Category B.2.1
Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2005-2266
Application: B.1.2 Changes in Product Specifications
Product: Lentek Pestcontro Ultrasonic Technology (Model PR3L)
Registration Number: 1595066
Active ingredients (a.i.): Ultrasonic device
PMRA Document Number: 1612154

Background

There are currently several devices registered which ultrasound to repel rats and mice inside structures.

Purpose of Application

The purpose of this application is to register a new domestic ultrasonic device, Lentek Pest Contro Ultrasonic Technology (Model PR3L) to repel mice and rats from homes, apartments and garages. This product is to be used indoors only. Lentek Pest Contro Ultrasonic Technology (Model PR3L) has a frequency range of 40 KHz +/- 10 KHz; a minimum intensity of 82 decibel (dB) at a distance of 2 metres from the source, and an approximate maximum of 122 dB at the source.

Chemistry Assessment

A chemistry assessment was not required for this submission.

Health Assessments

Exposure to sound greater than 100 dB within the hearing range of humans can permanently damage the sensitive sensory apparatus of the ear and may contribute to a loss of hearing. The majority of adverse health effects to humans, due to ultrasound exposure, have been reported at intensity levels above 140 dB.

For ultra sound having a frequency of 40 KHz in air, with no contact exposure of human body through water or some other media, The American Conference of Governmental Industrial Hygienist's (ACGIH) threshold limit value is 145 dB. The Canadian, Environmental health Directorate recommended exposure limit for air borne ultrasound having a frequency range of 30-50 KHz is 110 dB. Lentek Pest Contro Ultrasonic Technology (Model PR3L) has loudness of

122 dB at the source, which may result in physiological effects after prolonged exposure by humans. Since biological and harmful effects data from domestic use of ultrasonic device are lacking, it is advisable to avoid contact exposure and limit prolonged exposure to a distance of 2 metres from the device.

Very little information could be discerned regarding the potential effects of exposure to ultrasound by companion pets. Domestic cats hear within the frequency range of 45 Hz to 64,000 Hz and dogs are expected to have a slightly tighter range of 67 Hz to 45,000 Hz. As such, it is likely that non-target companion pets may also be affected by prolonged exposure to the ultrasound generated by Lentek Pest Contro Ultrasonic Technology (Model PR3L). The degree and type of adverse effect(s) could not be identified from the available information.

Concern from exposure to the ultrasound emitted by the end-use product is predominantly restricted to individuals/children and/or companion pets which are in the close proximity of the device for extended periods of time. Contact exposure to the ultrasonic wave by small children when they handle the operating device inadvertently is also a concern. Precautionary statements included on the label are considered adequate to minimize any risk due to exposure.

Environmental Assessment

An environmental assessment was not required for this submission.

Value Assessment

The efficacy of Lentek Pestcontro Ultrasonic Technology (Model PR3L) to repel mice and rats is expected to be similar to that of other ultrasonic devices registered for the same uses and producing similar ultrasonic sound waves.

Conclusion

The PMRA has completed an evaluation of Lentek Pestcontro Ultrasonic Technology (Model PR3L) and has found the information sufficient to support the registration of Lentek Pestcontro Ultrasonic Technology (Model PR3L) for use to repel mice and rats.

References

Applicant Supplied Data:
1070925, Mode of Action, DACO: 10.2.1

1070928, Efficacy: Small-Scale Trials - Request for Waiver, DACO: 10.2.3.3

1070929, Summary, DACO: 10.3.1

1070930, Non-Safety Adverse Effects, DACO: 10.3.2

1400254, 2005-2266 Response to Deficiency DACO: 4.7.7

1400255, 2005-2265 Response to Deficiency 10.2.3.3 and/or 10.2.3.4, DACO: 10.2.3.3

1407546, Summary of Product features, DACO: 11.1

Additional Information Considered
i. Published Information
1547988, INTRODUCTION TO THE PHYSICAL AGENTS, DACO: 4.8

1547991, 2001, Ultrasound/TLVs/Documentation, DACO: 4.8

1548016, 1991, Guidelines for the Safe Use of Ultrasound: Part II - Industrial and Commercial Applications, Safety Code 24, DACO: 4.8

1548120, 2005, INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY. ENVIRONMENTAL HEALTH CRITERIA 22., DACO: 4.8

1547997, 2006, Inaudible High-Frequency Sounds Affect Brain Activity: Hypersonic Effect, DACO: 4.8

ISSN: 1911-8082