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

New Substances Notification No. 18067: Quaternary ammonium compounds, bis(hydrogenated tallow alkyl)dimethyl, chlorides, reaction products with polyethylenepolyamines and tall-oil fatty acids, humates hydrochlorides

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 that 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

Quaternary ammonium compounds, bis(hydrogenated tallow alkyl)dimethyl, chlorides, reaction products with polyethylenepolyamines and tall-oil fatty acids, humates hydrochlorides (Chemical Abstracts Service Registry No. 68910-55-4) is a chemical of unknown or variable composition, complex reaction products, or biological material (UVCB) that can be classified as a quaternary ammonium compound.

Notified and Potential Activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for use as a component of drilling mud systems in oil field applications. No other activities are anticipated in Canada.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to soil and sediment. The substance is expected to be persistent in soil and sediment based on its long half-life (>182 and >365 days, respectively). The substance is not expected to bioaccumulate based on its high molecular weight making it unlikely to cross biological membranes.

Ecological Assessment

Based on the available hazard information on the substance, the substance has low acute toxicity in fish, invertebrates and algae (median lethal concentration (LC_{50}) and median effective concentration >100 mg/L). Calculation of the predicted no-effect concentration was not considered necessary given the low ecotoxicty.

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 and potential activities is expected to be minimal as no releases are expected during transportation and onshore drilling, or during manufacture or offshore drilling. The predicted environmental concentration for notified or potential activities was not calculated.

Based on the predicted low toxicity to aquatic organisms and low potential for environmental exposure, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on the substance, the substance has a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg-bw) and a low to moderate potential by the inhalation route of exposure (LC_{50} >1 mg/L). The substance has a low to moderate potential for subchronic toxicity following repeat inhalation doses in mammalian test animals (28-day no-observed-adverse-effect concentration (NOAEC) >0.6 mg/L/d and 40-50 day NOAEC = 0.04-0.4 mg/L/d), and a high potential for reproductive toxicity following inhalation exposure (NOAEC = 0.1-0.5 mg/L/d). It is not a sensitizer and it is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When used as a component of drilling mud systems in oilfield applications and other potential uses in offshore oilfield applications, direct exposure of the general population is not expected as the use is industrial in nature. Indirect exposure of the general population from environmental media such as drinking water, air or soil is not expected given that the substance does not partition to water or the atmosphere and has low mobility in soils. No additional uses were identified for the substance.

Based on the 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

The substance is not suspected 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 the *Hazardous Products Regulations* for products intended for workplace use.