

Section 12 Notice

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

Product Name: *Bengal 120 EC*
Registration Number: *29268*
Application Number: *2007-6008*
PMRA # : *1721416*

During the conditional registration period which has been granted to *insert product expiry date*, the following information is to be generated and must be provided to the Pest Management Regulatory Agency by *September 30, 2011* and should 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: 2.11.2
Title: *Description of Starting Materials*
Details: *The applicant must submit a description of the starting materials.*

DACO: 2.11.3
Title: *Detailed Production Process Description*
Details: *The applicant must clarify whether the precipitated product was filtered or collected using centrifugation.*

DACO: 2.11.4
Title: *Discussion of Formation of Impurities*
Details: *The applicant must provide a discussion of the formation of impurities.*

DACO: 2.13.1
Title: *Methodology/Validation*
Details: *The applicant must provide a chromatogram of the lowest calibration standard of the Methyl, Acid, Dichloro Methyl and Des Methyl impurities, which has been re-scaled to show the impurity peaks, and also must clarify the sample preparation and calculations for toluene.*

DACO: 2.13.3
Title: *Batch Data*
Details: *The applicant must provide the date(s) of manufacture of the five batches of Fenchlorazole-ethyl Technical.*

DACO: 2.14
Title: *Chemical and Physical Properties*
Details: *The applicant must provide GLP data characterizing the chemical and physical properties of the product.*

Part 3 **Chemistry Requirements for the Registration of Manufacturing Concentrates and End-use Products Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products**

DACO: 3.4.1
Title: *Enforcement Analytical Method*
Details: *The applicant must provide a validated analytical method capable of separating the stereoisomers of the active.*

DACO: 3.5.10, 3.5.14
Title: *Chemical and Physical Properties: Storage Stability Data, Corrosion Characteristics*
Details: *The applicant must provide the requested protocol, initiate a one-year study at ambient temperature and provide the expected date of completion.*

PART 9 **Environmental Toxicology**

DACO: 9.8.4
Title: *Terrestrial Vascular plants*
Details: *Terrestrial vascular plant studies conducted using the end-use product containing fenchlorazole-ethyl are required.*

DACO: 9.8.5
Title: *Aquatic Vascular plants*
Details: *Aquatic vascular plant studies conducted using the end-use product containing fenchlorazole-ethyl are required.*