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

New Substances Notification 20773: Fatty acids, tall-oil, reaction products with 2-[(2-aminoethyl)amino]ethanol (Chemical Abstracts Service Registry Number 68919-76-6)

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 fatty acids, tall-oil, reaction products with 2-[(2-aminoethyl)amino]ethanol (Chemical Abstracts Service Registry Number[1] 68919-76-6), and is considered a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities up to or greater than 10 000 kg/yr for the notified use as an additive in coatings. Potential uses may include Do-It-Yourself (DIY) consumer products and personal care products.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to soil and sediment. As a surfactant, some of the substance will also be present at the surface of the water or suspended organic matter. The substance is expected to persist in these compartments because it is not readily biodegradable (≤ 10% over 28 days). The substance is not expected to bioaccumulate (bioconcentration factor < 250 L/kg).

Environmental risk assessment

[1] The Chemical Abstracts Service Registry Number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

Based on the available hazard information, the substance has high acute toxicity to aquatic invertebrates (median effective concentration (EC_{50}) < 1 mg/L), moderate chronic toxicity to aquatic invertebrates (no-observed-effect-concentration (NOEC) and lowest-observed-effect-concentration 0.1-10 mg/L), high chronic toxicity to algae (10% effective concentration < 0.1 mg/L), and low chronic toxicity to terrestrial invertebrates (NOEC > 100 mg/kg dry soil). The substance is expected to have moderate-to-high acute toxicity to fish (median lethal concentration < 100 mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates), and by applying an assessment factor of 20 to account for extrapolation from severe effects to no sub-lethal effects and species sensitivity variation, the predicted no effect concentration (PNEC) was calculated to be in the range of 1-10 µg/L, which was used to estimate the risk to the environment.

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 cleaning of transportation vessels by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L with the exact value being below the PNEC value. For potential activities such as manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 1-10 µg/L, also below the PNEC.

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 harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance has low acute toxicity by the oral and dermal routes (median lethal dose > 2000 mg/kg body weight). The substance has moderate subchronic toxicity following repeated oral doses in mammalian test animals (90-day no-observed-adverse-effect level (NOAEL) 10-100 mg/kg-bw/day). The substance is expected to have a low to moderate reproductive/developmental toxicity following repeated oral doses in mammalian test animals as no adverse effects on reproduction or development were reported within the range of doses tested (20-200 mg/kg-bw/day). It is not expected to be a dermal sensitizer (local lymph node assay). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used industrially in coatings, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media is not expected given the specialized industrial use of the substance, which results in little or no release to the environment. Potential uses of the substance include DIY consumer products and personal care products, where direct exposure of the general population is expected to be mainly by contact with the skin at levels of 0.001-0.01 mg/kg/day

for DIY products and 0.01-0.1 mg/kg/day for personal care products. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels in the range of 10^{-5}-10^{-4} mg/kg/day and mainly by ingestion.

Based on the available information, the target margin of exposure (MOE_T) was calculated to be 100 for direct dermal exposure to the substance in personal care products and in DIY products. An MOE_T of 1000 was calculated for indirect oral exposure through drinking water. The MOE_T is the level of exposure at or above which there is no expected risk in the exposed population. The derived margin of exposure (MOE_D) is the ratio of the point of departure value to the available exposure doses and is compared to the MOE_T. As the MOE_D is higher than the MOE_T for all estimated human exposures, 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.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

Assessment conclusion

When the substance is used as notified or for other identified potential activities, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

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 the workplace.