

Evaluation Report for Category B, Subcategory B.3.9 Application

Application Number: 2017-2934 **Application:** Amendment

Product: Hartz UltraGuard Pro Flea & Tick Treatment for Dogs and Puppies

weighing greater than 28 kg

Registration Number: 30731

Active ingredients (a.i.): D-phenothrin (PHG) and s-methoprene (MPR)

PMRA Document Number: 2815529

Background

Hartz UltraGuard Pro Flea & Tick Treatment for Dogs and Puppies weighing greater than 28 kg (Reg. No. 30731) contains the active ingredients d-phenothrin and s-methoprene. The product is packaged in a premeasured dose that is applied down the back of a dog or puppy. The registered claims include "prevent flea eggs from hatching", "kills fleas (adults, eggs and larvae) and ticks" and "reduce biting by mosquitoes". The duration of protection is up to 30 days.

Purpose of Application

The purpose of this application is change to the pest claim from "kills fleas and ticks" to "controls fleas and ticks".

Chemistry Assessment

A chemistry assessment was not required.

Health Assessments

A health assessment was not required.

Environmental Assessment

An environmental assessment was not required.

Value Assessment

Based on the provided data and rationales, amending the pest claim from "kills fleas and ticks" to "controls fleas and ticks" was supported. The duration of protection (i.e., up to 30 days) remains unchanged.

Conclusion

The provided value information supported changing the pest claim to "controls fleas and ticks". The duration that the product provides protection continues to be up to 30 days.

References

Applicant Supplied Information:

2770653 2017, The substantiation and background to several label amendments that Hartz Canada Inc.

wishes to make to their registered product line, DACO: 10.1



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1874112	2009, A Study to Measure the Efficacy of an Adulticide/IGR Product Against Flea Egg Hatch and Adult Fleat
1874113	1999, A Study to Evaluate the Repellent Activity of an Adulticide/IGR Product Against
	Adult Ticks and Fleas on Dogs, DACO: 10.2.3.3
1874114	2009, Efficacy Studies - Summaries, DACO: 10.2.3.1
1874115	2010, 10.2.1 and 10.2.2, DACO: 10.2.1, 10.2.2
1874116	2010, Efficacy Summary, DACO: 10.1
1881169	2010, Value Summary, DACO: 10.1
2042583	1999, A Study to Evaluate the Repellent Activity of an Adulticide/IGR Product Against
	Adult Ticks and Fleas on Dogs, DACO: 10.2.3.2(C)
2042586	2000, A Study to Measure the Efficacy of An Adulticide IGR Product against Flea Egg Hatch
	and Adult Fleas and Ticks on Dogs with Weekly Immersion in Water, DACO 10.2.3.2(C)
2042587	2009, A Study to Measure the Efficacy of an Adulticide/IGR Product Against Flea Egg Hatch
	and Adult Fleas and Ticks on Dogs, DACO: 10.2.3.2(C)
2042588	2009, A Study to Measure the Efficacy of an Adulticide/IGR Product Against Flea Egg Hatch
	and Adult Fleas and Ticks on Dogs, DACO: 10.2.3.2(C)
2042589	2011, A Study to Measure the Efficacy of an Adulticide/IGR Product Against Flea Egg Hatch and Adult Flea
2042590	2000, Efficacy of an Experimental Stripe-On Formulation of TS# 11538 Administered
	Topically to Dogs Greater than 60 Pounds of Body Weight Infested with the Cat Flea
	(Ctenocephlides felis) and the Brown Dog Tick (Rhipicephalus sanguineus, DACO:
	10.2.3.2(C)
2042591	2011, Rationale for accepting efficacy data for Rhipicephalus sanguineus vs. Dermacentor
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