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

New Substances Notification No. 19240: Ethanol, 2-amino-, reaction products with carbon dioxide (Chemical Abstracts Service No. 174125-97-4)

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 ethanol, 2-amino-, reaction products with carbon dioxide (Chemical Abstracts Service Registry Number [1]174125-97-4).

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 additive. Potential uses may include industrial polyurethane applications.

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. The substance is not expected to be persistent in this compartment based on very high ready biodegradation (>85% over 28 days). The substance is not expected to bioaccumulate based on its miscibility with water, very high biodegradability and very low octanol-water partition coefficient (log K_{ow} ≤0). At high temperatures or if diluted in water, the substance is expected to decompose to monoethanolamine (MEA) and carbon dioxide (CO_2). MEA is expected to partition to air and is not expected to be persistent in this compartment based on its rapid oxidation resulting in an estimated short atmospheric half-life (1-6 hours).

Ecological assessment

Based on the available hazard information on the substance and the MEA decomposition product, the substance has low acute toxicity in fish (median lethal concentration >100 mg/L) and moderate acute toxicity in aquatic invertebrates and algae (median effective concentration (EC_{50}) in the range of 1-100

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mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 100 to account for acute to chronic extrapolation and species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 100-1000 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 resulting in a predicted environmental concentration (PEC) in the range of 0.1-1 µg/L. For potential activities such as manufacturing, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC in the range of 1-10 µg/L.

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 ecological harm in Canada.

Human health assessment

Based on the available hazard information for the substance and the MEA decomposition product, the substance is expected to have a low to moderate acute toxicity by the oral route (median lethal dose (LD_{50}) >300 mg/kg body weight), low acute toxicity by the dermal route (LD_{50} >2000 mg/kg body weight) and moderate to very high acute toxicity by the inhalation route (median lethal concentration <5 mg/L/4hour). The substance is expected to have low subchronic toxicity following repeat oral doses in mammalian test animals (32-day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/day). The substance is expected to have low reproductive/developmental toxicity by the oral route (NOAEL >1000 mg/kg-bw/day) and moderate reproductive/developmental toxicity by the dermal route (NOAEL >50 mg/kg-bw/day) following repeat doses in mammalian test animals. It is not a skin sensitizer (0% response (guinea pig maximization test); 0% response (Buehler scale)). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be in the range of 1000-10 000 µg/kg-bw/day based on the NOAEL of the oral reproductive/developmental toxicity study in 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 is not expected given the specialized industrial use of the substance, which results in little or no release to the environment. If potential uses of the substance were to include industrial polyurethane applications, 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 conservatively estimated to be at levels in the range of 0.1-1 µg/kg-bw/day.

Because the estimated human exposure is less than the PTDI, meaning at levels that do not pose a concern, 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 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 *Hazardous Products Regulations* for products intended for the workplace.