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

New Substances Notification 19950: Ethanesulfonic acid, 2-[methyl(1-oxododecyl)amino]-, sodium salt (1:1) (Chemical Abstracts Service Registry Number 4337-75-1)

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 CEPA, 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 ethanesulfonic acid, 2-[methyl(1-oxododecyl)amino]-, sodium salt (1:1) (Chemical Abstracts Service Registry Number[1] 4337-75-1).

Notified and potential activities

The substance is proposed to be imported into Canada in finished products in quantities greater than 10 000 kg/yr for the notified use as a surfactant in personal care products. Potential activities may include manufacturing of the substance and notified activities that would be associated with increased import volumes.

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 and air. The substance is not expected to be persistent based on the high biodegradation potential (60-85% over 28 days). The substance is not expected to bioaccumulate based on its very high water solubility (>10 000 mg/L), very low octanol-water partition coefficient (log $K_{ow} \leq 0$), and potential to be biotransformed in organisms.

Ecological assessment

Based on the available hazard information on structurally related chemicals, the substance has low acute toxicity to algae (median effective concentration (EC_{50}) >1 mg/L with no significant effects at highest concentration tested) and microorganisms (EC_{50} >100 mg/L) and moderate acute toxicity to fish (median lethal concentration (LC_{50}) 1-100 mg/L) and aquatic invertebrates (EC_{50} 1-100 mg/L). Using the LC_{50} from the most sensitive organism (fish), and by applying an assessment factor of 100 to account for

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acute to chronic extrapolation and species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 0.01-0.1 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 (1) blending and formulation with subsequent release to water and (2) consumer and commercial use and ultimate release down the drain, resulting in a predicted environmental concentration (PEC) in the range of 0.001-0.01 mg/L. For potential activities such as manufacturing and activities which result in increased import volumes, environmental exposure is expected to be mainly from release of the substance to water resulting in PECs in the range of 0.01-0.1 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 analogues, the substance is expected to have low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight) and low subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-effect level >300 mg/kg bw/day). It is not a dermal sensitizer (0% response on the Buehler scale). 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 is expected to be mainly by contact with the skin at levels in the range of 0.1-1 mg/kg bw/day for children and adults. Indirect exposure to the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 10^{-6}-10^{-4} mg/kg bw/day for children and adults. Potential activities include manufacturing of the substance, formulation of personal care products, and import of finished products which may result in increased import volumes, where indirect exposure of the general population from environmental media such as drinking water is conservatively estimated in the range of 10^{-5}-10^{-3} mg/kg bw/day for children and 10^{-6}-10^{-5} mg/kg bw/day for adults.

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 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.