

Re-evaluation Decision Document

RRD2006-02

Triclopyr

The purpose of this Re-evaluation Decision Document (RRD) is to notify registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated the active ingredient triclopyr and its associated uses as a herbicide on pastures, rangeland, non-crop areas, woodland management sites, forest management areas and lowbush blueberry site preparation areas.

On 22 September 2004, Proposed Acceptability for Continuing Registration (PACR) document <u>PACR2004-37</u>, *Re-evaluation of Triclopyr*, was published for consultation. The PMRA has reviewed the comments received and provides responses in Appendix I of this RRD. These comments did not result in substantive changes to the regulatory decision as described in PACR2004-37.

The PMRA has determined that triclopyr is acceptable for continued registration. Mitigation measures to further protect workers and the environment are specified in this RRD (Appendix II). The registrants have been informed by letter of the specific requirements affecting their product registrations and the regulatory options available to comply with this decision.

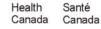
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Appendix I Comments and Responses to PACR2004-37

1.0 Comments on the Use Rate

The PMRA is proposing to reduce the maximum application rate for rangeland and pasture uses to 1.12 kg a.e.¹/ha per growing season. This rate is based on the United States Environmental Protection Agency's recommendation to limit the application rate to 1 lb a.e./acre presented in a 1998 Reregistration Eligibility Decision (RED). The registrant indicated that the United States Environmental Protection Agency (USEPA) has recently increased the tolerance (the maximum residue limit) to allow a 2 lb a.e./acre (2.24 kg a.e./ha) maximum application rate. Therefore, the registrant requested the PMRA to allow the same maximum use rate for pastures and rangelands.

Response

The PMRA has reviewed the USEPA's new decision allowing a maximum application of 2 lb a.e./acre (2.24 kg a.e./ha) for pastures and rangelands (Federal Register, August 2005). Given the similarities in the American and Canadian use patterns, the PMRA will allow the maximum application rate of 2.24 kg a.e./ha triclopyr, with one application per growing season on rangelands, pastures and sites where cattle can be grazed.

2.0 Comments on the Proposed Restricted Entry Statement

The PMRA recommended the following restricted entry interval (REI):

• "Do not enter or allow worker entry into treated areas within 12 hours of application."

The registrant claimed that a 12-hour REI is not practical in an outdoor situation. It would seriously impact several important uses such as basal bark and cut stump treatments where the applicator has to walk through the treatment area and apply the herbicide to individual trees. There is no broadcast spray application involved. In addition, the label statements on the American end-use products do not have an REI for these forestry uses.

Response

The USEPA required the 12-hour REI for broadcast applications, but not for the use on basal bark and for cut stump treatments. The PMRA concurs; consequently, the label statement regarding the REI will be modified as follows:

• "For broadcast treatment, do not enter or allow worker entry into treated areas during a restricted entry interval (REI) of 12 hours."

a.e. = acid equivalent

3.0 Comments on the Preharvest Interval and Grazing Restriction

The PMRA recommended a 14-day preharvest interval for grass hay and a restriction against grazing lactating dairy cattle until the next growing season.

The registrant claimed that this requirement differs from the statements approved by the USEPA for the American triclopyr labels. On the American labels, grazing and haying restrictions are related to the application rate, which is not the case with the statement being proposed by the PMRA. The registrant requested the PMRA to harmonize its recommended grazing and haying label statements with those on the American labels.

Response

According to the American labels verified by the PMRA, these having and grazing restrictions were implemented for some American products. Based on this, the PMRA continues to require a 14-day preharvest interval for grass hay and a restriction against grazing lactating dairy cattle until the next growing season. However, the PMRA will consider adequate data or a science-based rationale submitted in support of any alternative restrictions for grass hay and grazing.

4.0 Comments on the Proposed Statement Regarding Use in Residential Areas

The PACR recommended the following statement to the use directions:

• "Do not use in residential areas. Residential areas are defined as sites where bystanders including children may be potentially exposed during or after spraying. This includes around homes, schools, parks, playgrounds, playing fields, public buildings or any other areas where the general public, including children, could be exposed."

The registrant claimed that this statement is too broad and can be interpreted in different ways: individuals can "potentially" be exposed anywhere along a roadway, field or off-road area. Also, there is no time-line attributed to this statement, and the wording needs to be very specific to avoid confusion.

The registrant commented that recommended buffer zones would adequately protect residential areas without additional statements, that triclopyr products are commercial/industrial products approved for agricultural, industrial and forestry use patterns and that these products are not intended for residential use.

Response

Although triclopyr is not intended for use in residential areas, the use sites presented on the end-use product labels, e.g., rights-of-way, may result in application in residential areas; thus, use of triclopyr may result in potential bystander exposure. The statement "Do not use in residential areas [...]" is a standard statement used by the PMRA for this use pattern and is consistent with other Canadian labels. Consequently, the PMRA continues to require this statement to ensure that bystander exposure to triclopyr remains minimal.

Note that buffer zones are required to protect sensitive terrestrial and aquatic habitats and not bystanders.

5.0 Comments on the Groundwater Contamination Statement

The statement concerning groundwater contamination is worded in the PACR as follows:

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

The registrant claimed that the above statement is not correct. The USEPA groundwater advisory statement on the American label is as follows:

• "This chemical has properties and characteristics associated with chemicals detected in groundwater. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination."

The registrant requested the PMRA to use the same statement recommended in the RED.

Response

The groundwater advisory statement recommended by the PMRA is considered equivalent to the one recommended for American labels in the RED for triclopyr. For consistency among Canadian labels, the PMRA continues to require the standard groundwater advisory label statement, as stated in the PACR.

Appendix II Label Amendments for Triclopyr

NOTE: 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 above label statements.

Canadian end-use product labels must be amended to further protect the human health and the environment, as follows:

- Under the section entitled "PRECAUTIONS", the following statements must be included:
 - "For broadcast treatment, do not enter or allow worker entry into treated areas during a restricted entry interval (REI) of 12 hours."
 - "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."
 - "Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet."
- The section entitled "ENVIRONMENTAL HAZARDS" must include the following statement:
 - "The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g., sandy soil) and/or where the depth to the water table is shallow."
- The section entitled "DIRECTIONS FOR USE" must include the following:
 - "Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and parks is minimal."
 - "Do not use in residential areas. Residential areas are defined as sites where bystanders including children may be potentially exposed during or after spraying. This includes around homes, schools, parks, playgrounds, playing fields, public buildings or any other areas where the general public, including children, could be exposed."
 - a maximum rate of 2.24 kg a.e./ha and only one application per growing season for use on ranges, pastures and sites where cattle can be grazed;
 - a 14-day preharvest interval for grass hay; and

- a restriction against grazing lactating dairy cattle until the next growing season.
- The following statement must be added to the label of Garlon 3A Integrated Formulation Product (manufacturing concentrate; Registration Number 25842):
 - "POTENTIAL SKIN SENSITIZER"