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

New Substances Notification 21193: Carbopolycycle, acid-treated, oxidized, silver-doped (Confidential Accession Number 19610-8)

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 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. 21193 published in the *Canada Gazette* Part I, Vol. 156, No. 33 on August 13, 2023.

Substance identity

The notified chemical is carbopolycycle, acid-treated, oxidized, silver-doped (Confidential Accession Number 19610-8).

Notified uses

The substance is proposed to be manufactured in Canada in quantities less than 10 000 kg/yr for the notified use in medical personal protective equipment.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it may tend to partition to water, sediment, and soil. The substance is expected to be persistent in these compartments based on its inorganic nature which prevents biodegradation. The substance is expected to bioaccumulate based on very high bioconcentration factors (> 5000 L/kg) of a similar substance.

Environmental risk assessment

Based on the available hazard information, the substance has moderate toxicity to fish (median lethal concentration 1 to 100 mg/L), high acute toxicity to aquatic invertebrates (median effective loading rate (EL_{50}) < 1 mg/L), and high chronic toxicity to algae (10% effective loading

rate < 0.1 mg/L). Using the EL_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 100 to account for endpoint standardization, species variation, and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100 ng/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 manufacturing and processing by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 100-1000 ng/L. Environmental exposure from the notified activity is also expected to be from use of the substance in medical devices by release of the substance to water resulting in a PEC in the range of 1-10 ng/L.

Comparing the PEC for manufacturing and processing with the PNEC, the ratio is greater than 1, indicating that 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 manufactured and processed in Canada.

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). Components of the substance have high subchronic toxicity following repeated inhalation doses in mammalian test animals (90-day no-observed-adverse-effect concentration < 0.02 mg/L/6hr) and high reproductive/developmental toxicity following repeated oral doses in mammalian test animals (no-observed-adverse-effect level < 30 mg/kg-bw/d based on adverse effects on sperm and foetal viability). Although the notified substance is not mutagenic or clastogenic *in vitro*, components of the substance are genotoxic *in vitro* and *in vivo*. Therefore, the substance may cause genetic damage.

When the notified substance is used as an active ingredient in medical device products, direct exposure of the general population is assessed by the Medical Devices Directorate of Health Canada. Potential uses of the substance include consumer products, where direct exposure of the general population is expected to be mainly by contact with the skin and inhalation. Indirect exposure of the general population from environmental media such as drinking water and air is expected to be at low levels given the low potential for release to the environment under the notified conditions of use.

Based on the low potential for indirect exposure when used as notified, 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.

However, based on the potential for increased exposure combined with indications that components of the substance may cause genetic damage and have reproductive/developmental toxicity and subchronic toxicity, potential uses of the substance

could significantly alter the exposure and/or conditions of use resulting in the substance becoming harmful to human health.

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 have a harmful effect on the environment according to the criteria under paragraph 64 (*a*), 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 other potential uses in relation to the substance could result in the substance meeting the criteria under paragraph 64 (*c*).

Due to the identified risk to the environment related to the aquatic toxicity and the potential risk to human health related to genetic damage, reproductive/developmental toxicity and subchronic toxicity for other potential uses in relation to the substance, 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. 21193 was published in the *Canada Gazette* Part I, Vol. 156, No. 33 on August 13, 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.