



Evaluation Report for Category B, Subcategory B.1.2 Application

Application Number: 2008-1415
Application: B.1.2 (New source/site new registrant)
Product: Pt-PFC2139
Registration Number: 29292
Active ingredients (a.i.): *Chondrostereum purpureum* strain PFC2139 [CPO]
PMRA Document Number : 1736749

Background

Pt-PFC2139 is a technical grade active ingredient (TGAI) containing *Chondrostereum purpureum* strain PFC2139 as its active ingredient. Chontrol Peat Paste is an end-use product (EP) formulated from Pt-PFC2139. Chontrol Peat Paste is a commercial-class biological herbicide to be applied topically on freshly cut stumps for the control of sprouting or regrowth of red alder and sitka alder in rights-of-way and forest vegetation management situations.

Purpose of Application

The purpose of these applications is to register Pt-PFC2139 and Chontrol Peat Paste based on precedent products, namely Cp-PFC2139 (Reg. No. 27822) and Chontrol Paste (Reg. No. 27823). The new products are produced using new manufacturing procedures and formulation ingredients, but the active ingredient and existing use patterns remain the same.

Chemistry Assessment

Product characterization information was submitted in accordance with Part M2, Product Characterization and Analysis requirements outlined in Regulatory Directive, DIR2001-02, *Guidelines for the Registration of Microbial Pest Control Agents and Products*. Many of the information requirements for the microbial pest control agent and QA/QC methods were previously submitted and reviewed by the PMRA in support of the TGAI, Cp-PFC2139 (Reg. No. 27822), and the EP, Chontrol Paste (Reg. No. 27823). The manufacturing process and quality assurance associated with the production of the new TGAI, Pt-PFC2139, and the new EP, Chontrol Peat Paste, were described in detail and determined to be appropriate and acceptable. The QA/QC methods previously submitted and reviewed by the PMRA were adequate. The storage stability studies on 5 pilot-scale batches of Pt-PFC2139 and Chontrol Peat Paste were judged acceptable, however, confirmatory data on two commercial-scale batches of Pt-PFC2139 and Chontrol Peat Paste will be required to support full registration.

Health Assessments

Human health and safety testing was conducted on the currently registered TGAI, Cp-PFC2139 (Reg. No. 27822). Cp-PFC2139 contains *C. purpureum* strain PFC2139 which is also found in the TGAI proposed for registration, Pt-PFC2139. Results of human health and safety testing for Cp-PFC2139 were found to be acceptable. Based on previously submitted data, no overt signs of toxicity or pathogenicity were noted when *C. purpureum* strain PFC2139 was administered to rats and rabbits via the oral, pulmonary and dermal routes of exposure. In rabbit irritation studies, Chontrol Paste was slightly irritating when applied dermally and was minimally irritating when instilled into the eye. *Chondrostereum purpureum* is not known to produce mammalian toxins.

The applicant submitted a waiver rationale in lieu of human health and safety testing for both the TGAI and the EP. The rationales were based largely on the identity of the formulation ingredients. Respiratory exposure was considered the primary route of exposure. Given the paste formulation of the EP, however, inhalation is unlikely and a respirator is, therefore, not required.

A potential for eye irritation was also identified for Pt-PFC2139 and eye goggles are, therefore, required.

Like all microbial agents, *C. purpureum* strain PFC2139 is considered to be a potential sensitizing agent and exposures to *C. purpureum* strain PFC2139 may cause allergic reactions following repeated exposures at high concentrations. As a result, label statements indicating that Pt-PFC2139 and Chontrol Peat Paste are potential sensitizers and the requirement for standard personal protective equipment (e.g., long-sleeved shirt, pants, gloves, shoes and socks) are required.

The waiver rationale is considered acceptable. No further human health and safety testing is required for Pt-PFC2139 or Chontrol Peat Paste.

Environmental Assessment

Environmental fate and environmental toxicology data were waived for Pt-PFC2139 and Chontrol Peat Paste. Given that the active ingredient and existing use patterns remain the same, no additional environmental risks are anticipated. The nature of the formulation ingredients in the products are also not expected to pose a significant environmental risk.

Value Assessment

A value assessment was not required on this application.

Conclusion

The PMRA has completed an evaluation of the subject application and has found the information sufficient to register Pt-PFC2139 and Chontrol Peat Paste. Conditions of full registration are that acceptable storage stability data for two commercial-scale batches for each of Pt-PFC2139 and Chontrol Peat Paste are submitted within three years.

References

- PMRA 1587632 2007. Identification of mycobacteria in peat moss processing plants: application of molecular biology approaches. DACO: M2.9.1, M4.2.1.
- PMRA 1587633 2001. Random amplified ribosomal DNA restriction analysis for rapid identification of thermophilic Actinomycete-like bacteria involved in hypersensitivity pneumonitis. DACO M2.9.1, M4.2.1.
- PMRA 1587634 2006. Sensitization to airborne molds and its health effects in peat moss processing plant workers. DACO: M2.9.1, M4.2.1.
- PMRA 1587640 2007. Inhibitory effect of fulvic acid extracted from Canadian sphagnum peat on chemical mediator release by RBL-2H3 and KU812 cells. DACO: M2.9.1, M4.2.1.
- PMRA 1587821 MSDS - MATERIAL SAFETY DATA SHEETS - COMPONENTS. DACO: 0.9.1.
- PMRA 1587837 M2 Product Characterization and Analysis. DACO: M2.1, M2.10, M2.11, M2.12, M2.13, M2.14, M2.2, M2.3, M2.4 , M2.5, M2.6, M2.7, M2.8, M2.9, M2.9.1.
- PMRA 1587666 2006. Cellular uptake and cytotoxic potential of respirable bentonite particles with different quartz contents and chemical modify. DACO M2.9.1, M4.2.1.
- PMRA 1587668 Health Canada. 2006. Substances not Requiring Further Work for Human Health at This Time (July 27, 2006). Results based on July 27, 2006 and persistent and bioaccumulative status as of July 2006. DACO: M2.9.1, M4.2.1.
- PMRA 1587669 Health Canada. 2001. Substances in Products Regulated Under the Food and Drugs Act (F&DA) That Were In Commerce between January 1, 1987 and September 13, 2001. Environmental Assessment Regulations. DACO: M2.9.1, M4.2.1.
- PMRA 1587670 2006. Strategies to prevent mycotoxin contamination of food and animal feed: a review. DACO: M2.9.1, M4.2.1.
- PMRA 1587679 2005. Effect of clay minerals on immobilization of heavy metals and microbial activity in a sewage sludge-contaminated soil. DACO: M2.9.1, M4.2.1.
- PMRA 1587680 Remediation of a soil contaminated with heavy metals by immobilizing compounds. DACO: M2.9.1, M4.2.1.
- PMRA 1587818 M2 Product Characterization and Analysis. DACO: M2.1, M2.10, M2.11, M2.12, M2.13, M2.14, M2.2, M2.3, M2.4, M2.5, M2.6, M2.7, M2.8, M2.9, M2.9.1.

PMRA 1587682 2008, Waiver request, DACO: M4.2.2, M4.2.3, M4.3.1, M4.4, M4.5.2.

PMRA 1587815 Summary, DACO: M4.1,M4.2.1

PMRA 1587816 Exposure Assessment, DACO: M5.0

PMRA 1587838 Exposure Assessment, DACO: M5.0

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