

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2011-3248
Application: Changes to the Product Label
Product: Advantage II Large Cat
Registration Number: 27586
Active ingredients (a.i.): Imidacloprid
Pyriproxyfen
PMRA Document Number : 2459215

Purpose of Application

The purpose of this application was to amend the domestic class product, Advantage II Large Cat containing imidacloprid and pyriproxyfen for the control of fleas on cats by spot-on application. The amendments included label statements required for spot-on pet products as outlined in the Regulatory Directive DIR2010-02, *Label Improvements for Spot-on Pesticides Used for Flea and Tick Control on Companion Animals*.

Chemistry and Environmental Assessments

Chemistry and environmental assessments were not required for this application.

Health Assessments

The toxicity profile for Advantage II Large Cat has not changed, Based on a new revised exposure risk assessment for imidacloprid and pyriproxyfen in the product, the potential residential exposures and risks during application for adults and youth and post-application for adults, youth and children are acceptable.

Value Assessment

The label amendments do not impact the registered use pattern of Advantage II Large Cat.

Conclusion

Following review of the application the PMRA has approved the label amendments to Advantage II Large Cat.

References

PMRA Document Number	Reference
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172744	2002, Toxicological Summaries DACO: 4.1
2084167	2009, Evaluation of The General Safety of M880 DACO 4.9
1171253	1985, Residues of Bay 7391 10% w/v Spot-on in the Coat of Dogs at Various Times after Treatment.' DACO 5.9
1171254	1996, Kinetics of Imidacloprid in the Fur of Cats after Dermal Application of Imidacloprid Spot-on 10% . DACO 5.9
1171255	1996, Kinetics of Imidacloprid in the Fur of Cats after Dermal Application of Imidacloprid Spot-on 10% . DACO 5.9

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