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

New Substances Notifications 20000 and 20227: Heteromonocycle, alkenyl alkyl, alkyl salt (1:1), polymer with α-(2-methyl-1-oxo-2-propen-1-yl)-ω-methoxypoly(oxy-1,2-ethanediyl) and methyl alkenoic acid (Confidential Accession No. 19430-8)

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 heteromonocycle, alkenyl alkyl, alkyl salt (1:1), polymer with α-(2-methyl-1-oxo-2-propen-1-yl)-ω-methoxypoly(oxy-1,2-ethanediyl) and methyl alkenoic acid (Confidential Accession No. 19430-8). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains potentially cationic amines.

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 automatic dishwasher detergents. Potential uses may include use in hand dishwashing detergents.

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 sediment and soil. The substance is expected to be persistent in these compartments based on its high molecular weight and low biodegradability (10-30% over 28 days). The substance is not expected to bioaccumulate based on its high molecular weight, which will limit its ability to cross biological membranes.

Ecological assessment

Based on the available hazard information, the substance has low to moderate acute toxicity to fish (median lethal concentration >1 mg/L), moderate acute toxicity to aquatic invertebrates (median effective concentration (EC_{50}) 1-100 mg/L), moderate chronic toxicity to algae (10% effective concentration 0.1-10 mg/L) and low chronic toxicity to aquatic invertebrates (lowest-observed-effect-concentration >10 mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 100 to account for acute to chronic extrapolation, species sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 100-1000 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 activity is expected to be mainly from transportation and formulation from release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.1-1 µg/L and 0.01-0.1 µg/L, respectively. For potential activities such as manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 1-10 µg/L.

Comparing the PEC with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that the substance is unlikely to cause ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight). It is not a dermal sensitizer (0% response (Buehler test)). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an additive in automatic dishwasher detergents, direct exposure of the general population is not expected. Potential use of the substance includes hand dishwashing detergents, where direct exposure of the general population is expected to be mainly by contact with the skin at levels that do not pose a concern. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels given the low potential for environmental release.

Based on the low toxicity and the 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.

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. On the basis of this evaluation, it is eligible for listing on the Domestic Substances List.

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 *Hazardous Products Regulations* for products intended for the workplace.