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

New Substances Notification 20520: Polyphosphoric acids, polymers with dialkanolamine, alkyl alc., 2-oxepanone and tetrahydro-2*H*-pyran-2-one (Confidential Accession No. 19502-0)

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 polyphosphoric acids, polymers with dialkanolamine, alkyl alc., 2-oxepanone and tetrahydro-2*H*-pyran-2-one (Confidential Accession No. 19502-0). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains phosphorus above 0.2% by weight.

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 dispersant in industrial coatings. Potential uses may include use in coatings available directly to the general population.

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. As a surfactant, some of the substance will also be present at the surface of the water or associated with suspended organic matter. The substance is not expected to be persistent in water and soil based on ready biodegradation (30-60% over 28 days). The substance is not expected to bioaccumulate based on its high molecular weight, which will limit its ability to cross biological membranes.

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low to moderate acute toxicity to fish and algae (median lethal concentration and median effective concentration (EC_{50}) > 1 mg/L). The substance has moderate acute toxicity to aquatic invertebrates (EC_{50} of 1-100 mg/L). The substance has low to moderate chronic toxicity to aquatic invertebrates (lowest-observed-effect-concentration > 0.1 mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an 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 ecological risk.

The notified activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activities is expected to be mainly from equipment and transport vessels cleaning resulting in a predicted environmental concentration (PEC) in the range of 10-100 µg/L, with the exact value being below the PNEC value. No potential activities that could significantly increase environmental risks compared to those notified were identified.

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 risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight) and is likely to have a high subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level <30 mg/kg-bw/day). It is not a dermal sensitizer (> 10% estimated concentration required to produce a stimulation index of 3 (local lymph node assay)). It is not mutagenic *in vitro* and not likely to be clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The substance does not contain structural features associated with adverse human health effects.

When the notified substance is used as dispersant in industrial coatings, direct exposure of the general population is not expected due to the industrial nature of the use. Consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be contained within a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media is not expected given the specialized industrial use of the substance, which results in little or no release to the environment.

Potential uses of the substance include use as a dispersant in coatings available to the general population, where direct exposure of the general population is expected to be mainly by contact with the skin at levels that do not pose a concern. Indirect exposure of the general population from environmental media such as drinking water is considered negligible.

Based on the 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.

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