

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 9 1984

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

Code 412-621

4691-98

ANCHOR

Lindane

**MANGE &
LOUSE SPRAY**

FOR APPLICATION ON ANIMALS
AND BUILDINGS

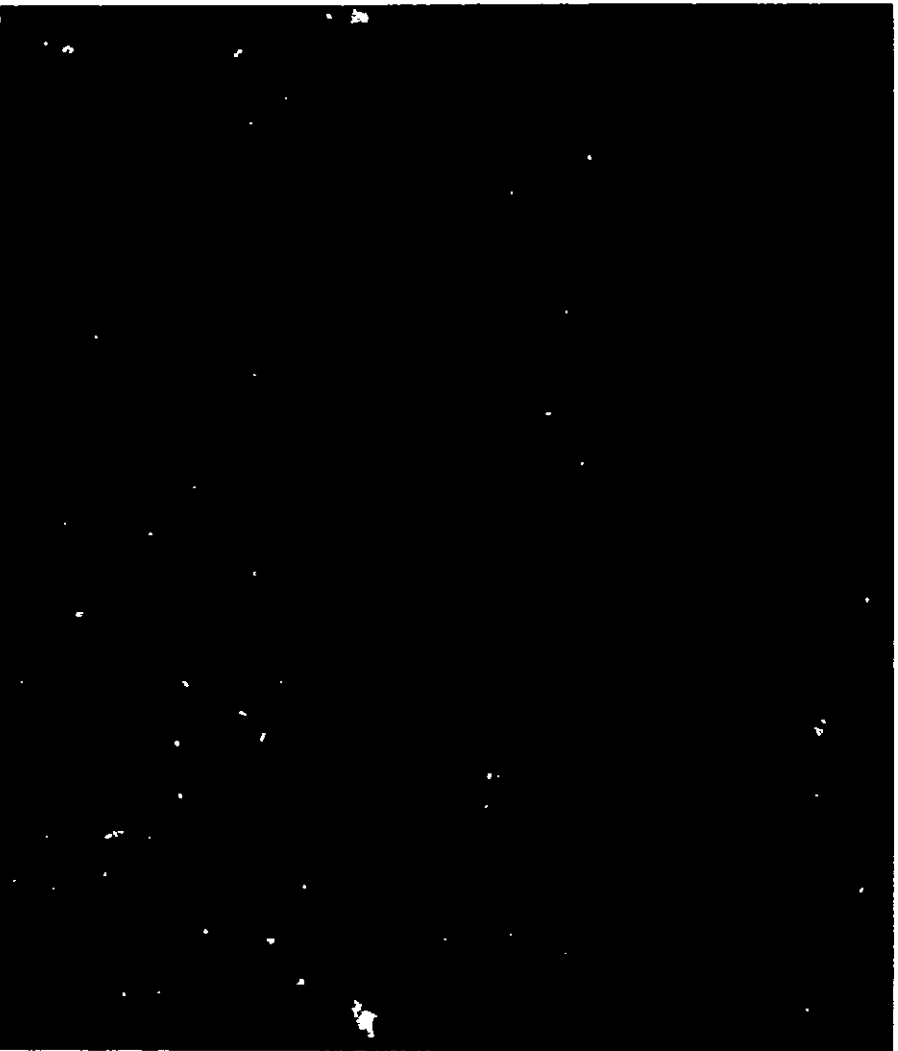
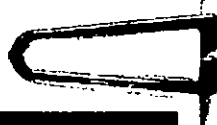
NET CONTENTS ONE GALLON

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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MAY 9 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Robert D. Gunderson
Philips Roxane, Inc.
2621 North Belt Highway
St. Joseph, MO 64502

Dear Mr. Gunderson:

Subject: Lindane RPAR
Anchor Lindane Mange & Louse Spray
EPA Reg. No.: 4691-98
Appl. Date: March 1, 1983

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provided that you make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

1. A STATEMENT OF PRACTICAL TREATMENT must be added to the labeling. We suggest the following statement, however, if your toxicological data suggests otherwise, please submit a draft STATEMENT OF PRACTICAL TREATMENT for prior approval:

"STATEMENT OF PRACTICAL TREATMENT

If swallowed-Call a physician or Poison Control Center immediately. Gastric lavage is indicated if material was taken internally. DO NOT INDUCE VOMITING: vomiting may cause aspiration pneumonia.
If inhaled- Remove victim to fresh air. Apply artificial respiration if indicated.
If on skin- Remove contaminated clothing and wash affected areas with soap and water.
If in eyes- Flush eyes with plenty of water. Call a physician immediately.

NOTE TO PHYSICIAN-Solvent presents aspiration hazard. Gastric lavage is indicated if material was taken internally.

2. We note the labeling bearing both "CAUTION" and "WARNING" as signal words; the signal word must be consistent throughout the labeling. Since both technical lindane and the solvent, xylene are in toxicity category II (WARNING); change "CAUTION" to "WARNING" wherever it appears on the labeling.
3. Move the "KEEP OUT OF REACH OF CHILDREN" to a position just above the front panel signal word. It is also preferred that the "KEEP OUT OF REACH OF CHILDREN" appear in all capital letters for maximum prominence.

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4. Change the heading "DIRECTIONS" to "DIRECTIONS FOR USE".
5. Insert "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." to immediately follow the heading "DIRECTIONS FOR USE".
6. Immediately preceding "WARNING: May be absorbed through the skin..." insert the following headings:

"PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS"

7. Add the following to appear in the "HAZARDS TO HUMANS..." section:
"Wash hands with soap and water after use and before eating or smoking."
8. From the "HAZARDS TO HUMANS..." section you may delete any duplicative information now found in the "STATEMENT OF PRACTICAL TREATMENT".
9. Immediately preceding "Do not contaminate water supplies..." insert the following heading:

"ENVIRONMENTAL HAZARDS"

10. Insert as the first sentence in the "ENVIRONMENTAL HAZARDS" section:
"This product is toxic to fish, birds and other wildlife."
11. Delete "Do not reuse container...empty." and insert an appropriate "STORAGE AND DISPOSAL" section in accordance with PR Notices 83-3 and 84-1.
12. Delete "Keep away from heat...flame." and insert:
"PHYSICAL OR CHEMICAL HAZARDS
Do not use or store near heat or open flame."

13. The RPAR Notice incorrectly indicated the language to be used for the RESTRICTED USE PESTICIDE statement. Delete "For application only by or under the direct supervision of a certified applicator" and insert the following at the top of the front panel above the product name. (Note: the type size requirements for the heading "RESTRICTED USE PESTICIDE" are the same as required for the front panel signal word.)

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"RESTRICTED USE PESTICIDE

For retail sale to and use only by Certified Applicators or persons under their direct supervision, and only for those uses covered by the Certified Applicator's certification."

14. In the directions for spraying livestock it is suggested that instructions for spraying with a 200 psi nozzle pressure be included. This pressure is necessary in order to penetrate the animals' hair to the skin.
15. In the building spray directions, a respirator statement must be added; please incorporate the following statement:

"Wear a pesticide respirator jointly approved by MSHA (Mine Safety and Health Administration) and by NIOSH (National Institute for Occupational Safety and Health) under the provisions of 30 CFR Part 11 for Lindane protection.

Submit an updated Confidential Statement of Formula for the subject product.

Submit five (5) copies of your revised final printed labeling before you release the product for shipment with the amended labeling.

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

If you hold a Federal registration, a supplemental registration, or a Special Local Needs registration, you may continue to produce new stocks of such products, using current labeling, until ~~May~~ ^{June} 1, 1984. After that date, all remaining inventories of affected products will fall under the Existing Stocks provisions stated in our letter of October 28, 1983.

Sincerely yours,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

Enclosure