



Regulatory Proposal

PRO2003-02

Data Requirements and Labelling for Oilseed Oriental Mustard [*Brassica juncea* (L.)]

This regulatory proposal is to inform registrants that the data requirements for a label claim for use of a pesticide on oilseed oriental mustard varieties are the same as those for a claim for any other oilseed, e.g., canola, and are different from the data required to support the registration of a pesticide for use on condiment mustard. For this reason, labels for both currently registered products and new products must clearly identify whether they are registered for condiment oriental mustard or oilseed oriental mustard, or both.

This proposal is being distributed for information and comment. Please provide your written comments to the Publications Coordinator within 45 days of the date of this regulatory proposal.

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1.0 Summary

Oriental mustard (*Brassica juncea* L.) varieties have traditionally been commercially grown in Canada for condiment use only. Additional varieties of oriental mustard have now been developed specifically as an oilseed crop. Data specific to oilseed crops are required to support the addition of a use on oilseed oriental mustard varieties to existing control product labels.

The terminology on most of the labels of pesticide products currently registered for use on oriental mustard is very general, i.e., mustard or oriental mustard. There is no information to indicate that this refers to condiment mustard as opposed to oilseed mustard.

Effective immediately, labels of currently registered products which refer only to mustard or oriental mustard will be interpreted to refer to condiment use only and will be legitimate only for that use.

Effective December 31, 2004 all labels must clearly specify whether the product is registered for condiment oriental mustard or oilseed oriental mustard, or both.

Labels of currently registered products which are really intended for use on condiment oriental mustard only, but which only specify mustard or oriental mustard, may be changed at the time of any other amendments, at renewal or by notification by adding the words “condiment type only” in brackets after “mustard” or “oriental mustard”.

2.0 Background

Oriental (brown) mustard (*B. juncea* L.) varieties have historically been grown commercially in Canada only for condiment (non-oilseed) purposes, such as in the production of dry and prepared mustards. Varieties of oriental mustard, not visually distinguishable from condiment mustard have, however, been developed as an oilseed crop for the Canadian prairies

3.0 Use of the term “mustard” on product labels

Currently registered products with labels indicating use on mustard crops could be interpreted to indicate acceptable use of these products on oilseed oriental mustard varieties because the labels do not specifically refer to condiment mustard. Use on oilseed oriental mustard, however, will not likely have been subject to an assessment of supporting data specifically for oilseed varieties of *B. juncea*.

Effective the date of this memorandum, the use of the general term “mustard” will be considered to include only varieties grown for condiment use. Application of a control product with “mustard” use directions to oilseed mustard varieties of *B. juncea* L. will be considered to be an *unregistered* use.

4.0 Data requirements to add oilseed mustard use

Data requirements to amend the registration of a control product to include use on oilseed oriental mustard are outlined below and are required to be submitted as a Category B submission.

4.1 Residue data

Since previous mustards were approved for condiment mustard only, the potential for residues in edible oil and meal fractions of oilseed oriental mustard have not been determined. Consequently, food/feed residue requirements, which are applicable to all control products to be used on oilseed, must be provided. This applies to all pesticides, i.e., insecticides, fungicides, herbicides, adjuvants, and plant growth regulators.

The *Residue Chemistry Guidelines (RCGs, DIR98-02)*, Sections 2 (Nature of the Residue—Plant, Livestock), 5 (Storage Stability Data), 8 (Meat/Milk/Poultry/Eggs), 9 (Crop Field Trials), and 10 (Processed Food/Feed) detail the data required to establish maximum residue limits (MRLs) for food crops in Canada for both new active ingredients and new uses of currently registered products. These data requirements are outlined in general below:

- (1) Metabolism studies—Plant metabolism studies on rapeseed, mustard seed and/or other oil seed crops and animal metabolism studies (goat and hen) are required to define residue of concern (ROC);
- (2) Residue data—Residue data for oilseed oriental mustard seeds from trials carried out in accordance with the proposed use pattern and residue data for livestock products resulting from feeding of treated oil seed meal are required:
Note: Existing residue chemistry data for rapeseed (canola) may be used to support the use on oilseed oriental mustard if the label directions for these two crops are identical and existing residue data on file for rapeseed are adequate (according to trial map, number of trials, and number of samples) to support the proposed use on oilseed oriental mustard;
- (3) Processing studies to quantitate residues in specific fractions including crude oil, meal, deodorized oil, salad oil and/or margarine manufactured from treated oil seed, must be performed under simulated industrial conditions;
- (4) Storage stability studies of residues in all human food and livestock commodities;

- (5) Validated analytical methodology for all human food and livestock feed commodities.

Section 15 of the *RCGs* allows for the establishment of crop groupings: “Crop groupings are meant to simplify the establishment of MRLs for a group of crops, based on residue data for certain crops that are representative of the group”. Crop Group 20—Oilseed (page 15–41) includes rape seed (*B. napus*), rape seed, Indian [*B. campestris (rapa)*] and mustard seed (*B. juncea* L.).

A group MRL may be established for oilseed crops (Group 20) based on residue data for rape seed and sunflower (representative commodities of this group) and would include oilseed oriental mustard if the proposed label directions are identical to those registered for rape seed and sunflower.

4.2 Non-safety adverse effects

Data requirements for non-safety adverse effects (crop tolerance) associated with the amendment of a control product registration to add the use on oilseed oriental mustard (*B. juncea* L.) are applicable only to herbicide, adjuvant and plant growth regulator control products. Additional, non-safety adverse effect data are not required to support amendments to add oilseed oriental mustard to fungicide and insecticide product labels if mustard uses are already indicated on that label.

Data requirements for the addition of a new crop to the product label as outlined in the *Efficacy Guidelines for Plant Protection Products (PRO2002-01)* would apply. Both the proposed label rate (1×) and twice the proposed application rate (2×) are required. The requirements for post-emergence graminicides will generally be less than for broad-leaf herbicides.

For currently registered products, labels include instructions for use on “mustard”, “tame mustard”, “condiment mustard (brown and oriental only)”, or “mustard (yellow only).”

Mustard crops consist of two species, oriental (*B. juncea* L.) and yellow/white (*Sinapis alba* L. = *Brassica hirta*). Therefore, the use of the general term “mustard” on a product label does not indicate that the product has been specifically evaluated for use on *B. juncea* L. However, for registered products with a history of use on “mustard”, there is less concern related to this general terminology. In consideration of this, data requirements are proposed which will allow for the demonstration of crop tolerance of oilseed mustard (*B. juncea* L.), while recognizing historical product use.

- (a) For products specifically labelled for use on oriental mustard:

Crop tolerance data requirements are waived.

- (b) For products generally labelled for use on mustard (no species differentiation):

Data for all products consisting of at least six replicated small plot trials (single year acceptable) conducted at geographically diverse sites are required, which demonstrate crop tolerance of oilseed oriental mustard at the maximum application rate and 2× maximum rate are required. Data waivers with scientific rationale for post-emergence graminicide products may be considered.

5.0 Product labelling

When an application is made for any label amendment to a control product with mustard uses on the label, or at the time of the renewal of registration, the product label will be amended to identify specific mustard uses.

For products indicating “mustard” use:
mustard (condiment type only)

For products indicating “oriental mustard” use:
oriental mustard (condiment type only)

When the required food residue and crop tolerance data requirements have been addressed, and the review of the data has determined that the product use on oilseed mustard (*B. juncea* L.) is acceptable, the product labelling may be amended to:

oriental mustard (condiment and oilseed types).

6.0 References

Regulatory Proposal PRO2002-01. *Efficacy Guidelines for Plant Protection Products*, Pest Management Regulatory Agency. August 20, 2002.

Regulatory Directive DIR98-02. *Residue Chemistry Guidelines*. Pest Management Regulatory Agency. June 1, 1998.