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

New Substances Notification No. 18771: Fatty acids, unsaturated, dimers, polymers with bisphenol A diglycidyl ether, formaldehyde, phenol, fatty acids and triethylenetetramine

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, fatty acids, unsaturated, dimers, polymers with bisphenol A diglycidyl ether, formaldehyde, phenol, fatty acids and triethylenetetramine (Confidential Accession No. 19052-8), can be classified as a poly(amine-aryl-cycloalkenamide)-arylether. The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations* because it contains 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 in coatings. Potential uses may include a variety of coating and resin applications and as a concrete and drywall sealer.

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 lack of hydrolysable functional groups and its complex chemical composition which will limit environmental biodegradation. The substance is not expected to bioaccumulate based on its high molecular weight, which will limit its ability 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 high acute toxicity in algae (median effective concentration (EC_{50}) <1 mg/L), moderate acute toxicity in aquatic invertebrates (median lethal concentration (LC_{50}) 1-100 mg/L), and moderate to high acute toxicity in fish (LC_{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 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 vessels through the release of the substance to water. The predicted environmental concentration (PEC) for notified activity is estimated to be 0.1-1 µg/L. Environmental exposure from potential activities is expected to be mainly from manufacturing and formulation activities through the release of the substance to water. The PEC for these potential activities is estimated to be 1-10 µg/L.

Comparing the PEC for the 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 moderate potential for acute toxicity by the oral route of exposure (median lethal dose 300-2000 mg/kg body weight). The substance contains terminal functional groups which have been associated with genotoxicity and skin sensitization. Bisphenol A (BPA) which is used in the synthesis of the notified substance is considered to be toxic under CEPA due to concerns for reproductive and developmental toxicity. However, BPA will be reacted into the notified substance during synthesis and unavailable for further exposure. Therefore, BPA toxicity is not expected due to exposure to the notified substance.

When the notified substance is used in industrial coatings, direct exposure is not expected. It is unlikely that the general population would come into direct contact with end-use products containing the substance. Indirect exposure of the general population from environmental media such as drinking water is expected to be negligible as significant environmental release is not expected.

Other potential uses of the substance include a variety of coating and resin applications and as a concrete and drywall sealer. Potential industrial and commercial uses of the substance are not expected to result in significantly different direct or indirect exposure scenarios than the notified use. Use of the substance in specialized consumer coating products could increase exposure by the dermal route, however the substance will be chemically reacted into a stable matrix once cured and will be unavailable for uptake. In the event of contact with the uncured substance, systemic uptake is not expected because of its high molecular weight, and its cationic and water extractable nature which further limit dermal absorption of lower molecular weight components.

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 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.