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

New Substances Notification No. 19998: 1,3-Bis(citraconimidomethyl)benzene (Chemical Abstracts Service No. 119462-56-5)

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 1,3-bis(citraconimidomethyl)benzene (Chemical Abstracts Service Registry Number[1] 119462-56-5).

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in rubber production.

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 a very short hydrolysis half-life in water (≤10 days). The substance and its product of hydrolysis are not expected to bioaccumulate based on the low octanol-water partition coefficient (log K_{ow} <3) and low predicted bioconcentration and bioaccumulation factors (<250 L/kg).

Ecological assessment

Based on the available hazard information, the substance has high acute toxicity in fish (median lethal concentration (LC_{50}) <1 mg/L), high acute toxicity in aquatic invertebrates (median effective concentration <1 mg/L), and moderate chronic toxicity to aquatic invertebrates (10% effective concentration 0.1-10 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying an assessment factor of 20 to account for extrapolation from severe to low effects, species sensitivity

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variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1-10 µg/L, which was used for ecological risk assessment.

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 environmental exposure is expected to be minimal based on the methods of formulation, manufacturing of tires and disposal, and the low concentration of the substance in end-use products. For potential activities such as manufacturing of the substance, environmental exposure is expected to be mainly by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L.

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.

Human health assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral and dermal route (median lethal dose (LD_{50}) >2000 mg/kg body weight) and low to moderate subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >50 mg/kg-bw/day; 2 generation study NOAEL 30-300 mg/kg-bw/day). The substance has low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOAEL >30 mg/kg-bw/day with no significant systemic effects at highest dose tested). It is an extreme dermal sensitizer (>80% response (Buehler test)). *In vitro* testing showed that the substance is not mutagenic; however, it was found to be clastogenic *in vitro*. Subsequent testing showed that the substance was not clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be in the range of 0.01-0.1 mg/kg-bw/day based on the NOAEL of the oral subcronic toxicity study in mammalian test animals. The PTDI is the estimated level of long-term exposure without risk of adverse health effects.

When the notified substance is used as an ingredient in rubber production, 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 is not expected given the specialized industrial use of the substance, which results in little or no release to the environment. No potential uses which could significantly increase human health risks compared to the notified uses were identified.

Because the estimated human exposure is less than the PTDI, meaning at levels that do not pose a 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.

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