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

New Substances Notification 20992: Alkanoic acid, compds. with bisphenol A-epichlorohydrin polymer-hydrolyzed *N*-(1,3-dimethylbutylidene)-*N*'-[2-[(1,3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-2-(methylamino)ethanol reaction products (Confidential Accession Number 19586-4)

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 is alkanoic acid, compds. with bisphenol A-epichlorohydrin polymer-hydrolyzed *N*-(1,3-dimethylbutylidene)-*N*'-[2-[(1,3-dimethylbutylidene)amino]ethyl]-1,2-ethanediamine-2-(methylamino)ethanol reaction products (Confidential Accession No. 19586-4). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains potentially cationic amine groups.

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 in industrial coatings. No other uses are anticipated in Canada.

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 soil and sediment. The substance is expected to be persistent in these compartments based on its expected very low biodegradation (≤ 10% 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 acute toxicity to fish and aquatic invertebrates (median lethal loading rate > 100 mg/L) and moderate acute

toxicity to algae (median effective loading rate (EL_{50}) 1-100 mg/L). Using the EL_{50} from the most sensitive organism (algae) and by applying an assessment factor of 50 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 risk to the environment.

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 from release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L. For potential activities such as manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 1-10 µg/L.

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 harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance is expected to have low acute toxicity by the oral route (median lethal dose > 2000 mg/kg body weight). The substance does not contain functional groups that have been associated with adverse human health effects.

When the notified substance is used in industrial coatings, consumers may come into contact with end-use products; however, direct exposure is not expected because the substance will be chemically consumed during the process 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 industrial use in coatings for other items, where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the low toxicity and 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 the *Hazardous Products Regulations* for products intended for the workplace.