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

New Substances Notification 20171: Heteropolycyclic alkanol, carbomonocycle-, alkanesulfonate (Confidential Accession Number 19434-2)

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 heteropolycyclic alkanol, carbomonocycle-, alkanesulfonate (Confidential Accession No. 19434-2).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in industrial cooling systems. Potential uses may include manufacturing, industrial application in metalworking fluids, as a precursor or catalyst, as a photosensitive compound, as a polymer additive, and as an electrolyte.

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 water. The substance is not expected to be persistent in water based on its moderate biodegradability (30-60% over 28 days). The substance is not expected to bioaccumulate based on its low experimental octanol-water partition coefficient (log K_{ow} <3) and low predicted bioaccumulation and bioconcentration factors (<250 L/kg).

Ecological assessment

Based on the available hazard information, the substance has low to moderate acute toxicity to fish (median lethal concentration (LC_{50}) >1 mg/L), moderate acute toxicity to aquatic invertebrates and algae (median effective concentration (EC_{50}) and LC_{50} 1-100 mg/L) and moderate chronic toxicity to algae (10% effective concentration 0.1-10 mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 40 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 1000-10 000 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 activity is expected to be mainly from cleaning of transportation vessels and use in industrial cooling

systems from release of the substance to water resulting in predicted environmental concentrations (PECs) in the range of 1-10 µg/L. For potential activities such as cleaning of different transport vessels and use in other industrial applications, environmental exposure is expected to be mainly from release of the substance to water resulting in PECs in the range of 100-1000 µg/L. For potential activities such as manufacturing and formulation, environmental exposure is expected to be mainly from release of the substance to water resulting in PECs in the range of 10-100 µg/L and 1-10 µg/L, respectively.

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 route (median lethal dose >2000 mg/kg body weight) and low subchronic toxicity following repeated oral doses in mammalian test animals (42-day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/day). The substance is expected to have a moderate reproductive/developmental toxicity following repeated oral doses in mammalian test animals (lowest-observed-adverse-effect level >100 mg/kg-bw/day). It is a weak dermal sensitizer (estimated concentration required to produce a stimulation index of 3 >10% (local lymph node assay)). It is expected to be mutagenic *in vitro* in bacteria and equivocal in mammalian cells. It is not clastogenic *in vitro.* However, it is negative for genotoxicity *in vivo* in three different organs (comet assay). By weight of evidence, the substance is unlikely to cause genetic damage to humans. The provisional tolerable daily intake (PTDI) was calculated to be in the range of 0.1-1.0 mg/kg bw/day based on the oral NOAEL of the reproductive/developmental toxicity study in mammalian test animals. The PTDI is the estimated level of long-term exposure without risk of adverse health effects.

When the notified substance is used in industrial cooling systems, 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 conservatively estimated to be at levels in the range of 10^{-5} to 10^{-4} mg/kg-bw/day for children and adults. Potential uses of the substance include other industrial uses, where direct exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 0.01-0.1 mg/kg-bw/day for children and adults.

Because all estimated human exposures are less than the PTDI, meaning at levels that do not pose a concern, 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 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.