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

New Substances Notification No. 19725: Sulfonic acids, C_{20-24}-alkane hydroxy and C_{20-24}-alkene, sodium salts (Chemical Abstracts Service No. 97766-43-3)

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 the Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance, and determined that the substance is 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.

In order to ensure that the substance does not cause harm to the Canadian environment or human health, its manufacture and import are authorized subject to conditions as described in Ministerial Condition No. 19725 published in the *Canada Gazette* Part I, Vol. 153, No. 8 on February 23, 2019.

Substance identity

The notified chemical is sulfonic acids, C_{20-24}-alkane hydroxy and C_{20-24}-alkene, sodium salts (Chemical Abstracts Service No. 97766-43-3), 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 in oil recovery applications. Potential uses may include laundry detergents, dishwashing products, household cleaning products, personal care products, and the manufacturing and formulation of various goods.

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 its inherent biodegradation (30-60% over 28 days). The substance is not expected to bioaccumulate based on its low to moderate octanol-water partition coefficient (log K_{ow} <5).

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have moderate to high acute toxicity in fish (median lethal concentration (LC_{50}) <100 mg/L), moderate acute toxicity in aquatic invertebrates and algae (median effective concentration 1-100 mg/L), and moderate chronic toxicity in aquatic invertebrates and algae (no-observed-effect-concentration 0.1-10 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying an assessment factor of 40 to account for acute to chronic extrapolation, species

sensitivity variation, and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1-10 µg/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 activity is expected to be mainly from cleaning of transportation vessels by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 10-100 µg/L. For potential activities such as manufacturing, formulation or use in consumer products, environmental exposure is expected to be similar to that of the notified use. However, if the substance is used in offshore oil recovery, an increased exposure potential may exist from release to water that could result in PECs in the range of 100-1000 µg/L.

Based on the potential for environmental exposure combined with moderate-high acute aquatic toxicity, the substance is anticipated to cause ecological harm in Canada. The risks have been identified with release of the substance to water when used in oil recovery applications, manufacturing, formulation or in consumer products.

Human Health Assessment

Based on the available hazard information for surrogate data on structurally related chemicals, the substance is expected to have a moderate acute toxicity by oral route (median lethal dose (LD_{50}) 300-2000 mg/kg body weight), a low acute toxicity by dermal route (LD_{50} > 2000 mg/kg body weight), a moderate chronic toxicity following repeat oral doses in mammalian test animals (2 years no-observed-adverse-effect level (NOAEL) of >100 mg/kg bw/day), a very high reproductive and developmental toxicity following repeat oral doses in three mammalian test species (NOAEL <50 mg/kg bw/day), and a moderate subchronic toxicity by the dermal route in mammalian test animals. It is not expected to be a skin sensitizer (guinea pig maximization test). It is not expected to be mutagenic *in vitro* or *in vivo* and is not expected to be clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI), which is the estimated long-term exposure without risk of adverse health effects, was calculated to be between 10-100 µg/kg bw/day for oral exposure based on a reproductive and developmental toxicity study. For dermal exposure, the PTDI was calculated to be between 1-10 mg/kg bw/day based on the subchronic dermal toxicity study.

When the notified substance is used in oil recovery applications, direct exposure of the general public is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels between 0.1-1 µg/kg-bw/day for adults and between 1-10 µg/kg-bw/day for children. If potential uses of the substance were to include personal care products, direct exposure of the general public is expected to be mainly by contact with skin at levels between 0.01-0.1 mg/kg bw/day. For house cleaning products, direct exposure of the general public is expected to be from inhalation, ingestion and dermal contact at levels between 0.0001-0.001 mg/kg bw/day, 0.001-0.01 mg/kg bw/day, and 0.01-0.1 mg/kg bw/day, respectively. If the substance is used in offshore oil recovery applications, indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels between 1-10 µg/kg bw/day.

Because all estimated human exposures are less than the PTDI, meaning at levels that do not pose a concern, 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

The substance is suspected to be harmful to the environment according to the criteria under paragraph 64(*a*), but not according to the criteria under paragraph 64(*b*) or to human health under paragraph (*c*) of the Act.

Due to the identified risk to the environment related to the aquatic toxicity, a ministerial condition was issued to restrict the manner in which the notifier may manufacture or import the substance with conditions on its use, disposal, environmental release and record-keeping in order to mitigate these potential risks. Ministerial Condition No. 19725 was published in the *Canada Gazette* Part I, Vol. 153, No. 8 on February 23, 2019.

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.