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

New Substances Notification No. 19043: Amides, tall-oil fatty, *N*-(hydroxyethyl), ethoxylated

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 polymer is amides, tall-oil fatty, *N*-(hydroxyethyl), ethoxylated (Chemical Abstracts Service No. 501019-85-8). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because its number average molecular weight is less than 1000 daltons.

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as a dispersing agent in paint formulations. Potential uses may include a variety of industrial and commercial applications, such as use as a foam stabilizer, emulsifier, suspending agent, antistatic agent, solubilizer coupling agent, fulling agent, scouring agent or wetting agent in metal working fluids, and use in consumer applications such as personal care products and cleaning products.

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 water based on its expected moderate to high biodegradability (30-85%). The substance is not expected to bioaccumulate because it is a surfactant.

Ecological assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have moderate acute toxicity in fish and aquatic invertebrates (median lethal concentration (LC_{50}) and median effective concentration 1-100 mg/L) and moderate chronic toxicity in algae (10% effective loading rate 0.1-10 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying an assessment factor of 50 to account for acute to chronic extrapolation and species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be between 0.01 and 0.1 mg/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 formulation by release of the substance to water at rates of 1 to 10 kg/day/site. The predicted environmental concentration (PEC) is estimated to be between 0.001 and 0.01 mg/L for notified activities. For potential activities such as manufacturing, environmental exposure is not expected to exceed that of the notified use.

Comparing the PEC for notified activities 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 route of exposure (median lethal dose >2000 mg/kg body weight) and is expected to have a low potential for acute toxicity by the dermal and inhalation routes of exposure. The notified substance is expected to have 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% response (Buehler scale)). It is not expected to be mutagenic *in vitro* or clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a dispersing agent in paints, consumers may come into contact with end-use products containing the substance at moderate levels. Direct exposure will be limited by the low frequency of use of products containing the substance and the low rate of diffusion of the substance through paint. Once the paint is cured, the substance will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is expected to be low given the low PEC and the moderate to high biodegradability of the substance which will further reduce the concentration of the substance in drinking water.

If the substance is used in industrial metal working fluids, direct and indirect exposure of the general population is not expected. If the substance is used in personal care products or consumer cleaning products, direct exposure of the general population is expected to be mainly by contact with the skin at moderate to high levels. However, based on the low potential for toxicity following acute and short-term repeated exposure, the notified substance would not be expected to pose a significant direct health risk to the general population. Indirect exposure of the general population from environmental media such as drinking water is expected to be similar to that of the notified use.

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