DP BARCODE: D319034; **Reg. No. / FILE SYMBOL No.**: 80289-U; **PRODUCT**: Orthosulfamuron (IR5878) Technical

February 22, 2007

SUBJECT: FEE. Product Chemistry Review on Orthosulfamuron (IR5878) Technical

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02-22-07

DP BARCODE: D319034
DECISION No.: 358188
EPA REG. No.: 80289-U
PRODUCT: Orthosulfamuron (IR5878) Technical
PCC: 108209
REGISTRANT: Isagro S.P.A
USE: Herbicide

INTRODUCTION:

The Agency has previously approved the Section 5 (Experimental-use) registration application for the technical grade active ingredient orthosulfamuron (see Product chemistry review dated 06-06-05; DP304195). The product chemistry data were submitted with MRID Nos. 462190-01 through 462190-14 and 465590-01. All the product chemistry data submitted were acceptable for the experimental-use permit. On June 20, 2005, Exponent (representative of Isagro SPA) submitted product chemistry data in support of the Section 3 registration application for orthosulfamuron technical produced by Lonza Ltd., located in Switzerland. The revised product chemistry data corresponding to 830 series subgroup A (guidelines 830.1620 and 830.1700) have been submitted under MRID Nos. 465789-01 thru 465789-03. The registrant has submitted a revised CSF for basic formulation (dated 02-22-07) based on the revised five batch analysis and the revised product label. The technical is produced on pilot plant scale and not yet produced on commercial scale. TRB has been asked to perform the evaluation of the product chemistry data submitted for the technical and determine whether the data submitted support the registration of the proposed technical.

SUMMARY OF FINDINGS:

1. The revised CSF for basic formulation (dated 02-22-07) is filled out completely and correctly. The nominal concentration (NC) of the active ingredient (99.0%) concurs with the product label claim nominal concentration. The CSF is in compliance with PR Notice 91-2. The proposed certified limits for the AI are based on the five batch analysis. The proposed upper certified limits for the impurities are based on preliminary analysis and are wider in order to cover the expected production variability when produced on commercial scale. The product chemistry data submitted corresponding to guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175 respectively.

2. The product chemistry data submitted corresponding to guideline reference 830.1620 (description of production process) satisfy the data requirements for 40CFR§158.162. The active ingredient was produced in [redacted] The batch production process has been described with full details [MRID No. 465789-03].

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

3. The data submitted corresponding the guideline reference 830.1700 (Preliminary analysis) satisfy the data requirements of 40CFR§158.170. Five representative batches of the 99.0% technical were analyzed for percent AI and the impurities. The content of the active ingredient was determined by reversed phase HPLC with a UV-DAD detector operating at 265 nm. The content of the impurities in the test substance was determined by reversed phase HPLC with a UV-DAD detector operating at 230 nm. One of the volatile impurity was quantified using GC with ECD (electron capture detector)[MRID No. 465789-02 & 465789-01].

CONCLUSIONS

TRB has reviewed the product chemistry data submitted for 830 series Subgroup A data for orthosulfamuron technical and has concluded that:

1. The revised CSF for basic formulation (dated 02-22-07) is acceptable.

2. The product chemistry data submitted corresponding to guidelines 830 series subgroup A (830.1620 & 830.1700) are acceptable. All other product chemistry data requirement were satisfied and were found to be acceptable as per product chemistry review (dated 06-06-05)on orthosulfamuron technical in an experimental-use permit application.

3. The registrant is advised to submit a revised CSF based on the five batch analysis of the technical samples produced on commercial scale when available.

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Page _____ is not included in this copy.

Pages 3 through 12 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

✓ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

✓ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Internal deliberative information.

_____ Attorney-Client work product.

_____ Claimed Confidential by submitter upon submission to the Agency.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
