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

New Substances Notification 21035: Cobalt lithium manganese nickel oxide (Chemical Abstracts Service Registry Number 182442-95-1)

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.

The significant new activity (SNAc) provisions of CEPA were applied to the substance because of potential environmental and human health impacts that could arise as a result of potential new activities. Order 2023-87-01-01 amending the Domestic Substances List outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 157, No. 1 on January 4, 2023. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergoes further assessment and risk management consideration.

Substance identity

The notified chemical is cobalt lithium manganese nickel oxide (Chemical Abstracts Service Registry Number[1] 182442-95-1).

Notified and potential uses

The substance is proposed to be manufactured in and imported into Canada in quantities up to or greater than 10 000 kg/yr for the notified use as a component in energy storage systems. No other uses are anticipated in Canada.

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 sediment and soil. The substance is expected to be persistent in these compartments because it is an inorganic substance. The substance is not expected to bioaccumulate because it is an inorganic solid.

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity to fish (no-observed-effect loading rate (NOELR) ≥ 100 mg/L) and aquatic invertebrates (NOELR ≥ 100 mg/L), and low chronic toxicity to algae (NOELR ≥ 10 mg/L). Using the NOELR from the most sensitive organism (fish) and by applying an assessment factor of 125 to account for acute to chronic extrapolation, species sensitivity variation, and unknown mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 100-1000 µg/L, which was used to estimate the risk to the environment.

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 activity is expected to be mainly from waste disposal of the substance resulting in a predicted environmental concentration (PEC) in the range of 0.001-1000 µg/L with the exact value being below the PNEC value.

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 harm to the environment in Canada when not manufactured at the nanoscale.

However, should the substance be manufactured as a nanomaterial, it may have different properties and behaviours. As such, additional information is required to further evaluate potential environmental risks. See the “Nanomaterial considerations” section below for further information.

Human health risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral and dermal routes (median lethal dose > 2000 mg/kg body weight, with no mortality observed at the highest dose tested) and very high acute toxicity by the inhalation route (median lethal concentration ≤ 2 mg/L). The substance has high subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level < 30 mg/kg bw/day) and high subchronic toxicity following repeated inhalation doses in mammalian test animals (90-day lowest-observed-adverse-effect concentration < 0.02 mg/L/6 hour). It is not a dermal sensitizer (local lymph node assay). It is not mutagenic *in vitro* and is not expected to be clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a component in energy storage systems, consumers may come into contact with end-use products containing the substance; however, direct

exposure is not expected because the substance will be contained within the final product and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of $1x10^{-8}$-$1x10^{-7}$ mg/kg bw/day. Indirect exposure of the general population from environmental media such as drinking water or air is not expected given the low potential for environmental release.

The target margin of exposure (MOE_T) was calculated to be 1000 based on the available information. The MOE_T is the level of exposure at or above which there is no expected risk in the exposed population. The derived margin of exposure (MOE_D) is the ratio of the point of departure value to the available exposure doses and is compared to the MOE_T. As the MOE_D is higher than the MOE_T for all estimated human exposures, 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 when the substance has particle sizes larger than the nanoscale (meaning > 100 nm).

The production of a substance at the nanoscale could alter its physical-chemical properties and environmental fate; this may in turn lead to changes in exposure scenarios, access to unanticipated biological compartments and exhibition of unconventional biological behaviour. As such, exposure to the substance at the nanoscale may result in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with this activity.

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

Nanomaterial considerations

While the substance was not notified with a particle size on the nanometer scale, there is evidence that it may be available commercially in nanopowder form. Additional information is therefore being requested given that substances in the 1-100 nanometer size range may exhibit significantly different physical chemical properties, environmental fate, toxicity, and exposure potential. For example, the PNEC would drop to the range of 10-100 µg/L for aquatic invertebrates. As such, more information is necessary to better characterize potential environmental and health risks. For more information on the use of the term “manufactured” in relation to the engineering of nanomaterials, see the Health Canada’s working definition for nanomaterial.

Other considerations

This substance is already subject to the Order 2023-87-01-01 amending the Domestic Substances List under CEPA. The United States Environmental Protection Agency also proposed a Significant New Use Rule (final rule) on the substance under Section 5(a)(2) of the *Toxic Substances Control Act*, which is subject to consent order under Section 5(e).

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.

Due to the identified potential for engineering or use of the substance at the nanometer scale and the uncertainty predicting environmental fate, hazard and exposure in those scenarios, the SNAc provisions of CEPA were applied to the substance in order to obtain information to ensure that the substance undergoes further assessment prior to its use as nanomaterial. Order 2023-87-01-01 amending the Domestic Substances List was published in the *Canada Gazette* Part II, Vol. 157, No. 1 on January 4, 2023.

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.