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

New Substances Notification No. 18343: Phosphoric acid, dipentyl ester, polymers with derivatized carbomonocycle alkyl ketone-substituted aldehyde polymer, isopropyl alcohol titanium(4+) salt and pentyl dihydrogen phosphate

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 phosphoric acid, dipentyl ester, polymers with derivatized carbomonocycle alkyl ketone-substituted aldehyde polymer, isopropyl alcohol titanium(4+) salt and pentyl dihydrogen phosphate (Confidential Accession No. 16383-3). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because the substance contains phosphorus and titanium above 0.2% by weight.

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 as an ingredient in inks for industrial packaging. Potential uses are expected to be similar to those notified but for commercial applications.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will rapidly hydrolyze, and the hydrolysis products will tend to partition to soil and sediment. The substance is not expected to be persistent in soil and sediment due to its rapid rate of hydrolysis resulting in half-lives of <182 days in soil and <365 days in sediment. The substance and its products of hydrolysis are not expected to bioaccumulate based on low expected bioaccumulation factors (<250 L/kg).

Ecological Assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have moderate acute toxicity in fish and aquatic invertebrates (no-observed-effect-

concentration 1-100 mg/L). The products of hydrolysis have low to moderate acute toxicity in fish and aquatic invertebrates (median lethal concentration and median effective concentration (EC_{50}) >1 mg/L) and low to moderate chronic toxicity in algae (EC_{50} >1 mg/L). 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 0.01-0.1 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 activity is expected to be mainly from cleaning of systems which use the notified substance by release of the substance to water at rates of 1 to 10 kg/day/site. For potential activities such as use of the notified substance in inks in commercial applications, environmental exposure is expected to be similar to that of the notified use. The predicted environmental concentration (PEC) is estimated to be 0.001-0.01 mg/L for notified and potential activities.

Comparing the PEC for 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 on the substance and surrogate data on structurally related chemicals, the substance is expected to have a low potential for acute toxicity by the oral (median lethal dose (LD_{50}) >2000 mg/kg body weight) and dermal routes of exposure (LD_{50} >1000 mg/kg body weight but with no significant effects) and low subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level >300 mg/kg-bw/day). It is expected to be a mild dermal sensitizer (9-28% response (guinea pig maximization test)). It is not expected to be mutagenic *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an ingredient in inks for industrial applications, consumers may come into contact with end-use products containing the substance, however direct exposure is not expected because the substance will be chemically reacted into a stable matrix once cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is not expected given the specialized industrial use of the substance, which results in little or no release to the environment. If the substance is used as an ingredient in inks for commercial applications, direct and indirect exposure of the general population is expected to be similar to that of the notified use.

Based on the expected low toxicity and low potential for exposure, 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 uses, it 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.