



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

Best Available Image

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Ms. Pat Bieler
Hartz Mountain Corp
400 Plaza Drive
Secaucus, NJ 07094

NOV 23/98

Dear Ms. Bieler:

Subject: Proposed Label Amendments Under PRN 96-6 for the Following Products:

EPA Reg. No.	Product Name	Submission Date
2596-49	Hartz 2 in 1 Collar for Cats	1 April 1998
2596-50	Hartz 2 in 1 Collar for Dogs	1 April 1998
2596-62	Hartz 2 in 1 Flea & Tick Collar for Dogs	25 March 1998
2596-63	Hartz 2 in 1 Flea & Tick Collar for Cats	25 March 1998
2596-78	Hartz 2 in 1 Flea & Tick Powder for Cats	10 April 1998
2596-79	Hartz 2 in 1 Flea & Tick Powder for Dogs	10 April 1998
2596-83	Hartz 2 in 1 Plus Seven Month Collar for Cats	1 April 1998
2596-84	Hartz 2 in 1 Plus Seven Month Collar for Dogs	1 April 1998
2596-119	Hartz Rabon Flea & Tick Dip for Dogs & Cats	29 May 1998
2596-122	Hartz 2 in 1 Fast Acting Flea & Tick Spray for Dogs III	29 May 1998
2596-123	Hartz 2 in 1 Fast Acting Flea & Tick Spray for Cats III	29 May 1998
2596-125	Hartz 2 in 1 Flea & Tick Pump for Dogs II	29 May 1998
2596-126	Hartz 2 in 1 Flea & Tick Pump for Cats II	29 May 1998
2596-136	Hartz 2 in 1 Flea & Tick Spray for Cats & Dogs	3 June 1998

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provided you

make the revisions indicated below before release for shipment of any product bearing amended labeling.

Technical review of your submission dated July 16, 1998, responding to EPA's June 16, 1998, objection to your request to deviate from the requirements of PR Notice 96-6, has been completed and supports your request to make some, but not all, of the deviations requested for the above-mentioned products.

Hartz 2 in 1 Collar for Cats, EPA Reg. No. 2596-49:

- a. Revise the first sentence of the first full paragraph under DIRECTIONS FOR USE to read as follows: "Do not use on kittens under 12 weeks of age." Although the data you cited support use of collars on dogs younger than 12 weeks, those data cannot be used for products that are applied to cats. The statement must be consistent with the definitive wording presented in PRN 96-6.
- b. Revise the statement concerning debilitated, aged, and medicated animals to read as follows: "Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals."
- c. Add the following statement regarding cholinesterase inhibitors: "Do not use this product on animals simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. However, flea and tick collars may be immediately replaced." The technical review of the data you cited does not support omitting this statement from this product label.

Hartz 2 in 1 Collar for Dogs, EPA Reg. No. 2596-50:

- a. Revise the first sentence of the first full paragraph under DIRECTIONS FOR USE to read as follows: "Do not use on puppies under 6 weeks of age." Although the statement, "It is not advisable to use this collar on puppies less than 6 weeks of age," had been previously approved by the Agency, the statement must now be revised to be consistent with the definitive wording presented in PRN 96-6 to clearly indicate the minimum age of animals.
- b. After the statement, "Consult a veterinarian before using the product on debilitated, aged, or medicated animals," insert the following statement: "If used on pregnant or nursing dogs, do not replace collar until the puppies are at least 6 weeks old."
- c. Add the following statement: "Do not use this product on animals simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. However, flea and tick collars may be immediately replaced." The technical review of the data you cited does not support omitting this statement from this product label.

Hartz 2 in 1 Flea & Tick Collar for Dogs, EPA Reg. No. 2596-62:

- a. Revise the first sentence in the paragraph that follows the list of pests controlled to read as follows: "Do not use on puppies under 6 weeks of age." Although the statement, "It is not advisable to use this collar on puppies less than 6 weeks of age," had been previously approved by the Agency, the statement must now be revised to be consistent with the definitive wording presented in PRN 96-6 to clearly indicate the minimum age of animals.
- b. After the statement, "Consult a veterinarian before using the product on debilitated, aged, or medicated animals," insert the following statement: "If used on pregnant or nursing dogs, do not replace collar until the puppies are at least 6 weeks old."
- c. Include the company or Animal Poison Control Center telephone number on the label so consumers can call for the purpose of receiving information concerning proper use of the product and specific actions to take in case of emergencies.
- d. Add the following statement: "Do not use this product on animals simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. However, flea and tick collars may be immediately replaced." The technical review of the data you cited does not support omitting this statement from this product label.

Hartz 2 in 1 Flea & Tick Collar for Cats, EPA Reg. No. 2596-63:

- a. Revise the first sentence of the first full paragraph under DIRECTIONS FOR USE to read as follows: "Do not use on kittens under 12 weeks of age." Although the data you cited support use of collars on dogs younger than 12 weeks, those data cannot be used for products that are applied to cats. The statement must be consistent with the definitive wording presented in PRN 96-6.
- b. Revise the statement concerning debilitated, aged, and medicated animals to read as follows: "Consult a veterinarian before using this product on debilitated, aged, medicated, *pregnant or nursing* animals."
- c. Add the following statement regarding cholinesterase inhibitors: "Do not use this product on animals simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. However, flea and tick collars may be immediately replaced." The technical review of the data you cited does not support omitting this statement from this product label.
- d. Include the company or Animal Poison Control Center telephone number on the label so consumers can call for the purpose of receiving information concerning proper use of the product and specific actions to take in case of emergencies.

4/11

Hartz 2 in 1 Flea & Tick Powder for Cats, EPA Reg. No. 2596-78:

- a. Revise the fifth sentence in the paragraph under PRECAUTIONARY STATEMENTS to read as follows: "Do not use on kittens under 12 weeks of age." Although the data you cited support use on dogs younger than 12 weeks, those data cannot be used for products that are applied to cats. The statement must be consistent with the definitive wording presented in PRN 96-6.
- b. Revise the statement concerning debilitated, aged, and medicated animals to read as follows: "Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals."
- c. Add the following statement regarding cholinesterase inhibitors to the PRECAUTIONARY STATEMENTS: "Do not use this product on animals simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. However, flea and tick collars may be immediately replaced." The technical review of the data you cited does not support omitting this statement from this product label.

Hartz 2 in 1 Flea & Tick Powder for Dogs, EPA Reg. No. 2596-79:

- a. Revise the fifth sentence in the paragraph that follows "CAUTION" to read as follows: "Do not use on puppies under 6 weeks of age." Although the statement, "It is not advisable to use this collar on puppies less than 6 weeks of age," had been previously approved by the Agency, the statement must now be revised to be consistent with the definitive wording presented in PRN 96-6 to clearly indicate the minimum age of animals.
- b. After the statement, "Consult a veterinarian before using the product on debilitated, aged, or medicated animals," insert the following statement: "If used on pregnant or nursing dogs, do not retreat until the puppies are at least 6 weeks old."
- c. In the precautionary paragraph, add the following statement: "Do not use this product on animals simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. However, flea and tick collars may be immediately replaced." The technical review of the data you cited does not support omitting this statement from this product label.

Hartz 2 in 1 Plus Seven Month Collar for Cats, EPA Reg. No. 2596-83:

- a. Revise the first sentence in the first full paragraph under DIRECTIONS FOR USE to read as follows: "Do not use on kittens under 12 weeks of age." Although the data you cited support use on dogs younger than 12 weeks, those data cannot be used for products that are applied to cats. The statement must be consistent with the definitive wording presented in PRN 96-6.

b. Revise the statement concerning debilitated, aged, and medicated animals to read as follows: "Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals."

c. Add the following statement regarding cholinesterase inhibitors: "Do not use this product on animals simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. However, flea and tick collars may be immediately replaced." The technical review of the data you cited does not support omitting this statement from this product label.

d. Delete the phrase: ". . . or augment its activity with another product registered for this use, such as Hartz 2 in 1 Flea and Tick Powder or Spray." from the sentence which begins, "Under conditions where cats are exposed to severe flea and tick infestations. . .". This phrase contradicts the required statement in comment c above.

Hartz 2 in 1 Plus Seven Month Collar for Dogs, EPA Reg. No. 2596-84:

a. Revise the first sentence in the paragraph under DIRECTIONS FOR USE to read as follows: "Do not use on puppies under 6 weeks of age." Although the statement, "It is not advisable to use this collar on puppies less than 6 weeks of age," had been previously approved by the Agency, the statement must now be revised to be consistent with the definitive wording presented in PRN 96-6 to clearly indicate the minimum age of animals.

b. After the statement, "Consult a veterinarian before using the product on debilitated, aged, or medicated animals," insert the following statement: "If used on pregnant or nursing dogs, do not replace collar until the puppies are at least 6 weeks old."

c. Add the following statement: "Do not use this product on animals simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. However, flea and tick collars may be immediately replaced." The technical review of the data you cited does not support omitting this statement from this product label.

d. In several places on the label, the word "cat" appears where it should say "dog". Since this product is for use only on dogs, replace every instance of the word "cat" with the word "dog".

Hartz Rabon Flea & Tick Dip for Dogs & Cats, EPA Reg. No. 2596-119:

a. Replace the retreatment interval with a specific time interval. "Repeat as needed for control" does not meet the PR Notice 96-6 criteria for product specific statements. You need to provide a specific number of days or weeks in the reapplication limitation statement, taking into consideration efficacy and domestic animal safety data, to meet the requirement of PR Notice 96-

6/11

6. Section IV, No. 3.

- b. Revise the last sentence in the paragraph under DIRECTIONS FOR USE to read as follows: "Do not use on kittens under 12 weeks of age, or puppies under 6 weeks of age." Although the data you cited support use on dogs younger than 12 weeks, those data cannot be used for products that are applied to cats. The statement must be consistent with the definitive wording presented in PRN 96-6.
- c. Revise the third sentence under PRECAUTIONARY STATEMENTS to read as follows: "Do not use on kittens under 12 weeks of age, or puppies under 6 weeks of age."
- d. Revise the statement concerning debilitated, aged, and medicated animals to read as follows: "Consult a veterinarian before using this product on debilitated, aged, or medicated dogs or cats, or pregnant or nursing cats. If used on pregnant or nursing dogs, do not retreat until the puppies are at least 6 weeks old."
- e. Add the following statement regarding cholinesterase inhibitors to the PRECAUTIONARY STATEMENTS: "Do not use this product on animals simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. However, flea and tick collars may be immediately replaced." The technical review of the data you cited does not support omitting this statement from this product label.

Hartz Fast Acting Flea and Tick Spray for Dogs, EPA Reg. No. 2596-122:

- a. Replace the reapplication limitations with a specific time interval. "Every few days." and "as needed." do not meet the PR Notice 96-6 criteria for product specific statements. You need to provide a specific number of days or weeks in the reapplication limitation statement, taking into consideration efficacy and domestic animal safety data, to meet the requirement of PR Notice 96-6, Section IV, No. 3.
- b. Revise the fifth sentence in the paragraph that follows "CAUTION" to read as follows: "Do not use on puppies under 6 weeks of age." Although the statement, "It is not advisable to use this collar on puppies less than 6 weeks of age," had been previously approved by the Agency, the statement must now be revised to be consistent with the definitive wording presented in PRN 96-6 to clearly indicate the minimum age of animals.
- c. After the statement, "Consult a veterinarian before using the product on debilitated, aged, or medicated animals," insert the following statement: "If used on pregnant or nursing dogs, do not retreat until the puppies are at least 6 weeks old."
- d. In the directions for use, add the following statement: "Do not use this product on animals simultaneously or within 30 days before or after treatment with or exposure to cholinesterase

7/11

inhibiting drugs, pesticides, or chemicals. However, flea and tick collars may be immediately replaced." The technical review of the data you cited does not support omitting this statement from this product label.

Hartz 2 in 1 Fast Acting Flea & Tick Spray for Cats III, EPA Reg. No. 2596-123:

a. Replace the reapplication limitations with a specific time interval. "Every few days," and "as needed," do not meet the PR Notice 96-6 criteria for product specific statements. You need to provide a specific number of days or weeks in the reapplication limitation statement, taking into consideration efficacy and domestic animal safety data, to meet the requirement of PR Notice 96-6, Section IV, No. 3.

b. Revise the fourth sentence in the paragraph under PRECAUTIONARY STATEMENTS to read as follows: "Do not use on kittens under 12 weeks of age." Although the data you cited support use on dogs younger than 12 weeks, those data cannot be used for products that are applied to cats. The statement must be consistent with the definitive wording presented in PRN 96-6.

c. Revise the statement concerning debilitated, aged, and medicated animals to read as follows: "Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals."

d. Add the following statement regarding cholinesterase inhibitors to the PRECAUTIONARY STATEMENTS: "Do not use this product on animals simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. However, flea and tick collars may be immediately replaced." The technical review of the data you cited does not support omitting this statement from this product label.

Hartz 2 in 1 Flea & Tick Repellent for Dogs, EPA Reg. No. 2596-125:

a. Below PRECAUTIONARY STATEMENTS, after the statement, "Consult a veterinarian before using the product on debilitated, aged, or medicated animals," insert the following statement: "If used on pregnant or nursing dogs, do not retreat until the puppies are at least 6 weeks old."

b. In the directions for use, add the following statement: "Do not use this product on animals simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. However, flea and tick collars may be immediately replaced." The technical review of the data you cited does not support omitting this statement from this product label.

c. Since the active ingredient and concentration in this product is identical to EPA Reg. No.

8/11

2596-122, this product should also have a statement on the front panel of the label indicating that it kills fleas and ticks.

d. Under "Directions for Use" delete the statement, "Use on bedding and other areas as needed." No directions are given for spraying inanimate objects.

Hartz 2 in 1 Flea & Tick Pump for Cats II (Flea and Tick Repellent for Cats), EPA Reg. No. 2596-126:

a. Revise the last sentence in the paragraph under PRECAUTIONARY STATEMENTS to read as follows: "Do not use on kittens under 12 weeks old." Although the data you cited support use on dogs younger than 12 weeks, those data cannot be used for products that are applied to cats. The statement must be consistent with the definitive wording presented in PRN 96-6.

b. Revise the statement concerning debilitated, aged, and medicated animals to read as follows: "Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals."

c. Add the following statement regarding cholinesterase inhibitors to the PRECAUTIONARY STATEMENTS: "Do not use this product on animals simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. However, flea and tick collars may be immediately replaced." The technical review of the data you cited does not support omitting this statement from this product label.

d. Under "Directions for Use" delete the statement, "Use on bedding and other areas as needed." No directions are given for spraying inanimate objects.

e. Please note that since the active ingredient and concentration in this product is identical to EPA Reg. No. 2596-123, this product should also have a statement on the front panel of the label indicating that it kills fleas and ticks.

Hartz 2 in 1 Flea & Tick Spray Cats & Dogs, EPA Reg. No. 2596-136:

a. Revise the last sentence under PRECAUTIONARY STATEMENTS to read as follows: "Do not use on kittens under 12 weeks of age, or puppies under 6 weeks of age." Although the data you cited support use on dogs younger than 12 weeks, those data cannot be used for products that are applied to cats. The statement must be consistent with the definitive wording presented in PRN 96-6.

b. Revise the statement concerning debilitated, aged, and medicated animals to read as follows: "Consult a veterinarian before using this product on debilitated, aged, or medicated dogs

9/11

or cats, or pregnant or nursing cats. If used on pregnant or nursing dogs, do not retreat until the puppies are at least 6 weeks old."

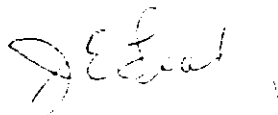
c. Add the following statement regarding cholinesterase inhibitors to the PRECAUTIONARY STATEMENTS: "Do not use this product on animals simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. However, flea and tick collars may be immediately replaced." The technical review of the data you cited does not support omitting this statement from this product label.

d. Under "Directions for Use" delete the statement, "Use on bedding and other areas as needed." No directions are given for spraying inanimate objects.

Submit two copies of your final printed labeling for each product before you release the products for shipment. Stamped copies of the labeling are enclosed for your records.

If you have any questions regarding this letter, please contact John Leahy of my team at (703) 305-6703.

Sincerely,



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

Enclosure

FRONT PANEL

-63

Enclosure 2
10/11

LONG TERM PROTECTION

**HARTZ
2 IN 1®
FLEA & TICK COLLAR**
with Rabon®*
FOR CATS

- With Deodorant (Optional Copy)
- Fresh Deodorant Scent (Optional Copy)
- Waterproof (Optional Copy)
- Safety Snap Buckle (Optional Copy)

Kills for 5 Months

(Ingredient Statement - optional front or back panel)

ACTIVE INGREDIENT:	BY WEIGHT (Nom.)
Tetrachlorvinphos (CAS # 22248-79-9)	14.55%
OTHER INGREDIENTS	85.45%
TOTAL	100.00%

CAUTION: Do not let children play with this collar.
 (See back panel for ingredient statement.)
 (See back panel for complete directions for use.)

CONTENTS: 1 COLLAR, NET WT. (Range from 12g to 15g depending on animal)

ACCEPTED
with COMMENTS
in EPA Letter Dated

NOV 23 1998

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the
registered under E:

2596-63

BACK PANEL

11/11

IMPORTANT: CONSUMER INFORMATION AND PET I.D. TAG OFFER PRINTED ON INSIDE OF PACKAGE

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON CATS

DIRECTIONS FOR USE

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

REMOVE COLLAR FROM PACKAGE UNROLL AND STRETCH TO ACTIVATE INSECTICIDE GENERATOR. As the collar begins to work, a fine white powder will appear on the surface.

The 2 in 1 collar will kill ticks, including the Deer Tick, which may carry Lyme Disease, for five months under normal conditions.

[It is not advisable to use this collar or similar pesticides on kittens less than 6 weeks of age] Do not unroll collar until ready to use. Place the Hartz 2 in 1 Flea & Tick Collar around the cat's neck, adjust for proper fit, and buckle in place. The collar must be worn loosely to allow for growth of the cat and to permit the collar to move about the neck. Generally, a properly fitted collar is one that when fastened will snugly slide over the cat's head. Leave 2 or 3 inches on the collar for extra adjustment and cut off and dispose of the extra length. Consult a veterinarian before using this product on debilitated, aged or medicated animals. Sensitivity may occur after using ANY pesticide product for pets. Some animals may become irritated by any collar if it is applied too tightly. If this occurs loosen the collar. If irritation continues, remove the collar from the animal. If signs of sensitivity occur remove the collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. This collar is intended for use only as an insecticide generator. For continuous flea and tick protection under normal conditions replace the collar every five months. Under conditions where cats are exposed to severe flea and tick infestations it may be necessary to replace the collar every 4 months. Ticks, which may be an occasional problem for cats, are harder to kill. The collar's full protection against ticks will be built up within a few days after being placed on the animal. The cat should be examined from time to time and the collar replaced when mature tick or flea populations begin to appear. Wetting will not impair the collar's effectiveness or the pet's protection. If the cat is out in the rain it is not necessary to remove the collar. The Hartz 2 in 1 collar may be worn with a regular collar.

DISPOSAL - Do not use empty pouch.

Dispose in trash collection.

EPA Reg. No. 2596-63

EPA Est. No. 2596-NJ-1

→ phone #

ChE inhib statement.

Made in U.S.A. by © The Hartz Mountain Corporation
Secaucus, New Jersey 07094

*Rabon is the Hartz trademark for Tetrachlorvinphos