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

Significant New Activity Notification 21986: 1,2-Oxathiolane, 2,2-dioxide (Chemical Abstracts Service Registry Number 1120-71-4)

**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 subsection 81(3) of the Act, the information in respect of the substance required under Order 2012-87-06-02 Amending the Domestic Substances List was submitted to the Minister of the Environment. The Minister of the Environment and the Minister of Health have assessed this information pursuant to section 83 of CEPA and have determined that, when the substance is used in industrial applications in electric vehicle battery manufacturing or for other potential uses such as an intermediate in chemical and polymer synthesis, 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. Based on the analysis of additional information received through this notification, it is proposed to amend the Domestic Substances List so that the substance is no longer subject to the Significant New Activity provisions under subsection 81(3) of CEPA.

**Substance identity**

The notified chemical is 1,2-oxathiolane, 2,2-dioxide (Chemical Abstracts Service Registry Number[1] 1120-71-4).

**Notified uses**

The substance is proposed to be imported or manufactured into Canada in quantities up to or greater than 100 000 kg/yr for the notified industrial use in electric vehicle battery manufacturing. Potential uses include other industrial uses such as in other electrochemical devices including electrode material, electrical double-layer capacitors or batteries and as an intermediate for the synthesis of various other chemicals and polymers.

**Environmental fate and behaviour**

1 The Chemical Abstracts Service Registry Number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to water. The substance is not expected to be persistent in water based on its very short half-life in water (hydrolysis half-life ≤ 10 days) and very high ready biodegradation (> 85% over 28 days). The substance and its product of hydrolysis are not expected to bioaccumulate based on very low octanol-water partition coefficients (log $K_{ow}$ ≤ 0).

**Environmental risk assessment**

Based on the available hazard information, the substance is expected to have moderate acute toxicity to fish (median lethal concentration ($LC_{50}$) 1-100 mg/L), moderate aquatic toxicity to invertebrates (median effective concentration 1-100 mg/L), and low aquatic toxicity to algae (10% effective concentration > 10 mg/L). A predicted no-effect concentration was not calculated given the rapid hydrolysis of the substance and the low potential for hazard to the environment of the hydrolysis product.

The notified activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. A predicted environmental concentration was not calculated due to the low potential for environmental exposure. No potential activities were identified that could significantly increase environmental risks compared to those notified.

Based on the low potential for ecotoxicity and environmental exposure, along with other lines of evidence including environmental fate, hazard, and exposure, the substance is unlikely to cause harm to the environment in Canada.

**Human health risk assessment**

Based on the available hazard information, the substance has a high acute toxicity by the oral route (median lethal dose ($LD_{50}$) = 50-300 mg/kg body weight) and by inhalation ($LC_{50}$ = 2-10 mg/L), and a moderate acute toxicity by the dermal route of exposure ($LD_{50}$ = 200-1000 mg/kg-bw). It has a high chronic toxicity following repeated oral doses (lowest-observed-effect-level < 30 mg/kg-bw/day) and high chronic toxicity following repeated dermal doses in mammalian test animals (no-observed-adverse-effect level < 20 mg/kg-bw/day). It is not a dermal sensitizer (0% response in a guinea pig maximization test). It is mutagenic *in vitro* and is clastogenic *in vitro* and *in vivo*. Therefore, the substance has the potential to cause genetic damage. It is carcinogenic in mammalian test animals by the oral and dermal routes of exposure. However, the general population is not expected to be exposed to this substance based on its notified, intended, or potential uses.

When the notified substance is used industrially for manufacturing electric vehicle batteries, consumers may come into contact with end-use manufactured products containing the notified substance; however, direct exposure is not expected because the substance will be contained in a sealed battery compartment from which it is not expected to be released. Indirect exposure

of the general population from environmental media is not expected given the specialized use of the substance, which results in no expected release to the environment or, if released, the risk of exposure to the notified substance through environmental media is unlikely because it hydrolyses rapidly to form other substances that do not share the same properties.

Potential uses of the substance include other industrial uses such as in other electrochemical devices including electrode material, electrical double-layer capacitors, or batteries, where direct and indirect exposure of the general population is not expected, similar to that for the notified use. The substance could also be used as an intermediate to synthesize other specialized chemicals and polymers; however, it is expected to be fully transformed during the chemical reactions to create these other substances, and no amount of the substance is expected to remain in the chemical or polymer that is found in the end-use formulations or products. As such, direct and indirect exposure of the general population to the substance from these potential uses is not anticipated.

Based on the negligible potential for exposure, if any, 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.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations of the general population who may be more susceptible or highly exposed.

**Assessment conclusion**

When the substance is used as notified or for potential activities, it is not suspected to be harmful to human health or the environment according to the criteria under section 64 of the Act. As such, it is proposed to amend the Domestic Substances List so that the substance, 1,2-oxathiolane, 2,2-dioxide (Chemical Abstracts Service Registry Number 1120-71-4), is no longer subject to the Significant New Activity provisions under subsection 81(3) 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 the *Hazardous Products Regulations* for products intended for the workplace.