

FEE**DATE OUT:** 02/ JUN/ 2005

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]**
DP BARCODE No.: 304906/ 304909 **File Symbol No.:** 80289-EUP-E
PRODUCT NAME: IR5878 0.5 GR
COMPANY: ISAGRO S.P.A.
FOOD USE [X] INTEGRATED FORMULATION []
PCC: 108209 **Decision No.** 342749

FROM: Debra Rate
Product Chemistry Team
Technical Review Branch/RD (7505C)

Debra Rate 06/08/05
STB 6/19/05

TO: James Tompkins / Erik Kraft RM 25
Herbicide Branch / RD (7505C)

INTRODUCTION:

The registrant has submitted for review a basic formulation CSF (dated 06/FEB/2004) and product chemistry studies (MRID No. 462190-47, 462190-48, 462190-49, 462190-50, and 462190-51) in support of the proposed experimental use, end-use product, IR5878 0.5 GR. The proposed end-use product has orthosulfamuron (0.51%) as its active ingredient (AI).

SUMMARY OF FINDINGS

1. The proposed experimental use, end-use product, IR5878 0.5 GR, uses the technical source, IR5878 Technical (Pending registration, EPA Reg. No. 80289-EUP-R, 98%) containing orthosulfamuron as its active ingredient (AI) with a product label claim of 0.51%.
2. The registrant has submitted a CSF for basic formulation (dated 06/FEB/2004) for the experimental use, end-use product, IR5878 0.5 GR. The CSF is filled out correctly and completely. However, the submitted CSF did not account for the 98% AI of the technical source. The nominal concentration of the AI does not concur with the product label claim nominal concentration, yet it falls within the proposed certified limits of the AI. It should be noted that although the CSFs satisfy the requirements of the 40§CFR158.155 and 158.175, the CSF should be adjusted to more accurately account for the 98% AI in the technical source prior to Section 3 registration. All of the inert ingredients have been cleared by the Agency.
3. The data submitted corresponding to the guideline reference 830.1600 (description of materials used to produce the product) satisfy the requirements of 40§CFR158.160. [MRID No. 463508-07]
4. The registrant has submitted data corresponding to guideline references 830.1650 (description of formulation process) and 830.1670 (discussion on the formation of impurities). The submitted data satisfy the data requirements of 40CFR§158.165 and 158.167, respectively. As no chemical reactions are involved in the formulation process, no new impurities are introduced into the end-use product. [MRID No. 463508-07]
5. An adequate method of enforcement is available. The % active ingredient, orthosulfamuron, was determined by HPLC/DAD (265 nm). This satisfies the guideline reference 830.1800 (enforcement analytical method) and the data requirements of 40CFR§158.180. [MRID No. 462190-49]
6. The product chemistry data to fulfill requirements for reference guidelines of Subgroup B are acceptable and satisfy the data requirement of 40CFR§158.190, except for 830.6317 (storage

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stability) and 830.6320 (corrosion characteristics). The results of these one year studies must be submitted to the Agency on completion.

CONCLUSIONS:

TRB has reviewed the submitted basic formulation CSF (dated 06/FEB/2004) and product chemistry data for the proposed end-use product, IR5878 0.5 GR, and has concluded that:

1. The product chemistry data submitted corresponding to 830 Series Subgroup A are acceptable.
2. The CSF for basic formulation (dated 06/FEB/2004) will be acceptable only if the pending registration of the technical source of the AI is completed. Also, upon Section 3 Registration, the CSF should be revised to more accurately reflect the true nominal concentration based on the reported nominal concentration of the AI (See finding #2.).
3. The product chemistry data submitted corresponding to 830 Series Subgroup B are acceptable, except for 830.6317 (Storage Stability) and 830.6320 (Corrosion Characteristics).
4. The results of the one year storage stability (830.6317) and corrosion characteristics (830.6320) studies must be submitted to the Agency on completion.

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 PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B)

Subgroup A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (Basic CSF)	Y	06/FEB/2004
830.1600. Beginning Materials	Y	462190-47
830.1650. Formulation Process	Y	462190-47
830.1670. Discussion of Impurities	Y	462190-47
830.1700. Preliminary Analysis	NA	
830.1750. Certified Limits (Basic CSF)	Y	06/FEB/2004
830.1800. Enforcement Analytical Method	Y	462190-49

Subgroup B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	Y	Light blue	462190-48
830.6303. Physical State	Y	Solid (cylindrical pellets)	462190-48
830.6304. Odor	Y	odorless	462190-48
830.6314. Oxidation/Reduction	NA	Does not contain Oxidizing or Reducing Agents.	CSF (dated 06/FEB/2004) 462190-47
830.6315. Flammability	NA	Not applicable.	CSF (dated 06/FEB/2004)
830.6316. Explodability	NA	Components are not considered to be explosive.	CSF (dated 06/FEB/2004) 462190-47
830.6317. Storage stability	N	Must be completed.	
830.6319. Miscibility	NA	Not applicable as the product is a solid.	
830.6320. Corrosion Characteristics	N	Must be completed.	
830.6321. Dielec. Bkd. Vltg.	NA	From the proposed label, it is not intended to be used around electrical equipment.	Label (dated 21/MAR/2005)
830.7000. pH	Y	pH = 9.27 (1% aqueous dispersion)	462190-50
830.7100. Viscosity	NA	Not applicable as the product is a solid.	
830.7300. Density/Bulk Density	Y	Pour Density = 0.74 g / mL Tap Density = 0.80 g / mL	462190-51

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled;
 NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

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830.1800 Enforcement Analytical Method: [MRID No. 462190-49]

Reagents:

orthosulfamuron, certified analytical standard
Acetonitrile, HPLC grade
Water, HPLC grade
Acetonitrile, RPE grade
Potassium dihydrogen phosphate, RPE grade
Sodium bicarbonate, RPE grade
Solvent mix: Acetonitrile / aqueous sodium bicarbonate 0.033 M (7:3 v/v)

Equipment and Conditions:

HPLC: High Performance Liquid chromatograph, Perkin Elmer Series 200
Column: Purosphere RP-18 5 μ m, 250 X 4 mm, MERCK
Detector: Diode Array Detector (DAD), Perkin Elmer
Auto sampler: Perkin Elmer Series 200
Column Oven: Perkin Elmer Series 200
Software: TURBOCHROM WS, Perkin Elmer
Ultrasonic bath: Mod. UNISSET AC, AGE
Balance accurate to 0.1 mg
Precision Pipette: capacity 50 ml
Volumetric flasks: capacity 50 ml
Erlenmeyer flasks: capacity 100 ml
Filtering apparatus: with Teflon membrane

Solvent A: Water / KH₂PO₄ (0.004 M)

Solvent B: Acetonitrile

Flow rate: 1.0 ml / min
Detector wavelength: 265 nm
Injection volume: 10 μ l

Retention Times:
orthosulfamuron: ~10.9 min

Gradient Program:

Step	Time (min)	Solvent A	Solvent B
1	0	75	25
2	1	75	25
3	10	20	80
4	1	20	80
5	10	75	25