

PM 22 773-56

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

EPA Reg. Number: 773-56	Date of Issuance: 11/23/77
Term of Issuance: Conditional	
Name of Pesticide Product: CLINAFARM Smoke Generator	

NOTICE OF PESTICIDE:
 Registration
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):
Pitman-Moore, Inc.
1201 Douglas Avenue
Kansas City, KS 66103-1438

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)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration 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 labeling changes listed below before you release the product for shipment:
 - a. Add the phrase "EPA Registration No. 773-56.
 - b. Your correct signal word is "DANGER". To your labeling add "DANGER. The unignited contents of the canister contains a strong oxidizing agent which may cause irreversible eye damage. After ignition of the canister, all persons should leave the treatment areas immediately. Avoid contact of product with skin, eyes or clothing. Wear goggles. Avoid breathing smoke. Wash thoroughly with soap and water after handling. Delay reentry into treatment areas until the smoke has settled or dissipated to avoid possible eye irritation. Remove contaminated clothing and wash before reuse." You must also indicate in the precautionary statement portion of the labeling

Signature of Approving Official:
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Date:

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how long workers should wait before reentry into the treatment area after canister ignition. Submit supporting documentation for this time period at the same time you submit your revised labels. Regarding the ingredient statement of your label, you must add "TOTAL"...100%. You must submit the aforementioned labels and documentation within thirty (30) days from the date of this registration notice.

c. Directly under the "Directions for Use" you must add the following misuse statement: "IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING."

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 your label is enclosed for your records.

Sincerely,

Cynthia Giles-Parker
Product Manager (22)
Fungicide-Herbicide Branch
Registration Division (H7505C)

Enclosure

CURRENT DRAFT LABEL

DRAFT LABEL

PRODUCT NAME: CLINAFARM Smoke Generator

DATE: June 17, 1992

SUPERSEDES: May 16, 1990

ITEM: Unit and Shipper Labels

PAGE: 2 of 4

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SHIPPER LABEL - FRONT PANEL

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CLINAFARM* Smoke Generator

For the control of Aspergillus organisms in cleaned poultry and turkey hatchery equipment prior to the introduction of eggs.

ACTIVE INGREDIENT:

Imazalil (enilconazole)*: 1-[2-(2,4-Dichlorophenyl)-2-(2-propenyloxy)ethyl]-1H-imidazole14.9% w/w
INERT INGREDIENTS.....85.1%

*U.S. PATENT No. 3,658,813 100.0% w/w

5 grams Imazalil (enilconazole) per canister

KEEP OUT OF REACH OF CHILDREN
WARNING

See Side Panel for Additional Precautionary Statements

Net Contents: 24 - 33.4 gram canisters

EPA Reg. No. 773-56

EPA Est. No. 39775-EN-01

Manufactured For
STERWIN
Laboratories Inc.
A Pitman-Moore Company

ACCEPTED
with COMMENTS
In EPA Letter Dated:

NOV 23 1992

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

773-56

DRAFT LABEL

PRODUCT NAME: CLINAFARM Smoke Generator
 DATE: June 17, 1992 SUPERSEDES: May 16, 1990
 ITEM: Unit and Shipper Labels PAGE: 1 OF 4
 COMPANY: Sterwin Products Inc., Pitman-Moore
 COUNTRY: USA
 REASON TO ISSUE: Revise directions for use text and add re-
 entry statement to Directions For Use.
 PREPARED BY: DABusa, Reg Affairs, Kansas City
 (Refer to 40 CFR for US/EPA type size requirements. Refer to
 US/EPA Pesticide Regulation Notice 83-3 for container dis-
 posal text appropriate for container size and material.)
 (92sdb001) UNIT LABEL - FRONT PANEL

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CLINAFARM
 Smoke Generator

- KEEP OUT OF REACH OF CHILDREN -
 - WARNING -

See outer container label for use directions, additional pre-
 cautionary statements and statements of practical treatment.
 Net Contents 33.4 g.

Manufactured For
 STERWIN
 Laboratories Inc.
 A Pitman-Moore Co.

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UNIT LABEL - SIDE PANEL

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INDICATIONS

For control of Aspergillus fumigatus contamination of cleaned
 poultry and turkey hatchery equipment prior to introduction
 of eggs: such as empty hatcher cabinets, setters, coolers,
 storerooms and egg and chick handling equipment.

ACTIVE INGREDIENT:

Imazalil (enilconazole): 1-[2-(2,4-dichlorophenyl)
 -2-(2-propenyloxy)ethyl]-1H-imidazole14.9% w/w
 INERT INGREDIENTS.....85.1%

100.0% w/w

Contents: 5 grams imazalil (enilconazole)
 EPA Reg. No. 773-56 EPA Est. No. 39775-EN-01

A product of Janssen Research

Clinafarm is a registered trademark of Janssen Pharmaceutica
 N.V.

(Lot #) Label Control Number XXXX

Manufactured For
 Sterwin Laboratories Inc.
 A Pitman-Moore Company
 Millsboro, DE 19966

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*****DRAFT LABEL*****

PRODUCT NAME: CLINAFARM Smoke Generator

DATE: June 17, 1992

SUPERSEDES: May 16, 1990

ITEM: Unit and Shipper Labels

PAGE: 3 of 4

SHIPPER LABEL - SIDE PANEL**CLINAFARM Smoke Generator****PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

WARNING. The unignited content of the canister is corrosive and causes irreversible eye damage. Avoid contact with skin, eyes or clothing. Wear goggles. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Avoid breathing the smoke.

STATEMENT OF PRACTICAL TREATMENT

If Contents are Swallowed: Promptly drink either a large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol. Call a physician or poison control center.

If in Eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Call a physician.

If on Skin: Wash thoroughly with soap and water.

If Inhaled: Get to fresh air. Get medical attention if respiratory irritation occurs.

PHYSICAL OR CHEMICAL HAZARDS Flammable. Do not store near heat or open flame.

DIRECTIONS FOR USE**INDICATIONS**

For the control of Aspergillus organisms in cleaned poultry and turkey hatchery equipment prior to the introduction of the eggs, such as empty hatcher cabinets, setters, coolers, storerooms, and egg and chick handling equipment. Imazalil will dramatically reduce the levels of infectious organisms and spores in treated areas. Each canister contains sufficient imazalil and smoke generating material to cover an enclosure of 400 to 500 cubic feet.

DIRECTIONS FOR USE

Do not remove canisters from the container except for immediate use. Treatment of the hatchery equipment should be the final step prior to introduction of the eggs. After the equipment has been thoroughly cleaned and disinfected, a smoke canister of imazalil should be placed on a noncombustible surface. Before starting, the area to be treated should be closed off to prevent air currents from diluting smoke. Ventilation ducts may be treated, but fans must be shut off. The wick of the canister should be ignited and all persons should leave the treated area. Within 60 seconds the canister will be through smoking. The smoke should be allowed to settle and contact the surfaces for no less than 1/2 hour but preferably up to 12 hours before fumigated equipment and areas are used. Persons should delay reentry of treated areas until smoke has settled or dissipated to preclude possible eye irritation.

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DRAFT LABEL

PRODUCT NAME: CLINAFARM Smoke Generator
DATE: June 17, 1992 SUPERSEDES: May 16, 1990
ITEM: Unit and Shipper Labels PAGE: 4 of 4

SHIPPER LABEL - SIDE PANEL

STORAGE AND DISPOSAL

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

STORAGE: Store in a cool, dry place. Storage temperatures should not exceed 100 degrees F.

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

CONTAINER DISPOSAL: Do not reuse container. Replace cap and dispose of in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

NOTICE OF WARRANTY

Sterwin Laboratories, Inc. A Pitman-Moore Company, makes no warranty of merchantability, fitness for any purpose, or otherwise, expressed or implied, concerning this product or its uses which extend beyond the use of the product under normal conditions in accord with the statements made on this label.

Manufactured For
Sterwin Laboratories, Inc.
A Pitman-Moore Company
Millsboro, DE 19966

U.S. Patent No. 3,658,813

Label Control Number XXX

A product of Janssen Research.
Clinafarm is a registered trademark of
Janssen Pharmaceutica N.V.

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