

Section 12 Notice

Additional Information Required to Fulfill the Terms and Conditions for Conditional Registration

Product Name: CARAMBA FUNGICIDE
Registration Number: 29767
Application Number: 2007-2949
PMRA # : 1911696

During the conditional registration period which has been granted to **December 31, 2013**, the following information is to be generated and must be provided to the Pest Management Regulatory Agency by **September 1, 2013** and should indicate the DACO numbers specified. A partial response to the outlined Terms and Conditions will not be accepted.

PART 7 FOOD, FEED AND TOBACCO RESIDUE STUDIES

DACO: 7.2
Title: Plant Analytical Methodology

Deficiency: An appropriate enforcement method for plant matrices that has been validated by an independent laboratory was not submitted.

Required Data: **The applicant should submit a modified plant analytical method for D0508 that reflects the recommendation of the ILV laboratory and is reviewed by the applicant's quality assurance unit. Additionally, the applicant must provide a confirmatory method either by modifying the method to provide information on a second MS/MS ion transition or an alternate chromatographic system.**

DACO: 7.2
Title: Animal Analytical Methodology

Deficiency: An enforcement method for animal matrices that has been validated by an independent laboratory was not submitted.

Required Data: **An enforcement method for animal matrices that has been validated by an independent laboratory must be submitted.**

DACO: 7.2
Title: Multiresidue Analytical Methods

Deficiency: Metconazole was not examined by CFIA or FDA multi-residue analytical methods. The behaviour was extrapolated from the results reported for other triazoles.

Required Data: **Metconazole should be tested through a valid and appropriate multiresidue method.**

DACO: 7.3
Title: Freezer Storage Stability

Deficiency: From collection to analysis rotational crop samples were stored frozen for a maximum of 12.6 months (wheat) (Study# V-0427115); 19 months (lettuce), 21 months (radish and wheat) (Study# V-04-27123), 18 months (radish tops and root) and 13 months (spinach) (Study# V-04-27131). No data are available to support the freezer storage interval for residues of M11 in wheat forage stored frozen for up to 21 months, as well as, residues of *cis*- and *trans*-metconazole in wheat grain and straw stored frozen for up to 18 months, in wheat forage and radish tops stored frozen for up to 21 months, and in lettuce stored frozen for up to 19 months.

Required Data: **Rotational crop studies are considered conditionally acceptable pending the submission of acceptable freezer storage stability data for M11 in wheat forage stored frozen for up to 21 months, as well as, for *cis*- and *trans*-metconazole in wheat grain and straw stored frozen for up to 18 months, in wheat forage and radish tops stored frozen for up to 21 months, and in lettuce stored frozen for up to 19 months.**

DACO: 7.4
Title: Supervised Residue Trial Study

Deficiency: The number and location of cereal field trials were not in accordance with DIR 98-02, nor were they performed at the approved Canadian application rate.

Required Data: Confirmatory crop field trials for barley, oats, rye and wheat conducted at the Canadian rate of 0.090 kg a.i./ha in Canadian representative growing regions are required. For barley, 5 field trials conducted in NAFTA Region 14 are required. For oats, 4 field trials conducted in NAFTA Region 14 are required. For rye, 1 field trial conducted in NAFTA Region 7 and 2 field trials conducted in NAFTA Region 14 are required. For wheat, 2 field trials conducted in NAFTA Region 7, 1 field trial conducted in NAFTA Region 7A and 3 field trials conducted in NAFTA Region 14 are required.

PART 10 **VALUE**

DACO: **10.2.3.3**
Title: **Efficacy: Small-scale Trials (Field, Greenhouse)**

Deficiency: No data or rationale on aerial application of Caramba Fungicide.

Required Data:

- **At least three confirmatory trials are required comparing efficacy of Caramba Fungicide when applied with high water volume (a minimum of 100 L of water per ha) versus low water volume (50 L of water per ha) on one of the crop/pest combination listed on the Caramba Fungicide label (e.i. barley/FHB, wheat/FHB, sugar beets/Cercospora leaf spot, etc.).**
- **Trials should be conducted under adequate disease pressures.**
- **If natural infection is absent, plants should be artificially inoculated with the appropriate pathogen (i.e. barley/FHB, wheat/FHB, sugar beets/Cercospora leaf spot, etc.) to ensure a good disease pressure.**
- **Follow the proposed label directions for use including: application rates, number of applications, time of application, methods of application and water volumes in the trials.**
- **Trials must include (a) a control (check) treatment, (b) a treatment with the product applied at the proposed rates, purposes, (c) treatment with 50 L of water per ha, (d) treatment with a high volume of water (a minimum of 100 L of water per ha), (e) a registered commercial standard product for comparison.**
- **The data must demonstrate that the proposed water volume for Caramba Fungicide (50 L of water per ha) will not negatively affect metconazole efficacy.**

- **Trials must make multiple assessments for both disease severity (DS) and disease incidence (DI).**
- **If any adverse effects are noted in the trial, clear notes must be made as to when symptoms initiated, how the plant was affected, if the effects were temporary or permanent, etc.**
- **Provide statistical analysis of data.**
- **All units must be in metric (L, kg, ml, g, etc.).**