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

New Substances Notification 17093: Germanium dioxide (Chemical Abstracts Service registry number 1310-53-8)

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 based on the available information, that when used as notified, the substance 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 2013-87-03-01 Amending the Domestic Substances List outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 147, No. 11 on May 22, 2013. 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 germanium dioxide (Chemical Abstracts Service registry number[1] 1310-53-8).

Notified and potential uses

The substance is proposed to be manufactured in and imported into Canada in quantities greater than 10 000 in kg/yr for the notified use as a catalyst and starting material for industrial production processes. Potential uses may include a variety of applications in telecommunications.

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 water. The substance is not expected to be persistent as it is expected to react with water to form germanic acid, which is expected to be persistent in water as it will be environmentally stable and unable to transform further. The substance and its transformation product are not expected to bioaccumulate based on high water solubility (1000-10 000 mg/L) and low octanol-water partitioning coefficient (log K_{ow} ≤0).

[1] The Chemical Abstracts Services 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.

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity in aquatic invertebrates (median effective concentration (EC_{50}) >100 mg/L). Using the EC_{50} from the aquatic invertebrate study and by applying an assessment factor of 1000 to account for species sensitivity variation, acute to chronic extrapolation, and extrapolation from a chronic maximum acceptable toxicant concentration to a predicted no-effect concentration (PNEC), the PNEC was calculated to be in the range of 100-1000 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 activities is expected to be mainly by release of the substance to water from manufacturing resulting in predicted environmental concentration (PEC) in the range of 0.01-0.1 µg/L, cleaning of transportation vessels resulting in a PEC in the range of 0.1-1 µg/L, and production of germanium resulting in a PEC in the range of 1-10 µg/L . For potential activities such as plastic production, environmental exposure is expected to be similar to that of the notified manufacturing activity.

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 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 “Nanomaterial considerations” section below for further information. 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.

Human health risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight) and moderate acute toxicity by the inhalation route (median lethal concentration 1-5 mg/L/4hr). It has a moderate toxicity following repeated inhalation doses in mammalian test animals (20-day no-observed-effect level 0.06-0.6 mg/L/hr). It is noted that inhalation toxicity is expected to be associated with insoluble forms of germanium, rather than soluble forms. The substance has a high subchronic toxicity following repeated oral doses in mammalian test animals (13-week no-observed-adverse-effect level (NOAEL) <50 mg/kg-bw/day). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. Inorganic germanium has been associated with adverse effects to the nervous system, kidneys and muscles based on literature-available studies with humans and mammalian test animals. It is noted that the toxicity of a substance tends to increase with decreasing particle size. The lowest NOAEL of the oral subchronic toxicity studies in mammalian test animals available from literature, in the range of 0.1 to 1 mg/kg-bw/day, was used to qualitatively estimate potential risk from oral ingestion.

When the notified substance is used as a starting material for industrial production of germanium compounds, direct exposure of the general population is not expected as the substance will be consumed during use. When the notified substance is used as a catalyst in the production of plastics, consumers may come into contact with end-use products containing the substance; however, direct

exposure is not expected because the substance will be encapsulated within a stable matrix, migration and leaching from end-use products is expected to be minimal, and the concentration of the substance in end-use products is low (<1%). Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 10^{-6}-10^{-5} mg/kg-bw/day for children and adults. No potential uses which could significantly increase human health risks compared to the notified uses were identified.

The estimated indirect human exposure when used as notified is significantly lower than the lowest oral subchronic NOAEL available in the literature. Based on the low potential for direct exposure and the low estimated indirect human exposure, when used as notified, the substance is unlikely to be harmful to human health when the substance has particle sizes larger than the nanoscale (meaning > 100 nm).

However, the potential use of the substance manufactured at the nanoscale could significantly alter the exposure resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with this activity.

Nanomaterial considerations

While the substance was not notified with a particle size on the nanoscale, there is evidence that it may be available commercially in the form of nanopowder. Substances in the 1-100 nanometer size range may exhibit significantly different physical and chemical properties, environmental fate, toxicity, and exposure potential. As such, more information is necessary to better characterize potential environmental and health risks.

Assessment conclusion

When the substance is used as notified, it is not suspected to be harmful to human health or the environment within the meaning of the criteria under section 64 of the Act. However, it is suspected that a significant new activity in relation to the substance could result in the substance meeting those criteria.

Due to the identified potential use of the substance engineered at the nanoscale and the uncertainty predicting environmental fate, hazard and exposure in those scenarios, the SNAc provisions under 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 2013-87-03-01 was published in the *Canada Gazette* Part II, Vol. 147, No. 11 on May 22, 2013.

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.