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

New Substances Notification 20610: Permanganic acid ($HMnO_4$), sodium salt (Chemical Abstracts Service Registry Number 10101-50-5)

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 permanganic acid ($HMnO_4$), sodium salt (Chemical Abstracts Service Registry Number[1] 10101-50-5).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as an oxidizing agent in drinking water and wastewater treatment. Potential uses may include as a disinfectant or bactericide, in medicinal applications or veterinary drugs, in soil remediation and various additional industrial applications. Some use patterns may be subject to different acts and regulations.

Environmental fate and behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water. The substance is not expected to be persistent because it is a strong oxidizing agent, which will be rapidly reduced to the transformation products, manganese dioxide (Mn^{4+}) and potentially dissolved manganese (Mn^{2+}), under environmental conditions. Manganese dioxide will tend to partition to soil and sediment, while dissolved manganese will tend to partition to water. The transformation products are expected to be persistent in these compartments. The substance is not expected to bioaccumulate based on its rapid reduction in the environment, and its transformation products are not expected to

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bioaccumulate in higher trophic levels based on their low to moderate experimental bioconcentration factors in fish.

Environmental risk assessment

Based on the available hazard information, the substance is expected to have moderate to high acute toxicity in fish and aquatic invertebrates (median lethal concentration (LC_{50}) < 100 mg/L; median effective concentration (EC_{50}) < 100 mg/L), and high acute toxicity to algae (EC_{50} < 1 mg/L). The transformation product, dissolved manganese, has low toxicity to aquatic plants (10% effective concentration (EC_{10}) > 10 mg/L), moderate chronic toxicity to algae and fish (EC_{10} 0.1-10 mg/L) and low to moderate chronic toxicity to aquatic invertebrates (EC_{10} > 0.1 mg/L; 25% effective concentration > 0.1 mg/L). In terrestrial environments, the transformation product, total manganese (including manganese dioxide and dissolved manganese), has low chronic toxicity to plants and invertebrates (EC_{50} > 10 mg/kg dry soil; 20% effective concentration > 10 mg/kg dry soil; EC_{10} > 10 mg/kg dry soil; no-observed-effect-concentration (NOEC) > 10 mg/kg dry soil).

The 2019 Canadian Water Quality Guidelines for the Protection of Aquatic Life [PDF] long-term guideline value for dissolved manganese was considered to be the predicted no-effect concentration (PNEC) for the aquatic environment ($PNEC_{aquatic}$), 0.43 mg/L, which was used to estimate risk to the aquatic environment. Using the 5th percentile hazard concentration for total manganese derived from a species sensitivity distribution calculated for terrestrial species, the PNEC for the soil environment ($PNEC_{soil}$) was determined to be in the range of 10-100 mg/kg dry soil, which was used to estimate risk to the terrestrial environment.

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 activities is expected to be mainly from use in water treatment by release of the substance to water resulting in a predicted environmental concentration ($PEC_{aquatic}$) in the range of 0.01-0.1 mg manganese/L, and by release of the substance to soil resulting in a predicted environmental concentration (PEC_{soil}) in the range of 10-100 mg manganese/kg dry soil, with the exact value being below the $PNEC_{soil}$ value. For potential activities such as manufacturing or use in soil remediation and various other applications, environmental exposure to the transformation products is expected to be quantitatively similar to, or less than that of the notified use of the substance.

Comparing the $PEC_{aquatic}$ with the $PNEC_{aquatic}$, and the PEC_{soil} with the $PNEC_{soil}$, the ratios are 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 risk assessment

Based on the available hazard information, 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 subchronic toxicity following repeated oral and dermal 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 toxicity (NOAEL 30-300 mg/kg bw/day) and high developmental toxicity (lowest-observed-adverse-effect level 10-30 mg/kg bw/day) following repeated oral doses in mammalian test animals. It is not expected to be a dermal sensitizer (0% response in a guinea pig maximization test). It is not expected to be mutagenic *in vitro* or clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

The oral provisional tolerable daily intake (PTDI) was calculated to be in the range of 0.01-0.03 mg/kg bw/day based on the LOAEL of the reproductive/developmental toxicity study in mammalian test animals. The dermal PTDI was calculated to be in the range of 0.3-3 mg/kg bw/day based on the NOAEL of the repeated dose dermal toxicity study in mammalian test animals. The PTDI is the estimated level of long-term exposure without risk of adverse health effects.

The notified substance contains manganese (in the form of permanganate), which is an essential element with significant biological roles in the human body and is only toxic in high concentrations. After absorption, it may be transformed to other oxidation states. However, the influence of manganese oxidation state changes on manganese toxicity is currently not well understood. Excessive intake of manganese is known to be a health concern to humans. Health Canada's maximum acceptable concentration for total manganese in drinking water is 0.12 mg/L.

When the notified substance is used industrially as an oxidizing agent in drinking water and wastewater treatment, direct exposure of the general population is not expected due to the industrial nature of the use where the substance is decomposed by reduction.

Indirect exposure of the general population to the notified substance through environmental media such as drinking water and air is not expected given that the substance is used as an oxidizer and would dissociate into sodium and permanganate followed by further transformation reactions and partitioning in environmental media. The transformation product, manganese, occurs naturally in the environment in various oxidation states and is widely distributed in water, soil and sediment. Health Canada’s drinking water guideline of 0.12 mg/L is intended to protect all Canadians, including subpopulations who may be more susceptible or highly exposed.

Potential uses may include in residential drinking water treatment systems or use in fish tanks or home aquariums where direct exposure of the general population is expected to be mainly by skin at levels in the range of 0.001-0.010 mg/kg bw/event. Indirect exposure of the general population from potential uses is expected to be similar to indirect exposure resulting from the notified use.

Based on low potential for exposure due to the industrial nature of the notified use, and because estimated human exposure for potential uses is less than the dermal PTDI, meaning at levels that do not pose a health concern, 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 who may be more susceptible or highly exposed.

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 the *Hazardous Products Regulations* for products intended for the workplace.