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

New Substances Notification No. 19344: Benzenesulfonic acid, (alkenediyl)bis[[[(hydroxyalkyl)amino]-(phenylamino)-triazin-2-yl]amino]-, *N*-(hydroxyalkyl) derivatives, sodium salts, compounds with polyalkyl-substituted(alkanol) (Confidential Accession No. 19236-4)

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 chemical is benzenesulfonic acid, (alkenediyl)bis[[[(hydroxyalkyl)amino]-(phenylamino)-triazin-2-yl]amino]-, *N*-(hydroxyalkyl) derivatives, sodium salts, compounds with polyalkyl-substituted(alkanol) (Confidential Accession No. 19236-4), and is a substance referred to as unknown or variable composition, complex reaction product or biological materials (UVCB).

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in paper applications. Potential uses may include use in consumer cleaning products, textiles and personal care products.

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, sediment and soil. The substance is expected to be persistent in these compartments based on its expected low biodegradability as observed in field samples and because its chemical structure is not susceptible to hydrolysis. The substance is not expected to bioaccumulate based on its low experimental tissue concentrations and very low octanol-water partition coefficient (log K_{ow} ≤0).

Ecological assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have low acute toxicity in fish and aquatic invertebrates (median lethal concentration and median effective concentration >100 mg/L) and low chronic toxicity in algae (no-observed-effect concentration and lowest-observed-effect concentration >10 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 mainly from cleaning of transportation vessels and consumer use by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.001-0.01 mg/L and 0.01-0.1 mg/L, respectively. For potential activities such as manufacturing, environmental exposure is expected to be similar to that of the notified consumer use.

Based on the low potential for ecotoxicity, 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 and dermal routes (median lethal dose >2000 mg/kg bw) and low subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >300 mg/kg bw/day). The substance is expected to have a low reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL 250-1000 mg/kg bw/day with no significant effects). It is not expected to be a skin sensitizer (>10% estimated concentration required to produce a stimulation index of 3 (local lymph node assay)). It is not expected to be mutagenic *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be in the range of 1-10 mg/kg bw/day based on the NOAEL of the oral subchronic toxicity study in mammalian test animals. The PTDI is the estimated long-term exposure without risk of adverse health effects.

When the notified substance is used in paper applications, consumers may come into contact with end-use products containing the substance; however, direct exposure will be negligible because the substance will be present at low concentration and fixed to the paper, and because the substance has limited ability to penetrate the skin. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 0.001-0.01 mg/kg bw/day for children and adults.

Potential uses of the substance include use as an ingredient in various consumer products such as teeth whitening products, where direct exposure of the general population is expected to be mainly by ingestion at levels in the ranges of 0.001-0.01 mg/kg bw/day and 0.01-0.1 mg/kg day for children and adults, respectively. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the ranges of 0.001-0.01 mg/kg bw/day and 0.0001-0.001 mg/kg bw/day for children and adults, respectively.

Because all estimated human exposures are less than the PTDI, meaning at levels that do not pose a concern, 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.