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

New Substances Notifications No. 19036 and 19374: Amines, coco alkyl, ethoxylated, compounds with polyethylene glycol monooleyl ether phosphate

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, coco alkyl, ethoxylated, compounds with polyethylene glycol monooleyl ether phosphate (Chemical Abstracts Service No. 120968-16-3). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because its number average molecular weight is less than 1000 daltons, and it contains cationic amine groups and phosphorus above 0.2 % by weight.

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 paints and coatings. Potential uses may include a variety of applications such as use in pharmaceuticals, cosmetics, cleaning products and plastics/textiles.

Environmental fate and behaviour

If released into the environment, the notified substance is expected to dissociate into two components, a cocoalkyl amine polyethyoxylate (CAP) and a polyethoxylated phosphate (PEP). Based on their physical and chemical properties, if released to the environment, the CAP portion of the substance will tend to partition to soil and sediment and the PEP portion will tend to partition to water. The CAP component of the substance is not expected to be persistent in soil and sediment as it is inherently biodegradable. The PEP component of the substance is also not expected to be persistent in water based on the biodegradation observed for a structurally related chemical. The CAP and PEP components of the substance are not expected to bioaccumulate based on their low to moderate bioconcentration factors (<1000 L/kg).

Ecological assessment

Based on the hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have moderate acute toxicity in fish and aquatic invertebrates (median lethal concentration (LC_{50}) and median effective concentration (EC_{50}) 1-100 mg/L) and moderate chronic

toxicity in algae (EC_{50} 1-100 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying an assessment factor of 100 to account for species sensitivity variation and acute to chronic toxicity extrapolation, the predicted no-effect concentration (PNEC) was calculated to be between 10 and 100 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 activities is expected to be mainly by release of the substance to water from cleaning of transportation vessels resulting in release rates of 10 to 100 kg/day/site, formulation activities resulting in release rates of 0.1 to 1 kg/day, and use of the substance in industrial paint or pigment applications resulting in release rates of 1 to 10 kg/day. For potential activities such as manufacturing, environmental exposure is expected to be similar to that of the notified use. The predicted environmental concentrations (PECs) for the notified uses are estimated to be between 10 and 100 µg/L for cleaning of transportation vessels and use in paints and pigments, and between 0.1 and 1 µg/L for formulation. The PEC for the potential manufacturing activities is between 10 and 100 µg/L.

Comparing the PEC for notified and potential activities 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 hazard information on the substance, the substance has a low potential for acute toxicity by the oral route of exposure (median lethal dose (LD_{50}) >2000 mg/kg body weight).

The hazard information on the two components (CAP and PEP) of the substance was also used in the assessment. Both components were negative for skin sensitization and were negative for *in vitro* mutagenicity and *in vitro* clastogenicity. CAP was negative for clastogenicity *in vivo*.

Based on available toxicity and surrogate data for chemicals structurally similar substances to the CAP component, CAP is expected to have moderate subchronic toxicity (90-day no-observed-effect level 10-100 mg/kg-bw/day), high reproductive toxicity (no-observed-adverse-effect level (NOAEL) <50 mg/kg-bw/day), and moderate developmental toxicity (NOAEL 250-1000 mg/kg-bw/day) following repeat oral doses in mammalian test animals.

Based on available hazard information for chemicals structurally similar to the PEP component of the notified substance, PEP is expected to have low subchronic toxicity following repeat dermal doses in mammalian test animals (28-day NOAEL >600 mg/kg-bw/day) and low reproductive and developmental toxicity (NOAEL >1000 mg/kg-b/day).

As a salt of two components the substance is expected to have lower irritation potency which in turn leads to lower toxicity potentials than either the cationic or the anionic component alone. Based on the toxicity information on the two components, the notified substance is concluded to be of low concern of genotoxicity and skin sensitization. Since the notified substance is a salt, it is likely to have lower irritation potency than the cationic and anionic components, the notified substance is likely to be of moderate concern for repeated and subchronic oral toxicity but of low concern for dermal exposure when used in non-irritating concentrations. It is expected to be of low concern for reproductive and developmental toxicity after dermal exposure.

When the notified substance is used in industrial paints and 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 cured and will be unavailable for uptake. When the notified substance is used in consumer paints and coatings, direct exposure of the general population is expected to be mainly by contact with the skin and inhalation at levels considered to be negligible given the low concentration of the substance in end-use products (≤5%), the short exposure period before paints/coatings dry and the substance is cured, use procedures (i.e., aerosol use in ventilated areas) and the limited ability of the substance to cross biological membranes (polymeric and ionic nature).

If the substance is used in consumer applications such as cosmetics and cleaning products, direct exposure of the general population is expected to be mainly by contact with the skin or by inhalation. Direct exposure via dermal contact is expected to be low given the limited ability of the substance to cross biological membranes due to its polymeric and ionic nature and high water solubility. Direct exposure via inhalation is expected to be low to moderate, which would be limited by the short duration of use and expected formulation at low concentrations. If the substance is used in other industrial applications, direct exposure of the general population is expected to be similar to that of the notified use.

Indirect exposure of the general population from environmental media such as drinking water is expected to be negligible for both notified and potential uses as the notified substance and its components are not expected to persist in the environment.

Based on the low to moderate potential for exposure and expected low to moderate toxicity, 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 uses, it is not suspected to be harmful to human health or the environment according to the criteria under section 64 of CEPA.

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.