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

New Substances Notification 21155: Alkenoic acid, compd. with polyalkylamino(ethanol) (Confidential Accession Number 19609-7)

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 chemical is alkenoic acid, compd. with polyalkylamino(ethanol) (Confidential Accession Number 19609-7).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities up to or greater than 10 000 kg/yr for the notified use as an industrial coating additive. Potential uses may include adhesives and sealants, lubricants/slip agents, non-metal-surface treatment products, leather treatment products, polishes and waxes, inks and toners, textile treatment products, dyes, machine wash liquids/detergents and automotive care products, cosmetics such as soap, and finger paints.

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, where it will dissociate into two components. The amine component will remain in water and the fatty acid component will eventually settle to sediments. As a surfactant, some of the fatty acid component will also be present at the surface of the water or suspended organic matter. The substance is not expected to be persistent in these compartments based on ready biodegradation (60-85% over 28 days). The substance is not expected to bioaccumulate based on low predicted bioaccumulation and bioconcentration factors (< 250 L/kg) for the amine component and low observed bioconcentration factors (< 250 L/kg) for analogues of the fatty acid component.

Environmental risk assessment

Based on the available hazard information, the substance is expected to have a high acute toxicity to fish (median lethal concentration (LC_{50}) < 1mg/L) and algae (median effective concentration (EC_{50}) < 1 mg/L) and moderate acute toxicity to aquatic invertebrates (EC_{50} 1-100 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying an assessment factor of 10 to account for acute to chronic extrapolation, 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 activities is expected to be mainly from cleaning of transportation vessels and industrial use by release of the substance to water resulting in predicted environmental concentrations (PEC) in the range of 0.1-1 µg/L and 0.01-0.1 µg/L, respectively. For potential activities such as manufacturing and formulation, environmental exposure is expected to be mainly from release of the substance to water resulting in PECs in the range of 1-10 µg/L and 0.1-1 µg/L, respectively.

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 and is expected to have a low acute toxicity by the dermal route (median lethal doses > 2000 mg/kg body weight). The substance is expected to have low subchronic toxicity following repeated oral doses in mammalian test animals (90-day no-observed-adverse-effect level [NOAEL] > 100 mg/kg-bw/day). The substance is expected to have low reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL > 1000 mg/kg-bw/day). It is not expected to be a dermal sensitizer based on the results of a local lymph node assay. It is not expected to be mutagenic *in vitro* or clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a coating additive for industrial applications, direct exposure of the general population is not expected due to the industrial nature of use. The general population may come in contact with end-use products containing the substance, however, direct exposure will be limited as the substance will be trapped within a stable matrix once the product is cured, and thus unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is not expected given the low potential for environmental release. Potential uses may include cosmetics such as soap and in finger paints, where direct exposure of the general population, including vulnerable subpopulations, is expected to be mainly by contact with the skin at low levels. Indirect exposure of the general population through environmental media such as drinking water is expected to be at levels that do not pose a concern, and similar to indirect exposure resulting from the notified use.

Based on 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.

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.