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

New Substances Notification No. 18279: Benzene, polyalkene derivatives, sulfonated, sodium salts

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, benzene, polyalkene derivatives, sulfonated, sodium salts (Confidential Accession No. 17584-7), can be classified as an anionic surfactant.

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 component of surfactant blends in oilfield applications. Potential uses may include offshore oilfield applications, metal working fluids, household and industrial cleaning products, personal care products, chemical and agricultural uses, and textiles and fabrics 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. Based on experimental biodegradation information the substance is not readily biodegradable (10-30%) but is unlikely to persist in water in the long-term. The substance is not expected to bioaccumulate based on its very high water solubility (>10 000 mg/L).

Ecological Assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have moderate to high acute toxicity in fish and aquatic invertebrates (median lethal concentration (LC_{50}) and median effective concentration (EC_{50}) <100 mg/L) and low to moderate acute toxicity in algae (EC_{50} >1 mg/L). The substance is expected to have moderate chronic toxicity in aquatic organisms (no-observed-effect concentration 0.1-1 mg/L). The predicted no-

effect concentration (PNEC) was estimated to be 100-1000 µg/L based on the reported PNEC of an analogue substance, which was used to estimate 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 activity is expected to be mainly from the cleaning of tank trucks used for the transportation of the substance by release of the substance to wastewater. The predicted environmental concentration (PEC) for notified activities is estimated to be 10-100 µg/L. The substance may have the potential to be used in offshore oilfield applications, metal working fluids, or various cleaning applications. The PEC for potential uses is estimated to be 10-1000 µg/L for releases to water.

Comparing the PEC for notified and potential uses 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 similar substances, the notified 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), a low to high acute toxicity by the dermal route(LD_{50} >200 mg/kg body weight), and a very high acute toxicity by the inhalation route (LC_{50} ≤0.5 mg/L). However, this is considered to be likely due to the corrosive properties of the substance and not due to systemic effects. The substance is expected to have a low subchronic toxicity following repeat oral doses in mammalian test animals (90-day no-observed-adverse-effect level (NOAEL) >100 mg/kg bw/d) and a low to moderate reproductive/developmental toxicity (NOAEL >250 mg/kg-bw/d). It is not expected to cause skin sensitization. It is not expected to be mutagenic *in vitro* or clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage. Based on negative results for tumorigenesis and mutagenicity in several studies, the substance is unlikely to be carcinogenic. The provisional tolerable daily intake (PTDI) was calculated to be 100-1000 µg/kg-bw/d based on the 90-day oral repeat dose study in mammalian test animals.

When the notified substance is used as a surfactant in oilfield applications, the potential for direct exposure of the general population is expected to negligible. The substance will be applied in industrial settings via direct injection into closed piping, and will be recycled or destroyed during use. Significant environmental releases of the substance are not expected, and as such the potential for indirect exposure of the general population from environmental media such as drinking water is expected to be low.

Given the structure and properties of the substance, potential uses include household and industrial cleaning products, personal care products, chemical and agricultural uses, and textiles and fabrics applications. Direct exposure of the general population is expected to be negligible for potential industrial uses of the substance.

If used in personal care or household cleaning products, there is the potential for direct exposure of the general population through inhalation and oral exposure at levels of 0.001 to 0.1 µg/kg body weight and 1 to 10 µg/kg body weight, respectively. Based on the ionic nature and high water solubility of the substance, dermal uptake is expected to be low. At an assumed dermal uptake efficiency of 1%, direct dermal exposure is estimated at levels of 10 to 1000 µg/kg body weight.

Indirect exposure to the general population via drinking water following releases of household cleaning products down the drain was estimated to be 1 to 10 µg/kg body weight.

Based on the low potential for exposure for the notified use and based on a comparison of the PTDI to the estimated exposure for potential uses, 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.