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

New Substances Notification No. 18324: Phenol, polymer with formaldehyde, glycidyl ether, polymers with polyethylene glycol, polypropylene glycol and polyethylenpolyamine, reaction products with 2-[(C_{12-14}-alkyloxy) methyl] oxirane

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

Phenol, polymer with formaldehyde, glycidyl ether, polymers with polyethylene glycol, polypropylene glycol and polyethylenpolyamine, reaction products with 2-[(C_{12-14}-alkyloxy) methyl] oxirane (Confidential Accession No: 19128-3) is a polymer that can be classified as a poly(arylether-amine). The substance does not meet the Reduced Regulatory Requirements criteria according to the New Substances Notification Regulations because it contains a high percentage of low molecular weight components and 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 as a component for protective coatings. 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 not expected to be persistent in soil because it is expected to biodegrade. The substance is not expected to bioaccumulate based on its low predicted octanol-water partition coefficient ($\log K_{ow}$ <3) and its very 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 chemicals, the substance has moderate to high acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration and median effective concentration (EC_{50}) <100 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 potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified and potential activities is expected to be mainly from manufacturing, processing and use by release of the substance to water at levels of 10 to 100 kg/day/site based on a highly conservative scenario. The predicted environmental concentration (PEC) for notified and potential activities is estimated to be 0.01-0.1 mg/L. No other potential uses were identified for the notified substance.

Comparing the PEC with the PNEC, the ratio is less than 1, indicating 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 has a moderate potential for acute toxicity by the oral route of exposure (median lethal dose 300-2000 mg/kg body weight).

When the notified substance is used as a component for coatings in do-it-yourself applications, direct exposure of the general population is expected to be mainly by contact with the skin, but is not expected to penetrate the skin due to its very high molecular weight, which prevents it from crossing biological membranes. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels. No other potential uses were identified for the notified substance.

Based on the low potential for exposure of the general population, 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, 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.