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

New Substances Notification No. 18702: 1-Propanaminium, *N*,*N*,*N*-trimethyl-3-[(1-oxo-2-propen-1-yl)amino]-, chloride (1:1), polymer with ethenamine and 2-propenamide, hydrochloride

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 polymer is 1-propanaminium, *N*,*N*,*N*-trimethyl-3-[(1-oxo-2-propen-1-yl)amino]-, chloride (1:1), polymer with ethenamine and 2-propenamide, hydrochloride (Chemical Abstracts Service No. 1659307-53-5). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because of the presence of potentially cationic amine groups.

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 use in the production of paper products. No other activities are anticipated in Canada.

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 sediment. The substance is expected to be persistent in soil and sediment because it does not have any functional groups that are susceptible to biodegradation, and its high molecular weight and complex structure will limit biodegradation potential. The substance is not expected to bioaccumulate based on its high molecular weight which will limit its ability to cross biological membranes.

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have moderate to high acute toxicity in algae (median effective concentration (EC_{50}) <100 mg/L), moderate acute toxicity in fish (median

lethal concentration 1-100 mg/L) and low acute toxicity in aquatic invertebrates (EC_{50} >100 mg/L). Cationic polymers are mitigated by dissolved organic carbon normally present under environmental conditions, and the ecotoxicity data is based on mitigated hazard information on the substance and surrogate data on structurally related chemicals. Using the EC_{50} from the most sensitive organism (algae) and by applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 100-1000 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 activity is expected to be mainly from cleaning of transportation vessels and vehicles by release of the substance to water. The predicted environmental concentration (PEC) is estimated to be 1-10 µg/L for notified activities and 0.1-1 µg/L for potential manufacturing activities.

Comparing the PEC for both notified and potential activities 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 a low potential for acute toxicity by the oral route of exposure (median lethal dose >2000 mg/kg body weight).

When the notified substance is used in the production of paper products, direct exposure of the general population is expected to be mainly by contact with the skin at low levels.

Based on the low toxicity, 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 used as notified, 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 *Hazardous Products Regulations* for products intended for the workplace.