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

New Substances Notification No. 19141: Amides, from dialkyleneamine and rape oil (Confidential Accession No. 19201-9)

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 amides, from dialkyleneamine and rape oil (Confidential Accession No. 19201-9), and is a substance referred to as unknown or variable composition, complex reaction products or biological materials (UVCB).

Notified and potential activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for the notified use in automotive coatings. Potential industrial uses may include use as a corrosion inhibitor or anti-scaling agent. Potential commercial and/or consumer uses may include adhesives, sealants, agricultural products, paints and coatings, paper and wood products, plastic products, fuel additives and lubricants and greases.

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 not expected to be persistent in soil and sediment based on its high ready biodegradation (60-85% 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, supported by its low predicted bioaccumulation and bioconcentration factors (<250 L/kg).

Ecological assessment

Based on the hazard information, the substance is expected to have low acute toxicity in fish and aquatic invertebrates (no adverse effects observed in saturated solutions) and low chronic toxicity in algae (no adverse effects observed in saturated solutions). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

The notified 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 by release of the substance to water at low rates. A predicted environmental concentration was not calculated due to the low potential for ecotoxicity. No potential activities which could significantly increase environmental risks compared to those notified were identified.

Based on the low potential for ecotoxicity, 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 and dermal routes (median lethal dose >2000 mg/kg body weight) and low subchronic toxicity following repeat oral doses in mammalian test animals (43-day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/day). The substance has a low potential for reproductive/developmental toxicity following repeat oral doses in mammalian test animals (no-observed-effect level >250 mg/kg-bw/day with no observed adverse effects). It is a moderate dermal sensitizer (1-10% concentration of substance expected to induce stimulation index of 3 (local lymph node assay)). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as in automotive coatings, 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 is not expected given the specialized industrial and commercial use of the substance, which results in little or no release to the environment. If the substance is used for potential commercial or industrial uses, direct and indirect exposure of the general population is expected to be similar to that of the notified use. If the substance is used in consumer lubricants, greases, paints and coatings, direct exposure of the general population is expected to be mainly by contact with the skin at low levels given the high molecular weight and high octanol-water partition coefficient (log K_{ow} >8) of the substance which will limit systemic uptake. Potential exposure will also be limited by the infrequent use of products containing the substance.

Based on its low to moderate 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 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.