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

New Substances Notification No. 18165: Substituted benzene,2,2'-[1,2-ethenediylbis[(3-sulfo-4,1-phenylene)imino[6-[bis aminoalkanol]-1,3,5-triazine-4,2-diyl]iminollbis-, hexasodium salt

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 that 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

Substituted benzene,2,2'-[1 ,2-ethenediylbis[(3-sulfo-4,1-phenylene)imino[6-[bis aminoalkanol]-1,3,5-triazine-4,2-diyl]iminollbis-, hexasodium salt (Confidential Accession No. 19212-0) is a chemical that can be classified as a stilbene fluorescent brightener.

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities greater than 1000 kg/yr for use as an optical brightener in paper products. Potential uses may include as an optical brightener in detergents, textiles or personal care products.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water and soil. The substance is expected to be persistent in these compartments in conditions where it is not exposed to light based on its resistance to biodegradation. Based on the potential for photolysis, the substance is not expected to be persistent in the upper layer of surface water and soil. The substance is not expected to bioaccumulate based on a very low octanol-water partition coefficient and very high water solubility.

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has low to moderate acute toxicity in aquatic organisms (median lethal concentration >1 mg/L) and moderate chronic toxicity in aquatic invertebrates (no-observed-effect concentration (NOEC) and lowest-observed-effect concentration of 0.1-10 mg/L). Using the chronic NOEC from the most sensitive organism (aquatic invertebrates) and by

applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 10-100 µg/L, which was used to estimate the ecological risk.

The notified 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 transportation of the formulated product, blending and use of the formulated substance at pulp and paper mills and potential use in manufacture and formulation by release of the substance to water at levels of 1-100 kg/day/site. The predicted environmental concentration (PEC) for notified and potential activities is estimated to be 1-100 µg/L.

Comparing the PEC with the PNEC, the ratio is less than 1, indicating that the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg-bw) and a low to moderate potential for subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >30 mg/kg-bw/d). It is not considered a sensitizer (effective concentration not calculated). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. A provisional tolerable daily intake (PTDI) of 10-100 µg/kg bw/day was calculated using the moderate NOAEL for subchronic toxicity.

When used in paper products, direct exposure of the general population is expected to be mainly by contact with the skin at very low levels because the substance becomes fixed into the cellulose matrix of the paper once applied and dried. Other potential uses may include as a brightener in detergents, textiles or personal care products such as tooth whiteners and toothpaste. When potentially used in tooth whitening products and toothpaste, oral exposure was estimated to be 10-100 µg/kg-d. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels of 0.1-1 µg/kg-d and mainly by ingestion. All exposure values were below the PTDI.

Based on estimated exposure values being lower than the PTDI, the notified 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 used as notified and other identified potential uses, the substance is not suspected 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 the *Hazardous Products Regulations* for products intended for workplace use.