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

New Substances Notification 19937: Phenol, alkyl derivs., reaction products with carbon dioxide, distn. residues from manuf. of phenol (polyalkenyl) derivs. and phenol (polyalkenyl) derivs., calcium salts (Confidential Accession No. 19382-0)

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, alkyl derivs., reaction products with carbon dioxide, distn. residues from manuf. of phenol (polyalkenyl) derivs. and phenol (polyalkenyl) derivs., calcium salts (Confidential Accession No. 19382-0), 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 imported into Canada in quantities greater than 10 000 kg/yr for the notified use as an oil additive. Potential uses may include use as an ingredient in asphalt.

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 sediment and soil. The substance is expected to be persistent in soil and sediment based on its low potential for biodegradation (10-30% over 28 days). The substance is not expected to bioaccumulate based on its low predicted bioconcentration factor (<250 L/kg).

Ecological assessment

Based on the available hazard information, the substance is expected to have low acute toxicity to fish and algae (no adverse effects observed in saturated solutions) and moderate acute toxicity to aquatic invertebrates (median effective loading rate (EL_{50}) 1-100 mg/L). Using the EL_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 100 to account for acute to chronic extrapolation, species sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be between 10-100 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 activity is expected to be mainly from cleaning of transportation vessels by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L. For potential activities, environmental exposure is expected to be at levels that do not pose a concern, similar to that of the notified use.

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 on surrogate data, the substance is expected to have a low acute toxicity by the oral and dermal routes (median lethal dose >2000 mg/kg body weight) and moderate to high subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) 30-300 mg/kg-bw/day, 90-day NOAEL 10-100 mg/kg-bw/day, and 2 generation parental NOAEL <5 mg/kg bw/day). The substance is expected to have a low reproductive/developmental toxicity following repeat oral doses in mammalian test animals (one generation, two generation, and teratogenicity NOAEL >100 mg/kg-bw/day). It is potentially a weak skin sensitizer as inconclusive results were obtained in guinea pig maximization and Buehler assays. It is not expected to be mutagenic *in vitro o*r clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be in the range of 10-100 µg/kg bw/day based on the NOAEL of the oral subchronic toxicity study in mammalian test animals. The PTDI is the estimated long-term exposure without risk of adverse health effects.

When the notified substance is used in oil products industrially and commercially, direct exposure of the general population is not expected due to the industrial and commercial nature of the use. Potential uses of the substance include oil products available to consumers. Direct exposure of the general population is expected to be infrequent (acute), mainly by contact with the skin at levels up to 100-1000 µg/kg bw/event. Since the substance showed low acute dermal toxicity, the substance is not likely to pose a significant direct health risk to the general population. Indirect exposure of the general population from environmental media such as drinking water from notified and potential uses is conservatively estimated to be at levels in the range of 0.01-0.1 µg/kg bw/day for children and 0.1-1 µg/kg bw/day for adults, which are levels that do not pose a concern. Therefore, the substance is 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.