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

New Substances Notification 19506: Butanedioic acid, 2-methylene-, polymer with 2-methyl-2-[(1-oxo-2-propen-l-yl)amino]-1-propanesulfonic acid, sodium salt (Chemical Abstracts Service Registry Number 1052620-22-0)

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 butanedioic acid, 2-methylene-, polymer with 2-methyl-2-[(1-oxo-2-propen-l-yl)amino]-1-propanesulfonic acid, sodium salt (Chemical Abstracts Service Registry Number[1] 1052620-22-0). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because the substance contains phosphorus above 0.2% by weight.

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified uses in industrial water cooling systems, and in commercial and consumer cleaning products. Potential uses may include other industrial applications, and commercial and consumer 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 water, and is expected to chelate with calcium and may adsorb to soil and sediment. The substance is expected to be persistent in these compartments based on its lack of hydrolysable functional groups. The substance is not expected to bioaccumulate based on its very low octanol-water partition coefficient (log K_{ow} ≤0) and its high molecular weight which will limit its ability to cross biological membranes.

Ecological assessment

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Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have low acute toxicity in aquatic invertebrates and algae (median effective concentration >100 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 low given the dispersive nature of the use, and that the substance will be removed from the water by chelating with calcium and adsorbing to soil and sediment. For potential activities such as manufacturing, environmental exposure is expected to be similar to that of the notified use. A predicted environmental concentration was not calculated due to the low potential for environmental exposure.

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

Human health assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have a low acute toxicity by the oral route (median lethal dose >300 mg/kg body weight with no observations of toxicity or compound-related deaths). In a 21-day repeated dermal toxicity study with mammalian test animals, no systemic effects were observed. The substance is not expected to have reproductive/developmental toxicity based on studies of structurally similar polycarboxylates where no adverse effects were observed. It is not expected to be a skin sensitizer based on data for structurally similar polycarboxylates. It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in industrial water cooling systems or commercial cleaning products, direct exposure of the general population is not expected due to the industrial and commercial nature of the use. When the notified substance is used in consumer cleaning products, direct exposure of the general population is expected to be mainly by contact with the skin at low levels based on the low concentration of the substance in end-use products, limited dermal contact with products containing the substance and the limited ability of the substance to cross biological membranes. Indirect exposure of the general population from environmental media such as drinking water is not expected given the low potential for environmental release. Potential uses of the substance include consumer detergents, where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the low potential for toxicity and 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.

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.