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

New Substances Notification No. 18944: Ethanamine, 2,2'-[1,2-ethanediylbis(oxy)]bis-

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 ethanamine, 2,2'-[1,2-ethanediylbis(oxy)]bis (Chemical Abstracts Service No. 929-59-9).

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as an industrial additive. Potential activities may include manufacturing and potential use as an additive in commercial and consumer applications.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water. The substance is not expected to be persistent in water based on its expected half-life (<182 days in water). The substance is not expected to bioaccumulate based on its very low octanol-water partition coefficient (log $K_{ow} \leq 0$).

Ecological Assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have low acute toxicity in fish (median lethal concentration (LC_{50}) >100 mg/L) and low to moderate acute toxicity in aquatic invertebrates (median effective concentration >1 mg/L). The substance is expected to have low chronic toxicity in aquatic invertebrates (no-observed-effect-concentration (NOEC) >10 mg/L) and low to moderate chronic toxicity in algae (NOEC >0.1 mg/L; 10% effective concentration (EC_{10}) >1 mg/L). Using the EC_{10} from the most sensitive organism (algae) and by applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 0.1-1 mg/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 low. For potential activities such as manufacturing, transportation and formulation, environmental exposure is expected to be mainly by release of the substance to water from cleaning of transportation vessels at levels of 100-1000 kg/day and from manufacturing and formulation at rates of 10-100 kg/day. The predicted environmental concentration (PEC) is estimated to be 0.1-1 mg/L for potential transportation activities and 0.01-0.1 mg/L for potential manufacturing and formulation activities.

Comparing the PEC for 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 as a result of potential use.

Human Health Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have a low to moderate potential for acute toxicity by the oral route of exposure (median lethal dose (LD_{50}) >300 mg/kg body weight) and a low potential for acute toxicity by the dermal and inhalation routes of exposure (dermal LD_{50} >2000 mg/kg bw; inhalation LC_{50} >20 mg/L). The notified substance is expected to have moderate subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-effect level (NOEL) 30-300 mg/kg-bw/day) and low to moderate subchronic toxicity following repeat dermal doses in mammalian test animals (90-day NOEL for systemic toxicity >200 mg/kg-bw/day, 90-day no-observed-adverse-effect-level (NOAEL) for local effects 20-200 mg/kg-bw/day). It is not expected to cause skin sensitization (0-8% response (guinea pig maximization test)). It is not mutagenic *in vitro* and is not clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

The provisional tolerable daily intake (PTDI) for oral exposure was calculated to be 1-10 mg/kg-bw/day based on the NOEL of the 28-day repeat oral dose study with mammalian test animals. The PTDI for dermal exposure was calculated to be 10-100 mg/kg-bw/day for systemic effects and 1-10 mg/kg-bw/day for local effects based on the systemic NOEL and local NOAEL of the 90-day repeat dermal dose study with mammalian test animals.

When the notified substance is used as an industrial additive, 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 additive in consumer applications, direct exposure of the general population is expected to be mainly by contact with the skin and/or by inhalation at levels of 0.1-1 mg/kg-bw/day for dermal exposure. Inhalation exposure is expected to be negligible.

Based on a comparison of the PTDI to the estimated 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.