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

New Substances Notification 20740: 2-Oxepanone, polymer with 2,2-bis(hydroxymethyl)-1,3-propanediol (Chemical Abstracts Service Registry Number 35484-93-6)

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 substance is 2-oxepanone, polymer with 2,2-bis(hydroxymethyl)-1,3-propanediol (Chemical Abstracts Service Registry Number[1] 35484-93-6).

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 coatings. Potential uses may include industrial, commercial and consumer applications such as paints 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 or sediment. The substance is not expected to be persistent in these compartments based on its high biodegradability (60-85%). The substance is not expected to bioaccumulate based on rapid biodegradation and low estimated bioaccumulation factor (<250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low to moderate acute toxicity to fish (median lethal concentration (LC_{50}) >1 mg/L), low to high acute toxicity to

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aquatic invertebrates (median effective concentration (EC_{50}) > 100 mg/L and LC_{50} <100 mg/L), moderate acute toxicity to algae (EC_{50} 1-100 mg/L) and low chronic toxicity to algae (10% effective concentration >10 mg/L). Using the LC_{50}, from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 20 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 0.01-0.1 mg/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 formulation and cleaning of transportation vessels resulting in predicted environmental concentrations (PECs) in the range of 0.001-0.01 mg/L and 0.01-0.1 mg/L respectively, with the exact values being below 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 0.01-0.1 mg/L, also below the PNEC.

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 a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight). The substance is expected to have a low developmental toxicity following repeated oral doses in mammalian test animals (no-observed-adverse-effect level >300 mg/kg-bw/day). It is not expected to be a dermal sensitizer (local lymph node assay). It is not expected to be mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in industrial 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 not expected given the specialized industrial use of the substance, which results in little or no release to the environment. Potential uses of the substance include various industrial and commercial activities, where direct exposure is expected to be low, similar to that of the notified use. Potential uses of the substance also include consumer products such as paints and adhesives, where direct exposure of the general population is expected to be mainly by contact with the skin. Direct exposure will be limited by the high molecular weight and high octanol-water partition coefficient of the substance, and the low frequency of use. Indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the low toxicity and low potential for exposure, 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.