

PM 23

264-566

9-15-98

1049



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (7515C)  
401 "M" St., S.W.  
Washington, D.C. 20461

EPA Reg.  
Number:  
264-566

Date of Issuance:  
SEP 15 1998  
Date of Expiration:  
NOV 1 2001

NOTICE OF PESTICIDE:  
 Registration  
 Reregistration

(under FIFRA, as amended)

Term of Issuance:  
Conditional

Name of Pesticide Product:  
Technical Isoxaflutole

Name and Address of Registrant (include ZIP Code):

Rhone-Poulenc Ag Company  
P.O. Box 12014  
2 T.W. Alexander Drive  
Research Triangle Park, NC 27709

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 sec. 3(c)(7)(C) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Make the following label changes before you release the product for shipment:
  - a. Revise the EPA Registration Number to read, "EPA Registration No. 264-566".
  - b. Add the statement "Causes moderate eye irritation" to the Precautionary Statements.
  - c. Revise the Environmental Hazards section to read: "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 the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

Signature of Approving Official:

Date:

SEP 15 1998

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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10. Submit one copy of the revised final printed label for the record 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 sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Donald Stubbs, Chief  
Herbicide Branch  
Registration Division (7505C)

Enclosures

DK: 305-7546: HB/PM23

CONCURRENCES

SYMBOL ▶	7505C							
SURNAME ▶	D. KENNY							
DATE ▶	9/15/98							

## EPA and Rhône-Poulenc Agreement for Plant Effects and Water Monitoring Data

### General

All protocols for those studies will be submitted by Rhône-Poulenc and reviewed by EPA..

### Plant Effects

1. Repeat seedling emergence and vegetative vigor study to be conducted in accordance with current guidance for guideline 123-1 (The EPA is not requiring this study. Although EPA is not requiring this study, the results from this study may be used for risk assessment purposes providing the study is reviewed by the EPA and accepted as core.)

- BALANCE® WDG as test material
- subirrigation
- 4 replications
- sandy loam soil (<2% organic matter)
- above soil plant dry weights, plant height, morphological abnormalities parameters
- low volume application with automated belt sprayer at 10 gallons/A; show calculations for application
- other study design modifications to better manage variability
- evaluate above soil plant weight, above soil plant height, and morphological abnormalities as the relevant parameters. Root weight measurements would not be evaluated per telephone discussion with M. Davy on 08-04-98
- conducted under GLP

2. Field perimeter runoff and littoral zone monitoring

#### Field perimeter monitoring (terrestrial)

- 4 paired sites (control and treatment) will be evaluated weekly for 30 days
- survey species and population in fall prior to spring application; survey prior to application and after rainfall event
- symptomology
- species richness and abundance
- two of the four sites will have a rainfall simulator to evaluate run-off exposure. Sites will be no-till production system. Consists of three side-by-side plots: one to collect flow rate and water concentrations: one to provide control plants (untreated) and one to observe effects to test plants. Rainfall event will occur 2 days after application and a second event at 10 days after application. Water will be applied at a minimum rate (to be determined dependent upon the site characteristics) Collection of water will be made during any rainfall event (simulated or natural occurrence) within 10 days of application.
- the other two sites will be pre-selected and rainfall monitored. When a notable rainfall event occurs (within 30 days of application), R-P will initiate monitoring of the site immediately and continue weekly monitoring for 30 days. (still to be agreed in the protocol upon with respect to number of monitoring events and what is consider as "notable" rainfall)
- rainfall will be measured through a rain gauge
- conducted under GLP

### EPA and Rhône-Poulenc Agreement for Plant Effects and Water Monitoring Data

Littoral zone monitoring (aquatic) - same conditions as above

- 4 paired sites (control and treatment) will be evaluated weekly for 30 days
- symptomology
- species richness and abundance
- survey species and population in fall prior to spring application; survey prior to application and after rainfall event

#### 3. Simulated pond study

- RPA 202248 will be used as the primary study test material in one pond; . second pond dosed above the plant(s) with 1% Balance\* as a worst-case drift exposure to an aquatic area; one of the dose level will encompass EPA's predicted PRZM-EXAMS concentration for parent isoxaflutole and RPA 202248
- square pools (2.3 X 2.3 X 0.5M): volume 1,500L
- 4 dose levels
- 10 aquatic plant species
- will develop some mechanism to evaluate rice in 1999 since it is not possible to add rice to the ongoing simulated pond study
- conducted under GLP

#### 4. Small plot irrigation study with RPA 202248

- 6 dose levels in spiked water which encompasses EPA's predicted PRZM-EXAMS concentration; sprayed from ground equipment
- crops - lettuce, radish, turnip, sugarbeet, tomatoes, cabbage
- symptomology
- yield data for lettuce, radish and turnip
- will conduct second study in 1999 with cotton, canola, oats, sunflower taken to yield; control and 4 replications; timing of application will be proposed in the protocol and will be agreed upon by EPA
- conducted under GLP

#### 5. Irrigation study on soybean

- 2 dose levels in spiked water which encompasses EPA's predicted PRZM-EXAMS concentration
- Volume of water equivalent to 1 inch of irrigation water per acre
- symptomology
- yield data
- conducted under GLP

#### 6. Terrestrial plant field study to address ground spray drift

- Control and 4 replications
- Crops - soybean, oat, canola, sunflower and rice
- Species will be either on separate or same plot, if appropriate
- Dose will be 1% of the maximum application rate (0.14 lb. ai/A) of BALANCE® by ground equipment
- Application timing - BALANCE® applied at the normal application timing and site to be agreed upon by EPA
- Measure yields
- Standard agricultural controls for weeds, insect and fungicides permitted for those specific crops
- conducted under GLP

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## EPA and Rhône-Poulenc Agreement for Plant Effects and Water Monitoring Data

### Water Monitoring

#### 1. Analysis and Methodology

- Analyze for parent isoxaflutole, RPA-202248 and RPA 203328.
- Work will be done to refine the soil methodology to achieve a lower detection limit. Current soil LOQ is at 5 ppb for each of the following analytes: isoxaflutole, RPA-202248, and RPA-203328. Sample analysis will be conducted under GLP, QA/QC.
- Confirm application of highest labeled use rate by quantifying residues on filter paper discs which are sprayed during soil application.
- Soil samples taken from 0 to 90 cm in the first 30 days of each study will not be composited.
- Soil samples taken deeper than 90 cm and samples taken after 30 days will be composited.
- Tracers will be used at all sites.
- Work to continue to refine water method to 22 ppt in water of total residues or 5 ppt for each parent and degradate. If further refinement is not possible, all detects will be considered above the limit of detection.

#### 2. Ground Water Prospective Studies

- A total of 4 prospective studies; 2 initiated in 1998, 2 in 1999.
- During 1998, initiate two prospective ground water studies on vulnerable, but not off labeled soils - contain no tile drains.
- Conducted in high corn production areas of the Midwest in fields
- Rhône-Poulenc will provide proposed site (state soil type) and EPA will promptly review all study documentation
- In 1999, initiate two additional studies on typical corn or benchmark soils. These studies will be conducted at locations which contain tile drains (See details below.).
- Each consist of 2-5 acres with shallow ground water (<25 feet).
- Study length will be 2-3 years. Termination will be based on data evaluation.

#### Characterization and Site Sampling

- Characterize each site with 8 soil borings.
- A minimum of 8 lysimeter clusters each with 3 sampling devices at 3 - 12 foot depths depending on site characteristics.
- A minimum of 8 well clusters each with 3 wells. One foot well screens will be used at the water table and 5 foot depths. A five foot screen will be used in the 10-15 ft well.
- Will be irrigated to insure that total irrigation plus rainfall is equal to or greater than 120% of the 30 year monthly rainfall average. Irrigation water will be appropriately characterized.
- An on site weather station will be installed at each site.
- In the initial year of the study, corn will be planted at each site. In subsequent years, during the course of the study, other crops may be grown. Application will only be made the first year at each site.
- During the first 30 days of the study, soil samples will be taken in  $\geq 15$  cm increments. (still needs to be agreed upon by EPA)
- Sampling will occur at 0, 1, 2 and 4 weeks. On day 0, a single soil increment will be collected. Multiple increments will be collected on other sample dates. (Still needs to be agreed upon by EPA)

### EPA and Rhône-Poulenc Agreement for Plant Effects and Water Monitoring Data

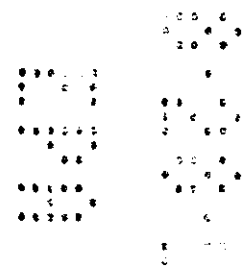
#### 3. Tile Drain Studies

##### Prospective studies

- Will be located in the Midwest or Plains States (high corn production area).
- Initiated in August 1999
- Will last for one growing season.
- Contain a number of ground water wells at least 4 clusters of 3 wells at each site, but no lysimeters.
- Although EPA does not require soil sampling from these sites, will collect composited soil samples. The soil sampling design will be according to Rhone Poulenc's choice.
- Will be irrigated to achieve 120% of the 30 year monthly average rainfall (irrigation plus rainfall  $\geq$  120%). In addition, the amount of water within 7 days of application will be 1 inch with at least  $\frac{1}{2}$  inch occurring on one day (to be provided by irrigation if necessary)
- Water flow from the tile drain will be continuously monitored.
- Will collect periodic water samples from one tile drain outlet, one drainage ditch and any adjacent river or stream fed by drainage ditch from these fields (1 sample/day/drain, ditch and river for each of the 2 sites).

##### Monitoring (irrigation water)

- Will monitor isoxaflutole residues in tile drain water and drainage ditches at 5 Midwest tile drain sites for one growing season, beginning in spring of 1999.
- These sites will not be irrigated.
- There will be no wells, lysimeters or soil sampling at these sites.
- Water flow from the tile drain will be monitored.
- Will collect periodic water samples from one tile drain outlet, one drainage ditch and any adjacent river or stream fed by drainage ditch from these fields (1 sample/day/drain, ditch and river for each of the 5 sites).



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## ATTACHMENT #2

Study	Expected Final Report Date
<b>Environmental fate</b>	
Two ground water prospective studies without tile drains	1-year interim report August 2000
Two ground water prospective studies with tile drains	1-year interim report August 2001
Tile drain monitoring (5 sites)	December 2000
<b>Plant Effects</b>	
Seedling emergence and vegetative vigor study to current guidance with BALANCE®	April 1999
Field perimeter and littoral zone monitoring with water concentration measurements	December 1999
Simulated pond study with RPA 202248 and BALANCE®	April 1999
Small plot irrigation study with RPA 202248 lettuce, radish, turnip, sugarbeet, tomato, cabbage	April 1999
Small plot irrigation study with RPA 202248 - cotton, canola, oats, sunflower	April 2000
Irrigation study on soybeans with RPA 202248	April 1999
Terrestrial plant field study to address ground spray drift with BALANCE®	April 2000
<b>Wildlife &amp; Aquatic Organisms</b>	
Avian reproduction with RPA 202248	December 1999
Quail dietary LC50 with RPA 203328	December 1998
Mysid shrimp toxicity with RPA 203328	December 1998
<b>Mammalian toxicity</b>	
Developmental neurotoxicity study with isoxaflutole (in reserve)	June 2000
<b>Residue chemistry</b>	
Field rotational crop study	October 1999

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# TECHNICAL ISOXAFLUTOLE

## For Manufacturing Purposes Only

### ACTIVE INGREDIENT:

Isoxaflutole [5-cyclopropyl-4-(2-methylsulfonyl-4-trifluoromethylbenzoyl) isoxazole]..... 98.0%

### INERT INGREDIENTS.....

2.0%

EPA Reg. No.: 264- 566

EPA Est. No.:

## KEEP OUT OF REACH OF CHILDREN CAUTION

For **EMERGENCY** information ONLY Call 24 Hours A Day 1-800-334-7577

### STATEMENT OF PRACTICAL TREATMENT

**IF SWALLOWED:** Call a physician or Poison Control Center. Drink 1 to 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention.

**IF INHALED:** Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

**IF IN EYES:** Flush eyes with plenty of water. Call a physician if irritation persists.

### PRECAUTIONARY STATEMENTS

#### CAUTION

#### HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed, inhaled or absorbed through skin. Avoid breathing vapors (dust or spray mist). Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

#### ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or regional office of the Environmental Protection Agency.

### DIRECTIONS FOR USE

It is a violation of law to use this product in a manner inconsistent with its labeling.

Only for formulation into a herbicide for use in field corn.

Formulators who use this product are responsible for obtaining EPA registration for their formulated products.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated  
SEP 15 1998

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
264-566

### STORAGE AND DISPOSAL

**STORAGE:** Do not store with foodstuff. Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty bag into application equipment. Then dispose of bag in a sanitary landfill, by incineration or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

### LIMITED WARRANTY AND DISCLAIMER

The manufacturer warrants that this product conforms to the chemical description on the label; that this product is reasonably fit for the purposes set forth in item (1) of the Directions for Use when it is used in accordance with such Directions; and that the statements under item (1) of the Directions, the warnings and other statements on this label, other than the suggested uses under items (2) and (3) of the Directions, are based upon responsible experts' evaluation of reasonable tests of effectiveness, of toxicity to laboratory



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animals and to plants, and of residues on food crops and upon reports of field experience. Tests have not been made on all varieties or in all states or under all conditions. THE MANUFACTURER NEITHER MAKES NOR INTENDS, NOT DOES IT AUTHORIZE ANY AGENT OR REPRESENTATIVE TO MAKE, ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, AND IT EXPRESSLY EXCLUDES AND DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

THIS WARRANTY DOES NOT EXTEND TO, AND THE BUYER SHALL BE SOLELY RESPONSIBLE FOR, ANY AND ALL CLAIMS, LOSSES, DAMAGES OR INJURIES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER OR NOT BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY IN TORT OR OTHERWISE SHALL BE LIMITED, AT THE MANUFACTURER'S OPTION, TO REPLACEMENT OF, OR THE REPAYMENT OF THE PURCHASE PRICE FOR, THE QUANTITY OF PRODUCT WITH RESPECT TO WHICH DAMAGES ARE CLAIMED. IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

**NOTICE TO BUYER**

Purchase of this material does not confer any rights under patents governing this product or the use thereof in countries outside of the United States. Seller's guarantee shall be limited to the terms set out on the label and subject thereto, the buyer assumes the risk to persons or property arising from the use or handling of this product on that condition.

**NET CONTENTS:**

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TECHNICAL ISOXAFLOTOL (PENDING) Submitted 8/27/98.

