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

New Substances Notification 19387: Hydrolysed reaction products of furan-2,5-dione and linear and branched alkenes (Confidential Accession No. 19287-5)

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 hydrolysed reaction products of furan-2,5-dione and linear and branched alkenes (Confidential Accession No. 19287-5), 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 imported into Canada in quantities greater than 10 000 kg/yr for the notified use as an additive in fuels. Potential uses may include a variety of industrial, commercial and consumer applications, such as laundry detergents and household cleaners, chemical intermediates, and food packaging.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released into the environment, it will tend to partition to water, soil and sediment. The substance is not expected to be persistent in these compartments based on its susceptibility to biodegradation over time (10-30% over 28 days). The substance is not expected to bioaccumulate based on its expected susceptibility to metabolic oxidation and expected low bioconcentration factor (<250 L/kg).

Ecological assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have low to moderate acute toxicity in fish (median lethal concentration 1-100 mg/L, median lethal loading rate >100 mg/L), moderate acute toxicity in aquatic invertebrates (median effective concentration (EC_{50}) 1-100 mg/L; median effective loading rate (EL_{50}) 1-100 mg/L), low acute toxicity in algae (EL_{50} >100 mg/L), and moderate chronic toxicity in aquatic invertebrates and algae (no-observed-effect concentration (NOEC) 0.1-10 mg/L). Using the NOEC from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 5 to

account for species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 0.01-0.1 mg/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 containers, with release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.001-0.01 mg/L. For potential activities such as manufacturing and use in laundry detergents, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 0.01-0.1 mg/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 for the substance and surrogate data on structurally related chemicals, the substance has low acute toxicity by the oral route (median lethal dose (LD_{50}) >2000 mg/kg body weight) and is expected to have low to moderate acute toxicity by the dermal route (LD_{50} >1000 mg/kg body weight). The substance is expected to have 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 substance is expected to have a moderate reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL 50-1000 mg/kg-bw/day). It is a strong skin sensitizer (0.1-1% estimated concentration required to produce a stimulation index of 3 (EC3) (local lymph node assay)). It is not mutagenic *in vitro* and is not expected to be clastogenic *in vitro*. 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 level of long-term exposure without risk of adverse health effects. The reference dose for skin sensitization (S-RfD) was calculated to be in the range of 1-10 µg/cm^2 based on the EC3 range of the local lymph node assay in mammalian test animals.

When the notified substance is used as an additive in fuels, direct exposure of the general population is expected to be mainly by contact with the skin at low levels given the low concentration of the substance in end-use products. In addition, its high molecular weight and expected high octanol-water partition coefficient will limit systemic uptake. 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. Potential uses of the substance include consumer detergents, where direct acute exposure of the general population is expected to be mainly by contact with the skin at levels in the range of 10-100 µg/kg-bw/day, and by inhalation at levels in the range of 0.1-1 µg/kg-bw/day. The level of residual substance on the skin was estimated to be in the range of 1-10 µg/cm^2 per event. Chronic exposure is expected to be mainly by contact with the skin at levels in the range of 0.1-1 µg/kg-bw/day, and by inhalation at levels in the range of 0.01-0.1 µg/kg-bw/day.

Because all estimated human exposures are less than the PTDI, meaning at levels that do not pose a concern, and less than the S-RfD, meaning at levels where skin sensitization is not expected, 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.