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

New Substances Notification 21432: Poly(oxy-1,2-ethanediyl), α-hydro-ω-[(1-oxo-2-propen-1-yl)oxy]-, ether with 2,2-bis(hydroxymethyl)-1,3-propanediol (4:1) (Chemical Abstracts Service Registry Number 51728-26-8)

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 poly(oxy-1,2-ethanediyl), α-hydro-ω-[(1-oxo-2-propen-1-yl)oxy]-, ether with 2,2-bis(hydroxymethyl)-1,3-propanediol (4:1) (Chemical Abstracts Service Registry Number[1] 51728-26-8)), and is considered a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

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 inks, coatings, adhesives and sealants. Potential uses include manufacture of these and other industrial or commercial inks and coatings.

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 air, water and sediment. The substance is not expected to be persistent in air and water but is expected to be persistent in sediment based on low biodegradability (10-30% over 28 days). The substance is not expected to bioaccumulate based on its low octanol-water partitioning coefficient (log K_{ow} 0-3).

1 The Chemical Abstracts Service Registry Number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

Environmental risk assessment

Given the available hazard information, the substance has moderate acute toxicity to fish and aquatic invertebrates (median lethal concentration (LC_{50}) 1-100 mg/L and median effective concentration 1-100 mg/L) and low chronic toxicity to algae (no-observed-effect loading rate > 10 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying an assessment factor of 100 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 to 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 resulting in a predicted environmental concentration (PEC) in the range of 1 to 10 µg/L, with the exact value being below the PNEC value. For potential activities such as manufacturing, formulation and cleaning of transportation vessels under different circumstances, environmental exposure is expected to be mainly from release of the substance to water resulting in PECs in the range of 1 to 10 µg/L, with the exact value being also below the PNEC value.

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 has low acute toxicity by the dermal route (median lethal dose > 2000 mg/kg body weight) and is expected to have low acute toxicity by the oral route (median lethal dose > 2000 mg/kg body weight). It is not a dermal sensitizer in mammalian test animals. The substance is reported to have high subchronic toxicity following repeated oral doses in mammalian test animals (no-observed-adverse-effect level < 30 mg/kg-bw/day). The substance has low reproductive and developmental toxicity in mammalian test animals, and it is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in industrial inks, coatings, adhesives and sealants, 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 and will be unavailable for uptake when cured. Direct exposure of the general population from potential manufacturing activity is expected to be at levels that do not pose a concern, similar to exposure from the notified use. Indirect exposure of the general population from environmental media is anticipated to be low given the specialized industrial use of the substance, which is not expected to result in significant release into the environment. Potential uses of the substance include manufacture and potential production of other industrial or

commercial inks and coatings. Potential manufacture releases and indirect exposure of the general population from environmental media such as drinking water are estimated to be low for adults and children (including for subpopulations that may be more susceptible or highly exposed) at levels in the range of 1×10^{-4}-1×10^{-3} mg/kg bw/day.

The target margin of exposure (MOE_T) is the level of exposure that is determined to be protective for an exposed population. The MOE_T for this substance was calculated to be 1000 based on the available information. The derived margin of exposure (MOE_D) is the ratio of the point of departure value to the estimated exposure levels and is compared to the MOE_T. Based on subchronic mammalian oral toxicity data and the estimated oral exposure, the calculated MOE_D is greater than the MOE_T, which indicates that human exposure to the substance through environmental media is not likely to pose a significant health risk to the general population, and is unlikely to be harmful to human health.

Given the low exposure associated with intended and potential uses, 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 subpopulations that 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.