Section 12 Notice Additional Information Required as a Post-Market

Requirement

Product Name: Ethofumesate Technical Herbicide

Registration Number: 20364
Application Number: 2022-5193
PMRA #: 3428404
Issued on: June 2, 2023

During the registration period which has been granted to December 31, 2028, the following information is to be generated and must be provided to the Pest Management Regulatory Agency by December 31, 2027 and should indicate the DACO numbers specified. A partial response to the outlined data requirements will not be accepted.

PART 2 CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF

A TECHNICAL GRADE OF ACTIVE INGREDIENT (TGAI) OR

AN INTEGRATED SYSTEM PRODUCT

Post-market Requirements:

DACO 2.11 (Manufacturing Methods): Current manufacturing method with a description of the starting materials (suppliers and specifications) and a detailed production process description (including amounts, reactions and production conditions, e.g. temperature, pressure, time). Please note that even if the manufacturing process has not changed, a description of the manufacturing process must still be submitted.

DACO 2.12 (Specifications – to be submitted under DACO 0.1.6003):

A completed Statement of Product Specification Form (SPSF) with the product's current manufacturing specifications, signed and dated.

DACO 2.13.3 (Batch Data): In lieu of batch data, recent quality control data from the last 5 batches of commercial-scale production. The information can be presented in raw or finished reports or as certificates of analysis and does not have to be GLP-compliant. Each report must include the active ingredient level, manufacturing location and date, and batch size. If available, provide data for impurities monitored during the production process or reported in the final product.



Please submit this information under a Category B.4.6 submission by December 31, 2027.