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

New Substances Notification 19332: 1-Butanaminium, *N*,*N*,*N*-tributyl-, ethyl carbonate (1:1) (Chemical Abstracts Service Registry Number 478796-04-2)

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-butanaminium, *N*,*N*,*N*-tributyl-, ethyl carbonate (1:1) (Chemical Abstracts Service Registry Number[1] 478796-04-2)

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 a component of a base catalyst in specialty industrial coating formulations. Potential activities may include manufacturing and potential uses may include use as a fungicide, as a corrosion inhibitor or as a catalyst in consumer paint formulations.

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 its susceptibility to biodegradation (10-30% over 28 days) and hydrolysis. The environmental products of hydrolysis are also not expected to be persistent in water as they are expected to degrade over time. The substance is not expected to bioaccumulate based on its very low octanol-water partition coefficients (log K_{ow} ≤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), moderate acute toxicity in aquatic invertebrates (median effective concentration 1-100 mg/L) and moderate chronic toxicity in algae (10% effective concentration (EC_{10}) 0.1-10 mg/L). Using the EC_{10} from the most sensitive

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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 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 mainly from cleaning of transportation vessels and use in industrial coatings by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.01-0.1 mg/L and 0.001-0.01 mg/L, respectively. For potential activities such as manufacturing, environmental exposure is expected to be quantitatively similar to that of the cleaning of transportation vessels associated with the notified activities.

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 on structurally related chemicals, the substance is expected to have moderate acute toxicity by the oral and inhalation routes (oral median lethal dose (LD_{50}) 300-2000 mg/kg body weight; inhalation LC_{50} 1-5 mg/L/4hr) and high acute toxicity by the dermal route (LD_{50} 200-1000 mg/kg body weight). The substance is expected to have moderate subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) 30-300 mg/kg bw/day). It is not expected to be skin sensitizers (0-8% response (guinea pig maximization test)). It is not expected to be mutagenic *in vitro*, or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be in the range of 0.1-1 mg/kg bw/day based on the NOAEL of the oral subchronic toxicity study in mammalian test animals. The PTDI is the estimated long-term exposure without risk of adverse health effects.

When the notified substance is used in specialty 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 cured and will be unavailable for uptake. The combined indirect exposure of the general population to the substance from environmental media such as drinking water is conservatively estimated to be at levels in the range of 0.01-0.1 mg/kg bw/day and 0.001-0.01 mg/kg bw/day for children and adults, respectively. Potential uses of the substance include consumer paints, where direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range of 0.01-0.1 mg/kg bw/event. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 0.001-0.01 mg/kg bw/day for adults and children.

Because all estimated human exposures are 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.