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

New Substances Notification No. 19278: Benzenesulfonic acid, (alkenediyl)bis[[[(hydroxyalkyl)amino]-(phenylamino)-triazin-2-yl]amino]-, *N*-(hydroxyalkyl) derivatives, salts (Confidential Accession No. 19277-5)

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 chemical is benzenesulfonic acid, (alkenediyl)bis[[[(hydroxyalkyl)amino]-(phenylamino)-triazin-2-yl]amino]-, *N*-(hydroxyalkyl) derivatives, salts (Confidential Accession No. 19277-5), and is a substance referred to as unknown or variable composition, complex reaction products and biological materials (UVCB).

Notified and potential activities

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

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 based on its expected resistance to hydrolysis and biodegradation. The substance is not expected to bioaccumulate based on the very low octanol-water partition coefficient (log K_{ow} ≤0) and low bioconcentration factors (<250 L/kg) of analogue substances.

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 (NOEC) >10 mg/L). Using the NOEC from the most sensitive organism (algae) and by applying an assessment factor of 5 to account for species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1-10 mg/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 of transportation vessels and use in paper production by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.001-0.01 mg/L for cleaning and in the range of 0.1-1 mg/L for use. For potential activities such as manufacturing, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC in the range of 0.01-0.1 mg/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 for the substance and surrogate data on structurally related chemicals, the substance is expected to have a low acute toxicity by the oral and dermal routes (lethal dose >2000 mg/kg body weight) 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 low reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL >1000 mg/kg-bw/day). It is not a skin sensitizer (>10% estimated concentration required to produce a stimulation index of 3 (local lymph node assay)). It is not 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 reproductive/developmental toxicity study in mammalian test animals.

When the notified substance is used in industrial paper applications, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be fixed to the paper, and leaching from the paper is not expected. 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.

If potential uses of the substance were to include household cleaners, personal care products or consumer textiles, direct exposure of the general population is expected to be mainly by contact with the skin. However, exposure is expected to be negligible because the high molecular weight, very high water solubility (>10 000 mg/L) and very low octanol-water partition coefficient (log K_{ow} ≤0) of the substance will limit systemic uptake. If potential uses of the substance were to include toothpaste and teeth whitening products, direct exposure of the general population is expected to be mainly by ingestion at conservatively estimated levels in the range of 0.01-0.1 mg/kg-bw/day for adults and children. Indirect exposure of the general population from environmental media such as drinking water resulting from consumer uses is expected to be negligible based on the infrequent and dispersed environmental release. If the substance is used for other industrial applications (such as printing or textiles), direct and indirect exposure of the general population is expected to be quantitatively similar to that of the notified use.

The estimated indirect exposure resulting from industrial uses and the estimated direct exposure resulting from the potential uses are both lower than the PTDI, meaning at levels that do not pose a concern. Considering this, and the expected negligible direct exposure resulting from the notified use,

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