

Section 12 Notice Additional Information Required as a Post-Market Requirement

Product Name: Rynaxypyr Technical Insecticide

Registration Number: 28979

Application Number: 2022-5998

PMRA # : 3503026

Issued on: September 20, 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, 2025 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

DACO: 2.11 / 2.12 / 2.13

Title: Manufacturing Methods / Specifications / Preliminary Analysis

Post-market

Requirements:

DACO 2.11 (Manufacturing Methods): A revised 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).

DACO 2.12 (Specifications – to be submitted under DACO 0.1.6003): A completed Statement of Product Specification Form (SPSF) with the product's new manufacturing specifications, signed and dated.

DACO 2.13.3 (Batch Data): GLP-compliant data for 5 batches for all components to a level of 0.1%.

DACO 2.13.4 (Impurities of Human Health or Environmental Concern): Based on the current manufacturing method provided, an impurity(ies) of health concern is suspected to be present in the technical product. Five-batch analytical data from a GLP-compliant study using validated method(s) for the impurity(ies) are required. The analysis is to be conducted with appropriate levels of method sensitivity.

Please submit this information under a Category B.4.6 submission by December 31, 2025.

