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

New Substances Notification 21008: 2-Propenoic acid, polymer with α-(methylalkenyl)-ω-hydroxypoly(oxy-1,2-ethanediyl), graft (Confidential Accession No. 19587-5)

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 the 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

The notified polymer is 2-propenoic acid, polymer with α-(methylalkenyl)-ω-hydroxypoly(oxy-1,2-ethanediyl), graft (Confidential Accession No. 19587-5). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains phosphorus above 0.2% by weight.

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as an additive in construction products. Potential uses may include pharmaceutical and biomedical applications.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to water, soil and sediment. The substance is expected to be persistent in these compartments because it is hydrolytically stable and not expected to be readily biodegradable. The substance is not expected to bioaccumulate based on its expected very low octanol-water partition coefficient (log $K_{ow} \leq 0$) and its high molecular weight, which will limit its ability to cross biological membranes.

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low chronic toxicity to algae (no-observed-effect concentration = 100 mg/L). A predicted no-effect concentration was not calculated given the low potential for hazard to the environment.

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 activity is expected to be mainly by release of the substance to water at low rates. For potential activities such as manufacturing, environmental exposure is expected to be at levels that do not pose a concern, similar to that of the notified activities. A predicted environmental concentration was not calculated due to the low potential for ecotoxicity and environmental exposure.

Based on the low potential for ecotoxicity and environmental exposure, the substance is unlikely to cause harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance is expected to have a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight). The substance does not contain structural features associated with adverse human health effects.

When the notified substance is used as an additive in construction applications, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be contained within a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media is expected to be low given the specialized industrial or commercial use of the substance, which results in little or no release to the environment. No potential uses that could significantly increase human health risks compared to the notified uses were identified.

Based on the low toxicity and low potential for exposure, 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.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

Assessment conclusion

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

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 the workplace.