

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

Product Name: TOPRAMEZONE TECHNICAL

Registration Number: 28140

Application Number: 2006-7933

PMRA #: 1444645

During the conditional registration period which has been granted to December 31, 2007, the following information is to be generated and must be provided to the Pest Management Regulatory Agency by **June 1, 2007**, and must indicate the DACO numbers specified. A partial response to the outlined Terms and Conditions will not be accepted.

Part 2 CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF A TECHNICAL GRADE OF ACTIVE INGREDIENT (TGAI) OR AN INTEGRATED SYSTEM PRODUCT

DACO: 2.12.2
Title: Statement Product Specification Form (SPSF)

Required DATA: A revised SPSF is required if batch data from commercial production are not consistent with components specified on the current SPSF.

DACO: 2.13.3
Title: Batch Data

Required DATA: Analytical data of five batches manufactured from full scale production are required, when available, to support the current specifications.

Part 4 TOXICOLOGY

DACO: 4.3.3
Title: Short Term Oral Toxicity in Rats

Required DATA: A 28-day study in rats to further strengthen the established mode of action for thyroid follicular cell tumour genesis. This study must test for the same 3 glucuronyltransferases and UDPGT at the same dose levels used in the 2 year oncogenicity study.

Part 8 ENVIRONMENTAL CHEMISTRY AND FATE

DACO: 8.2.3.4.2
Title: Aerobic Soil 20° - 30° C

Required DATA: The unidentified major transformation product must be identified along with its physicochemical properties.

DACO: 8.2.3.5.6
Title: Anaerobic Sediment/Water 20° - 30° C

Required DATA: The applicant must address the reason for the variability between the replicates in the anaerobic aquatic biotransformation and submit additional replicate data.

DACO: 8.2.3.4
Title: Biotransformation in Soil

Required DATA: Studies designed to address the kinetics of adsorption and desorption of pesticides on soils/sediment are not commonly conducted. Data on kinetics of adsorption/desorption of topramezone must be submitted, if available.

DACO: 8.2.3.5
Title: Biotransformation in Aquatic Systems

Required DATA: Studies designed to address the kinetics of adsorption and desorption of pesticides on soils/sediment are not commonly conducted. Data on kinetics of adsorption/desorption of topramezone must be submitted, if available.

DACO: 9.6.3.2
Title: Avian Reproduction Mallard Duck

Required DATA: A new reproductive toxicity study on mallard duck is required to establish a NOEC. Stability of topramezone under use conditions must be verified.

DACO: 9.8.2
Title: Fresh Water Algae

Required Data: A new algal toxicity study with freshwater diatom (*N. pelliculosa*) is required.