

PM03

264-577

7/17/98

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number: 264-577

Date of Issuance: JUL 17 1998

Term of Issuance: Conditional

Name of Pesticide Product: Icon 6.2 FS

NOTICE OF PESTICIDE:
[X] Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Larry Hodges
Rhone Poulenc AG Company
P.O. Box 12014
2 T.W. Alexander Drive
Research Triangle Park, NC 27709-2014

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 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.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(B). It will expire on July 1, 2002 unless 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; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Make the following label changes:
a. Revise the EPA Registration Number to read, "EPA Reg. No. 264-577".
b. Modify the statement below the ingredient statement to say that one gallon of Icon 6.2FS contains 6.3 pounds of fipronil.
c. Modify the environmental hazards statement to include estuarine invertebrates.

Signature of Approving Official: Joseph M. Vairano

Date: July 17, 1998

EPA Form 8570-6

CONCURRENCES

Table with columns for SYMBOL, SURNAME, and DATE. Row 1: SYMBOL 7505C, SURNAME Subold, DATE 7/17/98.

- d. Add to the storage and disposal statement directions to put on PPE before cleaning up spills.
- e. Add to the seed labeling statement the following:
Treated seed must be labeled in accordance with the requirements of the Federal Seed Act.

3. The following studies are required as a condition of registration and must be submitted within 3 years after the date of this registration:

A. An acceptable inhalation study for Icon 6.2FS. This study was provisionally accepted in a review dated January 13, 1998. A final report is under review within the Agency.

B. Storage stability data for MB46513.

C. A residue analytical method revised to remove directions for MB200766.

D. An additional crop field trial for rice in region 5.

E. Dermal and inhalation exposure data for workers in commercial seed treatment plants.

G. Acute toxicity studies with mysids which compare the parent to the degradates MB46513, MB46136, and MB45950. Depending on the results of these studies, chronic studies may be required.

H. Sediment toxicity studies using the parent and the three degradates MB46513, MB46136, and MB45950. These studies may be conducted as part of an iterative process which first investigates the toxicity of the degradates to mysids.

I. Additional information to resolve a contradiction between the half-life derived from the aerobic aquatic metabolism study and the half-life derived from the anaerobic aquatic and aerobic soil metabolism studies.

I. Environmental fate data to (1) establish validity of preliminary batch equilibrium data, (2) determine the persistence of degradates in terrestrial and aquatic environments, and (3) confirm in the field the results of exposure modeling based on laboratory fate data.

J. Physical and chemical property and fate data on fipronil degradates must be supported by formal study submissions.

K. Additional information on aquatic field dissipation may be required when the study review is completed.

4. To provide for the periodic evaluation of anticipated residues, the Agency will require residue to be submitted every 5 years as long as the tolerances remain in force.

5. Any developmental neurotoxicity or other toxicity study

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using the photodegradate MB46513 conducted by the registrant should be submitted to the Agency.

6. You must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether fipronil shares a common mechanism of toxicity with any other substance, and, if so, whether any tolerances for fipronil need to be modified or revoked.

7. Submit two copies of the revised final printed label for the record.

8. Suggested changes to the information bulletin which will accompany the treated seed are included in attachment A.

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.

Recommended Changes to the Bulletin Entitled
Rice Seed Treated with Icon 6.2 FS Insecticide

1. The Precautionary Statements should match the Precautionary Statements on the Icon 6.2 FS label. The protective clothing for handlers should include coveralls over short sleeved shirt and short pants, waterproof gloves and chemical resistant footwear plus socks.

2. The bulletin should state that the Worker Protection Standard should be observed. An Agricultural Use box is recommended, and it should include an REI of 24 hours and the following statement:
For early entry to seeded areas that involves contact with plants, seeds, soil or water, wear coveralls over long-sleeved shirt and long pants, socks and chemical resistant footwear and waterproof gloves.

3. The Environmental Hazards statement should include the following: Exposed treated seeds may be hazardous to birds and other wildlife. Cover, incorporate or clean up treated rice seeds that are spilled during loading or are visible on soil surfaces in turn areas. Do not store excess treated seed beyond planting time. Dispose of excess treated seed by burial away from streams and bodies of water. Treated seed should not be planted in rice cultivation areas where drainage water is released to small low-flow receiving water bodies. Treated seed should not be planted in rice cultivation areas where local drainage is released in close proximity to estuarine water bodies. Do not contaminate water when disposing of equipment washwaters or rinsate.

4. You should include some method for advising users how to stay within the maximum application rate of 0.05 lb ai/A.

ICON™ 6.2 FS Insecticide

For Commercial Treatment of Rice Seed Only

ACTIVE INGREDIENTS:

Fipronil: 5-amino-1-(2,6-dichloro-4-(trifluoromethyl) phenyl)-4-((1,R,S)-(trifluoromethyl)sulfinyl)-1H-pyrazole-carbonitrile 56%

INERT INGREDIENTS..... 44%

One gallon of ICON™ 6.2 FS Insecticide contains 6.2 pounds of the active ingredient Fipronil.

EPA Reg No. 264-XXX

EPA Est. No.

ACCEPTED
with COMMENTS
In EPA Letter Dated:
JUL 17 1998

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the Pesticide registered under EPA Reg. No. 264-XXX-577

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KEEP OUT OF REACH OF CHILDREN WARNING - AVISO

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577

For PRODUCT USE Information Call 1-800-334-9745

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 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 thoroughly with 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.

GENERAL

Contact a physician immediately in all cases of suspected poisoning. Transport patient to a physician or hospital immediately and SHOW A COPY OF THIS LABEL TO THE PHYSICIAN. If poisoning is suspected in animals, contact a veterinarian.

NOTE TO PHYSICIAN:

There is no specific antidote. All treatment should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

MAY BE FATAL IF SWALLOWED, ABSORBED THROUGH SKIN, OR INHALED; CAUSES MODERATE EYE IRRITATION. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R or HE filter. Wear disposable coveralls (such as Tyvek) over long-sleeved shirt and long pants, chemical resistant (such as nitrile) gloves, chemical resistant boots, and protective eyewear (such as face shield or goggles). Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands thoroughly with soap and water before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

SYMPTOMS OF POISONING: In severe cases of overexposure by oral ingestion, lethargy, muscle tremors, and, in extreme cases, possibly convulsions, may occur.

ENVIRONMENTAL HAZARDS

This product is toxic to birds, fish, and aquatic invertebrates. 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.

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DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
Read entire label before using this product.

STORAGE AND DISPOSAL

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

STORAGE

Store unused product in original container only, in cool, dry area, out of reach of children and animals

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance

In case of spill, clean up immediately. Soak up with sand, earth or other suitable material and dispose of wastes in a landfill approved for pesticide disposal. Ensure adequate decontamination of tools and equipment following cleanup

CONTAINER DISPOSAL

Triple rinse (or equivalent) the empty container. Then offer container for recycling or reconditioning or puncture and dispose of container in a sanitary landfill, by incineration, or, if allowed by state and local authorities, by burning. If container is burned, stay out of smoke

ICON™ 6.2 FS INSECTICIDE IS FOR COMMERCIAL TREATMENT OF RICE SEED ONLY.

ICON™ 6.2 FS Insecticide is an aqueous flowable formulation for use as a seed treatment on rice to control rice water weevil, rice stem borer and chinch bugs. It may be applied to dry rice seed which will be drilled or broadcast, and to pre-germinated rice after the seed is soaked and drained. Dry rice seed treated with ICON™ 6.2 FS Insecticide cannot be soaked or pre-germinated before planting.

ICON™ 6.2 FS Insecticide may be applied as a water-based slurry with other registered rice seed treatment materials, such as fungicides, micronutrients, and plant growth regulators. Potential tank mix partners should be tested for physical compatibility with ICON™ 6.2 FS Insecticide and added dyes or polymers before mixing in a large tank for seed treatment

The rate of ICON™ 6.2 FS Insecticide to be applied to the seed depends upon the seeding rate (pounds of seed per acre). Adjust the rate of seed treatment to ensure that each acre is treated with 0.025 to 0.05 lb ai. per acre.

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Dry Rice Seed

ICON™ 6.2 FS Insecticide should be applied with a seed treatment machine which can provide an accurate application of chemicals to seeds. ICON™ 6.2 FS Insecticide can be applied with a polymer to improve evenness and adherence and reduce dust. Follow manufacturer's directions for quantity of polymer (such as CelPril's CELGARD) to be used. Use 12-24 fl. oz. of slurry per 100 lb. seed or follow machine and polymer manufacturer's recommendations for slurry volumes for rice. Use sufficient EPA approved seed dye or colored polymer to achieve a distinctive unnatural color on the seed.

To apply ICON™ 6.2 FS Insecticide using a mixing tank, place 3/4 of the water and all of the polymer or dye needed into the mixing tank and begin agitation. Measure the amount of ICON™ 6.2 FS Insecticide needed and add to the tank. Use the remaining water to thoroughly rinse the measuring container. Add rinsates to the tank. Maintain agitation during application.

Pre-Germinated Rice Seed

ICON™ 6.2 FS Insecticide can be applied to pre-germinated rice seed. The seed should be drained for at least 4 hours after removal from the soak tank, so that the seed is no longer dripping. ICON™ 6.2 FS Insecticide can be tank-mixed with other pesticides which are registered for application to pre-germinated rice seed. Apply using equipment designed specifically for treatment of pre-germinated rice seed. An application rate of 16-24 fl. oz. of slurry per 100 lbs. of seed gives good coverage on seed with no free liquid on the seed surface. Use sufficient EPA approved seed dye or colored polymer to achieve a distinctive unnatural color on the seed.

To apply ICON™ 6.2 FS Insecticide using a mixing tank, place 3/4 of the water and all of the polymer or dye needed into the mixing tank and begin agitation. Measure the amount of ICON™ 6.2 FS Insecticide needed and add to the tank. Use the remaining water to thoroughly rinse the measuring container; add rinsates to the tank. Maintain agitation during application.

Pre-germinated seed treated with ICON™ 6.2 FS Insecticide can be stored for up to 48 hours, depending on the development of the rice roots. Treated seed should not be stored so long that the roots become entangled. Treated seed may NOT be rinsed with water to slow germination.

SEED LABELING

Federal law requires that bags containing treated seeds shall be labeled with the following information "This seed has been treated with ICON™ 6.2 FS Insecticide. Do not use for food, feed, or oil purposes. Store away from foods and feeds."

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NOTICE- READ CAREFULLY CONDITIONS OF SALE AND LIMITED WARRANTY STATEMENT

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment or a combination of treatments. No claims are made to guarantee germination of carry-over seed.

LIMITED WARRANTY AND DISCLAIMER

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is reasonably fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warnings, and other statements on this label are based upon responsible experts' evaluation of reasonable tests of effectiveness, of toxicity to laboratory animals and to plants, and 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, NOR DOES IT AUTHORIZE ANY AGENT OR REPRESENTATIVE TO MAKE, ANY OTHER WARRANTIES, EXPRESSED 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 LOSS OR DAMAGE WHICH RESULTS FROM THE USE OF THIS PRODUCT IN ANY MANNER WHICH IS INCONSISTENT WITH THE LABEL DIRECTIONS, WARNINGS, OR CAUTIONS.

BUYER'S EXCLUSIVE REMEDY AND MANUFACTURER'S OR SELLER'S EXCLUSIVE LIABILITY 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 WHEN USE OR HANDLING IS NOT IN ACCORDANCE WITH LABEL DIRECTIONS.

NOTICE TO BUYER

Purchase of this material does not confer any rights under patents governing this product or the use thereof in countries outside the United States.

Rhône-Poulenc Ag Company
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ICON™ is a trademark of Rhône-Poulenc Ag Company in the USA.

ICON™ 6.2 FS Insecticide for Rice Seed Treatment (PENDING) Submitted 4/22/97, Resubmitted 9/18/97, Resubmitted 1/9/98, Resubmitted 5/27/98, Resubmitted 7/2/98.