

FBI

DATE OUT: 27/July/ 2007

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MUP [] EP [X]**
DP BARCODE No.: D320064 **EPA File Symbol No.:** 80289-L
PRODUCT NAME: IR5878 50 WG
COMPANY: Isagro S. p. A.
FOOD USE [X] INTEGRATED FORMULATION []
PCC: 108209 **Decision No.** 358204
ACTION CODE: R01.0

Wu 1/31/2007
STB 7/31/07

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INTRODUCTION:

The Registrant has submitted a basic CSF for an end-use product, and has proposed a product specific label (both dated January 26, 2005) to support the registration of the aforesaid formulation EPA File Symbol 80289-L under the provision of FIFRA §3. It is a herbicide applied to water where rice is seeded.

The product chemistry data from the subject formulation have been previously reviewed twice (dated June 27, 2005 and Feb 23, 2007). The conclusion reached from the February 23, 2007 review is that the subject end-use product can be acceptable for registration pending the acceptance of the storage stability (830.6317) and the corrosion characteristics (830.6320) data by TRB and the source material for the subject formulation (currently EPA Reg. No. 80289-4, 98%, IR 5878 Technical) become a registered product.

With the current package the registrant has submitted the results of the one year storage stability (830.6317) and the corrosion characteristics (830.6320) studies under MRID 46598801, which were not completed prior to the previous reviews.

TRB has been requested to evaluate the recently submitted storage stability (830.6317) and the corrosion characteristics (830.6320) data and other criteria that may be required for the registration of the subject end-use product under the provision of FIFRA § 3.

SUMMARY OF FINDINGS:

1. This formulation contains Orthosulfamuron as an active ingredient (50.0%).
2. The source material for the aforesaid formulation is EPA Reg. No. 80289-4, 98% (IR5878 Technical, CAS No. 213464-77-8). This technical Orthosulfamuron formulation has been conditionally registered with the Agency since February 14, 2007.

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3. The nominal concentration of the active ingredient is 50%. The certified limits of the active and inert ingredients are in compliance with 40 CFR§ 158.175 (b) (2).
4. The CSF of the basic formulation (dated January 26, 2005) is filled out completely and correctly. The nominal concentration of the active ingredient match with the label claim. This is in compliance with PR Notice 91-2. All the inert ingredients used in this CSF have been cleared by the Agency for food use.
5. The product chemistry data submitted for Subgroup A from EPA File Symbol No. 80289-L, IR5878 50 WG corresponding to guidelines 830.1550 (product identity and composition, 830.1600 (materials used to produce the product), 830.1650 (description of formulation process), 830.1670 (discussion of formation of impurities), 830.1750 (certified limits) satisfy the product chemistry data requirements of 40 CFR §158.155, 158.160, 158.165, 158.167, and 158.175 respectively for the subject and alternate formulations [MRID 46219057]. No chemical reactions occur during the manufacturing of the subject formulation. No additional impurities other than those found in IR5878 Technical should occur in the end-use product.
6. The method proposed for the cited product corresponding to guideline 830-1800 (enforcement analytical method) satisfy the data requirements of 40 CFR§158.190 [MRID 46219059] for the subject formulation. HPLC method was used equipped with Diode Array Detector (UV-DAD), wavelength 265 nm and Column type - Purosphere RP-18 e 5µm, 250 X 4 mm, MERCK.
7. The physico-chemical properties of the formulation, storage stability (830. 6317) and corrosion characteristics (830.6320) were determined after 12 and 24 months of storage at ambient temperature. The results were compared with those obtained before the storage.

The concentrations of the active ingredient determined at the initial phase, after 12 months and 24 months of storage at the ambient temperature were 50.85%, 50.62% and 50.24% respectively. The test results indicate that the active ingredient is stable after 24 months of storage at the ambient temperature. This satisfies the storage stability (830.6317) data requirements for registration of the formulation.

The corrosion characteristics (830.6320) of the formulation were determined at the similar intervals as stated above by storing the product in 1 Kg sac with triple layers made of polyester / aluminum / polyethylene. No signs of corrosion were visible after 24 months of storage.

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CONCLUSIONS:

TRB has reviewed the revised basic CSF and has concluded that:

1. The revised CSF for the basic formulation (dated 1/26/2005) is acceptable.
2. The product chemistry data (Subgroup A and B) including storage stability (830.6317) and corrosion characteristics 830.6320) are acceptable.
3. All product chemistry data required for the subject formulation to be registered under FIFRA § 3 are satisfied.