

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

July 24, 2024

Anna McGrath Senior Regulatory Affairs Specialist The Hartz Mountain Corporation 200 Plaza Drive Secaucus, New Jersey 07094-3688

Subject: Notification per PRN 98-10 – Add dog images, brackets around already approved

claims, removal of clock icon and 'ComfiFit', and adding optional years of

business

Product Name: Hartz Reference #158 EPA Registration Number: 2596-188

Application Date: 7/18/2024

Case Number: 622698

Dear Anna McGrath:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "NOTIFICATION" and placed in our records.

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 (FIFRA) 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) lists 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.

If you have any questions, please contact Hester Dingle at 202-566-2596 or at dingle.hester@epa.gov.

Sincerely,

or Jac

Jacquelyn Herrick, Product Manager 3 Invertebrate and Vertebrate Branch 1 Registration Division, (7505T) Office of Pesticide Programs

HARTZ Reference No. 158

{Note to Reviewer: Primary Brand Name not to be used on any product labels; only Alternate Brand Names will be used. Alternate Brand Names are listed at end of document.}

{FRONT PANEL} NOTIFICATION

2596-188

ACTIVE INGREDIENTS:	Percentage by Weight
Deltamethrin	4.00%
(S)-methoprene	1.02%
Other Ingredients	<u>94.98%</u>
Total	100.00%

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

07/24/2024

DO NOT ALLOW CHILDREN TO PLAY WITH COLLAR CAUTION

See Back[Side][Insert] [Panel[s]] for First Aid, [Additional] Precautionary Statements and Directions for Use. Do not use on puppies under 12 weeks [of age].

NET CONTENT: 1 [2] [3] [{color designation}] collar[s] [with [silver] [Reflect-X Shield] [Reflective Technology]]

NET WT.: 1 Collar, Net Wt. 1.1 oz. [2.2 oz. Contains 2 Collars, Each Collar 1.1 oz.] [3.3 oz. Contains 3

Collars, Each Collar 1.1 oz.] Made [in the U.S.A.] by

The Hartz Mountain Corporation

400 200 Plaza Drive

Secaucus, NJ 07094 [U.S.A.] EPA Registration No. 2596-188

EPA Est. No. 2596-OH-1

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS

{Note to Reviewer: Product is sold in package containing 1, 2, or 3 collars. The claims below correspond to the number of collars in the package.}

{For 1 collar package:}

One {Product Name} collar provides 6 [six] months protection against fleas, ticks and mosquitoes.

{For 2 collar package:}

Each {Product name} collar offers 6 [six] months protection against fleas, ticks and mosquitoes, worn one at a time, providing a total of 12 [twelve] months protection against fleas, ticks and mosquitoes.

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{For 3 collar package:}

Each {Product name} collar offers [six] 6 months protection against fleas, ticks and mosquitoes, worn one at a time, providing a total of 18 [eighteen] months protection against fleas and ticks.

{BACK PANEL}

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals.

CAUTION: Do not open protective pouch until ready to use. Do not let children play with this collar.

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 and before eating, drinking, chewing gum, using tobacco or using the toilet.

Do not use on puppies under 12 [twelve] weeks. DO NOT USE ON CATS. 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 amount of water. If symptoms persist, consult a veterinarian immediately.

This product is not a substitute for prescribed heartworm preventative.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals.

FIRST AID	
If swallowed	Call 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.
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 eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after 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. You may also contact 1-800-275-1414 for emergency medical treatment information, twenty-four (24) hours a day, seven (7) days a week.

{<u>Optional Product Information</u> - Note to Reviewer: All or some of the 12 Optional Product Information bullet points below may be used on the marketplace label.}

[Product Information]

- [{Product Name}] [Collar] kills fleas, flea eggs, and ticks and repels mosquitos for 6 [six] months.
- [{Product Name}] [Collar] is a sustained release system [containing Deltamethrin and (s)-methoprene] which provides [flea, tick & mosquito protection] [protection from fleas, ticks & mosquitos] from head to tail.
- [{Product Name}] [Collar] has been specifically formulated using insecticide release technology.
- [{Product Name}] has been specifically formulated to contain an insecticide and repellent [Deltamethrin].
- Maximum effectiveness may not occur for 2-3 weeks after collar placement.
- Fleas (Ctenocephalides sp.) and ticks on the dog will be killed.
- [{Product Name}] [Collar] can be used to kill fleas, ticks [and repel mosquitos*]
- One [{Product Name}][Glide & Guard][technology] [Flexible Fit] [Gentle Fit] [Easy Adjust] [Collar] will kill [fleas][and][ticks] for 6 [six] months.
- One [{Product Name}][Glide & Guard][technology] [Flexible Fit] [Gentle Fit] [Easy Adjust] [Collar] will repel mosquitoes for 6 [six] months.
- One [{Product Name} [Glide & Guard] [technology] [Flexible Fit] [Gentle Fit] [Easy Adjust]] [collar] will kill fleas, ticks and repel mosquitoes for 6 six months

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Collar will kill ticks including: Brown dog tick (Rhipicephalus sanguineous), American dog tick (Dermacentor variabilis) and deer tick (Ixodes scapularis and Ixodes pacificus) which may transmit

Lyme disease. [The collar is to be replaced every six (6) months and worn continuously.]

Reapply a new [Glide & Guard][technology] [Flexible Fit] [Gentle Fit] [Easy Adjust] collar every six (6) months.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For external use only. Do not let children play with this collar. Do not use on puppies under 12 weeks of age.

Do not open pouch until ready to use. Do not unroll collar until ready to use. Place the [{Product Name}] [collar] around the dog's neck, adjust for proper fit, and buckle in place. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Living and rest areas of infested dog must also be treated with appropriate pest control measures to ensure control of [persisting] [persistent] pest infestation.

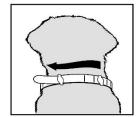
Wetting will not impair the collar's effectiveness or the dog's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. [{Product Name}][Collar] may be used in addition to a lead or constraint collar. [Use only one [{Product Name}] [collar] at a time.] This collar should be worn continuously. Reapply a new collar every six (6) months.

[How to Apply]

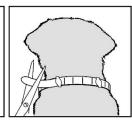
[Remove collar from protective pouch directly before use. Unroll collar and make sure that there are no remnants from the plastic connectors inside the collar.

Insert the end of the collar through the buckle. Adjust the collar around the dog's neck without tightening it too tight or leaving it too loose. As a guide, it should be possible to insert 2 fingers comfortably between the collar and the neck. Pull excess collar through the loop(s). Collar length of greater than 1 inch (2 cm) beyond the loop(s) should be cut off unless it is on a growing puppy, where some additional length may be needed for adjustment as the dog's grows.

The collar should be worn continuously for the 6 month protection period. Check periodically and adjust if necessary, especially when puppies are rapidly growing. Replace the collar after 6 months for optimal tick, flea and mosquitos protection.]







STORAGE AND DISPOSAL

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

Pesticide Storage: Keep this product in its tightly closed original container, when not in use.

Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

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

{Optional/Alternate Label Claims}

{Fleas}

- {Product name} contains Deltamethrin and (S)-Methoprene [insecticides], which have been specifically, formulated using insecticide release technology [and secure twin buckle system[design]].
- Flea [control] [prevention][repellent] for dogs [and puppies] [12 weeks of age and older]
- Kills fleas, flea eggs[,][and ticks]
- Kills Fleas
- Kills fleas and ticks
- Kills [adult] fleas for 180 days[!]
- Kills [adult] fleas for 6 [six] months[!]
- Provides [long lasting][ComfiFit] protection for 180 days against fleas [and ticks]
- Provides [long lasting][Gentle Fit] protection for six [6] months against fleas [and ticks]
- Prevents flea infestation
- Kills fleas that may transmit bartonellosis
- Kills ticks that may transmit anaplasmosis
- Kills [adult] fleas which may transmit tapeworm
- Kills [adult] fleas which may cause flea bite anemia
- Kills [adult] fleas, which 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]
- Fleas on the dog will be killed
- Long lasting [flea] protection for 6 [six] months
- Flea control [prevention]
- Contains a Flea IGR [insect growth regulator]
- Contains an IGR [insect growth regulator]
- Kills flea eggs to prevent infestation for 6 months
- Halts the flea life cycle by killing flea eggs and larvae
- Provides protection against flea infestation
- Kills flea eggs [to prevent] infestation
- Prevents infestation by killing flea eggs
- Plus insect growth regulator[IGR]
- Focused on breaking the life cycle
- Breaks the flea life cycle
- Kills flea eggs before they hatch

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- Prevents flea eggs from hatching
- Active ingredient [specifically] targeting flea eggs, stopping their ability to mature

{Ticks}

- Kills ticks [for] 6 [six] [months]
- Kills deer ticks
- Tick collar for dogs
- Tick [control] for dogs [and puppies] 12 weeks of age and older
- Kills deer ticks for 180 days[!]
- Kills deer ticks for 6 [six] months[!]
- Provides [long lasting] protection for 180 days against ticks
- Kills ticks that may transmit Lyme Disease
- Kills ticks that may transmit babesiosis
- Kills ticks including deer ticks which may transmit Lyme Disease
- 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 [that may transmit Lyme disease, American dog tick, and Brown dog tick]

{Note to Reviewer – All claims with an asterisk (*) will also show the qualifying statement "*Except California" on the label.}

{Mosquitos}

- Repels mosquitos*
- Repels mosquitos* [for] 6 [six] [months]
- Repels mosquitos* before they bite*
- Mosquito* repelling collar * {*Except California}

{Multiple Pests}

- Kills fleas and ticks [for 6 [six] months]
- Kills fleas and ticks [for 180 days]
- Repels mosquitoes [for 6 six months]
- Repels mosquitoes [for 180 days]
- Kills fleas and ticks and repels mosquitos* [for180 days[!]]*
- Provides [long lasting] protection [for 180 days] against fleas, mosquitos* and ticks *
- Provides [long lasting] protection for 6 [six] months against fleas, mosquitos* and ticks
- Kills fleas, deer ticks, and repels mosquitos for6 months [six months]*
- Dog collar for flea, mosquito* and tick control *
- Flea, tick and mosquito* collar for dogs
- Starts killing fleas and ticks for 6 [six] months and repels mosquitos* for six
 [6] months

{*Except California}

{Collar Claims}

- One size fits all
- Right fit
- Fits just right
- Just right fit
- Fits securely
- Stays in place
- Great fitting collar
- Comfort fit
- Engineered for comfort
- Stay in place design
- Will not slide [or stretch]
- Adjustable [collar]
- Break away collar
- Break away buckle
- Easy release collar{Color designation} collar [with [Silver] Reflect-X Shield]
- Easy release collar (Color designation) collar [with [Silver] Reflective Technology]
- White collar [blue collar] [red collar] [purple collar] [orange collar] [black collar] [green collar]
 [brown collar] [tan collar] [gold collar] [silver collar]
- For puppies 12 weeks of age and older
- With Reflect-X Shield
- With Reflective Technology
- Re-attachable
- Provides an added dimension of nighttime visibility for you and your dog
- Fits necks [up to] 15 inches [15 "] [20 inches] [20 "] [23 inches] [23 "][26 inches] [26 "]
- [Fast 'n' Easy] buckle Technology
- Glide and Guard Technology
- Easy Adjust
- Adjustable Buckle
- EZ Buckle
- [Secure] Twin Buckle [Technology]
- [Secure] Dual Buckle [System] [Technology]
- Easy & Secure
- Easy 'n' Secure
- Soft & Secure
- Soft 'n' Secure
- Soft 'n' Fasten [Fit]
- Comfort Technology
- SecureFlex
- Comfi Lock
- Gentle Fit
- Flexible Fit
- Flex Fit

- Smart Flex [Technology] [Fit]
- Snug & Flex Fit
- ComfiFit
- FlexiFit
- Patented [collar] [buckle] [design]
- Patent Pending
- Smooth & Fasten
- Smart Flex Fit
- Comfort Flex
- Injection Mold Smart comfort texture

{Marketing Claims}

- Save Now
- Buy Now
- New collar design { "New collar design" claim only to be used in first 6 months following product launch}
- New & Improved (collar design) design { "New" claim only to be used in first 6 months following product launch}
- Improved collar design
- Mold Injected design
- Mold injected soft texture
- [Mold injected][collar color] comfort fit
- [Mold injected][collar color] Smart Fit
- [Mold injected][collar color] gentle fit
- [Mold injected][collar color] flexible fit
- [Mold injected][collar color] textured
- [Color] Collar
- Innovative [mold injected] [color] collar
- Redesigned {"Redesigned" claim only to be used in first 6 months following product launch}
- Smart design
- Great Value
- NEW {"New" claim only to be used in first 6 months following product launch}
- Value size Remove and replace collar every 6 months
- [Multi-pack –] 2 six month collars
- [Multi-pack –] Two 6 [six] month collars
- Buy more and save
- Bonus pack Remove and replace collar every 6 [six]months
- [Bonus pack –] Two [6 [six] month] collars
- Coupon inside
- [Now] available without a visit to the veterinarian { The word "Now" in this claim only to be used in first 6 months following product launch}
- [Value Pack –] 2 six month collars
- [Value Pack –] Two 6 [[six] month collars
- Buy [x] and Save

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{All Other Claims}

- Continuous Protection for 6 [six] months
- Long lasting [protection] for 6 [six] months
- Full body protection for 6 [months]
- Not affected by water
- Convenient
- {Illustration of dog appropriate to collar size}
- Glow in the dark
- Reflective
- Designed and tested to [perform][work]
- Two [2] collars each provide 6 months [of] protection
- Two [2] 6 [six] month collars for one [1] year of [continuous] protection
- Two [2] 6 [six] month collars for twelve [12] months of [continuous] protection
- From the company with over 90 [95] [96] [97] [98] [99] [100] years [of] experience [caring for pets]
- From the company with over 90 [95] [96] [97] [98] [99] [100] years [of] experience [devoted to pets]
- Hartz, the company with over 90 [95] [96] [97] [98] [99] [100] years' experience [devoted to and caring for pets]
- Caring for pets for over 90 [95] [96] [97] [98] [99] [100] years
- Hartz the company with over 90 [95] [96] [97] [98] [99] [100] years of commitment to [caring for] pets

{Optional Graphics for Label}

{Icon / graphic for Adult Fleas}:

[Adult Fleas]





{Icon / graphic for Adult Ticks}:

[Adult Ticks]





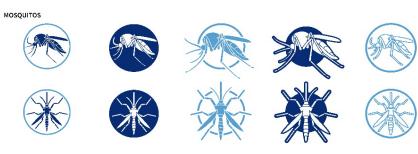
{Icon / graphic for Mosquitos.} {*Except California}:

[Mosquitos]*





{*Except California}

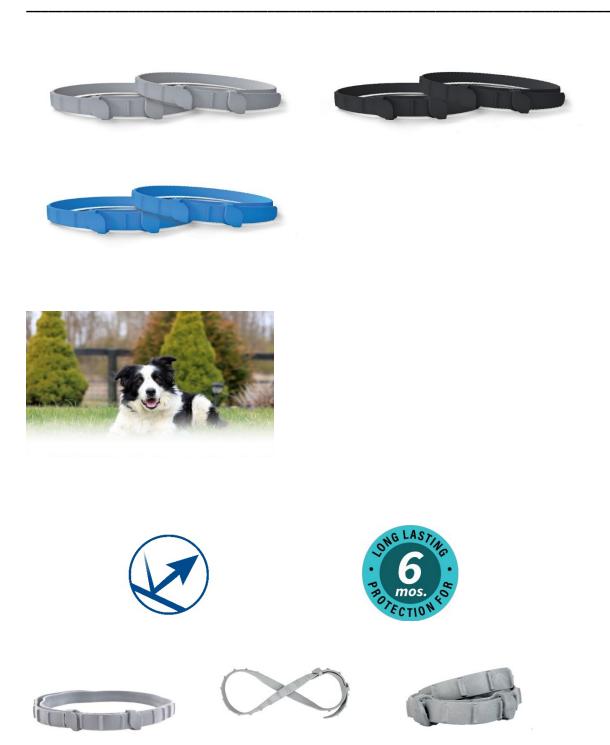


{*Except California}

{Icon/ graphic for Flea Eggs}:

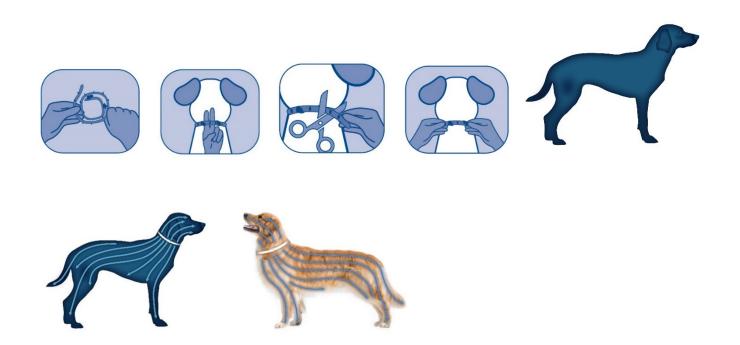
[Flea Eggs]





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{Note to Reviewer: The clock image below with red arrow pointing in a clockwise direction, is deleted from the July 18, 2024 label. }

























{Flea Eggs} FLEA EGGS











{Flea Larvae}

FLEA LARVAE











{Adult Fleas}













{Adult Ticks}















{Small to Medium Dogs}



{Large Dogs}



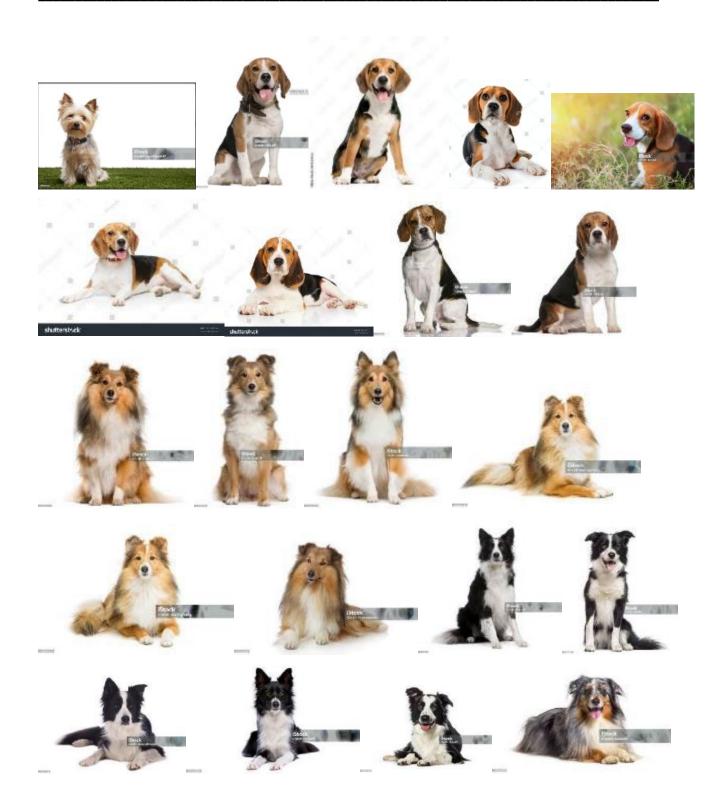
{Two-dog Image}



{Note to Reviewer: The following additional images (page 17 to page 25) have been added to the label dated July 18, 2024}:

{<u>Additional Images - Small to Medium Dogs</u>}





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dh.ThatStadk

Sh.Restrick



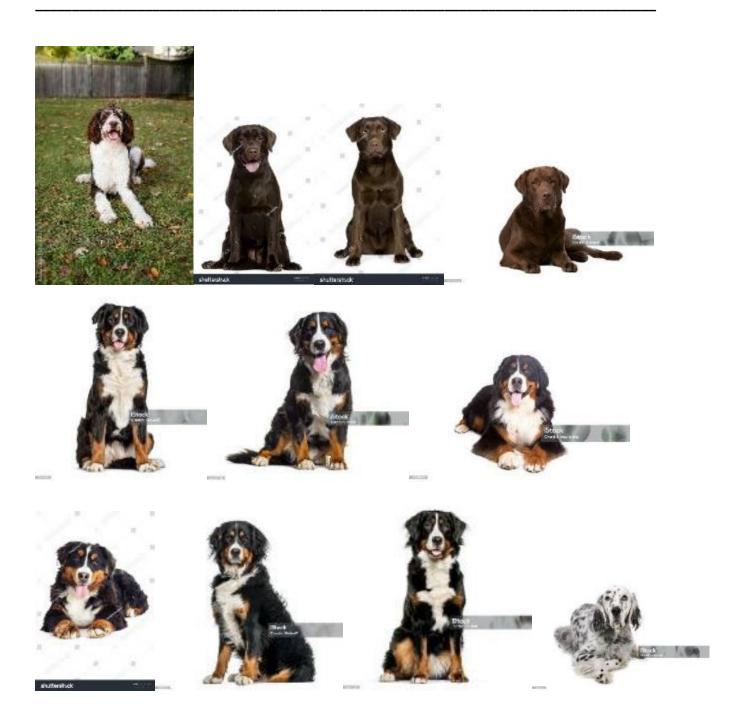


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{Additional Images - Large Dogs}



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{Note to Reviewer: Optional/alternate text are contained in [brackets]. Text contained in (parenthesis) are NOT optional. Notes to Reviewer are contained in {braces} and will not appear on final marketplace label.}

{Alternate Brand Names}

Hartz UltraGuard Pro® Flea and Tick Collar for Dogs & Puppies 12 Weeks &Older Hartz UltraGuard Pro® Flea and Tick Collar for Dogs & Puppies 12 Weeks and Older

Hartz UltraGuard Pro® Flea and Tick Collar for Dogs & Puppies 12 Weeks & Older Hartz UltraGuard Pro® Flea and Tick Collar for Dogs & Puppies 12 Weeks and Older Hartz UltraGuard Pro® Flea and Tick Collar for Dogs & Puppies of All Sizes 12 Weeks & [and] Older

Hartz UltraGuard Plus® Flea and Tick Collar for Dogs & Puppies 12 Weeks & [and] Older Hartz UltraGuard Plus® Flea and Tick Collar for Dogs & Puppies of All Sizes 12 Weeks & [and] Older

InControl by Hartz® Flea and Tick Collar for Dogs & Puppies 12 Weeks & Older InControl by Hartz® Flea and Tick Collar for Dogs & Puppies 12 Weeks and Older

Hartz® InControl Flea & Tick Collar for Dogs & Puppies 12 Weeks &[and] Older Hartz® InControl Kills & Flea & Tick Collar for Dogs & Puppies 12 Weeks & [and] Older

Hartz UltraGuard® Flea & Tick Collar for Dogs & Puppies 12 Weeks & [and] Older

Hartz UltraGuard Plus® Flea & Tick Collar for Dogs & Puppies 12 Weeks & Older Hartz UltraGuard Plus® Flea & Tick Collar for Dogs & Puppies 12 Weeks and Older Hartz UltraGuard Pro® Flea & Tick Collar for Dogs & Puppies 12 Weeks & Older Hartz UltraGuard Pro® Flea & Tick Collar for Dogs & Puppies 12 Weeks and Older

Hartz UltraGuard ProMax® Flea and Tick Collar for Dogs & Puppies 12 Weeks & Older Hartz UltraGuard ProMax® Flea and Tick Collar for Dogs & Puppies 12 Weeks and Older Hartz UltraGuard ProMax® Flea and Tick Collar for Dogs & Puppies of All Sizes 12 Weeks & [and] Older

Hartz UltraGuard Provet® Flea and Tick Collar for Dogs & Puppies 12 Weeks & Older Hartz UltraGuard Provet® Flea and Tick Collar for Dogs & Puppies 12 Weeks and Older Hartz UltraGuard Provet® Flea and Tick Collar for Dogs & Puppies of All Sizes 12 Weeks & [and] Older

Hartz UltraGuard Pro Advanced® Flea and Tick Collar for Dogs & Puppies 12 Weeks & Older Hartz UltraGuard Pro Advanced® Flea and Tick Collar for Dogs & Puppies 12 Weeks and Older Hartz UltraGuard Pro Advanced® Flea and Tick Collar for Dogs & Puppies of All Sizes 12 Weeks & [and] Older