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

New Substances Notification 19424: Amines, *N*'-[3-[(3-aminopropyl)amino]propyl]-*N*,*N*-bis(hydrogenated tallow alkyl)trimethylenedi- (Chemical Abstracts Service Registry Number 1884578-89-5)

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 amines, *N*'-[3-[(3-aminopropyl)amino]propyl]-*N*,*N*-bis(hydrogenated tallow alkyl)trimethylenedi- (Chemical Abstracts Service Registry Number[1] 1884578-89-5), and is considered a substance of unknown or variable composition, complex reaction products or biological materials (UVCB).

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 in industrial lubricants. Potential uses may include consumer products such as paints and coatings, and a variety of industrial applications as emulsifiers, dispersing agents, corrosion inhibitors and epoxy curing agents.

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 sediment. The substance is expected to be persistent in these compartments based on its very low biodegradability (≤10% over 28 days). The substance is not expected to bioaccumulate based on its low water solubility (0.01-10 mg/L) which will limit its ability to cross biological membranes, and its low bioaccumulation and bioconcentration factors (<250 L/kg).

Ecological assessment

Based on the available hazard information, the substance has low acute toxicity in fish (no adverse effects observed in saturated solutions) and high acute toxicity in aquatic invertebrates (median

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effective concentration <1 mg/L). The substance has moderate chronic toxicity in aquatic invertebrates (no-observed-effect concentration (NOEC) and 10% effective concentration (EC_{10}) 0.1-10 mg/L) and high chronic toxicity in algae (EC_{10} <0.1 mg/L). The substance has low chronic toxicity in soil organisms (NOEC >10 mg/kg dry soil). Using the EC_{10} from the most sensitive organism (algae) and by applying an assessment factor of 10 to account for 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 ecological risk.

The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substances throughout its life cycle. Environmental exposure from the notified activity is expected to be mainly from cleaning of transportation containers, with release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.1-1 µg/L. For potential activities such as manufacturing, formulation, and other industrial or consumer uses, environmental exposure is expected to be mainly from the release of the substance to water resulting in a PEC in the range of 1-10 µg/L. For potential use in metalworking fluids, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 0.1-1 µg/L.

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 has a low potential for acute toxicity by the oral route of exposure (median lethal dose >2000 mg/kg body weight) and moderate subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) 30-300 mg/kg-bw/day). The notified substance has low potential for reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL >1000 mg/kg-bw/day with no developmental effects observed). It is not skin sensitizers (0-8% response (guinea pig maximization test)). It is not mutagenic *in vitro* or clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in industrial lubricants, direct exposure of the general population is not expected due to the industrial nature of the use. Potential uses of the substance include consumer products such as paints and coatings, where direct exposure of the general population is expected to be mainly by contact with the skin at negligible levels given the very high octanol-water partition coefficient (log K_{ow} >8) which will limit systemic uptake. Indirect exposure of the general population from environmental media such as drinking water resulting from notified or potential uses is expected to be negligible given the low water solubility.

Based on the low potential for exposure, the substance is not likely to pose a significant health risk to the general population, and are 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.