

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2011-3240

Application: New End-Use Product **Product:** Advantage II Kittens

Registration Number: 31517

Active ingredients (a.i.): Imidacloprid

Pyriproxyfen

PMRA Document Number: 2459201

Purpose of Application

The purpose of this application was to register a new domestic class product, Advantage II Kittens, containing imidacloprid and pyriproxyfen, for the control of fleas on cats by spot-on application.

Chemistry and Environmental Assessments

Chemistry and environmental assessments were not required for this application.

Health Assessments

Advantage II Kittens is considered to be slightly acutely toxic via the oral route, and of low acute toxicity via the dermal and inhalation routes in rats. It is considered to be moderately irritating to the eyes and non-irritating to the skin of rabbits, and not a dermal sensitizer in guinea pigs. On the basis of the provided companion animal safety studies and additional information, the proposed product is considered to be safe for use on kittens when label directions are followed.

Based on the revised health risk assessment conducted for imidacloprid and pyriproxyfen and using the revised toxicology end points, 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 value of Advantage II Kitten is based on precedent products that combine imidacloprid and pyriproxyfen to control of fleas on cats by spot-on application (Advantage II Large Cat, registration number 27586 and Advantage II Small Cat, registration number 27585).

Conclusion

Following review of the application, the PMRA has approved the registration of Advantage II Kittens for the control of fleas on cats by spot-on application.



References

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