

80289-4

02-22-2007

1/4



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

80289-4

Date of Issuance:

2-22-07

Term of Issuance:

Conditional

Name of Pesticide Product:

IR5878 Technical

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Isagro S.p.A.
Centro Uffici San Siro-Edificio d-ala 3
Via Caldera, 21-20153 Milan, Italy

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

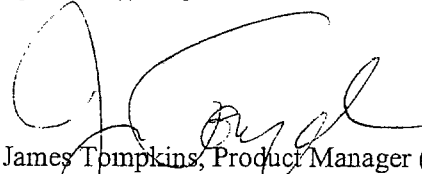
This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided you agree in writing to:

1. Submit the results of the one year storage stability and corrosion characteristics studies..
2. Submit an analytical reference standard to the National Pesticide Standards Repository.
3. For the submitted goat metabolism study (MRIDs 46578962 and 46578963), the registrant needs to provide the dates of sample extraction, initial TLC analysis, and metabolite identification analyses in order to determine sample storage intervals. If the initial quantitative TLC analyses were conducted within 6 months of sample collection, then supporting storage stability data will not be required to support the additional analyses for metabolite identification in goat matrices.
4. Submit radiovalidation data (using samples from the rice metabolism study) for the method chosen for tolerance enforcement purposes. A confirmatory method or method specificity data may also be needed. If the LC/MS/MS method (Report ISA-0102V) is proposed for tolerance enforcement, a separate confirmatory method would not be required if analyte identification is confirmed by analyzing sample extracts using LC/MS/MS and

demonstrating that the ion ratios for the two MS/MS ion transitions acquired during analysis agree with the average ion ratios obtained from the calibration standards.

5. Follow specific directions for each multiresidue method used by FDA published in that Agency's Pesticide Analytical Manual, Vol. I (PAM Vol. I) and provide recovery data for orthosulfamuron through these methods.

Signature of Approving Official:



James Tompkins, Product Manager (25)
Herbicide Branch, Registration Division (7505P)

Date:

2/22/07

EPA Form 8570-6

You will submit one copy of your final printed labeling before you release the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). A stamped copy of labeling is enclosed for your records. If you have any questions please contact Erik Kraft at 703-308-9358.

Sincerely,



James Tompkins
Product Manager (25)
Herbicide Branch
Registration Division (7505C)

IR5878 Technical

Herbicide for Manufacturing or Formulating Use Only

ACTIVE INGREDIENT

Orthosulfamuron 99.0%

INERT INGREDIENTS 1.0%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID	
If Swallowed:	-Call a poison control center or doctor immediately for treatment advice. -Have person sip a glass of water if able to swallow. -Do not induce vomiting unless told to do so by a poison control center or doctor. -Do not give anything to an unconscious person.
If in Eyes:	-Hold eye open and rinse slowly and gently with water for 15-20 minutes. -Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. -Call a poison control center or doctor for treatment advice.
If on skin or clothing:	-Take off contaminated clothing. -Rinse skin immediately with plenty of water for 15-20 minutes. -Call a poison control center or doctor for treatment advice.
If inhaled:	-Move person to fresh air. -If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. -Call a poison control center or doctor for further treatment advice.
Have the product container label with you when calling a poison control center or doctor, or going for treatment. For Chemical Emergency Spill Leak Fire Exposure or Accident Call CHEMTREC Day or Night Domestic North America 800-424-9300 International 703-527-3883 (collect calls accepted)	

EPA Registration No. 80289-

EPA Establishment No. _____

Manufactured by Isagro SpA for:



Isagro USA, Inc
430 Davis Drive, Suite 240
Morrisville, NC 27560

ACCEPTED
with COMMENTS
in EPA Letter Dated

2-22-07

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

80289-4

NET CONTENTS: _____

4
4

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS
CAUTION**

Harmful if swallowed, absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wear protective eyewear. Avoid breathing spray.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying local sewage treatment plant authority. For guidance contact your local State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read entire label. Use this product only for formulation into herbicide products for the following uses: Rice

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store under well vented, cool and dry storage conditions. Do not store under moist conditions.

PESTICIDAL DISPOSAL: Wastes resulting from the use of this product must be disposed of on-site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Dispose of the empty container according to state and local regulations. Place in trash or offer for recycling if available, or, if allowed by state and local authorities, by burning. If burned stay out of smoke.

LIMITATION OF WARRANTY AND LIABILITY

Read the entire label before using this product, including this Limitation of Warranty and Liability.

If the terms are not acceptable, return the product at once unopened for a refund of the purchase price.

This Company warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes set forth in the Directions for Use when used in accordance with the Directions for Use under normal conditions. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ISAGRO MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.