

## Evaluation Report for Category B, Subcategory 3.12 Application

**Application Number:** 2018-0823  
**Application:** Changes to End-Use Product Labels – New Site or Host  
**Product:** Advantage II Small Cat / Rabbit  
**Registration Number:** 27586  
**Active ingredients (a.i.):** Imidacloprid, Pyriproxyfen  
**PMRA Document Number:** 2993461

### Purpose of Application

The purpose of this application was to add a claim of control of fleas on pet rabbits weighing over 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 Large Cat / Rabbit is considered safe for use on pet rabbits aged 4 months and older weighing over 4 kg, when applied according to label directions.

The use of Advantage II Large Cat / Rabbit as a spot-on treatment, to control fleas on rabbits (over 4kg), is not expected to result in risks of concern for adults treating these pets, or adults and children who contact treated rabbits, 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. The value information supported a claim that a 0.8 ml application of Advantage II Large Cat will control fleas on pet rabbits weighing over 4 kg for up to 8 days. In addition, this use has value as there are no other products registered, under the *Pest Control Products Act* for control of fleas on pet rabbits.

### 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 rabbits weighing over 4 kg.

## References

### A. List of Studies/Information Submitted by the Registrant

<b>PMRA Document Number</b>	<b>References</b>
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2874317	2018, Use Description Scenario Advantage II Large Cat; use on pet rabbits (over 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
2854595	2000, Efficacy and safety of imidacloprid spot-on formulation for treatment of flea infestations in domestic rabbits, 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

### B. Additional Information Considered

#### i) Published Information

2988003	American Veterinary Medical Foundation, Web page accessed on 4/23/2019, 2012 U.S. Pet Ownership Statistics, <a href="http://www.avma.org/KB/Resources/Statistics/Pages/Market-research-statistics-US-pet-ownership.aspx?mode=full">www.avma.org/KB/Resources/Statistics/Pages/Market-research-statistics-US-pet-ownership.aspx?mode=full</a> , DACO: 5.2
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