

Section 12 Notice

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

Product Name: *Authority 480 Herbicide*
Registration Number: *29012*
Application Number: *2006-4414*
PMRA # (English PDF): *1597252*

During the conditional registration period which has been granted to December 31, 2010, the following information is to be generated and must be provided to the Pest Management Regulatory Agency by **September 30, 2010** and should indicate the DACO numbers specified. A partial response to the outlined Terms and Conditions will not be accepted.

PART 0 INDEX

DACO: 0
Title: Index

Details: Please submit an electronic index of the data package submitted in response to this letter. Please refer to **Regulatory Directive 2006-05, Requirements for Submitting Data Index, Documents and Forms**, for additional information.

PART 1 LABEL

DACO: 1
Title: Label

Details: The applicant is required to submit a revised label on which the following phrase is added: “Contains sodium o-phenylphenate (present as tetrahydrate) at 0.036% as a preservative.” Note that there is no hyphen between “sodium” and “o-phenyl...”

PART 8 ENVIRONMENTAL CHEMISTRY AND FATE

DACO: 8.3.3
Title: Aquatic Field Dissipation Study

Details: **An aquatic field dissipation study. As per Regulatory Directive 1999-05, these data may be completed and submitted during the conditional registration period.**

DACO: 8.3.2
Title: Terrestrial Field Dissipation Study (Canada)

Details: **1) The raw data used to calculate the mean concentrations in soil in the Manitoba study are required. These data should be submitted as soon as possible to allow the proper review of the study;**
2) If the use pattern changes, additional field dissipation studies conducted in ecoregions relevant to the proposed use may be required.

DACO: 8.5
Title: Other Environmental Fate Studies

Details: **EPA data evaluation report (DER) of the following study: A copy of the DER for the final report on the Small-Scale Prospective Groundwater Monitory study for Sulfentrazone in a Setting Classified as 95th Percentile Based on Vulnerability to Groundwater Contamination should be submitted when available.**

DACO: 8.5
Title: Other Environmental Fate Studies

Details: **Both final reports and the EPA data evaluation reports (DER) for the Small-Scale Prospective Groundwater Monitory study for Sulfentrazone in a Setting Classified as 85th and 75th Percentile Based on Vulnerability to Groundwater Contamination should be submitted when available.**

PART 9 ENVIRONMENTAL TOXICOLOGY

DACO: 9.9
Title: Other Studies/Data/Reports (Mesocosm study)

Details: **The PMRA has serious concerns about the environmental fate characteristics of this chemical. This study may be required based on the potential risk to aquatic systems due to the mobility, persistence and toxicity of sulfentrazone and the potential toxicity of the 3-carboxylic acid sulfentrazone transformation product to non-target algae and vascular plants, primary producers in ecosystems. Should the company choose, they could integrate collection of this data with the aquatic field dissipation study.**

PART 10 VALUE

DACO: 10.0
Title: Stewardship Plan/Risk Mitigation Plan

Details: **FMC must elaborate on the economic and social impact that the presence of sulfentrazone in groundwater will have and its possible effect on crops when groundwater, dugout water or well water is used for irrigation. FMC must present a stewardship program that will include a risk mitigation plan to address the impact that sulfentrazone will have on any crop, ornamental plant and/or turf when contaminated water is used for irrigation purposes. This risk mitigation plan must include an education plan for growers and the public about the presence of sulfentrazone in well water and in groundwater, including the potential impact of sulfentrazone on rotational crops and on ornamental plants. This stewardship program must also include details how FMC plans to measure the amount of sulfentrazone in water, treat the contaminated water and compensate people if the use of Authority 480 results in crop/ornamental plant/turf injury. FMC must be ready to publish these risk mitigation measures.**

DACO: 10.2.3.3
Title: Efficacy

Details: **Additional data are required to confirm that the rates of 105 to 140 g a.i./ha will control the weeds that are currently listed on the Authority 480 label, i.e., kochia, lamb's quarters, redroot pigweed and wild buckwheat. FMC must provide a minimum of eight (8) additional**

trials for each of these weeds, conducted over one (1) or two (2) years at different locations in Saskatchewan. A minimum of two (2) trials must be provided for each soil texture/organic matter rate structure, e.g., 2 trials must be provided for medium textured soil with an organic matter content of <1.5%, 2 trials must be provided for medium textured soil with an organic matter content between 1.5 and 3.0%, etc. Each trial must include the following rates of application: 70, 105, 140, and 210 g a.i./ha and must include three (3) ratings of percent visual control.

DACO: 10.3.3
Title: Damage to Rotational Crops

Details: Additional data are required to confirm the list of rotational crops that will appear on the Authority 480 label. Canadian rotational crop trials (3 to 5 trials) must be conducted in the Prairie provinces and one of those trials MUST be conducted in Scott, Saskatchewan. Each trial must include ALL the labelled rotational crops (alfalfa, canola, field corn, sweet corn, sorghum, soybeans, sunflowers, spring wheat and winter wheat) in order to confirm that injury to those crops will not occur in the years following an application of Authority 480.

In addition, all trials MUST also include the following crops: durum wheat, barley, sugar beet and lentils.

One additional trial MUST be conducted in Eastern Canada and must include ALL the labelled rotational crops (alfalfa, canola, field corn, sweet corn, sorghum, soybeans, sunflowers, spring wheat and winter wheat) in order to confirm that injury to those crops will not occur in the years following an application of Authority 480. The following crops MUST also be tested in that trial: dry edible beans (a number of different market class such as pinto navy, white, etc.), tomatoes and sugar beets.

In each trial, Authority 480 must be applied at the maximum rate (1x) of application and at twice (2x) and three times (3x) the maximum rate of application. Each crop must be seeded one (1), two (2), AND three (3) years after the initial application of herbicide. Three (3) ratings for visual injury for each crop must be reported. A weed-free control must be included in every trial and yield must also be reported for each crop in every trial. Trial reports must include all soil characteristics such as soil type, soil texture, pH and percent organic matter. Rainfall throughout the evaluation period (including year of application and all subsequent years) must also be included in the trial reports.