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

New Substances Notification No. 18292: Formaldehyde polymers with substituted-carbonmonocycle, (tetraalkenyl) derivatives

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 that 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

Formaldehyde polymers with substituted-carbonmonocycle, (tetraalkenyl) derivatives (Confidential Accession Number 18944-8) is a polymer that can be classified as a formaldehyde polymer. The substance does not meet the Reduced Regulatory Requirements criteria according to the New Substances Notification Regulations because of the presence of functional groups of concern.

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 as a lubricant additive. Potential uses are expected to be similar to those notified.

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 based on its long half-life in these compartments (>182 and >365 days, respectively). The substance is not expected to bioaccumulate based on its high molecular weight making it unable to cross biological membranes.

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related polymers, the substance has low acute toxicity in fish, aquatic invertebrates and algae (median lethal loading and median effective loading >100 mg/L). Calculation of the predicted no-effect concentration was not considered necessary given the low ecotoxicity.

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 not expected. Therefore, a predicted environmental concentration for notified and potential activities was not calculated. No other potential uses have been identified.

Based on the low ecotoxicity to aquatic organisms and low potential for environmental exposure, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on the substance, the substance has a low potential for acute toxicity by the oral route of exposure (median lethal dose >2000 mg/kg-bw) and a low potential for subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level >300 mg/kg-bw/d). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When used as an industrial lubricant additive, direct exposure of the general population is expected to be negligible. Indirect exposure of the general population from environmental media such as drinking water is considered unlikely as no releases to the aquatic environment are anticipated. When potentially used as a lubricant for do-it-yourself consumers, direct exposure of the general population is possible, but is expected to be low due to the low concentration of the substance in end-use products, infrequent use of these products and short duration of exposure. The high octanol-water partition coefficient is also expected to limit its dermal uptake. Indirect exposure from potential uses is expected to be similar to notified use.

Based on the low potential for exposure in conjunction with 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 or for other identified potential uses, 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 the *Hazardous Products Regulations* for products intended for workplace use.