



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

MAR 27 2003

Diane deBruin  
Schering-Plough Animal Health Corporation  
1095 Morris Avenue  
P.O. Box 3182  
Union, New Jersey 07083-1982

Subject: Clinafarm Smoke Generator  
EPA Registration Number 773-56  
Your label amendment application dated February 11,  
2003

Dear Ms. deBruin,

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended is acceptable, provided that you comply with the following conditions.

1. Make the following changes to the label.

a. At the top of the right column on the first page, move "HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS" to its own line below the heading "PRECAUTIONARY STATEMENTS" and change "HAZARDOUS" to "HAZARDS".

b. At the top of the right column on the first page, move "DANGER" to a line below "HAZARDS TO HUMANS AND DOMESTIC ANIMALS".

2. Submit one copy of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration may be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

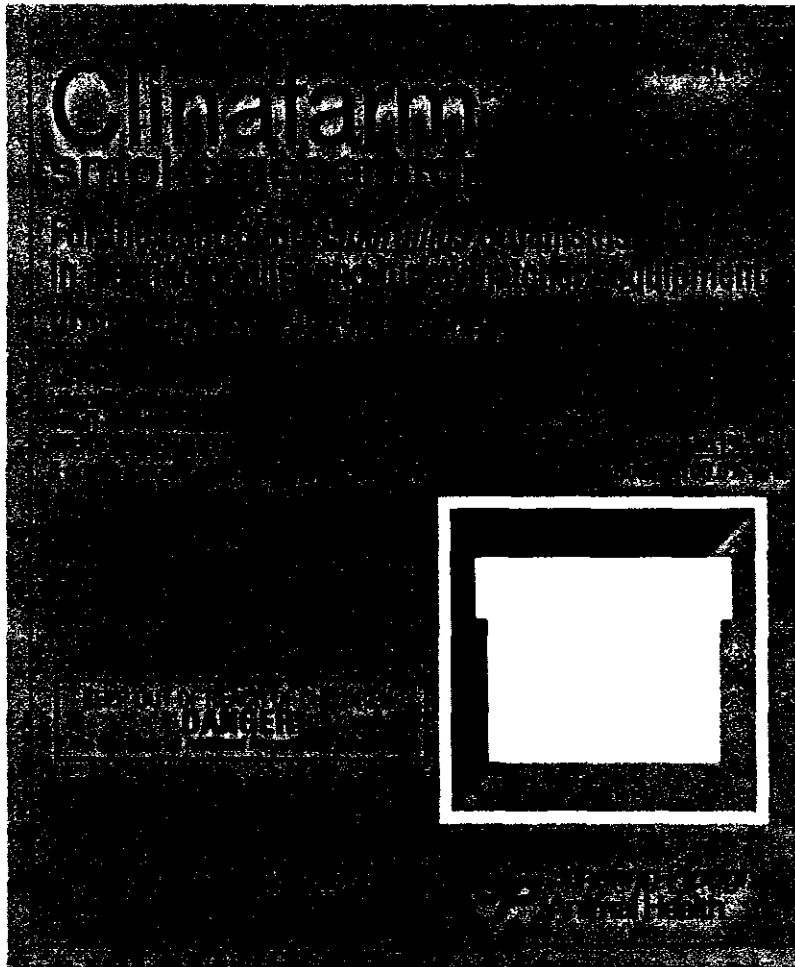
2/4

If you have any questions about this letter, please contact John Bazuin at (703)305-7381.

Sincerely yours,

Dennis McNeilly  
Acting Product Manager (22)  
Fungicide Branch  
Registration Division (7505C)

Attachment: Label stamped "ACCEPTED with COMMENTS"



## Clinafarm® smoke generator

### PRECAUTIONARY STATEMENTS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS DANGER

The unaltered content of the container contains a strong oxidizing agent which may cause irreversible eye damage. After ignition of the container, all persons should leave the treated area 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. Do not reenter unventilated areas for 12 hours after treatment. For ventilated areas, do not reenter treatment areas until ventilation ducts and fans have been opened and on for at least 30 minutes and at least 1-2 air exchanges have occurred. For either unventilated or ventilated areas, do not reenter if treatment smoke is still visible. Remove contaminated clothing and wash before reuse.

#### FIRST AID

|                        |   |
|------------------------|---|
| If in Eyes             | <ul style="list-style-type: none"> <li>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.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>  |
| If Swallowed           | <ul style="list-style-type: none"> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> <li>Promptly drink either large quantity of milk, egg white, potato solution, or, if these are not available, large quantities of water. Avoid alcohol.</li> </ul> |
| If on Skin or Clothing | <ul style="list-style-type: none"> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>   |
| If Inhaled             | <ul style="list-style-type: none"> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>   |

#### HOT LINE NUMBER

Have the product container or label with you when calling the poison control center or doctor or going for treatment. You may also contact the Rocky Mountain Poison Center at 1-303-535-4999 for emergency medical treatment information.

#### PHYSICAL OR CHEMICAL HAZARDS:

Flammable. Do not store near heat or open flame.

#### DIRECTIONS FOR USE

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

##### INDICATIONS

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

##### DIRECTIONS FOR USE:

Do not remove containers from 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 single container of Insectall should be placed on a noncombustible surface. Before starting, the area to be treated should be closed off to prevent air currents from blowing smoke. Ventilation ducts may be treated, but fans must be shut off. The wick of the container should be ignited and all persons should leave the treated area. Within 60 seconds the container 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 hatched equipment and areas are used. Delay reentry into treatment areas until the smoke has settled or dissipated to avoid possible eye irritation. Do not reenter unventilated areas for 12 hours after treatment. For ventilated areas, do not reenter treatment areas until ventilation ducts and fans have been opened and on for at least 30 minutes and at least 1-2 air exchanges have occurred. For either unventilated or ventilated areas, do not reenter if treatment smoke is still visible.

#### STORAGE AND DISPOSAL

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

**STORAGE:** Store in a cool, dry place. Storage temperature should not exceed 100°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

SCHERING-PLOUGH ANIMAL HEALTH CORP. 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:  
Schering-Plough Animal Health Corp., Union,  
NJ 07083.  
Copyright © 2003, Schering-Plough  
Animal Health Corp. All rights reserved.  
Rev. 11/02

EPA Reg. No. 773-56  
EPA Est. No. 30775-EM-01  
A product of Janssen Research. Clinafarm® is a registered trademark of Johnson & Johnson.  
Made in United Kingdom



082183/aw\_11652

L A B

JANSSEN-CILAG  
ELC Progress  
Tel. Inge Vermeir: 32 14806515 - Fax CPM: 32 14805157  
LABEL Clinafarm Smoke 24x5g Market: usa  
Article Number: aw\_11652 Sickcode:  
Dimensions: 230 x 120mm (3P\_OH/L/004/V1) Operator: Swat  
File Name: usc\_aw\_11652\_230x120\_e

- PMS Black
- PMS 422
- PMS 201
- Diecut

Perforation ----

1. 09/01/2003
2. 14-01-2003
- 3.
- 4.
- 5.
- 6.

ACCEPTED  
with COMMENTS  
In EPA Letter Dated:

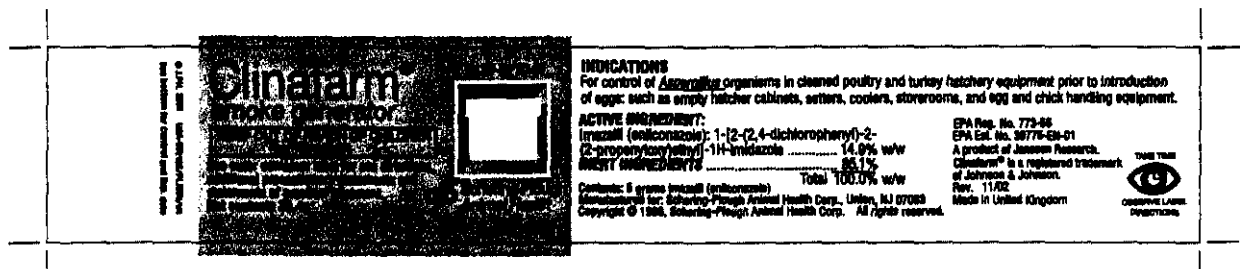
MAR 27 2003

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

1113-56

3/4

4/14



L A B

JANSSEN-CILAG  
 ELC Prepress  
 Tel. Inge Vermeiren: 32 14606915 - Fax CPM: 32 14605157  
 LABEL Clinafarm Smoke 24x5g  
 Article Number: plj007\_v4  
 Dimensions : 150.8 x 25.4mm  
 File Name: usa\_plj007\_v4\_150m8x25m4\_e

Market: usa  
 Sickcode:  
 Operator: Erzs

- PMS Black
- PMS 422
- PMS 201
- Diecut
- Perforation -----

1. 03/10/2002
2. 29/10/2002 (Bart)
3. 18/11/2002 (Erzs)
- 4.
- 5.
- 6.

