

Evaluation Report for Category B, Subcategory 2.4, 2.6, 3.9, 3.11, 3.12 Application

Application Number: 2009-1397
Application: B.2.4 (changes in product chemistry – proportion of formulants)
B.2.6 (changes in product chemistry – new combination of TGAIs)
B.3.9 (changes to product label – level of control)
B.3.11 (changes to product label – new pests)
B.3.12 (changes to product label – new site or host).
Product: K9 Advantix IGR 10
Registration Number: 29777
Active ingredients (a.i.): Imidacloprid [IMI], Permethrin [PFL], Pyriproxyfen [PRX]
PMRA Document Number : 1945033

Purpose of Application

The purpose of this application is to register a new end-use product, K9 Advantix IGR 10, based on a precedent product, K9 Advantix 10 Flea and Tick Adulticide (Registration Number 27658). Related submissions 2009-1398, 2009-1399 and 2009-1426 are for the same product, packaged in different sized doses, for larger and smaller hosts.

Chemistry Assessment

K9 Advantix IGR 10 is formulated as a solution containing Imidacloprid at a nominal concentration of 8.8 %, Permethrin at 44.0 % and Pyriproxyfen at 0.44%. This end-use product has a density of 1.14 g/cm³ and pH of 3.74. With the exceptions of storage stability and corrosion characteristics, the chemistry requirements for K9 Advantix IGR 10 are complete.

Health Assessments

K9 Advantix IGR 10 is of low acute toxicity by the oral, dermal and inhalation routes, is moderately irritating to the eye and mildly irritating to the skin, and is not a dermal sensitizer. No adverse effects were noted at the exaggerated dose used in a Safety to Treated Animals study conducted using adult dogs. The results of this study indicate that the product is deemed safe to use on adult dogs, when applied according to label directions. However, adverse effects were observed in a similar study in puppies at exaggerated doses, and no assurance of the safety of the products at the label rate was demonstrated in the study. Therefore, the study does not provide assurance that the product is safe for use on puppies.

An occupational risk assessment was not performed for K9 Advantix IGR 10 because the use pattern fits within the existing use profiles for pyriproxyfen, imidacloprid and permethrin. The potential exposure to the applicator and the post-applicator is not expected to exceed that of registered products.

A food residue assessment was not required for this application.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

K9 Advantix IGR 10 contains a combination of active ingredients, which are used to kill all stages (i.e., eggs, larvae and adults) of fleas and adults ticks on dogs. It is a similar product to K9 Advantix 10 Flea and Tick Adulticide (Registration Number 27658; 8.8% imidacloprid and 44% permethrin), which is used to kill adult fleas and ticks on dogs.

K9 Advantix IGR 10 also contains 0.44% pyriproxyfen, which prevents the eggs and larvae of fleas from developing into adults. Pyriproxyfen is registered at similar concentrations in other products (i.e., Advantage Plus 10; Registration Number 27581; 9.1% imidacloprid and 0.46% pyriproxyfen).

Conclusion

The PMRA has completed an evaluation of the subject application and has found the information sufficient to register the new end-use product, K9 Advantix IGR 10.

References

PMRA Reference Number

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- 1747343 2008, Mode of Action, DACO: 10.2.1
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