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

New Substances Notification No. 18581: Quaternary ammonium compounds, benzylalkyldimethyl, salts with bentonite

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 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 chemical, benzylalkyldimethyl, salts with bentonite (Confidential Accession No. 19227-5), is a substance of unknown or variable composition, complex reaction products, or biological material (UVCB) that can be classified as an organoclay, quaternary ammonium compound.

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for use as an additive in consumer products. Potential uses may include pollutant remediation.

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 not expected to be persistent in soil and sediment based on ready biodegradation data (10-30 %). The substance is not expected to bioaccumulate based on its very low octanol-water partition coefficient (log $K_{ow} \leq 0$). In addition, its high molecular weight and large particle size limit its ability to cross biological membranes.

Ecological Assessment

Based on the available hazard information, the substance has low acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration (LC_{50}) and median effective concentration (EC_{50}) >100 mg/L). Surrogate data on quaternary ammonium compounds indicate moderate acute toxicity in fish and aquatic invertebrates (LC_{50} and EC_{50} 1-100 mg/L) and moderate to high chronic toxicity in fish, aquatic invertebrates, and algae (no-observed-effect concentration (NOEC) <10 mg/L). This difference in toxicity suggests that the rate of release of quaternary ammonium compounds from the clay matrix of the substance is likely low enough to mitigate toxicity. Using the EC_{50} from the most sensitive organism (aquatic invertebrate) for the surrogate

quaternary ammonium compound and by applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) for the aquatic environment was calculated to be 10-100 µg/L, which was used to estimate the aquatic ecological risk.

Based on surrogate data on quaternary ammonium compounds, the substance is expected to have low toxicity in terrestrial plants, soil invertebrates and sediment invertebrates (EC_{50} and NOEC >100 mg/kg soil dry weight (dw)). Using the NOEC from the most sensitive organism (soil invertebrates) and by applying an appropriate assessment factor, the PNEC for the soil environment was calculated to be 100-1000 mg/kg soil dw, which was used to estimate the terrestrial 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 the formulation and blending of end-use products by release of the substance to water. The predicted environmental concentrations (PEC) were estimated to be 0.1-100 µg/L in the aquatic environment for notified activities. Environmental exposure from potential activities is expected to be mainly from pollutant remediation or manufacturing. The PEC for potential activities is estimated to be 1-10 µg/L in the aquatic environment, and 0.1-1 mg/kg in the terrestrial environment.

Comparing the PEC with the PNEC in aquatic and terrestrial environments, 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 the substance and surrogate data on structurally related chemicals, the substance is expected to have a low potential for acute toxicity by the oral, dermal and inhalation routes of exposure (oral and dermal median lethal dose >2000 mg/kg body weight, inhalation LC_{50} >20 mg/L) and a low potential for subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level >300 mg/kg-bw/d). It is a non-sensitizer (0-8% response (guinea pig maximization test)). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When used as an additive in consumer products, direct exposure of the general population is mainly by contact with the skin at low levels. Given the high molecular weight and very low octanol-water partition coefficient ($\log K_{ow} \leq 0$) of the substance, it is not expected to cross biological membranes. Indirect exposure of the general population from environmental media such as drinking water is expected to be low.

Based on the low potential for direct or indirect exposure and the low toxicity, 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 uses, it 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.