

Evaluation Report for Category B, Subcategory B.3.4 Application

Application Number: 2005-2264

Application: Evaluation Report for Category B, Subcategory B.3.4

Product: Reason 500SC Fungicide

Registration Number: 27462

Active ingredients (a.i.): Fenamidone (FED) 500 g/L

PMRA Document Number: 1312952

Background

Reason 500SC Fungicide was first registered November 12, 2003. It is registered to control late blight and early blight in potato. For specific details of uses, diseases controlled, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

Purpose of Application

This application is to amend the registration of Reason 500SC Fungicide to add aerial spray for potatoes. The product was originally registered for ground spray only.

Chemistry Assessment

A chemistry assessment was not required since there was no change to product chemistry.

Health Assessment

A toxicology assessment was not required since there was no change to the formulation.

The requested use for Reason 500 SC does not fit within the existing use pattern for fenamidone. A risk assessment was conducted using the Pesticide Handler's Exposure Data Base (PHED) to quantify exposure to fenamidone while mixing, loading and applying using aerial equipment. Post-application exposure was not re-assessed since the requested application rate was the same as the registered application rate on potatoes.

Calculated margins of exposure (MOEs) for aerial mixing/loading and applying Reason 500 SC exceed the target of 100 and are considered to be acceptable.



Residues of fenamidone on potatoes grown for food and feed from aerial treatment using Reason 500 SC Fungicide are covered by the existing maximum residue level (MRL) for fenamidone residues in/on potatoes since the use directions are identical to those for the currently registered ground application of this product. Therefore, no increase in dietary exposure is anticipated.

Environmental Assessment

Fenamidone has been shown to be of potential risk to mammals, beneficial insects, freshwater and marine algae. A buffer zone of 8 m is stipulated on the registered label for ground application in order to protect sensitive estuarine and marine habitats from off-target exposure from spray drift. In order to mitigate the environmental risk from aerial spray drift, a larger buffer zone is needed to protect estuarine and marine habitats. It was also determined that an additional buffer zone for aerial application is necessary for the protection of sensitive freshwater habitats from aerial spray drift. A revised label was required to include environmental protection statements and information on buffer zones.

The new buffer zone requirements are shown in the table below:

| Method of application | Buffer Zones (metres) Required for the Protection of: | | | | | |
|-------------------------|---|---------|------------------|--------------------------------------|---------|---------------------|
| | Freshwater Habitat of Depths: | | | Estuarine/Marine Habitats of Depths: | | |
| | Less than 1 m | 1 - 3 m | Greater than 3 m | Less than 1 m | 1 - 3 m | Greater than 3 m |
| Field sprayer | 0 | 0 | 0 | 8 | 0 | 0 |
| Aerial (fixed-wing) | 10 | 0 | 0 | 10 | 1 | 0 |
| Aerial (rotary-wing) | 10 | 0 | 0 | 10 | 0 | 0 |

Value Assessment

Two trials conducted in Ontario and Manitoba tested Reason 500SC as a tank-mix with Dithane DG or Bravo 500 applied in low (aerial) or high (ground) volume ground sprays at the proposed rates of 200 ml/ha Reason + 1.25 kg/ha Dithane DG or 1.25 L/ha Bravo 500. The results showed no difference in efficacy for early and late blight when applied in a low or high volume in either of the tank-mixes.

Trials using double the rates were also conducted both by air and ground application. Although the rates were higher than proposed, the data showed no difference in efficacy regardless of whether applied by air or by ground.

The data support aerial use of Reason as a tank-mix to control early and late blight in potatoes.

Conclusions

The PMRA has completed an evaluation of the subject application and has found the information sufficient to amend the registration of Reason 500SC Fungicide to add aerial spray for control of early and late blight in potatoes.

References

- 7.4.1.1 PMRA 1070731. Reason 500 SC Fungicide, Aerial application to Potatoes. DACO 5.2 Use Description Scenario. Bayer CropScience Inc. Study report date: 17-August-2005. pp.2 DACO 5.2 Volume 1.
- 7.4.1.2 PMRA 1070732. Worker Exposure and Risk Assessment for Fenamidone Resulting from Aerial Application of REASON 500 SC FUNGICIDE to Potatoes. Bayer CropScience Inc. Study report date: 18-August-2005. pp.1-13. DACO 5.3 Volume 1.
- 7.6.1 PMRA1070733. REASON 500 SC Fungicide (Fenamidone) Data in Support of Aerial Application in Potato. Bayer CropScience Inc. Study report date: 31-May-2005. pp. 1-86. DACO 10.1, 10.3.1, 10.3.3 Volume 1.

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