on the end use product label.