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

New Substances Notification No. 19109: Phenol, 4-branched alkyl derivatives sulfurized, calcium salts, overbased (Confidential Accession No. 19194-2)

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 phenol, 4-branched alkyl derivatives sulfurized, calcium salts, overbased (Confidential Accession No. 19194-2), and is considered a substance of unknown or variable composition, complex reaction products and 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 as an oil additive. No other activities are anticipated in Canada.

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 soil and sediment based on its very low biodegradability (≤10% at 28 days). The substance is not expected to bioaccumulate based on its high molecular weight and low water solubility (0.01-10 mg/L) which will limit its ability to cross biological membranes.

Ecological assessment

Based on the hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have low acute toxicity in fish and aquatic invertebrates (median lethal loading rate >100 mg/L) and low chronic toxicity in algae (no-observed-effect-loading rate >10 mg/L). 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 activities is expected to be mainly from cleaning of transportation vessels by release of the substance to water at rates of 1 to 10 kg/yr. 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 and environmental exposure, 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 of exposure (oral median lethal dose (LD_{50}) >300 mg/kg body weight, dermal LD_{50} >1000 mg/kg body weight; no toxicity observed at highest doses for either exposure route) and low subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/day). The substance has a low reproductive/developmental toxicity by the oral route of exposure (NOAEL >250 mg/kg-bw/day with no significant toxicity). It is not a skin sensitizer (0% response (Buehler scale)). It is not mutagenic *in vitro* and is not clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an oil additive in consumer products, direct exposure of the general population is expected to be mainly by contact with the skin but products containing the substance are used infrequently and for short duration. Dermal absorption is expected to be at low levels given the limited ability of the substance to cross biological membranes. 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 as notified, 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.