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

New Substances Notification No. 18460: Phosphoric acid, mixed esters with 2-ethyl-1-hexanol and polyethylene glycol monotridecyl ether, potassium salts

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 polymer, phosphoric acid, mixed esters with 2-ethyl-1-hexanol and polyethylene glycol monotridecyl ether, potassium salts (Chemical Abstracts Service Registry No. 68937-46-2), can be classified as phosphate esters and ethoxylated polyethylene glycol. The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations* because it contains phosphorus above 0.2% by weight and a high percentage of low molecular weight components.

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for use in architectural paint. Potential activities may include manufacturing, and use in other paint and coating formulations, adhesives, and other applications.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water, soil and sediment. The substance is not expected to be persistent in water, soil or sediment based on its moderate biodegradability (30-60%) and expected half-life (<182 days in water and soil and <365 days in sediment). The substance is not expected to bioaccumulate based on its low octanol-water partition coefficient ($\log K_{ow}$ 0-3) and low bioconcentration and bioaccumulation factors (<250 L/kg).

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have low acute toxicity in algae (median effective concentration (EC_{50}) >100 mg/L) and moderate acute toxicity in aquatic invertebrates (EC_{50} 1-

100 mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) 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 drums and use in coatings by release of the substance to water at low levels. Environmental exposure from potential activities such as manufacturing is expected to be similar to that of the notified use. The predicted environmental concentration (PEC) for notified and potential activities is estimated to be 1-100 µg/L.

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, the substance has a low acute toxicity by dermal route (median lethal dose >2000 mg/kg body weight).

When the notified substance is used in architectural paint, direct exposure of the general population is not expected as the substance will be contained in the coating once dried. In do-it-yourself uses, exposure is expected to be mainly by dermal contact and inhalation of aerosols containing the substance. However, the concentration of the substance in end use paints is very low (0.5%), and potential for exposure is limited to the time it takes the paint to dry. The ionic nature of the substance will further limit absorption; therefore, uptake via dermal contact or inhalation is not expected. Indirect exposure of the general population from environmental media such as drinking water is expected to be negligible. The substance has potential uses in other paint and coating formulations, adhesives, and other applications. The potential for direct and indirect exposure from the potential uses is expected to be similar to that from the notified use.

Based on the low potential for systemic uptake of the substance in and the low acute dermal 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 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 the *Hazardous Products Regulations* for products intended for workplace use.