

1007-91



9/11/2003

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

1/5

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

SEP 11 2003

John B. Baker
Associate Director, Regulatory Affairs
Pfizer Inc. dba Pfizer Animal Health
601 West Cornhusker Highway
Lincoln, NE 68521

Subject: Amendment - Updating First Aid Statement per PR Notice 2001-1
Durasect II
EPA Reg. No. 1007-91
Your Submission Dated June 18, 2003

Dear Mr. Baker:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

1. Revise front of the label-- replace " Inert Ingredients" with the phrase "Other Ingredients".

Note, base on the acute oral toxicity of your product (Toxicity Category IV) you are not required to have a If swallowed first aid statement. You may carry the statement if you wish. If you have any questions regarding this action, please contact BeWanda Alexander of my team at (703) 305-7460.

Sincerely,

A handwritten signature in black ink, appearing to read "G. LaRocca".

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

Durasect II

Long-Acting Livestock Pour-On

- Ready to use pour-on for beef cattle, lactating and non-lactating dairy cattle, and calves
- Patented water repellent formulation
- Effective in the control of pyrethroid-resistant horn flies
- Up to 6-week control of horn flies¹
- Controls face flies for at least 4 weeks
- Controls biting lice
- No withdrawal time
- Treats 60 500-lb cattle or 30 1000-lb cattle

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Precautionary Statements

Active Ingredients:

Permethrin (3-phenoxyphenyl) methyl ± cis, trans-3-(2,2-dichloroethenyl) 2,2-dimethylcyclopropane carboxylate*	5.00%
Pyrethrins	0.10%
Piperonyl butoxide, technical**	1.00%
Inert ingredients	93.90%
TOTAL	100.00%

* cis/trans ratio: Min. 35% (±) cis and max. 65% (±) trans
 ** Equivalent to 0.80% butylcarbityl (8-propylpiperonyl) ether and 0.20% related compounds





Net Contents: 900 ml.



002 05-9757-35-0

ACCEPTED
 with COMMENTS
 In EPA Letter Dated
 SEP 11 2003
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act,
 as amended, for the pesticide
 registered under EPA Reg. No.
 1007-91

Pfizer

	Project Name	Part Number	Date	Dimensions
	Durasect II	05-9757-35-0	3/2/00	5 1/2" (H) x 3 1/2" (W)
	Project Number	Country	Visual Code Bar(s)	
	1286	US		
		Die (CAD)#	Code(s) 067219047422	
Editor	Michele Brettmann	Colors:		
Coordinator	Penny Rousseau			
Artist	Lance Evenson	PMS 116	PMS 3425	Black
Proofreader	Diane Mattison			80% Black



DIRECTIONS FOR USE
 It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
READY TO USE No dilution necessary, see directions below.

ANIMAL TREATMENTS:
Lactating and Non-Lactating Dairy Cattle, Beef Cattle, and Calves
Target Insects: Horn flies, face flies, and biting lice. **Application:** Apply along back and down face. Use 0.1 fl oz (3 mL) per 100 lb (45 kg) body wt of animal, up to 1 fl oz (30 mL) for any one animal. If face flies are a particular concern, apply 0.1 fl oz (3 mL) down centerline of forehead and rest of dose along back of animal.

Durasect II Long-Acting Livestock Pour-On is to be applied with the squeeze-and-pour bottle provided. To use the squeeze-and-pour bottle, remove the cap and inner seal from the calibrated dosing chamber. Estimate the animal's weight and calculate the dose. Squeeze the bottle to fill the dosing chamber to the desired level. Apply product per directions above; do not use product as a spray. Repeat treatment as needed, but not more than once every 2 weeks. For optimum lice control, additional treatments at 14-day intervals may be necessary.

*Duration of activity for horn fly control may vary due to pyrethroid resistance, environmental conditions and management factors (i.e. sanitation, animal husbandry, facilities, etc.).

Precautionary Statements
CAUTION
 Hazards to Human and Domestic Animals
 Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

First Aid	
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for further treatment advice.
IF IN EYES	<ul style="list-style-type: none"> 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. Call a poison control center or doctor for further treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.



Environmental Hazards
 This pesticide is extremely toxic to fish. Do not contaminate water by cleaning of equipment or disposal of wastes. Apply this product as specified on the label.

Storage and Disposal
Do not contaminate water, food, or feed by storage or disposal.
Storage: Keep container sealed when not in use. Do not store near food or feed.
Disposal: Triple rinse (or equivalent). Then offer for recycling, or puncture and discard in trash. The container is made of High Density Polyethylene (HDPE) #2 and can be offered for recycling.

EPA Est. No 67517-MD-1 EPA Reg. No. 1007-01

Distributed by:
 Pfizer Animal Health
 Exton, PA 19341, USA
 Div. of Pfizer Inc
 NY, NY 10017

7032000
 07-9757-35-2

	Project Name	Date	Part Number	Draft#	Dimensions
 PACKAGE DESIGN & DEVELOPMENT Animal Health	Durasect II	13MAY03	07-9757-35-2	1	3 1/2"(W) x 5 1/2"(H)
	Project # Country	2D Matrix:	Visual Code Bar(s)		
Editor	Michele Brettmann	Code(s):	Die (CAD)#s		
Team Leader	Penny Rousseau	Colors:  Black			
Graphic Specialist	Carolyn Teachout				
Artist	Lance Evenson				
Proofreader	Diane Mattison	SKU: 7032000			

Durasect II

Long-Acting Livestock Pour-On

- Ready to use pour-on for beef cattle, lactating and nonlactating dairy cattle, and calves
- Patented water repellent formulation
- Effective in the control of pyrethroid-resistant horn flies
- Up to 8-week control of horn flies*
- Controls face flies for at least 4 weeks
- Controls biting lice
- No withdrawal time
- Treats 30 600-lb cattle or 15 1000-lb cattle

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Precautionary Statements

Active Ingredients:

Permethrin (3-phenoxyphenyl) methyl \pm cis, trans-3-(2,2-dichloroethenyl) 2,2-dimethylcyclopropane carboxylate*	5.00%
Pyrethrins	0.10%
Piperonyl butoxide, technical**	1.00%
Inert ingredients	93.90%
TOTAL	100.00%

*cis/trans ratio: Min. 20% (c) cis and max. 80% (c) trans





**Equivalent to 6.60% butylcarbitol (3-propylpiperonyl) ether and 0.20% related compounds

Net Contents: 450 mL



08 05-0700-35-0

Uffizi

	Project Name	Part Number	Date	Dimensions
	Durasect II	05-9756-35-0	3/2/00	4" (H) x 2 3/4" (W)
	Project Number	Country	Visual Code Bar(s)	
	1286	US		
		Die (CAD#)	Code(s) 087219047408	
Editor	Michele Brettmann	Colors:		
Coordinator	Penny Rousseau			
Artist	Lance Evenson	PMS 116	PMS 3425	Black
Proofreader	Diane Mattson			80% Black



INSTRUCTIONS FOR USE
 It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
READY TO USE: No dilution necessary, see directions below.

ANIMAL TREATMENTS: **Swimming and Non-Swimming Bony Carps, Bow Carps, and Gobies**
Target Insects: Horn Flies, Face Flies, and biting flies. **Application:** Apply along back and down fish.
 Use 0.1 fl oz (3 mL) per 100 lb (45 kg) body wt of animal, up to 1 fl oz (30 mL) for any one animal. If
 used this often in particular seasons, apply 0.1 fl oz (3 mL) down swimming of fish and rest of dose
 along back of animal. **Durasect II Long-Acting Urethane Pour-On** is to be applied with the squeeze-
 and-pour bottle provided. To use the squeeze-and-pour bottle, remove the cap and inner seal from
 the collapsed dosing chamber. Estimate the animal's weight and calculate the dose. Squeeze the
 bottle to fill the dosing chamber to the desired level. Apply product per directions above; do not use
 product as a spray. Repeat treatment as needed, but not more than once every 2 weeks. For optimum
 fish control, additional treatments at 14-day intervals may be necessary.

Duration of activity for horn fly control may vary due to environmental resistance, environmental conditions
 and management factors (i.e., sanitation, animal husbandry, facilities, etc.).

Precautionary Statements

CAUTION
 Hazardous to Humans and Domestic Animals

Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or
 clothing. Wash thoroughly with soap and water after handling.

First Aid	
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-30 minutes. Call a poison control center or doctor for further treatment advice.
IF IN EYES	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-30 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for further treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.


Environmental Hazards: This pesticide is extremely toxic to fish. Do not contaminate water by clean-
 ing of equipment or disposal of wastes. Apply this product as specified on the label.

Storage and Disposal:
 Do not contaminate water, food, or feed by storage or disposal.
 Storage: Keep container sealed when not in use. Do not store near food or feed.
 Disposal: Triple rinse (or equivalent). Then offer for recycling, or pressure and discard in trash.
 The container is made of High Density Polyethylene (HDPE) #2 and can be offered for recycling.

EPA Est. No. 07817-000-1 EPA Reg. No. 1807-01

Manufactured by:
 Pfizer Animal Health
 Kenilworth, PA 19047, USA
 Div. of Pfizer Inc.
 NY, NY 10017

7031000
 07-8756-35-2

Pfizer PACKAGE DESIGN & DEVELOPMENT Animal Health	Project Name		Date	Part Number	Draft	Dimensions
	Durasect II		13MAY03	07-9756-35-2	1	2 3/4" (W) x 4" (H)
Project #		Country	2D Matrix:	Visual Code Bar(s)		
2445		US	Code(s):	Die (CAD) #s		
Editor	Michele Brettmann	Colors:		 Black		
Team Leader	Penny Rousseau					
Graphic Specialist	Carolyn Teachout					
Artist	Lance Evenson					
Proofreader	Diane Mattison					
						SKU: 7031000