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

New Substances Notification No. 19090: D-Glucitol, 1-deoxy-1-(methylamino)-, *N*-coco 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 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 notified chemical is D-glucitol, 1-deoxy-1-(methylamino)-, *N*-coco acyl derivatives (Chemical Abstracts Service No. 1591783-13-9), and is considered a substance of unknown or variable composition, complex reaction products and biological materials (UVCB).

Notified and potential activities

The substance is proposed to be imported into Canada in quantities up to 10 000 kg/yr for the notified use as a surfactant in household cleaners and personal care products. Potential uses may include use as an oil and gas fracturing flowback aid.

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 water. The substance is not expected to be persistent in soil or water based on its expected high ready biodegradation (60-85% over 28 days). The substance is not expected to bioaccumulate based on its low predicted bioconcentration factor (<250 L/kg).

Ecological assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has moderate acute toxicity in fish (median lethal concentration 1-100 mg/L) and high acute toxicity in aquatic invertebrates (median effective concentration (EC_{50}) <1 mg/L). The substance is expected to have moderate chronic toxicity in aquatic invertebrates (no-observed-effect-concentration (NOEC) and lowest-observed-effect-concentration 1-10 mg/L; 21-d EC_{50} 1-100 mg/L) and low chronic toxicity in algae (NOEC >10 mg/L). It has low chronic toxicity in plants and soil organisms (NOEC >10 mg/kg dry soil) and low chronic toxicity in soil microorganisms (7-, 14- and 28-day NOEC >10 mg/kg dry soil). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 50 to account for species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be between 10 and 100 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 activities is expected to be mainly from blending, formulation and use by consumers by release of the substance to water, resulting in a predicted environmental concentration (PEC) between 0.01 and 0.1 µg/L. For potential activities such oil and gas fracturing applications, environmental exposure is expected to be quantitatively similar to that of the notified use.

Comparing the PEC with the PNEC, 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 hazard information on the substance and surrogate data on structurally related chemicals, the substance has a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >300 mg/kg body weight with no systemic toxicity) and low subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level >300 mg/kg-bw/day). It is not a skin sensitizer (0-8% response (guinea pig maximization test)). It is not mutagenic *in vitro* or clastogenic *in vivo*, and is not expected to be clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a surfactant for personal care products, direct exposure of the general population is expected to be mainly by contact with the skin at levels of 10 to 100 µg/kg bw/d for adults and 100 to 1000 µg/kg bw/d for children. When the notified substance is used as a surfactant in household cleaners, direct exposure of the general population is expected to be mainly by contact with the skin at levels of 1 to 10 µg/kg bw/d for adults. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels of 0.001 to 0.01 µg/kg bw/d for adults and children.

If the substance is used as an oil and gas fracturing flowback aid, direct exposure of the general population 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 expected to be at low levels for adults and children.

Based on the low toxicity and 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

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 *Hazardous Products Regulations* for products intended for the workplace.