Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 7.0 Application

Application Number: 2022-0615
Application: Reinstatement of Registered Product
Product: Hartz Incontrol Flea & Tick Collar for Cats
Registration Number: 13266
Active ingredient (a.i.): Tetrachlorvinphos
PMRA Document Number: 3464120

Background

As per Special Review Decision (SRD2021-01, *Tetrachlorvinphos and Its Associated End-Use Products*), residential postapplication dermal non-cancer and cancer risks resulting from exposure to pet collars containing tetrachlorvinphos were not shown to be acceptable. In addition, risks were not shown to be acceptable for exposure when applying pet collars. Therefore, all flea and tick pet collar products, including Hartz Incontrol Flea & Tick Collar for Cats, were cancelled due to application and postapplication risks.

Purpose of Application

The purpose of this application was to reinstate the registration of Hartz Incontrol Flea & Tick Collar for Cats, by addressing the health risks identified in SRD2021-01.

Chemistry Assessment

Hartz UltraGuard Flea & Tick Collar for Cats is formulated as a slow-release generator containing containing tetrachlorvinphos at a concentration of 14.55%. This end-use product has a density of 1.15 g/cm^3. The chemistry requirements for this product have been fulfilled.

Health Assessments

Information pertaining to the acute hazard profile of the end-use product, as well as available companion animal safety studies, was reviewed to support the request for registration re-instatement. With respect to the safety of animals wearing the collar, no significant concerns were identified from the available companion animal safety studies. With respect to the acute hazard profile, due to the product design, the collars are not expected to pose acute oral or inhalation toxicity hazards, or result in eye irritation. The active ingredients tetrachlorvinphos is of low acute toxicity via the dermal route and only slightly irritating to the skin; as such, collars impregnated with tetrachlorvinphos are not expected to result in systemic toxicity or irritation via the dermal route. However, the tetrachlorvinphos has been classified as a dermal sensitizer, and the available dermal sensitization study conducted with collars impregnated with tetrachlorvinphos failed to conclusively demonstrate that the collars do not pose a dermal sensitization hazard due to limitations in the conduct of the study. This

uncertainty is of particular concern given the degree of direct dermal contact of both humans and pets associated with the use of pet collars. Therefore, in order for the reinstatement of these products to be considered in the future, additional information would be required to conclusively demonstrate that the collars do not pose a dermal sensitization hazard.

Exposure assessments included previously reviewed data from the Special Review of tetrachlorvinphos (SRD2021-01) and a new *in vitro* dermal absorption study, which was relied upon to refine the dermal absorption value from 22% to 9%. Updated health risk assessments lead to the conclusion that non-cancer risks of concern are expected for applicators in commercial settings (Calculated Margin of Exposure (MOE) < Target MOE). Cancer risks of concern ($\geq 1x10^{-6}$) were also identified for adults, youth and children from residential postapplication dermal and aggregate exposures. The risks of concern could not be further mitigated with the available data. Therefore, re-instatement of this product cannot be supported.

A dietary risk assessment was not required for this application.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

The reinstatement of registration for Hartz Incontrol Flea & Tick Collar for Cats was supported based on extrapolation from previously registered uses of the same product to kill fleas for five months and ticks for four months. The re-instatement of this product will maintain an alternative for pet owners to kill fleas and ticks on cats.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found that the health risks associated with the reinstatement of Hartz Incontrol Flea & Tick Collar for Cats, are not shown to be acceptable. This end-use product will expire on March 3, 2024.

References

PMRA Document Number	Reference
3425376	1997, Dermal Sensitization Test Buehler Method, DACO: 4.6.6
3425377	1993, Domestic Animal Safety Effect of a Single Heavy Label Dose Pump Spray Treatment on Cats, DACO: 4.6.9,86 - 1,870.7200, IIIA 7.10
3425378	1993, Domestic Animal Safety Effect of a Single Heavy Label Dose Pump Spray Treatment on Cats, DACO: 4.6.9,86 - 1,870.7200, IIIA 7.10
3425379	1993, Domestic Animal Safety Effect of a Single 2x Dose Pump Spray Treatment on Cats, DACO: 4.6.9,86 - 1,870.7200, IIIA 7.10
3425381	1993, Domestic Animal Safety Effect of a Single 2x Dose Aerosol Spray Treatment on Cats, DACO: 4.6.9,86 - 1,870.7200, IIIA 7.10
3426892	2017, Weight Loss Study of Rabon Release from HUG Flea & Tick Collar, DACO: 4.6.9,86 - 1,870.7200, IIIA 7.10
1841056	1991, Hartz Mountain Domestic Animal Safety Study 2X Tolerance of a 5 Month Collar on Cats Protocol 90-6, Test No. 1105, DACO: 4.9
1841091	1992, Collar Safety Evaluation Test No. 1103, DACO: 4.9
3309376	2021, In Silico Predictions of Dermal Absorption of Tetrachlorvinphos in Rat and Human, DACO: 5.8
3309377	2021, The In Vitro Percutaneous Absorption of Radiolabelled Tetrachlorvinphos at Three Concentrations in Aqueous and Lipid Vehicles through Human and Rat Split-Thickness Skin, DACO: 5.8
3335747	2022, Estimated Dermal Penetration of Tetrachlorvinphos (TCVP) in Humans Based on In Vitro and In Vivo Data, DACO: 5.8
3335748	2022, The In Vitro Percutaneous Absorption of Radiolabelled Tetrachlorvinphos (TCVP) at Three Concentrations in Aqueous and Lipid Vehicles through Human and Rat Split-Thickness Skin, DACO: 5.8

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