

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 9, 2020

Joseph Conti Sr. Director, Regulatory, Research & Development The HARTZ Mountain Corporation 400 Plaza Drive Seacaucus, NJ 07094

Subject: PRIA Label Amendment – Submission to add repels claims against fleas, ticks,

and mosquitoes

Product Name: Hartz Reference 156 EPA Registration Number: 2596-187

Application Date: 12/5/2019 Decision Number: 558484

Dear Mr. Conti:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact Anna Katrina Briley by phone at (703) 347-0262, or via email at briley.anna-katrina@epa.gov.

Sincerely,

Jacquelyn Herrick, Product Manager 03 Invertebrate & Vertebrate Branch 1 Registration Division (7505P) Office of Pesticide Programs

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Enclosure

# HARTZ REFERENCE 156 **{FRONT PANEL}**

**Active Ingredient:** 

**Other Ingredients.....** 96.00% **Total**......100.0%

## ACCEPTED

Jul 09, 2020

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

2596-187

### DO NOT ALLOW CHILDREN TO PLAY WITH COLLAR **CAUTION**

See [Back] [Insert] [or] [Side] [Panel[s]] for First Aid and [Additional] Precautionary Statements

{Throughout the label, whenever the terms {Color designation} or {Collar color} are indicated, the collar colors will be one of the following color designations in this registration's corresponding Confidential Statements of Formula: Orange, Blue, Purple, Red, Green, Gray, Black, Gold, or Silver.}

**NET CONTENTS:** [1][2] [{Collar color}][reflecting][reflective] Collar

**Net Wt.** [1 Collar, Net Wt. 1.1 oz. (31g)]

{or}

[2 Collars, Net Wt. 2.2 oz (62g); each collar 1.1 oz (31g)]

Made [in the U.S.A.] by: The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094 [U.S.A.] EPA Registration No. 2596-187 EPA Est. No. 2596-OH-1

### **{BACK PANEL}**

#### Read Entire Label Before Each Use.

ONLY for Dogs 12 weeks of age and older. {A statement of purpose of the product (flea and tick control for dogs) and the duration of protection per collar indicated in the optional claims section, will be included on the front panel.}

{Product name} provides 6 [six] months protection against fleas and ticks.

07/05/20

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS



#### DO NOT USE ON CATS

#### **CAUTION:**

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

#### **Hazards to Domestic Animals**

Do not open protective [pouch] [wrapper] [package] [envelope] [blister] until ready to use. Do not use on dogs under 12 [twelve] weeks of age. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your dog with mild soap and rinse with large amount of water. If signs continue, consult a veterinarian immediately. This collar is intended for use only as an insecticide generator and is not to be taken internally by humans or animals.

[{Product name}] [collar], containing deltamethrin insecticide, has been specifically formulated using insecticidal release technology. [Collar] [{Product name}] will kill ticks for [6] [six] months. Collar will kill ticks including: Brown dog tick [(Rhipicephalus sanguineus)], American dog tick [(Dermacentor variabilis)] and deer tick [(Ixodes scapularis and Ixodes pacificus)] which may transmit Lyme disease. [Collar] [{Product name}] kills fleas [and repels mosquitoes\*.] The collar is to be worn continuously. Reapply a new collar every [6] [six] months.]

#### **FIRST AID**

IF SWALLOWED: 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 a poison control center or doctor. Do not give anything by mouth to an unconscious person. IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice. IF IN EYES: 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 treatment advice.

**HOT LINE NUMBER:** Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product [including health concerns, medical emergencies or pesticide incidents], you may call [1-800-275-1414] [X-XXX-XXXX-XXXX], twenty four [24] hours per day, seven [7] days per week.

07/05/20

#### STORAGE AND DISPOSAL

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

**PESTICIDE STORAGE:** Store this product in a cool dry place away from children and pets.

**PESTICIDE Disposal and Handling**: Do not reuse container or used collar. Dispose of in trash.

#### [Product Information]

[[{Product name}] [This collar] kills fleas and ticks and [&] repels mosquitos for 6 [six] months. [{Product name}] [Collar] is a sustained release system [containing deltamethrin] which provides insecticidal [protective] activity from head to tail. Use [{Product name}] [collar] year round, replacing collar every six months for effective control of fleas and [&] ticks and to repel mosquitos that may transmit [Rocky Mountain spotted fever][and] [Lyme disease.]]

[[Collar] [{Product name}] will kill fleas and [&] ticks for 6 [six] months when worn continuously. Collar will kill ticks including: Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis) and deer tick (Ixodes scapularis and Ixodes pacificus) which may transmit Lyme disease. [Collar will repel mosquitos for 6 months.] Reapply a new collar every 6 [six] months.]

#### **DIRECTIONS FOR USE:**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. {For Multi-Packs, the following statement will be included}: Use only one collar per dog at a time.

#### **RESTRICTIONS:**

Do not use on dogs under 12 weeks of age. Do not open [pouch] [wrapper][package] [envelope][blister] until ready to use. Do not let children play with collar. Use only one collar per dog at a time. Do not use on cats. Do not use on dogs under 12 weeks.

Remove collar from package and unroll. Place the [{Product name}] [collar] around the dog's neck, adjust for proper fit, and buckle in place. The collar is to be worn loosely to allow for growth of the dog and to permit collar to move [around] [about] the dog's neck. A properly fitted collar is one that, when fastened, will snugly slide over the dog's head and allow for 2 fingers to be placed comfortably between the collar and the dog's neck. Leave 2 [two] to 3[three] inches on the collar for extra adjustment and cut off and dispose of the extra length. Maximum effectiveness may not occur for 2-3 weeks after collar placement.

Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing dogs. Sensitivities may occur after using ANY pesticide products for dogs. If signs of sensitivity occur, remove collar and bathe your dog with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

Wetting will not impair the collar's effectiveness or the dog's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove collar. [{Product name}] [Collar] may be used in addition to a lead or constraint collar. The collar is to be worn continuously. Reapply a new collar every 6 [six] months.]

#### **{OPTIONAL LABEL CLAIMS}**

#### **Fleas**

- [{Product name} contains [deltamethrin] [insecticide] [an insecticide] which has been specifically formulated using insecticide release technology.]
- [Flea [control][prevention] for dogs 12 weeks of age and older [over 12 weeks of age]]
- [Kills Fleas]
- [Kills [adult] fleas for 180 days[!]]
- [Kills [adult] fleas for 6 months[!]]
- [Provides [long lasting] protection for 180 days against fleas]
- [Provides [long lasting] protection for 6 months against fleas]
- [Prevents new flea infestation]
- [Kills adult fleas before they lay eggs]
- [Kills fleas that may cause anemia]
- Kills fleas that may cause bartonellosis]
- [Kills [adult] fleas which may transmittapeworm]
- [Kills [adult] fleas which may cause flea bite anemia]
- [Kills [adult] fleas that may reduce the incidence of [FAD] [flea allergy dermatitis]]
- [Kills [adult] fleas which may be a source of [flea allergy dermatitis][FAD] [and][flea bite anemia] [and] [tapeworm]]
- [Kills fleas]
- [Starts killing fleas for 6 months]
- [Starts killing fleas for six months]
- [Kills fleas for [6] [six] months]

*{The following optional label claim will always be accompanied by the asterisked \* statement}:* 

- [{Product name} contains deltamethrin, the same active ingredient [found][used] in Scalibor Protective Brand for Dogs.\*
  - \* Product is not manufactured or distributed by Merck.]

#### **{OPTIONAL LABEL CLAIMS - continued}**

#### Fleas {continued}

MASTER LABEL

- [Fleas on the dog will be killed]
- [Long lasting [flea] protection for 6 months]
- [Continuous [flea] protection for 6 months]
- [Flea [control][prevention]]

#### **Ticks**

- [Kills ticks]
- [Tick collar for dogs]
- [Tick [control][prevention] for dogs 12 weeks of age and older [over 12 weeks of age]]
- [Kills ticks for 180 days[!]]
- [Kills ticks for 6 months[!]]
- [Provides [long lasting] protection for 180 days against ticks]
- [Provides [long lasting] protection for 6 months against ticks]
- [Kills ticks that may transmit babesiosis]
- [Kills ticks including deer ticks which may transmit Lymedisease]
- [Kills ticks which may transmit Rocky Mountain spotted fever]
- [Kills ticks which may transmit [anaplasmosis][babesiosis][ehrlichiosis] [and Lyme disease]
- [Kills ticks for 6 [six] months including Deer tick [which may vector Lyme disease and anaplasmosis], American dog tick[which may vector Rocky Mountain spotted fever].
- [Kills deer ticks][for 6 months]
- [Kills deer ticks]

#### **Mosquitos**

- [Repels mosquitos\*]{\*Except California}
- [Repels mosquitos\* for six [6] months] {\*Except California}
- [Repels mosquitos\* before they bite]\* {\*Except California}
- [Repels mosquitos\* so they don't bite] {\*Except California}
- [Mosquito\* repelling collar] {\*Except California}

#### **<u>{OPTIONAL LABEL CLAIMS - continued}</u>**

#### **Multiple Pests**

- [Kills fleas and ticks for 180 days[!]]
- [Kills fleas and [&] ticks for 180 days[!]]
- [Kills fleas and [&] ticks for 6 months[!]]
- [Provides [long lasting] protection for 180 days against fleas and [&] ticks]
- [Provides [long lasting] protection for 6 months against fleas and [&] ticks]
- [Kills fleas and ticks [for] [6 months]]
- [Dog collar for flea and [&] tick control]
- [Dog collar for flea, mosquito\* & tick control] {\*except California}
- [Flea and [&] tick collar for dogs]
- [Flea, mosquito\* & tick collar for dogs] {\*except California}
- [Kills fleas and [&] ticks]
- [Kills fleas and [&] ticks and repels mosquitos\*] {\*Except California}
- [Kills fleas & ticks and repels mosquitos\* before they bite] {\*Except California}
- [Kills fleas & ticks before they bite]
- [6 [Six] Month flea and [&] tick protection]

#### **Collar Claims**

{For all Optional Collar Claims, whenever the terms {Color designation} or {Collar color} are indicated, the collar colors will be one of the following color designations in this registration's corresponding Confidential Statements of Formula: Orange, Blue, Purple, Red, Green, Gray, Black, Gold, or Silver}:

- [Right fit]
- [Fits just right]
- [Just right fit]
- [Fits securely]
- [Stays in place]
- [Great fitting collar]
- [Comfort fit]

#### **MASTER LABEL**

#### **{OPTIONAL LABEL CLAIMS - continued}**

- [Engineered for comfort]
- [Stay in place design]
- [Fits all size dogs]
- [Adjustable [collar]]
- [Fits securely]
- [Inner collar focuses pesticide toward the dog]
- [Easy release collar]
- [Outer shield reflects direct light]
- [{Color designation}] collar [with Silver Reflect-X Shield]]
- [{Color designation}] collar [with Reflect-X Shield]]
- [White & purple collar]
- [White & blue collar]
- [Gray & white collar]
- [{Color designation} & {Color designation}]
- [{Collar color}] with reflective technology visible to headlights]
- [Water resistant]
- [With Reflect-X Shield]
- [Provides an added dimension of nighttime visibility for you and your dog]
- [Full body protection]
- [Reflecting]
- [Reflect direct light]
- [Long lasting protection for 6 months]
- [One size fits all]

#### **All Other Claims**

- [Continuous Protection for 6 months]
- [Long lasting protection for 6months]
- [All weather collar]
- [Not affected by water]
- [Water resistant]
- [Water will not impair the efficacy]
- [One size fits all dogs]
- [Water will not [impair] [affect] your dog's protection]
- [Convenient]
- [Glow in the dark]
- [Reflective]
- [Designed and tested to [perform][work]]
- [Formulated with insecticide release technology]
- [Full body protection]
- [Long lasting protection for 6 months]

MASTER LABEL

#### **{OPTIONAL LABEL CLAIMS - continued}**

- [Sustainable release technology [for long lasting control for 6 months][for long lasting [flea] [flea and tick] [flea, tick and mosquito] control for 6 months]
- With color strip
- [Outer shield reflects light]
- [With Reflect-X Shield]

#### **Marketing Claims**

- Two collars provides 12 [twelve] consecutive months of protection [\*] / [\*\*]
- Two collars, one at a time = 12 [twelve] months of protection [\*\*]
- Two collars, one at a time, provides 12 [twelve] consecutive months of protection [\*\*]
- Two collars = 12 [twelve] consecutive months of protection [\*] / [\*\*]
- 6 [six] months protection each collar [2][two] collars [\*]
- 2 [Two] Collars; One collar = 6 [six] months of protection [\*\*]

{One or both statements below will appear in the same font size, in close proximity to the claim above on same label panel, indicated with \*/\*\*}

- [\*] Use one collar per dog at a time
- [\*\*] One collar provides 6 months of protection.

{For all Optional Marketing Claims, whenever the terms {Color designation} or {Collar color} are indicated, the collar colors will be one of the following color designations listed in this registration's corresponding Confidential Statements of Formula: Orange, Blue, Purple, Red, Green, Gray, Black, Gold, or Silver}:

- [Save Now]
- [Buy Now]
- [Great Value]
- [NEW] {Will be removed after having been on the market for 6 months.}
- [Value pack 2 six [6] month collars]
- [Value pack Two 6 [six] month collars]
- [Multi-pack 2 six [6] month collars]
- [Multi-pack Two 6 [six] month collars]
- [Buy more and save]
- [Bonus pack]
- [Coupon inside]
- [Buy [x] and Save]  $\{x = 1 \text{ unit of sale, i.e. one box as seen on store shelves}\}$
- [From the company [Hartz] with over 90 years [of] experience caring for dogs]
- [From the company with over 90 years [of] experience]
- [Hartz the company with over 90 years [of] experience]
- Scalibor® is a registered trademark of Merck Animal Health
- [No biting]
- [Flea & tick collar for dogs]
- [Flea, tick and [&] mosquito\* collar for dogs] {\*Except California}

7/05/20

#### **<u>{OPTIONAL LABEL CLAIMS - continued}</u>**

## Flea Icon / Graphic

{Icon / graphic for adult fleas}:



[Adult Fleas]



{Icon / graphic for adult ticks}:



[Adult Ticks]



{Icon / graphic for mosquito. {\*Except California}:



[Mosquitos]\*

{\*Except California}

#### **{Alternate Brand Names}**

Hartz® Ultra Guard® Flea & Tick Prevention Collar for Dogs Hartz® Ultra Guard® Flea and Tick Prevention Collar for Dogs

Hartz® Ultra Guard Pro® Flea & Tick Collar for Dogs Hartz® Ultra Guard Pro® Flea and Tick Collar for Dogs

Hartz® Ultra Guard Pro® Flea & Tick Reflecting Collar for Dogs Hartz® Ultra Guard Pro® Flea and Tick Reflecting Collar for Dogs

Hartz® Ultra Guard Plus® Flea & Tick Collar for Dogs Hartz® Ultra Guard Plus® Flea and Tick Collar for Dogs

In Control by Hartz® Flea and Tick Collar for Dogs In Control by Hartz® Flea & Tick Collar for Dogs

Hartz® In Control® Flea & Tick Collar for Dogs Hartz® In Control® Flea and Tick Collar for Dogs

In Control by Hartz® Flea and Tick Reflecting Collar for Dogs In Control by Hartz® Flea & Tick Reflecting Collar for Dogs

Hartz® In Control® Flea & Tick Reflecting Collar for Dogs Hartz® In Control® Flea and Tick Reflecting Collar for Dogs

Hartz® Advanced Care® Flea and Tick Collar for Dogs Hartz® Advanced Care® Flea & Tick Collar for Dogs Hartz® Advanced Care® Flea and Tick Reflecting Collar for Dogs Hartz® Advanced Care® Flea & Tick Reflecting Collar for Dogs

Hartz® Ultra Guard® Flea, Tick & Mosquito Prevention Collar for Dogs Hartz® Ultra Guard Pro® Flea, Tick & Mosquito Collar for Dogs Hartz® Ultra Guard Pro® Flea, Tick & Mosquito Reflecting Collar for Dogs

Hartz® Ultra Guard Plus® Flea, Tick & Mosquito Collar for Dogs Hartz® Ultra Guard Plus® Flea, Tick & Mosquito Reflecting Collar for Dogs

In Control by Hartz® Flea, Tick & Mosquito Collar for Dogs In Control by Hartz® Flea, Tick & Mosquito Reflecting Collar for Dogs

Hartz® In Control® Flea, Tick & Mosquito Collar for Dogs Hartz® In Control® Flea, Tick & Mosquito Reflecting Collar for Dogs