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

New Substances Notification 19877: Fatty acids, C_{8-16}, 2-sulfopropyl esters, sodium salts (Chemical Abstracts Service Registry Number 2244880-58-6)

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 fatty acids, C_{8-16}, 2-sulfopropyl esters, sodium salts (Chemical Abstracts Service Registry Number[1] 2244880-52-6), and is a substance referred to as Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

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 personal care products. The substance will be formulated in Canada into the final end-use product. Potential activities include manufacturing of the substance.

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 the environment based on its high biodegradation rate (>85% over 28 days). The substance is not expected to bioaccumulate based on high water solubility and metabolic potential.

Ecological assessment

Based on the available hazard information, the substance is expected to have low to moderate acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration (LC_{50}) and median effective concentration >1 mg/L). Using the LC_{50} from the most sensitive organism (fish) 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 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 are expected to be mainly from formulation, processing and use resulting in release of the substance to water, resulting in a predicted environmental concentration (PEC) in the range of 0.001-0.1 mg/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 0.001-0.1 mg/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 on structurally related chemicals, the substance is expected to have a low acute toxicity by the oral route (>300 mg/kg body weight when corrected for purity) and low subchronic toxicity following repeated oral and dermal doses in mammalian test animals (91-92 day oral no-observed-adverse-effect level (NOAEL) >100 mg/kg bw/day; 28-day dermal NOAEL >600 mg/kg bw/day). It is a weak dermal sensitizer (guinea pig maximization test). It is not expected to be mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in personal care products, direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range 10-1000 mg/kg bw/day. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 10^{-3}-10^{-5} mg/kg bw/day for children and 10^{-4}-10^{-6} mg/kg bw/day for adults and mainly by ingestion. Potential activities include manufacturing, where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified activities and use.

Based on the low toxicity and low potential for 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 for the notified activities, 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 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 *Hazardous Products Regulations* for products intended for the workplace.