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

New Substances Notification No. 19002: *N*,*N*'-Alkylenebismorpholine

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 *N*,*N*'-Alkylenebismorpholine (Confidential Accession No. 19173-1).

Notified and Potential Activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for the notified use as an industrial chemical inhibitor. Potential uses may include use as an industrial biocide, lubricant or coolant.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to air and water, and will hydrolyze rapidly in water. The substance is not expected to be persistent in air based on an expected half-life of <2 days. The substance and its hydrolysis products are not expected to be persistent in water based on their very high ready biodegradation (>85% over 28 days). The substance and its hydrolysis products are not expected to bioaccumulate based on low bioconcentration factors (<250 L/kg).

Ecological Assessment

Based on the available hazard information on the substance and its hydrolysis products, the substance has low acute toxicity in fish (median lethal concentration (LC_{50}) >100 mg/L) and moderate acute toxicity in aquatic invertebrates and algae (LC_{50} and median effective concentration (EC_{50}) 1-100 mg/L). The hydrolysis product has low acute toxicity in fish (LC_{50} >100 mg/L) and moderate acute toxicity in aquatic invertebrates (EC_{50} 1-100 mg/L). The hydrolysis product has low chronic toxicity in fish (no-observed-effect-concentration (NOEC) >10 mg/L) and moderate chronic toxicity in aquatic invertebrates and algae (NOEC 0.1-10 mg/L). The hydrolysis product also has low acute toxicity in plants and soil organisms (EC_{50} >100 mg/kg dry soil). Using the EC_{50} from the most sensitive organism (algae), and by applying

an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 1000 to 10 000 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 substance throughout its life cycle. Environmental exposure from the notified activities is expected to be mainly from cleaning of transportation vessels and formulation by release of the substance to water at rates of 0.01 to 1 kg/day/site. For potential activities such as manufacturing, environmental exposure is expected to be mainly by release of the substance to water at rates of 1 to 10 kg/day/site. The predicted environmental concentration (PEC) is estimated to be 0.01 to 10 µg/L for notified activities and 1 to 10 µg/L for other potential activities.

Comparing the PEC for notified and potential activities 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 has a moderate potential for acute toxicity by the oral route of exposure (median lethal dose 300-2000 mg/kg bw). The substance exhibits moderate to high subchronic toxicity following repeat oral doses in mammalian test animals (90-day no-observed-effect level <100 mg/kg-bw/day), however this is likely due to corrosive properties of the substance rather than systemic toxicity. It is not a skin sensitizer (0-8% response (guinea pig maximization test)). It is mutagenic and clastogenic *in vitro*. Therefore, the substance has the potential to cause genetic damage, but it was not found to be mutagenic or clastogenic *in vivo*. Overall, the notified substance has a moderate potential to elicit a mutagenic response.

When the notified substance is used as an industrial chemical inhibitor, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media such as drinking water is not expected given the specialized industrial use of the substance, which results in little or no release to the environment. If the substance is used as an industrial biocide, lubricant or coolant, direct and indirect exposure of the general population is expected to be similar to that of the notified use.

Based on the 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.

Assessment Conclusion

When used as notified or for other identified potential uses, the substance is not suspected to be harmful to human health or the environment according to the criteria under section 64 of CEPA.

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.