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

New Substances Notification No. 18079: Alkyl alcohol triester with boric acid (H_3BO_3)

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 that 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

Alkyl alcohol triester with boric acid (H_3BO_3) (Confidential Accession No. 18880-7) is a chemical that can be classified as a borate ester.

Notified 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 copper and lead corrosion inhibitor in lubricating oils used in passenger cars and heavy duty diesel oils. Potential uses may include as a component of brake fluids.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water, however it undergoes rapid hydrolysis into two breakdown products. The substance is not expected to be persistent in water due to its rapid hydrolysis; one of its breakdown products is expected to be persistent in the environment, while the other is not. The substance is not expected to bioaccumulate based on its rapid hydrolysis in water, and neither breakdown product is expected to be bioaccumulative.

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 aquatic organisms (median lethal concentration and median effective concentration 1-100 mg/L) and moderate chronic toxicity in aquatic invertebrates (no-observed-effect concentration (NOEC) 0.1-10 mg/L). The predicted no-effect concentration was calculated to be 0.01-0.1 mg/L using the chronic NOEC from the most sensitive organism (aquatic invertebrates), which was used to estimate the ecological risk.

No significant releases are expected from the notified uses of the substances and therefore calculation of a predicted environmental concentration was not required. The potential use as a component of brake fluids is not expected to differ significantly from the notified use.

Based on the low potential for ecological hazard and notified uses of the substance that are expected not to result in releases, 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 a structurally related chemical, the substance has a low potential for acute toxicity by the oral route of exposure (median lethal dose (LD_{50}) >2000 mg/kg body weight), a low potential for acute toxicity by the dermal route of exposure (LD_{50} >2000 mg/kg body weight), and low potential for subchronic toxicity following repeat oral doses in mammalian test animals (no-observed-adverse-effect level (NOAEL) >300 mg/kg bw/day). It is a minimal to mild eye irritant (maximum average score = 2.3-15), and a mild skin irritant (primary irritation index = 1.6-3). It is not mutagenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage. There is a very high potential for developmental toxicity by the oral route of exposure (NOAEL <50 mg/kg bw/day) for one breakdown product, which was used to calculate a provisional tolerable daily intake (PTDI). It is a weak to moderate skin sensitizer (effective concentration 1.0 to >10% (local lymph node assay scale); 28-64% response (Buehler scale)). These data were used to calculate a sensitization reference dose.

When used as a copper and lead corrosion inhibitor in lubricating oils used in passenger cars and heavy duty diesel oils, direct exposure of the general population is expected to be mainly by contact with the skin. Dermal exposure is estimated to be lower than the sensitization reference dose. Indirect exposure of the general population from environmental media such as drinking water in the event of an unforeseen environmental release is expected to be less than the PTDI. The potential use as a component of brake fluids is not expected to differ significantly from the notified use.

Based on the low potential for direct or indirect exposure, the substance is not likely to pose a significant health risk to the general population when used as notified, and is therefore unlikely to be harmful to human health.

Assessment Conclusion

When used as notified or for other 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 the *Hazardous Products Regulations* for products intended for workplace use.