

Evaluation Report for Category B, Subcategory 2.3 Application

Application Number: 2009-1212
Application: B.2.3-Changes to EP Chemistry-Identity of Formulants
Product: Vet-Kem Integral Buckle Flea & Tick Collar for Dogs
Registration Number: 18505
Active ingredients (a.i.): Propoxur (BAY)
PMRA Document Number English PDF: 2021059

Purpose of Application

The purpose of this application was to replace a formulant with the two alternate formulants. The proposed formulation changes were found to be chemically equivalent to the registered product (Reg.No. 18505).

Chemistry Assessment

Vet-Kem Integral Buckle Flea & Tick Collar for Dogs is formulated as a slow releasing collar containing the active ingredient propoxur at a minimum concentration of 9.4%. The chemistry requirements for Vet-Kem Integral Buckle Flea & Tick Collar for Dogs have been completed.

Health Assessments

The replacement of one of the formulants in the product with one of the two alternate formulants is not expected to alter the toxicity profile of the product.

The potential exposure to the active ingredient propoxur is not expected to exceed exposure from the currently registered product. The proposed formulation changes are supported.

A food exposure assessment was not required for this application.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

The formulation changes are not expected to impact efficacy of the product.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Vet-Kem Integral Buckle Flea & Tick Collar for Dogs, and has found the information sufficient to replace one formulant with one of the two alternates.

References

PMRA Number	Title
1740551	2009, Comparison of Laboratory Rate of Release Studies of Phthalate and Citroflex Plasticized Collars, DACO:3.1.1,3.1.2,3.2.1,3.3.1,3.4.1,3.5.10,3.5.11,3.5.12,3.5.13, 3.5.14,3.5.15,3.5.6,3.5.7,3.5.8,3.5.9
1740552	2009, VET-KEM INTEGRAL BUCKLE FLEA & TICK COLLAR FOR DOGS; PCP18505 Value Summary, DACO: 10.1,10.2.3.1,10.2.3.2,10.3.1,10.3.2
1793637	2009, Wellmark collars-Uniplex response-letter of intent-26august2009, DACO: 0.8
1793638	Anonymous, 2009, Uniplex-tox summary-HSDB-26august2009, DACO: 4.8
1793639	Anonymous, 2003, Assessment of Data Availability and Test Plan for Acetyl Tributyl Citrate (ATBC), DACO: 4.8
1793640	Johnson, W. (2002). Final Report on the Safety Assessment of Acetyl Triethyl Citrate, Acetyl Tributyl Citrate, Acetyl Trihexyl Citrate and Acetyl Trioctyl Citrate. <i>International Journal of Toxicology</i> , 21, 1-17. doi:10.1080/10915810290096504, DACO: 4.8

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