

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

345-5405891  
17

26 JUN 1992

Mr. Joseph E. Dyer  
PITMAN-MOORE INC.  
1201 Douglas Avenue  
Kansas City, KS 66103

Dear Mr. Dyer:

Subject: NOMINAL CONCENTRATION, DRAFT LABELING AND APPLICATION FOR UPDATED CSF'S  
**Prolate 1E Emulsifiable**  
EPA Registration Number 59-235  
Your Application Dated October 18, 1991 and  
Facsimile Submission Received On October 22, 1991

The labeling and confidential statement of formulas (CSF) 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 following labeling changes listed below before you release the product for shipment bearing the amended labeling:

1). In regard to the labeling, change the percent active ingredient to 11.6%.

2). In response to your question regarding nominal concentration. The nominal claim of 11.60% allows certified limits of + or - 5% added to the nominal, which makes the standard Certified Limits as follows:

★ Lower Limit =  $11.6\% - (5\% \times 11.6\%) = 11.02\%$

★ Upper Limit =  $11.6\% + (5\% \times 11.6\%) = 12.18\%$

As long as the label claim is 11.6% active ingredient and the Certified Limits remain within the standard range there is no need to submit additional data for minor changes within the range. If the Certified Limits violate the standard and/or the label claim changes, the product must be amended and data submitted. The data requirements will depend on the degree of changes and how the profile of your product is effected (i.e. efficacy and precautionary category).

CONCURRENCES

SYMBOL	H7505C						
SURNAME	A. Heyward						
DATE	6/26/92						

3). In reference to the CSFs (basic and alternate formulation), please provide the following information:

- a. The upper and lower Certified Limits based on the pure active ingredients.
- b. Correct the source product as per ICI Americas letter dated May 20, 1992 as follows:
  - ★ In column number 10 of the CSF, the product's name should be "PROLATE Technical Livestock Insecticide, etc...".
  - ★ In column number 12 of the CSF, the source product's EPA registration number should be "10182-233".
- c. The lower Certified Limit should be lower than (13b) % by weight when in pure active form, and upper certified Limit should be higher than 13b, and should be reported in pure active ingredient form.

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

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

Sincerely yours,

George T. LaRocca  
Product Manager (13)  
Insecticide-Rodenticide Branch  
Registration Division (H7505C)

Enclosure:

\*\*\*DRAFT LABEL\*\*\*

PRODUCT NAME: Prolate 1E EMULSIFIABLE LIQUID  
DATE: October 24, 1991 SUPERSEDES: March 11, 1991  
ITEM: Container Label  
COMPANY: Coopers Animal Health Inc. COUNTRY: USA  
REASON TO ISSUE: To update label per EPA letter dated 8/13/91  
and per PR Notice 91-2 "Accuracy of Stated Percentages for  
Ingredients Statement"  
PREPARED BY: Joseph E. [redacted], 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 disposal  
text appropriate for container size and material.  
(A:JED7100.DOC)

MAIN (FRONT) PANEL

=====

PROLATE 1E

EMULSIFIABLE LIQUID

A BEEF AND NON-LACTATING DAIRY CATTLE INSECTICIDE FOR THE CONTROL  
OF LICE, CATTLE TICKS, SOUTHERN CATTLE TICKS, WINTER TICKS, LONE  
STAR TICKS, GULF COAST EAR TICKS, HORNFLIES, SARCOPTIC MANGE AND  
SCABIES MITES

AND

A SWINE INSECTICIDE FOR CONTROL OF LICE AND SARCOPTIC MANGE

For use on cattle and swine only. Not for use on horses, sheep  
or goats.

ACTIVE INGREDIENTS:

N-(mercaptomethyl) phthalimide  
S-(O,O-dimethyl phosphorodithioate)..... 11.7%

INERT INGREDIENTS:..... 88.3%  
TOTAL 100.0% wt./wt.

Contains 1 pound Active Ingredient Per Gallon  
EPA Regis. No. 59-235 EPA Est. No. 6175-LA-1

WARNING

KEEP OUT OF REACH OF CHILDREN

See Other Precautions on Side Panels  
Read All Directions Before Using This Product

Net Contents: 1 US Gallon (128 US oz.)

Coopers Animal Health Inc.  
1201 Douglas Avenue  
Kansas City, Kansas 66103-1438 USA  
(label number)

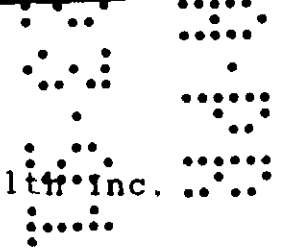
PROLATE is a registered trademark of Coopers Animal Health Inc.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated

26 JUN 1992

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

59-235



## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### WARNING

Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. Harmful if swallowed. Avoid breathing spray mist. Applicators must wear long-sleeved shirt, long pants, elbow length waterproof gloves, waterproof apron and unlined waterproof boots. Wash all contaminated clothing with soap and hot water before re-use. Wash thoroughly before eating, drinking or using tobacco.

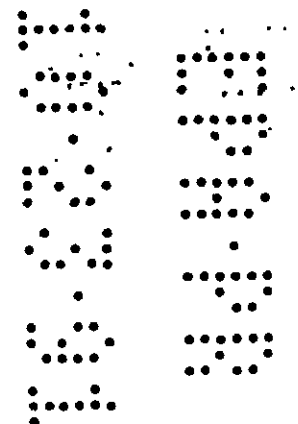
#### STATEMENT OF PRACTICAL TREATMENT:

IF IN EYES - Rinse immediately with plenty of water. Call a physician immediately. IF ON SKIN - Wash promptly with soap and water. Remove contaminated clothing. IF SWALLOWED - Call a physician or Poison Control Center immediately. Do not induce vomiting. IF SPRAY MIST IS INHALED - Remove to fresh air. Apply artificial respiration if indicated.

NOTE TO PHYSICIAN AND VETERINARIAN: Prolate 1E is an organophosphate insecticide and a cholinesterase inhibitor. If signs of cholinesterase inhibition are present, atropine is antidotal. 2-PAM is also antidotal and may be administered in conjunction with atropine. If ingested do not induce vomiting as this may induce an aspiration hazard. Usual symptoms of organophosphate poisoning in man include: headache, blurred vision, weakness, nausea, discomfort in the chest, vomiting, abdominal cramps, diarrhea, salivation, sweating, pin-point pupils. Usual symptoms of poisoning in animals include salivation, labored breathing, loss of balance, staggering and pin-point pupils.

ENVIRONMENTAL HAZARDS: This pesticide is extremely toxic to fish. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters. Drift or runoff from treated areas may be hazardous to aquatic organisms in neighboring areas.

PHYSICAL OR CHEMICAL HAZARDS: Do not use or store near heat or open flame. Protect from temperatures below 20 degrees F.



**DIRECTIONS FOR USE**

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

**BEEF AND NON LACTATING DAIRY CATTLE**

Do not treat non-lactating dairy cattle within 28 days of freshening.

See Table For Feedlot Use Only Provision

To Control	Method To Use	Dilution Rate	
		Feedlot Use Only 21 - Day Pre-slaughter Interval	General Use 3 - Day Pre-slaughter Interval
Lice	Dip	1:60	
	Spray	1:49	1:150
Hornflies	Dip	1:60	
	Spray	1:49	1:200
Scabies Mites (For control of scabies mites, two treatments, 10-14 days apart are required.)	Dip	1:60	
Sarcoptic Mange	Dip	1:60	
	Spray	1:49	1:100
Cattle Ticks	Dip	1:60	1:240
	Spray	1:49	
Southern Cattle Ticks	Dip	1:60	1:240
	Spray	1:49	
Winter Ticks	Dip	1:60	
	Spray	1:49	1:100
Lone Star Ticks	Dip	1:60	
	Spray	1:49	1:100
Gulf Coast Ear Ticks	Dip	1:60	
	Spray	1:49	1:100

**SWINE**

To Control	Method To Use	Dilution Rate 1 Day Pre-slaughter Interval
Lice	Spray	1:49 or 1:100
Sarcoptic Mange	Spray	1:49 or 1:100

#### DIP VAT CHARGING PROCEDURE

Prior to charging vat, empty out old contents and thoroughly clean the vat. Add water to the vat. Add Prolate 1E at a rate of 1 gallon to each 60 or 240 gallons of water. See Storage and Disposal statements on this label.

Important: Add super phosphate at a rate of 100 pounds per 1000 gallons of vat solution. Super phosphate is added to control the pH of the solution and to insure vat stability. Super phosphate is usually available at most fertilizer dealers as 0-45-0 or 0-46-0.

Stir the vat thoroughly, preferable with a compressed air device; however, any form of thorough mixing is adequate since Prolate 1E emulsifies readily.

Restir vat contents prior to each use.

#### DIP VAT REPLENISHMENT

During the dipping operation, each time the vat's volume is reduced by 1/8 to 1/4 of its original volume, replenish the vat as follows:

Replenish vat with water and add Prolate 1E at a rate of 1 gallon for each 50 or 200 gallons of water added.

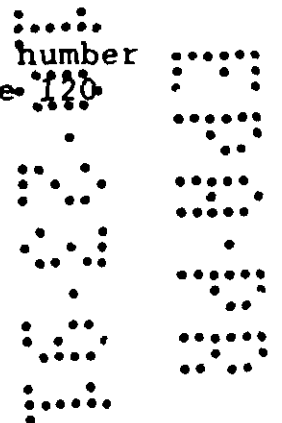
Important: Add super phosphate as necessary to maintain pH between 4.5 and 6.5. Stir well and resume dipping. Repeat replenishment process as necessary. For evaporation add additional water accordingly. For added water due to rainfall, merely replenish vat with Prolate 1E according to label directions.

#### DIP VAT MAINTENANCE

When utilizing the Prolate 1E Field Test Kit dipping may continue as long as the Prolate concentration is maintained and adjusted between 0.15% and 0.25% for the 1:60 dilution or 0.02% and 0.05% for the 1:240 dilution, and the vat is not too foul for satisfactory use as indicated by foul odor or excessive darkening of solution. Refer to U.S.D.A.V.S. Memorandum 556.9 for use of the Field Test Kit. Information on availability of the Field Test Kit may be obtained from your Coopers/Pitman-Moore representative.

When not utilizing the Prolate 1E Field Test Kit the vat should be emptied, cleaned and recharged each time one of the following occurs:

1. When the vat has been charged for 120 days.
2. When the dip becomes too foul for satisfactory use within 120 day limit.
3. If the number of animals dipped equals twice the number of gallons of the initial batch values within the 120 day limit.



#### SPPAY METHOD: CATTLE AND SWINE

At the 1:49 dilution rate, mix one gallon of Prolate 1E with 49 gallons of water and stir thoroughly. Apply the fresh mixture as a high-pressure spray, taking care to wet the skin, not just the hair. Apply to the point of runoff. For cattle, do not apply within 21 days of slaughter. For swine, do not apply within 1 day of slaughter.

At the 1:100 dilution rate, the 1:150 dilution rate, or the 1:200 dilution rate mix one gallon of Prolate 1E with 100 gallons, 150 gallons or 200 gallons of water respectively, and stir thoroughly. Apply as directed for the 1:49 dilution rate. For cattle do not apply within 3 days of slaughter. For swine, do not apply within 1 day of slaughter.

#### BACKRUBBERS - CATTLE

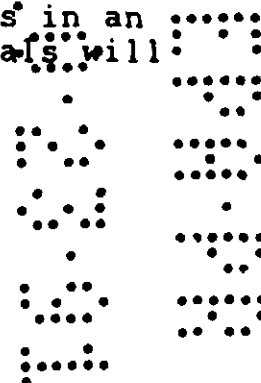
To control hornflies on beef cattle, dilute 1 gallon Prolate 1E in 50 gallons fuel oil or other suitable carrier and charge backrubber device or soak sack or cloth as required. Retreat backrubber as needed.

#### OFFICIAL ERADICATION PROGRAM

Where Prolate 1E is recommended in federal or state eradication programs, it is required that specific use directions be followed. Consult state or federal authorities for detailed recommendations. Consult the Animal and Plant Health Inspection Service, Veterinary Services.

#### WARNINGS

1. Prolate 1E is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides or chemicals. Atropine is antidotal. Consult veterinarian at first sign of adverse reaction.
2. Cattle may be slaughtered 21 days after treatment at a dip rate of 1:60 or a spray rate of 1:49. Cattle treated at a spray rate of 1:100, 1:150 or 1:200 or dip rate of 1:240 may be slaughtered 3 days after treatment.
3. Swine may be slaughtered one day after treatment.
4. In swine, single applications for lice and sarcoptic mange control are usually effective however, should a second application be necessary, it may be made 14 days following first treatment.
5. For swine: do not treat sick, convalescent, or stressed animals. Do not apply directly to suckling pigs.
6. For cattle: do not treat sick convalescent, stressed, or animals less than 3 months old except in federal or state eradication programs where immediate treatment of all animals in an infested herd is mandatory. Hand dipping of young animals will prevent swallowing of dip solution.



7. Do not treat non-lactating dairy cattle within 28 days of freshening. If freshening should occur within the 28 day period after treatment that milk must not be used as human food.

8. Be sure free access to drinking water is available to cattle prior to dipping. Do not dip excessively thirsty or overheated animals. Following dipping, allow animals adequate space and ventilation to thoroughly dry. Do not allow animals to become crowded or overheated.

9. **IMPORTANT:** In cattle, repeat treatment as necessary, but not more often than every 7-10 days. Treatment for lice, ticks, scabies mites, sarcoptic mange, and hornflies may be made any time of the year except when cattle grub larvae are in the gullet or spinal canal. Consult your veterinarian, extension livestock specialist or extension entomologist regarding timing of treatment.

#### STORAGE AND DISPOSAL

Pesticide Disposal - Do not contaminate water, food, or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Metal Container Disposal - Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Plastic Container Disposal - Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

