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

New Substances Notification 21272: Guanidine, *N,N*'-diphenyl-, hydrochloride (1:1) (Chemical Abstracts Service Registry Number 24245-27-0)

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 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 guanidine, *N,N*'-diphenyl-, hydrochloride (1:1) (Chemical Abstracts Service Registry Number[1] 24245-27-0).

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 in paper manufacturing. Potential uses may include applications in the manufacture of rubber goods.

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 in this compartment based on high ready biodegradation (> 60% over 28 days). The substance is not expected to bioaccumulate based on its low predicted bioaccumulation and bioconcentration factors (< 250 L/kg) and a low bioconcentration factor for an analogue substance (< 250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance has moderate chronic toxicity to algae (10% effective concentration 0.1-10 mg/L), and is expected to have moderate acute

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toxicity to fish and aquatic invertebrates (median lethal concentration (LC_{50}) and median effective concentration 1-100 mg/L), and moderate chronic toxicity to fish and aquatic invertebrates (no-observed-effect concentration 0.1-10 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying an assessment factor of 50 to account for acute to chronic extrapolation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 10 to 100 µg/L, which was used to estimate the risk to the 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 activity is expected to be mainly from cleaning of transportation vessels by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.1 to 1.0 µg/L. For potential activities such as manufacture of rubber goods, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 0.01 to 100 µg/L, with the exact values 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.

Human health risk assessment

Based on the available hazard information, the substance has a high acute toxicity by the oral route (median lethal dose (LD_{50}) 50-300 mg/kg body weight) and is expected to have low acute toxicity by the dermal route (LD_{50} > 2000 mg/kg-bw). The substance is expected to have moderate subchronic toxicity following repeated oral doses in mammalian test animals (90-day lowest-observed-adverse-effect level (LOAEL) 10-100 mg/kg-bw/day; 28-day LOAEL 30-300 mg/kg-bw/day). Furthermore, it is expected to have high reproductive/developmental toxicity following repeated oral doses in mammalian test animals (LOAEL < 30 mg/kg-bw/day). It is not expected to be a dermal sensitizer (0% response (guinea pig maximization test)). The substance was equivocal for *in vitro* mutagenicity in bacterial test system and positive for clastogenicity *in vitro*. However, based on test results for an analogue substance, the substance is expected to be negative for *in vitro* mutagenicity in mammalian cells and negative for clastogenicity *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an additive in paper manufacturing, direct exposure of the general population is not expected due to the industrial nature of the use. Consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because leaching of the substance from paper during normal use is unlikely and given the low concentration in end-use products (< 1%). Indirect exposure of the general population from environmental media is not expected given the specialized industrial use of the substance, which results in little or no release to the environment. Potential uses of the substance include the manufacturing of rubber goods, where direct and indirect exposure of

the general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the low potential for exposure from the notified use and potential uses, the human health hazards associated with the substance regarding the acute and subchronic toxicity as well as reproductive and developmental toxicity is expected to be mitigated as the general population is not expected to come in contact with the substance.

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.