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

New Substances Notification 20679: 1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with oxirane, 4-(dimethylamino)benzoate (Chemical Abstracts Service registry number 2067275-86-7)

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 determined that the substance is 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.

In order to ensure that the substance does not cause harm to the Canadian environment or human health, its manufacture and import are authorized subject to conditions as described in Ministerial Condition No. 20679 published in the *Canada Gazette* Part I, Vol. 155, No. 24 on June 12, 2021.

Substance identity

The notified polymer is 1,3-propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with oxirane, 4-(dimethylamino)benzoate (Chemical Abstracts Service registry number[1] 2067275-86-7). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because its number average molecular weight is less than 1000 daltons.

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 ultraviolet (UV) curable inks, coatings and adhesives. 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 not expected to be persistent in these compartments based on the moderate hydrolysis half-life. The substance is not expected

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to bioaccumulate based on its low predicted bioaccumulation and bioconcentration factors (<250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity to fish and aquatic invertebrates (no adverse effects observed in saturated solutions), low chronic toxicity to fish (no adverse effects observed in saturated solutions), moderate chronic toxicity to aquatic invertebrates (10% effective concentration (EC_{10}) 0.1-10 mg/L), and low to high chronic toxicity to primary producers such as various types of algae (no-observed-effect-concentration <10 mg/L; EC_{10} 0.1-10 mg/L; no adverse effects observed in saturated solutions). Using the EC_{10} from the most sensitive organism (primary producer) and by applying an assessment factor of 10 to account for potential reproductive toxicity, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1-100 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 formulation by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L, with the exact value being below the PNEC value, and from cleaning of transportation vessels by release of the substance to water resulting in a PEC in the range of 10-100 µg/L, with the exact value being above the PNEC value. 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 10-100 µg/L, also above the PNEC.

Based on the potential for environmental exposure, combined with the high chronic aquatic toxicity and the potential for reproductive toxicity, the substance is anticipated to cause harm to the environment in Canada. The risks have been identified with release of the substance to water when disposed, formulated or manufactured.

Human health risk assessment

Based on the available hazard information, the substance has low acute toxicity by the oral and dermal routes (median lethal dose >2000 mg/kg body weight). The substance is a reproductive toxicant and has moderate subchronic systemic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level 30-300 mg/kg-bw/day). It is a weak skin sensitizer (>10% estimated concentration required to produce a stimulation index of 3 (local lymph node assay)). It is not mutagenic *in vitro* but is clastogenic *in vitro*. Therefore, the substance has the potential to cause genetic damage.

When the notified substance is used as a photo initiator in starting the polymerization process within UV curable coating/ink formulations, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be encapsulated within a stable matrix once the product is cured 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. Concern for sensitization, systemic toxicity, genetic damage and reproductive toxicity for the general public is mitigated as the substance is UV cured and overall direct and indirect exposure are not likely. No other potential uses that could significantly increase human health risks compared to the notified uses were identified.

Based on the low potential for exposure, and considering other available lines of evidence, 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.

Other considerations

This substance is controlled in another jurisdiction. The United States Environmental Protection Agency (US EPA) has issued both a consent order and a significant new use rule (SNUR) on the substance. The concerns for the US EPA were sensitization, reproductive toxicity, systemic effects, and ecotoxicity. The consent order and SNUR limit the use to the notified use as a photo initiator within UV curable coating/ink formulations, and prohibits any other use which would result in either inhalation exposure or release to surface waters at concentrations above 12 µg/L.

Assessment conclusion

The substance is suspected to have a harmful effect on the environment according to the criteria under paragraph 64(a), but is not suspected to constitute a danger to the environment on which life depends according to the criteria under paragraph 64(b), and is not suspected to constitute a danger to human health according to the criteria under paragraph 64(c) of the Act.

Due to the identified risk to the environment related to the chronic aquatic toxicity and potential for reproductive toxicity, a ministerial condition was issued to restrict the manner in which the notifier may manufacture or import the substance with conditions on its use, handling and disposal in order to mitigate these potential risks. Ministerial Condition No. 20679 was published in the *Canada Gazette* Part I, Vol. 155, No. 24 on June 12, 2021.

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.