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

New Substances Notification No. 18036: D-Glucitol, 1-deoxy-1-(methylamino)-, *N*-C_{8-10} acyl derivatives

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

D-Glucitol, 1-deoxy-1-(methylamino)-, *N*-C_{8-10} acyl derivatives (Chemical Abstracts Service Registry No. 1591782-62-5) is a chemical that can be classified as a nonionic surfactant.

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities to a maximum of 10 000 kg/yr for use as surfactant in oil and gas fracturing. Potential uses may include acting as a surfactant in shampoos or dishwashing detergents.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water. The substance is not expected to be persistent in environmental media (water, soil, or sediment) because it is readily biodegradable. The substance is not expected to bioaccumulate based on its low octanol-water partition coefficient ($\log K_{ow}$ 0-3) and because it is readily biodegradable.

Ecological Assessment

Based on the available hazard information on the substance and data on a structurally related chemical, the substance has low to moderate acute toxicity in aquatic organisms (median lethal concentration (LC_{50}) and median effective concentration >1 mg/L) . The predicted no-effect concentration (PNEC) was calculated to be 100-10 000 µg/L using the LC_{50} for the surrogate substance from the most sensitive organism (fish), which was used to estimate the ecological risk.

The notified and other potential activities in Canada, such as a surfactant in shampoos and dishwashing detergent, 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 transportation vessels (drums) and formulation by release of the substance to water. The predicted environmental concentration (PEC) for the notified activity is estimated to be 0.1-1 µg/L. Environmental exposure from potential activities is expected to be mainly from manufacturing and transportation vessels (totes) by release of the substance to water. The PEC for other potential activities is estimated to be 1-100 µg/L.

Based on the risk quotient which is much less than 1, 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 a structurally related chemical, the substance has a moderate potential for acute toxicity by the oral route of exposure (median lethal dose (LD_{50}) >300-2000 mg/kg), and a low potential for acute toxicity by the inhalation and dermal routes of exposure (LC_{50} > 20 mg/L and LD_{50} >2000 mg/kg, respectively). The substance has a moderate potential for subchronic toxicity by the oral route of exposure (28-day no-observed-adverse-effect level (NOAEL) 30-300 mg/kg bw/day) . The substance has a low potential for developmental toxicity. It is not a skin irritant or sensitizer. It is not mutagenic *in vitro* or clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The substance is not an endocrine disruptor. The provisional tolerable daily intake (PTDI) was calculated to be 1-10 mg/kg-bw/d based on the NOAEL of 30-300 mg/kg-bw/d from the repeated dose study in mammalian test animals.

When used as a surfactant in oil and gas fracturing, direct exposure of the general population is not expected. Indirect exposure of the general population from environmental media such as drinking water is expected to be low. When used for other potential activities including as a surfactant in shampoos or dishwashing detergents, direct exposure of the general population is expected to be mainly by contact with the skin at levels of 1-100 µg/kg-bw/d.

Based on the lack of direct exposure associated with the notified use and based on a comparison of the PTDI to the estimated exposure for potential uses, 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 used as notified or for other identified potential uses, 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.