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

New Substances Notification 20275: Benzoic acid, 2,2'-[[2,4(3,5 or 4,6)-dihydroxyphenylene]bis(2,1-diazenediyl)]bis-, 1,1'-bis[(dialkylamino)alkyl] ester, hydrochloride (1:2) (Confidential Accession Number 19499-7)

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 benzoic acid, 2,2'-[[2,4(3,5 or 4,6)-dihydroxyphenylene]bis(2,1-diazenediyl)]bis-, 1,1'-bis[(dialkylamino)alkyl] ester, hydrochloride (1:2) (Confidential Accession No. 19499-7).

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 a paper colourant. Potential uses may include paint colourant and textile dye.

Environmental fate and behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to soil and sediments. The substance is not expected to be persistent based on its very short half-life in wet soils and sediments (hydrolysis half-life ≤10 days). However, the principal environmental product of hydrolysis is expected to be persistent in water, soil and sediment. The substance and its product of hydrolysis are not expected to bioaccumulate based on low estimated bioconcentration and bioaccumulation factors.

Ecological assessment

Based on the available hazard information, the substance has moderate acute toxicity to fish and aquatic invertebrates (median lethal concentration and median effective concentration 1-100 mg/L), moderate chronic toxicity to fish and aquatic invertebrates (no-observed-effect concentration (NOEC) 0.1-10 mg/L) and low chronic toxicity algae (10% effective concentration >10 mg/L). Using the NOEC from the most sensitive organism (fish) and by applying an assessment factor of 4 to account for species sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100 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 activities are expected to be mainly from use at the notified pulp and paper plant and cleaning of

transportation vessels by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L. Environmental exposure from use at other pulp and paper plants is expected to be by release of the substance to water resulting in PECs in the range of 0.1-100 µg/L. For potential activities such as manufacturing and cleaning of different transportation vessels, environmental exposure is expected to be at levels similar to that of the notified use.

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 moderate acute toxicity by the oral route (median lethal dose (LD_{50}) 1000-2000 mg/kg body weight), low acute toxicity by the dermal route (LD_{50} >2000 mg/kg body weight) and moderate to high toxicity following repeated oral exposure in mammalian test animals (90-day-no-observed-adverse-effect level (NOAEL) 10-100 mg/kg bw/day; 28-day NOAEL <30 mg/kg bw/day). It is not a dermal sensitizer (0% response (guinea pig maximization test)). It is not mutagenic 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 0.01-0.1 mg/kg bw/day based on the NOAEL of the oral 90-day toxicity study in mammalian test animals. The PTDI is the estimated level of long-term exposure without risk of adverse health effects.

When the notified substance is used as a colorant in pulp and paper industry, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be encapsulated within a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 0.0001-0.001 mg/kg bw/day for children and 0.00001-0.0001 mg/kg bw/day for adults. Potential activities include manufacturing, where 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 0.0001-0.001 mg/kg bw/day for adults.

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.