

Summary of Risk Assessment Conducted Pursuant to subsection 83(1) of the Canadian Environmental Protection Act, 1999

New Substances Notification No. 17758: 4-Phytase

Regulatory Decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the Canadian Environmental Protection Act, 1999 (CEPA), and pursuant to section 83 of that Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance, and have determined that it is not anticipated to enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health.

Substance Identity

4-Phytase (Chemical Abstracts Service Registry No. 9001-89-2) is a chemical that can be classified as an enzyme.

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities greater than 1 000 kg/yr for use as a component in ethanol manufacturing. No other activities are anticipated in Canada.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water. The substance is not expected to be persistent in water because of its readily biodegradable nature. The substance is not expected to bioaccumulate based on its high water solubility and large molecular size.

Ecological Assessment

Based on the available hazard information, the substance has low chronic toxicity (maximum allowable toxicant concentration (MATC) >10 mg/L) in algae. Using the chronic MATC from the most sensitive organism (algae) and by applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 1000-10000 µg/L which was used to estimate the ecological risk.

The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activities is expected to be mainly from cleaning transportation vessels and subsequent release of the substance to sewage treatment plants at levels of 10-100 kg/day. Environmental exposure from the potential activity is expected to be mainly from manufacturing by the release

of the substance to sewage treatment plants at a rate of 10-100 kg/day. The predicted environmental concentration (PEC) for notified and potential activities is estimated to be 1-10 µg/L.

Comparing the PEC with the PNEC, the ratio is less than 1, indicating that the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on the substance, the substance has a low potential for acute toxicity by the oral route of exposure (median lethal dose > 2000 mg/kg), a low potential for acute toxicity by the inhalation route of exposure (median lethal concentration >5 mg/L/4 hours), and a low potential for subchronic toxicity following repeat oral doses in mammalian test animals (90-day no-observable-effect level >100 mg/kg-bw/d). It is a weak sensitizer and it is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When used as a component in ethanol manufacturing, direct exposure of the general population is expected to be low. Indirect exposure of the general population from environmental media such as drinking water is expected to be low given that the substance readily biodegrades in the environment.

Based on the low potential for direct and indirect exposure, and the low oral and inhalation toxicity in laboratory animals, the substance is not likely to pose a significant health risk to the general population, and is therefore unlikely to be harmful to human health.

Assessment Conclusion

When the substance is used as notified and for other identified potential uses, it is not suspected to be harmful to human health or the environment according to the criteria under section 64 of CEPA.

A conclusion under CEPA, on this substance, is not relevant to, nor does it preclude an assessment against the hazard criteria for Workplace Hazardous Materials Information System that are specified in the Controlled Products Regulations or the Hazardous Products Regulations for products intended for workplace use.