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

New Substances Notification 21449: 1-Propanone, 1,1'-(oxydi-4,1-phenylene)bis[2-hydroxy-2-methyl- (Chemical Abstracts Service Registry Number 71868-15-0)

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 1-propanone, 1,1'-(oxydi-4,1-phenylene)bis[2-hydroxy-2-methyl- (Chemical Abstracts Service Registry Number[1] 71868-15-0).

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 additive in industrial inks and coatings. Potential uses may include ultraviolet (UV)-curable consumer coatings, adhesives and cosmetics.

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 sediment and soil. The substance is expected to be persistent in these compartments based on its very low biodegradability (≤ 10% over 28 days). The substance is not expected to bioaccumulate based on its low estimated bioconcentration factor (BCF < 250 L/kg) and a low measured BCF for a structurally similar analogue substance (< 250 L/kg).

Environmental risk assessment

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.

Based on the available hazard information, the substance has moderate acute toxicity to fish and aquatic invertebrates (median lethal concentration and median effective concentration (EC_{50}) 1-100 mg/L) and high toxicity to algae (EC_{50} < 10 mg/L). Using the EC_{50} from the most sensitive organism (algae), and by applying an assessment factor of 2 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 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 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. 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 10-100 µg/L and 1-10 µg/L, respectively, with the exact values being below the PNEC value.

Comparing the PEC with the PNEC, the ratio is expected to be 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 [LD_{50}] > 2000 mg/kg body weight) and has low acute toxicity by the oral route (LD_{50} > 2000 mg/kg body weight). The substance is not a skin or eye irritant, nor is it a dermal sensitizer in mammalian test animals. The substance has high subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level < 30 mg/kg-bw/day). It is not mutagenic *in vitro* and is not clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The substance does not contain structural features associated with adverse human health effects.

When the notified substance is used in industrial inks and coatings, 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 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 UV-curable cosmetics, where direct exposure is expected to be mainly by contact with skin at levels in the range of 1×10^{-5}-1×10^{-4} mg/kg bw/day mg/kg bw/day for adults. Potential uses of the substance also include UV-curable consumer coatings and adhesives, where direct exposure is expected to be mainly by contact with skin at levels in the range of 1×10^{-4}-1×10^{-3} mg/kg bw/day for adults. Potential activities include

formulation and manufacturing, where indirect exposure of the general population is expected to be low, similar to that of the notified use.

The target margin of exposure (MOE_T) is the level of exposure that is determined to be protective for an exposed population. The oral 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 oral MOE_T, which indicates that human exposure to the substance through environmental media does not pose a significant health risk to the general population and is unlikely to be harmful to human health.

The dermal MOE_T was calculated to be 100 based on the available information. Since the dermal MOE_D is higher than the dermal MOE_T for all estimated human exposures, the substance is not likely to pose a significant health risk to the general population from consumer product use 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 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.