

Evaluation Report for Category B, Subcategory B.4.6 Application

Application Number: 2013-0243
Application: To fulfill conditions or registration on a product with full registration
Product: Hartz Ultraguard Flea and Tick Pump Spray for Dogs
Registration Number: 30181
Active ingredients (a.i.): Tetrachlorvinphos
s-methoprene
PMRA Document Number: 2397375

Background

Hartz Ultraguard Flea and Tick Pump Spray for Dogs (Registration Number 30181; guarantee 1.08% tetrachlorvinphos and 0.07% s-methoprene) was first registered for use in Canada in 2011. Tetrachlorvinphos is an organophosphate insecticide, and s-methoprene is an insect growth regulator that interferes with an insect's life cycle preventing the insect from reaching maturity or reproducing.

Purpose of Application

The purpose of this application was to address the conditions of full registration for Hartz Ultraguard Flea and Tick Pump Spray for Dogs relating to the requirements for the Companion Animal Safety Study (CASS).

Chemistry, Environmental and Value Assessments

Chemistry, environmental and value assessments were not required for this application.

Health Assessments

Based on the studies provided, Hartz Ultraguard Flea and Tick Pump Spray for Dogs is considered to be of low acute toxicity in rats via the oral and inhalation routes. The product is also considered to be of low acute toxicity in rabbits via the dermal route, minimally irritating to the eyes and skin in rabbits, and not a dermal sensitizer in guinea pigs.

Results of the Companion Animal Safety Studies (CASS) suggest that repeat dosing could possibly lead to a progressive build-up of a systemic dose in the animals. The results of the studies also indicate that animals were beginning to recover at day 28 (21 days post dose). The CASS does not provide information relating to the recovery profile in a scenario with more than two product applications, which could conceivably occur in situations of heavy pest infestation. In the absence of results from a CASS conducted with more than two weekly applications, and in

light of the fact that results from the CASS in both adult dogs and pups suggest a potential build-up of a systemic dose, and given the methodology issues with respect to measurement of cholinesterase activity, the product label was modified to not be applied more often than once per month.

Conclusion

The PMRA has reviewed the application for Hartz Ultraguard Flea and Tick Pump for Dogs and has determined that the toxicological conditions of registration for Hartz Ultraguard Flea and Tick Pump Spray for Dogs have been fulfilled.

References

PMRA

Document

Number	Reference
1156506	1990, Acute oral toxicity of Hartz Mountain Corporation sample#8951c (902433)(Hartz 2 in 1 Flea and Tick Spray for Cats/Dogs), DACO: 4.6.1
1156507	1990, Acute dermal toxicity of hartz mountain corporation sample#8951c (902434)(Hartz 2 in 1 Flea and Tick Spray for Cats/Dogs), DACO: 4.6.2
1156508	1990, Primary dermal irritation Hartz Mountain Corporation sample#8951c (902435)(Hartz 2 in 1 Flea and Tick Spray for Cats/Dogs), DACO: 4.6.5
1156509	1990, Primary eye irritation Hartz Mountain Corporation sample#8951c (902432)(hartz 2 in 1 flea and tick spray for cats/dogs), DACO: 4.6.4
1156511	1990, Delayed contact hypersensitivity in guinea pigs of hartz mountain sample#8951c (902437)(Hartz 2 in 1 Flea and Tick Spray for Cats/Dogs), DACO: 4.6.6
1156512	1990, Acute inhalation toxicity testing Hartz Mountain Corporation sample, 8951a-aerosol, 906045 (Hartz 2 in 1 Flea and Tick Spray for Cats/Dogs), DACO: 4.6.3
2265744	2012, Tolerance of a flea and tick dermal treatment when topically administered on study days 0 and 7 to adult dogs at 1 x, 3 x and 5 x the recommended dose, DACO: 4.9
2265745	2012, Tolerance of a flea and tick dermal treatment when topically administered on study days 0 and 7, to pups eleven weeks (77 to 83 days) old at 1 x, 3 x and 5 x the recommended dose, DACO: 4.9

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