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

New Substances Notification No. 18807: 2-Propenoic acid, 2-methyl-, 2-(2-butoxyethoxy)ethyl ester

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 chemical, 2-propenoic acid, 2-methyl-, 2-(2-butoxyethoxy)ethyl ester (Chemical Abstracts Service Registry No. 7328-22-5), can be classified as a methacrylate ester.

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 use as a reactive monomer and binder in floor coatings. Potential uses may include as a plasticizer in various coating applications and as a co-monomer in acrylic plastic components.

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. The substance is not expected to be persistent in air due to estimated rapid oxidation resulting in a short half-life (\leq 2 days) and is not expected to be persistent in water based on its very high biodegradability (>85%). The substance is not expected to bioaccumulate based on its low octanol-water partition coefficient (logKow 0-3) and low estimated bioconcentration and bioaccumulation factors (<250 L/kg).

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has moderate acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration and median effective concentration 1-100 mg/L) and low chronic toxicity in aquatic invertebrates (no-observed-effect concentration >10 mg/L). Based on modelling data for the degradation products of the substance, the degradation products have low acute and chronic toxicity (acute effect concentration >100 mg/L; chronic effect concentration

>10 mg/L). Using the lowest-observed-effect-concentration from the most sensitive organism (fish) and by applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be $100-1000 \,\mu\text{g/L}$, 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 through the release of the substance to water. Environmental exposure from other potential activities is expected to be mainly from manufacturing and formulation activities through the release of the substance to water. The predicted environmental concentration (PEC) for both the notified and potential activities is estimated to be $0.1-1~\mu g/L$.

Comparing the PEC for the 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 on the substance and surrogate data on structurally related chemicals, the substance has a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg body weight) and a low potential for subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/d). The substance has a low potential for reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL >1000 mg/kg-bw/d). It is not a dermal sensitizer (0-8% response (guinea pig maximization test)). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as as a reactive monomer and binder in floor coatings, the substance is intended for industrial and commercial use and direct exposure of the general population is not expected. The substance is expected to have reacted chemically in the polymer matrix of coatings once cured and unavailable for release. Indirect exposure of the general population from environmental media such as drinking water or air is expected to be low.

Other potential uses of the substance include its use as a plasticizer in various coating applications and as a co-monomer in acrylic plastic components. These other potential uses are not expected to result in a significant change to the direct or indirect exposure of the general population compared to the notified use.

Based on the low toxicity and low potential for direct or indirect 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 the substance is used as notified or for other identified potential uses, it 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 the *Hazardous Products Regulations* for products intended for workplace use.