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

New Substances Notification 19958: Benzaldehyde, reaction products with polyalkylenepolyamines, hydrogenated (Confidential Accession No. 18498-3)

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 based on the available information, that when used as notified, the substance 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.

The significant new activity (SNAc) provisions of CEPA were applied to the substance because of potential human health impacts that could arise as a result of potential new activities. Order 2020-87-03-01 Amending the Domestic Substances List outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 154, No. 4 on February 19, 2020. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substances undergo further assessment and risk management consideration.

Substance identity

The notified chemical substance is benzaldehyde, reaction products with polyalkylenepolyamines, hydrogenated (Confidential Accession No. 18498-3), and is a substance referred to as unknown or variable composition, complex reaction products or biological materials (UVCB).

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 50 000 kg/yr for the notified use in industrial coating formulations. Potential uses may include use in consumer products such as coatings and adhesives.

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, soil and sediment. The substance is expected to be persistent in these compartments based on lack of degradation by hydrolysis or biodegradation. The substance is not expected to bioaccumulate based on its low octanol-water partition coefficients (log K_{ow} 0-3).

Ecological assessment

Based on the available hazard information, the substance has low acute toxicity in fish (median lethal concentration >100 mg/L), moderate acute toxicity in aquatic invertebrates (median effective

concentration 1-100 mg/L), and moderate chronic toxicity in algae (10% effective concentration (EC_{10}) 0.1-10 mg/L). Using the EC_{10} from the most sensitive organism (algae) and by applying an assessment factor of 5 to account for species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100 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 substances throughout its life cycle. Environmental exposure from the notified activities is expected to be mainly cleaning of transportation vessels by release of the substance to water resulting in predicted environmental concentrations (PEC) in the range of 10-100 µg/L. For potential activities such as manufacturing, environmental exposure is expected to be similar to that of the notified use.

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 ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance is expected to have moderate acute toxicity by the oral route (median lethal dose 300-2000 mg/kg body weight) and moderate subchronic toxicity following repeated oral doses in mammalian test animals (28--day no-observed-adverse-effect level 30-300 mg/kg-bw/day). It is expected to be a strong dermal sensitizer (0.1-1% estimated concentration required to produce a stimulation index of 3 (local lymph node assay)). It is not expected to be mutagenic *in vitro* and is not clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) were calculated to be in the range of 0.1 to 1 mg/kg bw/day based on the NOAEL of the oral subchronic toxicity study in mammalian test animals. The PTDI is the estimated level of long-term exposure without risk of adverse health effects.

When the notified substance is used as in industrial coating formulations, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 0.0001-0.001 mg/kg bw/day for adults and 0.001-0.01 mg/kg bw/day for children. These values are 100-1000 times lower than the level of oral exposure below which adverse effects are expected to occur. However, if the substance is used in consumer coatings or adhesives an increased level of direct dermal exposure may exist, and is conservatively estimated to be at levels in the range of 1-10 mg/kg-event with dermal concentrations of 1-10 mg/cm^2. Indirect exposures of the general population from any potential uses are expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the low potential for exposure when used as notified, the substance is not likely to pose a significant health risk to the general population, and are therefore unlikely to be harmful to human health. However, based on increased direct exposure combined with indications that the substance may be a skin sensitizer and the lack of information concerning repeated dose dermal toxicity, the potential use of the substance in consumer products could result in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

Assessment conclusion

When the substance is used as notified, it is not suspected to be harmful to human health or environment within the meaning of the criteria under section 64 of the Act. However, it is still suspected that a significant new activity in relation to the substance could result in the substances meeting those criteria.

Due to the potential risk to human health related to dermal sensitization and repeated dermal dose toxicity if the substance is potentially used in consumer products, a SNAc order was issued to obtain information to ensure that the substance undergo further assessment before these potential activities are undertaken. Order 2020-87-03-01 was published in the *Canada Gazette* Part II, Vol. 154, No. 4 on February 19, 2020.

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 *Hazardous Products Regulations* for products intended for the workplace.