

DATE OUT: 27/ JUN/ 2005

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]**
DP BARCODE No.: 304902, 304910 **File Symbol No.:** 80289-EUP-E
PRODUCT NAME: IR5878 50 WG
COMPANY: ISAGRO S.P.A.
FOOD USE [X] INTEGRATED FORMULATION []
PCC: 108209 **Decision No.** 342749, 345729

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

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. 462190-57, 462190-58, 462190-59, 462190-61, and 462601-09) in support of the proposed experimental use, end-use product, IR5878 50 WG. The proposed end-use product has orthosulfamuron (50%) as its active ingredient (AI).

SUMMARY OF FINDINGS

1. The proposed experimental use, end-use product, IR5878 50 WG, uses the technical source, IR5878 Technical (Pending registration, EPA Reg. No. 80289-EUP-1, 98%) containing orthosulfamuron as its active ingredient (AI) with a product label claim of 50%.
2. The registrant has submitted a CSF for basic formulation (dated 06/FEB/2004) for the experimental use, end-use product, IR5878 50 WG. The CSF is filled out correctly and completely. The nominal concentration of the AI concurs with the product label claim nominal concentration. The CSF is in compliance with PR Notice 91-2. **However, all of the inert ingredients have not been cleared for use by the Agency.** The data submitted corresponding to guideline 830.1750 (certified limits) satisfies the requirements of 40§CFR158.175. The data submitted corresponding to guideline 830.1550 (product identity and composition) does not satisfy the requirements of 40§CFR158.155. See the Confidential Appendix for the details of the uncleared inerts. *the inerts have been cleared E.N. 1-22-07*
3. The reviewer has spoken with the registrant (01/JUN/2005 and 09/JUN/2005) about the missing information and the registrant, working to get the information, could give no timeline on when it would be obtained.
4. 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. 462190-57]
5. 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. 462190-57]
6. 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

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(enforcement analytical method) and the data requirements of 40CFR§158.180. [MRID No. 462190-59]

7. 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 stability) and 830.6320 (corrosion characteristics). The results of these one year studies must be submitted to the Agency on completion. [MRID No. 462190-57, 462190-58, 462190-59, 462190-61, and 462601-09]

CONCLUSIONS:

TRB has reviewed the submitted basic formulation CSF (dated 06/FEB/2004) and product chemistry data for the proposed end-use product, IR5878 50 WG, 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) is not acceptable. See Finding #2 and Confidential Appendix for details.
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.

CONFIDENTIAL APPENDIX:

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1. Uncleared inert ingredients:



The registrant must supply from the manufacturer a 100% composition statement including the chemical name, CAS Reg. No. and % in the formulation so that the total adds up to 100%.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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

PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B)			
Subgroup A	Data Required Fulfilled	MRID No.	
830.1550. Chemical Identity (Basic CSF)	N	06/FEB/2004	
830.1600. Beginning Materials	Y	462190-57	
830.1650. Formulation Process	Y	462190-57	
830.1670. Discussion of Impurities	Y	462190-57	
830.1700. Preliminary Analysis	NA		
830.1750. Certified Limits (Basic CSF)	Y	06/FEB/2004	
830.1800. Enforcement Analytical Method	Y	462190-59	
Subgroup B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	Y	greyish	462190-58
830.6303. Physical State	Y	Solid (cylindrical pellets)	462190-58
830.6304. Odor	Y	Very faint (odorless)	462190-58
830.6314. Oxidation/Reduction Action	NA	Does not contain Oxidizing or Reducing Agent.	CSF (dated 06/FEB/2004) 462190-57
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) 462190-57
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 = 6.86 (1% aqueous dispersion)	462601-09
830.7100. Viscosity	NA	Not applicable as the product is a solid.	
830.7300. Density/Bulk Density	Y	Tap Density = 0.65 g / mL	462190-61

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable

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830.1800 Enforcement Analytical Method: [MRID No. 462190-59]

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 Φ m, 250 X 4 mm, MERCK
Detector: Diode Array Detector (DAD)
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
Volumetric flasks, capacity 50 ml
Filtering apparatus

Solvent A: Water / KH₂PO₄ (0.004 M)
Solvent B: Acetonitrile

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