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

New Substances Notification 20191: Amines, polyethylenepoly-, reaction products with succinic anhydride polyalkenyl derivs., metalloid salt (Confidential Accession Number 19433-1)

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 amines, polyethylenepoly-, reaction products with succinic anhydride polyalkenyl derivs., metalloid salt (Confidential Accession No. 19433-1). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains potentially cationic amines.

Notified and potential uses

The substance is proposed to be imported into Canada in quantities less than 10 000 kg/yr for the notified use as a dispersant in automotive fluids. Potential uses include as an emulsifier in the mining industry, in lubricating oil, gasoline, lubricants, hydraulic fluids, and in cutting fluids.

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. The substance is expected to be persistent in these compartments based on its low biodegradation (10-30% over 28 days). The substance is not expected to bioaccumulate based on its high molecular weight which will limit its ability to cross biological membranes.

Ecological assessment

Based on the available hazard information, the substance is expected to have low to moderate acute toxicity to fish and daphnia (median lethal concentration (LC_{50}) 1-100 mg/L; median lethal loading rate and median effective loading rate >100 mg/L), moderate to high acute toxicity to algae (median effective concentration (EC_{50}) <10 mg/L), low acute toxicity to soil invertebrates (LC_{50} >100 mg/kg dry soil), low chronic toxicity to daphnia (no-observed-effect loading rate 1-10 mg/L) and low chronic toxicity to algae (no-observed-effect loading rate >10 mg/L). Using the EC_{50} from the most sensitive organism (algae) and by applying an assessment factor of 20 to account for acute to chronic extrapolation, species sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100 μg/L, which was used to estimate the ecological risk.

The notified activity in Canada was assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activity is expected to be mainly from use from release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 μg/L. No potential activities which could significantly increase environmental risks compared to those notified were identified.

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 available hazard information, the substance is expected to have a low acute toxicity by the oral and dermal routes (median lethal dose (LD_{50}) >2000 mg/kg body weight) and low subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/day). The substance is expected to have low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOAEL >300 mg/kg-bw/day). It is not expected to be a dermal sensitizer (0% response (Buehler test)). It is not expected to be mutagenic *in vitro* 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 dispersant in automotive fluids, consumers may come into contact with end-use products containing the substance; however, the potential for direct exposure is expected to be low because of the infrequent use, the high molecular weight which will limit absorption, and the low concentration of the substance used in end-use products. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels given the low potential for environmental release. No potential uses which could significantly increase human health risks compared to the notified uses were identified.

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