

Section 12 Notice

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

Product Name: *Sulfentrazone Technical Herbicide*
Registration Number: *29011*
Application Number: *2006-4413*
PMRA # (English PDF): *1597257*

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 guarantee value is identical to that in Box 14B of the updated SPSF.**

PART 4 TOXICOLOGY

DACO: 4.8 Other Studies
Title: Toxicology profile of 3-carboxylic acid sulfentrazone

Details: **Please provide a rationale comparing the toxicity of 3-carboxylic acid-sulfentrazone to the parent, including any available toxicology data on 3-carboxylic acid-sulfentrazone.**

PART 8 ENVIRONMENTAL CHEMISTRY AND FATE

DACO: 8.2.2.1
Title: Analytical Methodology (parent compound and transformation products) - Soil

Details: **Depending on the outcome of PMRA's review of the new field dissipation study, a new validated non-radioactive analytical method for the determination of sulfentrazone and its major transformation products in Canadian soil may be required. Please note that any transformation products present at level greater than 10% of the initial concentration of the pesticide at any time during the study, as well as those products that have not attained 10% (e.g. 8 - 9%) but show a continuous increase in concentration up until the termination of the study, are considered to be major. Also, transformation products that are of human health or environmental concern (i.e. predicted or demonstrated toxicity) are considered to be major, even if their maximum concentrations are less than 10% of the initial parent concentration.**

DACO: 8.2.2.4
Title: Analytical Methodology (parent compound and transformation products) - Biota

Details: **The applicant is required to submit a validated non-radioactive analytical method for the determination of sulfentrazone and its major metabolites in an animal (fish) matrix. This data is required for the environmental monitoring of biota and not for the monitoring of food residues.**

DACO: 8.2.3.5.4
Title: Aerobic Water/Sediment Biotransformation

Details: **Sulfentrazone is expected to be persistent in the environment based on the terrestrial laboratory and field studies. The fate in aquatic environments and the potential risk to aquatic organisms can not be adequately assessed at this time since the fate of sulfentrazone and its transformation products have not been characterised in aerobic aquatic environments. As discussed at the meeting between FMC and PMRA (May 8, 2008), FMC as agreed to conduct an aquatic field dissipation study to address this deficiency. For modelling purposes, PMRA will assume no transformation in aquatic systems. If FMC agrees to this assumption, a laboratory conducted aerobic aquatic biotransformation study is no longer required.**

DACO: 8.2.3 and 8.2.4
Title: Laboratory Studies of Transformation and Mobility (3-carboxylic acid sulfentrazone)

Details: **The following information is required to calculate estimated drinking water concentrations for the 3-carboxylic acid sulfentrazone: solubility (2.14.7), hydrolysis (8.2.3.2), photolysis (8.2.3.3.2), soil aerobic biotransformation (8.2.3.4.2), aquatic aerobic biotransformation (8.2.3.5.4) and adsorption/desorption (8.2.4.2).**

Registrant Response: The response and waiver provided by the registrant were not accepted by the PMRA. This was discussed at the May 8, 2008 meeting between FMC and PMRA.

Required data: **The response and waiver provided by the registrant were not accepted, the previously identified data requirements are still required.**

DACO: 8.2.1
Title: Summary of Physicochemical Properties ($\log K_{OW}$) (3-carboxylic acid sulfentrazone and the 3-hydroxymethyl sulfentrazone)

Previously Required data: **Information on the $\log K_{OW}$ for the 3-carboxylic acid sulfentrazone is required to assess the potential for bioaccumulation against the TSMP criteria. If a predicted K_{OW} value is provided, a similar prediction with the parent should also be provided so that the PMRA can compare the predicted with the empirical value.**

Registrant

Response: The registrant provided an estimated log K_{ow} value for the 3-carboxylic acid sulfentrazone using KOCWIN.

PMRA Response: **The PMRA has determined that this is acceptable and no additional data are required.**

PART 9 ENVIRONMENTAL TOXICOLOGY

DACO: 9.2.4.2
Title: Acute Oral Toxicity Study on Honeybees

Details: **An acute oral toxicity study is required to confirm non-toxicity to honey bees.**

Registrant Response: The response and waiver provided by the registrant were not accepted by the PMRA. This was discussed at the 08-05-2008 meeting between FMC and PMRA.

Details: **The response and waiver provided by the registrant were not accepted, the previously identified data requirements are still required. As noted, sulfentrazone is used as a systemic herbicide, therefore, oral ingestion can potentially occur and risk from this route of exposure needs to be adequately characterised.**

DACO: 9.5.3.2
Title: Fish, Life Cycle Toxicity Test

Details: **A full life cycle toxicity test in fish.**

Registrant Response: The response and waiver provided by the registrant were not accepted by the PMRA. This was discussed at the 08-05-2008 meeting between FMC and PMRA.

Details: **The response and waiver provided by the registrant were not accepted, the previously identified data requirements are still required. Based on available data and modelling results, the PMRA has concluded that sulfentrazone is likely to be persistent in aquatic ecosystems. The PMRA has agreed that should the results of an aquatic field dissipation study indicate that sulfentrazone is not persistent and long-term exposure to fish may not occur, this data requirement would be waived. Should the results indicate that sulfentrazone is persistent, this study will be required.**

DACO:

9.9

Title:

Chronic Toxicity Study on Earthworms

Details:

The environmental fate characteristics of sulfentrazone indicate that it is expected to be persistent in the soil. Exposure to earthworms and other terrestrial invertebrates on a chronic basis is likely. As discussed at the meeting between FMC and PMRA (May 8, 2008), a chronic toxicity study on earthworms is no longer required.