

Evaluation Report for Category B, Subcategory 4.6 Application

Application Number: 2011-1130
Application: To fulfill conditions of registration on a product with full registration.
Product: DOM Manufacturing Concentrate
Registration Number: 29602
Active ingredients (a.i.): *Lactococcus lactis* ssp. *lactis* strains LL64/CSL and LL102/CSL, and *Lactococcus lactis* ssp. *cremoris* strain M11/CSL
PMRA Document Number: **2061923**

Purpose of Application

The purpose of this application was to address outstanding conditions of the full registration for the manufacturing concentrate DOM Manufacturing Concentrate (Reg. No.29602). Applications have also been made for the technical products *Lactococcus lactis* ssp. *lactis* Technical (2011-1131; Reg No. 29600), *Lactobacillus rhamnosus* Technical (2011-1135; Reg No. 29598), *Lactobacillus casei* Technical (2011-1138; Reg No. 29599), *Lactococcus lactis* ssp. *cremoris* Technical (2011-1140; Reg No. 29601), and the associated end-use product, Organo-Sol (2011-1129; Reg. No. 29603).

As a condition of full registration, the registrant was required to address the requirement for a strain-specific identification method for the microbial pest control agents (MPCAs).

Chemistry Assessment

The data submitted describes various standard genetic methods, as well as phenotypic tests that are currently applied to the identification of lactic acid bacteria. The PMRA is satisfied that any one, or a combination of several, of these methods could be used for positive identification of the lactic acid bacteria in Organo-Sol, namely *Lactobacillus casei* strain LPT-111, *Lactobacillus rhamnosus* strain LPT-21, *Lactococcus lactis* ssp. *lactis* strain LL64/CSL, *Lactococcus lactis* ssp. *lactis* strain LL102/CSL, and *Lactococcus lactis* ssp. *cremoris* strain M11/CSL.

Health, Environmental and Value Assessments

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

Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the PMRA website <http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/incident/index-eng.php>. Only incidents in which the pesticide is determined to be linked to the effects (Canadian causality of highly probable, probable and possible; US causality of highly probable, probable and possible) are considered in the reviews. Incidents from Canada and the United States were searched and reviewed for products containing *Lactobacillus casei*, *Lactobacillus rhamnosus*, or *Lactococcus lactis* as well as for the organic acids/fermentation products, citric and lactic acid.

Human Health

As of June 1, 2011 there were no human health incident reports submitted to the PMRA for products containing *Lactobacillus casei*, *Lactobacillus rhamnosus*, or *Lactococcus lactis* or citric and lactic acid.

There have however, been 52 human incident reports summarized by the California Department of Pesticide Regulation (CalDPR) for products containing citric acid for which the causality is established as possible, probable, or definite.

All the incidents were non-agricultural related, occurring in the workplace involving accidental exposure (i.e., spray/splash, inhalation) to disinfectants /cleaning products. All but one of the products contained more than just citric acid as the active ingredient (e.g., phosphoric acid, sodium hypochlorite, hydrogen chloride, etc). The most common effects reported from exposure were minor symptoms such as eye irritation, respiratory symptoms (e.g., cough, difficulty breathing, shortness of breath, or throat discomfort), gastrointestinal discomfort (e.g, nausea and/or vomiting), headaches, dizziness or skin rashes. Ten incidents reported more serious symptoms such as a persistent skin rash, wheezing, fainting, and moderate eye irritation.

There was also one incident summarized by the CalDPR for a non-agricultural product containing lactic acid. Following exposure to a disinfecting solution, an asthmatic laboratory technician reported difficulty breathing.

The effects reported to the CalDPR are consistent with exposure to citric and lactic acid which is known to cause skin, eye and pulmonary irritation. The PMRA has concluded that the information from the incident reports supports the current toxicity database for citric and lactic acid, however, it did not impact the risk assessment for Organo-Sol.

Environment

As of May 20, 2011, there were no environmental incidents reported in the PMRA Incident reporting database nor in the U.S. EPA's Ecological Incident Information System (EIIS) for products containing *Lactobacillus casei*, *Lactobacillus rhamnosus*, or *Lactococcus lactis*, nor citric and lactic acid.

Conclusion

The PMRA has reviewed all available information for DOM Manufacturing Concentrate and has determined that the data submitted fulfils the requirement for a strain-specific identification method for the MPCAs. All outstanding data requirements have been addressed and DOM Manufacturing Concentrate is now fully registered without conditions.

References

PMRA Document Number

Reference

2024794

Response to PMRA Decision Letter, DACO: M2.7 CBI

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