Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.3, 2.4, 3.1 Application

Application Number: 2012-0734
Application: Product Chemistry – Identity and Proportion of Formulants and Change in Application Rate
Product: Virkon Greenhouse
Registration Number: 24210
Active ingredients (a.i.): Potassium peroxymonosulfate present as potassium peroxymonosulfate
PMRA Document Number: 2205599

Purpose of Application

The purpose of this application was to reinstate an end-use product, Virkon Greenhouse PCP 24210. This product was first registered in 1995 and went NELI in 2000. The product was previously registered with the name Virkon, and had a Drug Identification Number (DIN) as well as a PCP number. For the reinstatement, the company wishes to register the product under a new name that reflects only the use in greenhouses as a disinfectant of hard surfaces and equipment in greenhouses.

The source of technical grade active ingredient, Oxone Monopersulfate Compound (Reg. No. 23137, guarantee: 43% potassium peroxymonosulfate sulfate), is fully registered. There is no other end-use product containing potassium peroxymonosulfate sulfate currently registered in Canada.

There have been slight changes to the product formulation since last registration, (modified proportions and replacement of one formulant) which are supported with data (refer to Sub. No. 2012-2004).

Potassium peroxymonosulfate sulfate is also registered in the US and was re-evaluated in 1993 along with other peroxy compounds. In the US, peroxy compounds are registered for indoor uses only.

Chemistry Assessment

Virkon Greenhouse is formulated as a soluble powder containing potassium peroxymonosulfate, present as potassium peroxymonosulfate sulfate at a nominal concentration of 21.4%. This end-use product has a density of 0.970 – 0.990 g/mL at 24°C and a pH of 2.1 – 2.3. The chemistry requirements for Virkon Greenhouse have been completed.

Canada

Health Assessments

Virkon Greenhouse is of low acute toxicity to rats via the oral (LD_{50} = 1.48 g/kg bw) and inhalation (LC_{50} > 6.147 mg/L routes of exposure and of low acute toxicity to rabbits via the dermal route (LD_{50} >2.0 g/kg bw). It is considered to be corrosive to the eyes and skin of rabbits. It is not a dermal sensitizer in guinea pigs.

The acute health risks and occupation exposure to Virkon Greenhouse are acceptable after a qualitative health risk assessment. Appropriate exposure label amendments are on the label to mitigate the acute hazards.

Environmental Assessment

No additional environmental data were required for the reinstatement of Virkon Greenhouse. Based on its use pattern, Virkon Greenhouse is considered to have a limited potential for environmental exposure when used according to label directions.

Value Assessment

Only one of the submitted trial summaries was found to be representative of the proposed use, rate and contact time for Virkon Greenhouse, which confirmed that it is effective at controlling greenhouse pathogens when applied at a rate of 1% w/v solution for 10 minutes. Furthermore, as part of the gathered use history information, Virkon is registered and used in many countries, including the United States, France and with the Therapeutics Products Directorate of Health Canada for cleaning and disinfection of surfaces and equipment by saturating surfaces or soaking utensils in a 1% w/v solution of Virkon for 10 minutes. Therefore, based on the weight of evidence, the value of Virkon Greenhouse as a greenhouse disinfectant against bacteria, fungi and viruses at a 1% dilution for 10 minutes is supported.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Virkon Greenhouse, and has found the information sufficient to reinstate the product.

References

PMRA Document Number	Reference
2298366	2013, Virkon Greenhouse: Description of the pest problem, DACO: 10.2.2
2298371	2011, Efficacy of Virkon against Greenhouse Pathogens, DACO: 10.2.3.2(D)
2298378	2013, Virkon Greenhouse: Summary Non-Safety Adverse Effects, DACO: 10.3.1
2298380	2013, Virkon Greenhouse: Other studies/data/reports, DACO: 10.6
2298395	2013, Virkon Greenhouse Antimicrobial: Mode of action, DACO: 10.2.1
2339021	Virkon Disinfectant/Cleaner P.W.S., DACO: 10.2.4
2339024	2005, US EPA - Efficacy Review for EPA Reg. No. 71654-7, Virkon, DACO: 10.2.4
2339025	2011, US EPA - Virkon (R) S, DACO: 10.2.4
2338625	2013, Virkon Registered label-France, DACO: 1.5
2195116	Description of Formulation process, DACO: 3.2.2 CBI
2195117	2005, H26819 Enforcement Analytical Method, DACO: 3.4.1 CBI
2195119	2005, Physical and Chemical Characteristics of H26820: Oxidation/Reduction: Chemical Incompatability, pH, and Bulk Density, DACO: 3.5.6,3.5.7,3.5.8 CBI
2195121	2005, Certified Limits EPA Reg. No. 7165406, DACO: 3.3.1 CBI
2195122	2006, Physical and Chemical Characteristics of H26820 Storage Stability and Corrosion Characteristics, DACO: 3.5.10 CBI
2298396	2013, Chemistry-3.2.1-starting materials-05April2013, DACO: 3.2.1 CBI
2298397	2005, H26819 Enforcement Analytical Method, DACO: 3.4.1 CBI

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