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

New Substances Notification 19871: Poly(oxy-1,2-ethanediyl), α-sulfo-ω-(tridecyloxy)-, sodium salt (1:1) (Chemical Abstracts Service Registry Number 54116-08-4)

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 poly(oxy-1,2-ethanediyl), α-sulfo-ω-(tridecyloxy)-, sodium salt (1:1) (Chemical Abstracts Service Registry Number[1] 54116-08-4), 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 surfactant in body wash and shampoo products. Potential uses may include cleansers, conditioners, exfoliants, makeup or makeup removers, and moisturizers. Potential activities may include manufacturing of the substance, and blending and formulation of products.

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 this compartment based on the high biodegradation potential (60-85% over 28 days). The substance is not expected to bioaccumulate based on its high water solubility and low octanol-water partitioning coefficient (log K_{ow} 0-3) which will limit its ability to cross biological membranes.

Ecological assessment

Based on the available hazard information, the substance has moderate acute toxicity in fish, aquatic invertebrates, and algae (median lethal concentration and median effective concentration (EC_{50}) 1 – 100 mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates), and by applying an assessment factor of 100 to account for acute to chronic extrapolation and species sensitivity variation,

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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 activities 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 use in personal care products containing the substance 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 use in additional personal care products, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 10^{-3} to 10^{-2} mg/L. For potential activities such as manufacturing, and blending and formulation, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 10^{-3} to 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 the substance is unlikely to cause ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance is expected to have a low to moderate acute toxicity from the oral route (median lethal dose [LD_{50}] >1 000 mg/L), low acute toxicity from the dermal route ([LD_{50}] >1 000 mg/L) and low sub-chronic toxicity following repeated oral doses in mammalian test animals (90-day to 2-year dietary studies). The substance is expected to have a low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (2-year dietary studies). It is not expected to be a dermal sensitizer. It is not mutagenic *in vitro* and is not clastogenic *in vitro or in vivo*. Therefore, the substance is unlikely to cause genetic damage. Given the general lack of quantifiable adverse effects for the notified substance and analogues, a chronic or sub-chronic NOAEL cannot be determined.

When the notified substance is used as a component of shampoos and body washes, direct exposure of the general population is expected to be mainly through contact with the skin at levels less than 5 mg/kg-bw/day under a worst case scenario (infants 0 – 5 mo.). 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^{-5}-10^{-4} mg/kg-bw/day for children and 10^{-6}-10^{-5} mg/kg-bw/day for adults.

If potential activities were to include use of the substance in personal care products other than shampoos and body washes, as well as formulation and blending, direct exposure of the general population is expected to be mainly by contact with the skin at levels less than 110 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^{-5}-10^{-4} mg/kg-bw/day for children and adults.

If potential activities involving the substance were to include manufacturing, direct exposure of the general population is not expected and 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^{-4}-10^{-3} mg/kg bw/day for children and 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.