

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2018-0782

Application: Changes to End-Use Product Labels – New Site or Host

Product: Advantage II Small Cat / Rabbit / Ferret

Registration Number: 27585

Active ingredients (a.i.): Imidacloprid, Pyriproxyfen

PMRA Document Number: 2992979

Purpose of Application

The purpose of this application was to add a claim of control of fleas on pet ferrets (weighing between 0.4 and 4 kg) and pet rabbits (weighing between 1.5 and 4 kg) to the label of the end-use product.

Chemistry and Environmental Assessments

Chemistry and environmental assessments were not required for this application.

Health Assessments

Advantage II Small Cat / Rabbit / Ferret is considered safe for use on pet ferrets aged 10 weeks and older weighing between 0.4 and 4 kg and on pet rabbits aged 4 months and older weighing between 1.5 and 4 kg, when applied according to label directions.

The use of Advantage II Small Cat / Rabbit / Ferret as a spot-on treatment, to control fleas on rabbits and ferrets (up to and including 4kg), is not expected to result in risks of concern for adults treating these pets, or adults and children who contact treated rabbits and ferrets, when following the label precautions and directions.

A food residue exposure assessment was not required for this application.

Value Assessment

Value information reviewed in support of the new uses included one study conducted on pet rabbits and three studies conducted on pet ferrets. The value information supported a claim that a 0.4 ml application of Advantage II Small Cat will control fleas on pet ferrets for up to 4 weeks, and will control fleas on pet rabbits for up to 8 days. In addition, these uses have value as there are no other products registered, under the *Pest Control Products Act*, for control of fleas on pet rabbits or pet ferrets.



Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the addition of the claim of control of fleas on pet ferrets and pet rabbits (up to and including 4 kg).

References

A. List of Studies/Information Submitted by the Registrant

PMRA Document Number	References
2874323	2018, Use Description Scenario Advantage II Small Cat; use on pet ferrets and pet rabbits (up to and including 4kg), DACO: 5.2
2876792	2012, Pilot General Safety Evaluation of M880 Insecticide on Pediatric Ferrets, DACO: 4.6.9
2876793	2018, Evaluation of the General Safety of M880 on 10-Week-Old Ferrets, DACO: 4.6.9
2897230	2018, Short term, rodent and neurotoxicity, DACO: 4.8
2897231	2000, Advantage 40 for Cats-Target Animal Tolerance in Rabbits, DACO: 4.6.9
2854590	2017, Part 10-27585-AdvantageIISC-FerretRabbit, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.4, 10.3, 10.3.1, 10.3.2(B), 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 10.5.5
2854593	Fisher, M.A., Jacobs, D.E., Hutchinson, M.J., McCall, J.W., 2001, Efficacy of Imidacloprid on Ferrets Experimentally Infested with the Cat Flea, <i>Ctenocephalides felis</i> , Compendium on Continuing Education for the Practising Veterinarian Vol. 23, No. 4(A): 8-10, DACO: 10.6
2854595	2000, Efficacy and safety of imidacloprid spot-on formulation for treatment of flea infestations in domestic rabbits, DACO: 10.6
2854596	Hutchinson, M.J., Jacbobs, D.E., Menke, N., 2001, Establishment of the cat flea (<i>Ctenocephalides felis felis</i>) on the ferret (<i>Mustela putorius furo</i>) and its control with imidacloprid, Medical and Veterinary Entomology 15: 212-214, DACO: 10.6
2854597	Hutchinson, M.J., Jacobs, D.E., Bell, G.D., Menke, N., 2001, Evaluation of imidacloprid for the treatment and prevention of cat flea (<i>Ctenocephalides felis felis</i>) infestations on rabbits, Veterinary Record 148: 695-696, DACO: 10.6
2854598	2011, Laboratory Evaluation of the Efficacy of Advantage II Small Cats (9.1% Imidacloprid + 0.46% Pyriproxyfen) for the Treatment and Control of Cat Fleas (<i>Ctenocephalides felis</i>) on Ferrets (<i>Mustela putorius furo</i>), DACO: 10.6
2854599	2007, Efficacy of Advocate spot-on (Imidacloprid 10% / Moxidectin 1%) against Fleas (<i>Ctenocephalides felis</i>) on Ferrets (<i>Mustela putorius furo</i>), DACO: 10.6

B. Additional Information Considered

i) Published Information

2987992 American Veterinary Medical Foundation, Web page accessed on 4/23/2019, 2012 U.S. Pet Ownership Statistics, www.avma.org/KB/Resources/Statistics/Pages/Market-research-statistics-US-pet-ownership.aspx?mode=full, DACO: 5.2

SSN: 1911-8082	
Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government anada 2019	Services
Ill rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any for neans, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior wermission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.	rm or by any ritten