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

New Substances Notification 21194: Carbopolycycle, acid-treated, oxidized (Confidential Accession Number 19612-0)

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 determined that the substance is 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.

In order to ensure that the substance does not cause harm to the Canadian environment or human health, its manufacture and import are authorized subject to conditions as described in Ministerial Condition No. 21194 published in the *Canada Gazette* Part I, Vol. 156, No. 35, August 27, 2022.

Substance identity

The notified chemical is carbopolycycle, acid-treated, oxidized (Confidential Accession Number 19612-0).

Notified and potential uses

The substance is proposed to be manufactured in and imported into Canada in quantities less than 10 000 kg/yr for the notified use as a precursor to manufacture a substance further used in personal protective equipment (PPE) for medical purposes. Potential uses may include non-medical PPE, cosmetic products, food packaging materials, electronics, battery electrodes, construction materials and as a component in nanocomposites.

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, sediment, and soil. The substance is expected to be persistent in sediment based on its long half-life (> 365 days) in this compartment and low biodegradation (10-30% over 28 days). The substance is expected to bioaccumulate based on literature studies of similar substances with a high bioconcentration factor and susceptibility to metabolic oxidation.

Environmental risk assessment

Based on the available hazard information, the substance has moderate acute toxicity in fish and aquatic invertebrates (median effective concentration 1-100 mg/L) and moderate to high chronic toxicity in algae (10% effective concentration (EC_{10}) < 10 mg/L). Hazard information on similar substances from the literature indicate that the substance is expected to have a high acute toxicity in fish larvae and insect larvae (lowest-observed-effect concentration < 1 mg/L), and low chronic toxicity to soil invertebrates (EC_{10} > 10 mg/kg dry soil).

Using the hazard information above supplemented with additional data from the literature, a species sensitivity distribution (SSD) was constructed using lethal and sub-lethal endpoints for freshwater aquatic species. The resultant aquatic predicted no-effect concentration (PNEC) was determined to be between 1 µg/L and 10 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 lifecycle. Environmental exposure from the notified activities is expected to be mainly from cleaning of transportation vessels, manufacturing and processing by release of the substance to water resulting in an aquatic predicted environmental concentration (PEC) in the range of 1-10 µg/L, and from the subsequent application of biosolids generated through wastewater treatment to land resulting in a soil PEC in the range of 100-1000 µg/kg dry soil.

Based on the PEC for freshwater exposure to aquatic organisms combined with the PNEC derived from the SSD, the substance is anticipated to cause harm to the environment in Canada. The risks have been identified with release of the substance to water when imported and used as a precursor in manufacturing processes.

Human health risk assessment

Based on the available hazard information, the substance is expected to have a moderate acute toxicity by the oral route (median lethal dose > 300-2000 mg/kg body weight) and high subchronic toxicity following repeated inhalation doses in mammalian test animals (90-day no-observed-adverse-effect level (NOAEL) < 0.02 mg/L/6hr). The substance is expected to have a high developmental toxicity following repeated oral doses in mammalian test animals (NOAEL < 30 mg/kg-bw/day). It is expected to be mutagenic *in vitro* and is clastogenic *in vivo*. Therefore, the substance has the potential to cause genetic damage.

When the notified substance is used as a precursor to manufacture a substance used in PPE for medical purposes, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 0.0001 to 0.001 mg/kg-bw/day for children and adults. Potential use of the substance in non-medical PPE was further evaluated at this time, where direct exposure of the general population is expected to be mainly by inhalation of shed particles at levels of < 0.0001 mg/L. Indirect exposure of the general population from environmental media such as drinking water and air is expected to be low.

For the notified activity, based on the low potential for direct exposure, and considering other available lines of evidence, the substance is not likely to pose a significant health risk to the general population. For indirect exposure, the target margin of exposure (MOE_T) via the oral route was calculated to be 3000 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 (POD) value to the available exposure doses and is compared to the MOE_T. As the MOE_D derived for indirect exposure of the general population via drinking water ingestion is higher than the MOE_T for all the age groups considered, the substance is not likely to pose a significant health risk to the general population via indirect exposure. Therefore, the substance is unlikely to be harmful to human health via the notified use.

However, the assessment further evaluated the potential uses identified. The MOE_T via inhalation was calculated to be 300 based on the available information. The MOE_D was calculated to be 20-200 based on the inhalation POD, i.e., the NOAEL of the inhalation subchronic toxicity study in mammalian test animals. Because the MOE_D is less than the MOE_T, the substance is anticipated to be harmful to human health. These risks are associated with the potential uses of the substance in products where the substance may be released as respirable particles (e.g., certain non-medical PPE, cosmetics).

The assumptions made in the assessment and the risk management measures applied 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

The substance is suspected to be harmful to the environment according to the criteria under paragraph 64 (a) of the Act, but is not suspected to constitute a danger to human health according to the criteria under paragraph 64 (c) of the Act when used as notified. However, it is suspected that some potential uses may result in the substance becoming harmful to human health according to the criteria under paragraph 64 (c).

Due to the identified risk to the environment and human health related to the aquatic toxicity and pulmonary toxicity, a ministerial condition was issued to restrict the manner in which the notifier may manufacture or import the substance with conditions on its use, handling and disposal in order to mitigate these potential risks. Ministerial Condition No. 21194 was published in the *Canada Gazette* Part I, Vol. 156, No. 35 on August 27, 2022.

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.