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

New Substances Notification 20752: 1,3'-Bipyridinium, 5',5'''-[(phenylmethylene)bis(4,1-phenylene-2,1-diazenediyl)]bis[1'-[3-(dimethylamino)propyl]-1',6'-dihydro-2'-hydroxy-4'-methyl-6'-oxo-, chloride (1:2) (Chemical Abstracts Service Registry Number 1142950-68-2)

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 1,3'-bipyridinium, 5',5'''-[(phenylmethylene)bis(4,1-phenylene-2,1-diazenediyl)]bis[1'-[3-(dimethylamino)propyl]-1',6'-dihydro-2'-hydroxy-4'-methyl-6'-oxo-, chloride (1:2) (Chemical Abstracts Service Registry Number[1] 1142950-68-2).

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 dye in the pulp industry. No other uses are anticipated in Canada.

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 or sediment. The substance is expected to be persistent in these compartments because the substance is not hydrolyzed in water and not biodegradable. The substance is not expected to bioaccumulate based on low predicted bioconcentration and bioaccumulation factors (<250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance has moderate acute toxicity to fish, aquatic invertebrates and algae (median lethal concentration (LC_{50}) and median effective concentration 1-100 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying an appropriate assessment factor of 40 to account for acute to chronic extrapolation, 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 risk to the environment.

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 activity is expected to be mainly from cleaning of transportation vessels and use as a dye for pulp and paper at the notified paper plant from release of the substance to water resulting in predicted environmental concentrations (PECs) in the range of 1-10 µg/L. For potential activities such as manufacturing, cleaning of larger transportation vessels and use as a dye for paper in other facilities, environmental exposure is expected to be quantitatively similar to that of the notified use.

Comparing the PECs 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 harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance is expected to have moderate acute toxicity by the oral route (median lethal dose (LD_{50}) 300-2000 mg/kg body weight) and low acute toxicity by the dermal route (LD_{50} >2000 mg/kg body weight). It has moderate subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level 30-300 mg/kg-bw/day). The substance has a low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (no-observed-effect level >30 mg/kg-bw/day with no evidence of reproductive/developmental toxicity). It is expected to be a moderate dermal sensitizer (1-10% estimated concentration required to produce a stimulation index of 3 (local lymph node assay)). It is not mutagenic *in vitro* and is not expected to be clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage. However, one of its potential metabolites is of concern for potential carcinogenicity.

When the notified substance is used as a dye for paper products, consumers may come into contact with the end-use paper containing the substance; however, direct exposure is not expected because the substance will have a high affinity for the paper fibres 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 ranges of 10^{-5} to 10^{-4} mg/kg bw/day and 10^{-4} to 10^{-3} mg/kg bw/day for adults and toddlers, respectively. For potential activities such as manufacturing, indirect exposure of the general population from

environmental media such as drinking water is conservatively estimated to be at levels in the range of 10^{-4} to 10^{-3} mg/kg bw/day for adults and toddlers.

The target margin of exposure (MOE_T) is 1000 based on the available toxicity information. The MOE_T is the level of exposure at or above which there is no expected risk in the exposed population. The derived margin of exposure (MOE_D) is the ratio of the point of departure value to the available exposure doses and is compared to the MOE_T. As the MOE_D is higher than the MOE_T for all estimated human exposures, 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.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

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