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

New Substances Notification 21338: Sulfonic acids, branched alkane hydroxy and branched alkene, sodium salts (Confidential Accession Number 18520-7)

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, its manufacture and import are authorized subject to conditions as described in Ministerial Condition No. 21338 published in the *Canada Gazette* Part I, Vol. 157, No. 3 on January 21, 2023.

Substance identity

The notified chemical is sulfonic acids, branched alkane hydroxyl and branched alkene, sodium salts (Confidential Accession No. 18520-7), and is considered a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as an additive for oilfield applications. Potential uses may include household cleaning products, cosmetics, and the manufacturing of textiles and leather.

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. As a surfactant, some of the substance will also be present at the surface of the water or suspended organic matter. The substance is not expected to be persistent in this compartment based on its expected inherent biodegradation (30-60% over 28 days). The substance is not expected to bioaccumulate based on the low bioconcentration factors for analogue substances (< 250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance has moderate to high acute toxicity to freshwater fish (median lethal concentration (LC_{50}) < 100 mg/L), moderate acute toxicity to

freshwater invertebrates (median effective concentration (EC_{50}) 1-100 mg/L), moderate acute toxicity to freshwater algae (EC_{50} 1-100 mg/L), and low to moderate chronic toxicity to freshwater algae (no-observed-effect concentration > 0.1 mg/L). The substance is expected to have low to moderate acute toxicity to saltwater fish (LC_{50} 1-100 mg/L; median lethal loading rate (LL_{50}) > 100 mg/L), low acute toxicity to saltwater invertebrates (EC_{50} > 100 mg/L; LL_{50} > 100 mg/L), and moderate acute toxicity to saltwater algae (EC_{50} 1-100 mg/L). Using the LC_{50} from the most sensitive organism (freshwater fish) and by applying an assessment factor of 20 to account for acute to chronic extrapolation 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 risk to the environment.

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 predicted environmental concentrations (PECs) in the range of 0.1-100 µg/L. For potential activities such as manufacturing, formulation, or use in consumer products, environmental exposure is expected to be mainly from release of the substance to water resulting in PECs in the range of 10-100 µg/L.

Comparing the PECs for certain activities with the PNEC, the ratios are greater than 1. This, along with all other available lines of evidence, indicates that the substance is anticipated to cause harm to the environment in Canada. Risks have been identified with release of the substance to water when disposed of after transportation vessel cleaning or after end-use in consumer products, or when used in manufacturing or product formulation.

Human health risk assessment

Based on the available hazard information, the 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), and a moderate to high acute toxicity by the dermal route (LD_{50} 200-2000 mg/kg-bw). It is expected to have moderate subchronic toxicity following repeated oral doses in mammalian test animals (90-day no-observed-adverse-effect level (NOAEL) 10-100 mg/kg-bw/day) and low subchronic toxicity following repeated dermal doses in mammalian test animals (90-day NOAEL > 200 mg/kg-bw/day). The substance is expected to have a moderate reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOAEL 30-300 mg/kg-bw/day). It is not expected to be a skin sensitizer (guinea pig maximization test, local lymph node assay and in a human repeated insult patch test). It is not expected to be mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The Points of Departure (POD) were based on the NOAELs of the subchronic oral and dermal toxicity studies in mammalian test animals.

When the notified substance is used as an additive for oilfield applications, direct exposure of the general population is not expected due to the industrial nature of the use. Potential uses of the substance include cosmetics, where direct exposure of the general population is expected

to be mainly by contact with the skin at levels in the range of 1-10 mg/kg-bw/day for children and adults. Potential uses of the substance also include cleaning products, where direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range of 0.01-1.0 mg/kg-bw/day for children and adults. Indirect oral exposure of the general population from environmental media is estimated to be maximally at levels in the range of 0.001-0.01 mg/kg-bw/day for children and adults.

The target margin of exposure (MOE_T) was calculated to be 30 based on the available information. The MOE_T is the level of exposure at or above which there is no expected risk in the exposed population. The derived margin of exposure (MOE_D) is the ratio of the POD value to the available exposure doses and is compared to the MOE_T. As the MOE_D is higher than the MOE_T for all estimated human exposures, 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.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

Assessment conclusion

The substance is suspected to have a harmful effect on the environment according to the criteria under paragraph 64 (*a*) but not (*b*) of the Act, and is not suspected to constitute a danger to human health according to the criteria under paragraph 64 (*c*) of the Act.

Due to the identified risk to the environment related to 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, handling and disposal in order to mitigate these potential risks. Ministerial Condition No. 21338 was published in the *Canada Gazette* Part I, Vol. 157, No. 3 on January 21, 2023.

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 the workplace.