

Section 12 Notice **Additional Information Required to Fulfill the Terms and Conditions for Conditional Registration**

Product Name: Flumioxazin Technical
Registration Number: 29233
Application Number: 2007-4517
PMRA Document Number: 1710309

During the conditional registration period, which has been granted to **December 31, 2012**, the following information is to be generated and must be provided to the Agency by **September 30, 2012**, and should indicate the DACO numbers specified below. 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 2 CHEMISTRY

DACO: 2.13.2
Title: Confirmation of Identity

Details: The applicant must provide data (mass spectra and/or chromatograms) confirming the identities of the active and the impurities in the technical product.

DACO: 2.13.1
Title: Methodology/Validation

Details: The applicant must provide representative chromatograms of the analytical standards of the active ingredient and impurities in support of the validity of the method.

DACO: 2.13.3
Title: Batch data

Details: The applicant must provide five batch data from full scale production of the technical product manufactured by Sumitomo, Japan. The expected completion date of the study must be provided in the interim. The applicant may need to update the product specifications to reflect full scale production, when available.

PART 8 ENVIRONMENTAL CHEMISTRY AND FATE

DACO: 8.2.1
Title: Summary of Physicochemical Properties (log KOW) (482-HA, APF, THPA, HPA, SAT-482-HA, SAT-482-HA-2, DAPF)

Details: Information on the logKOW for the 482-HA, APF, THPA, HPA, SAT-482-HA, SAT-482-HA-2 and DAPF transformation products is required to determine whether they meet the TSMP criteria for bioaccumulation. If a predicted KOW 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.

DACO: 8.2.2.3 (Water)
Title: Analytical methodology (parent compound and transformation products)

Details: The applicant is requested to provide analytical methods for the determination of all major transformation products in water. The chemical names and structures of all identified metabolites must be provided.

DACO: 8.2.3.5.4
Title: Aerobic Water/Sediment Biotransformation

Details: Either one of the following two studies is required: an aerobic water biotransformation study, or a water/sediment biotransformation study. As per Regulatory Directive 1999-05, these data may be completed and submitted during the conditional registration period if such registration is granted.

PART 9**ENVIRONMENTAL TOXICOLOGY**

- DACO:** 9.2.4.2
Title: Bees/Pollinators: Acute Oral
- Details:** The Acute Oral Honeybee toxicity study previously submitted to the European Union.
- DACO:** 9.2.5 and 9.2.6
Title: Predators and Parasites
- Details:** The laboratory studies conducted on *Peocilus cupreus*, *Chrysoperla carnea*, *Aleochara bilineata*, *Pardosa amenata*, *Typhlodromus pyri* and *Aphidius rhopalosiphi* and submitted to the European Union for review.
- DACO:** 9.3.2; 9.3.3; 9.5.2.1; 9.5.3.1; 9.8.5
Title: *Daphnia* sp. Acute; *Daphnia* sp. Chronic (Life-Cycle); Cold Water Fish Acute; Fish, Early Life Cycle Toxicity Test; Aquatic Vascular Plants.
- Details:** Ecotoxicology studies on daphnids, rainbow trout and aquatic vascular plants conducted with transformation products expected to accumulate in the aquatic environment are conditionally required, pending the results of the aerobic aquatic biotransformation study.
- DACO:** 9.6.2.2
Title: Mallard Duck (Oral Toxicity)
- Details:** The acute oral toxicity study on mallard duck submitted to the European Union for review.
- DACO:** 9.8.5
Title: Aquatic Vascular Plants
- Details:** Overspray (foliar exposure) aquatic plant toxicity study conducted with Flumioxazin 51 WDG on duckweed (*Lemna* spp.) is required to characterise the risk from drift to aquatic plants. The analytical methodology used to confirm the test concentrations should monitor both the parent compound and the major transformation products expected in water because of the instability of the parent in aquatic systems.

PART 12

FOREIGN REVIEWS

DACO:

12.8.5

Title:

Other Environmental Fate Studies

Details:

EPA data evaluation reports (DER) for the following study: Terrestrial Field Soil Dissipation of Flumioxazin on Bare Soil in Washington, when available.