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

New Substances Notification 20807: 1,6-Octadien-3-ol, 3,7-dimethyl-, acid-isomerized (Chemical Abstracts Service Registry Number 73018-51-6)

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 1,6-octadien-3-ol, 3,7-dimethyl-, acid-isomerized (Chemical Abstracts Service Registry Number[1] 73018-51-6), and is considered a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

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 the mining industry. Potential uses may include use as a fragrance in consumer products, including personal care products and baby wipes.

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 air and water. The substance is not expected to be persistent in these compartments based on atmospheric oxidation (half-life in air < 2 hours) and inherent biodegradation (60-85% over 28 days). The substance is not expected to bioaccumulate based on 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 acute toxicity to aquatic invertebrates (median effective concentration (EC_{50}) 1-100 mg/L) and fish (median lethal concentration 1-100 mg/L) and is expected to have moderate chronic toxicity to algae (10% effective concentration 0.1-10 mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 10 to account for acute to chronic extrapolation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 0.1-1 mg/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 activities 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 0.01-0.1 mg/L. For potential activities such as manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 0.01-0.1 mg/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 harm to the environment 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) and moderate subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) 30-300 mg/kg-bw/day). The substance has a moderate reproductive/developmental toxicity following repeated oral doses in mammalian test animals (systemic and reproductive NOAEL 30-300 mg/kg-bw/day). It is not a dermal sensitizer in Guinea pigs. It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in the mining industry, 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 10^{-5}-10^{-4} mg/kg bw/day for adults and 10^{-4}-10^{-3} mg/kg bw/day for infants. Potential uses of the substance include use as a fragrance in consumer products such as personal care products and baby wipes, where direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range of 0.1-1 mg/kg bw/day. Potential activities include manufacturing, where 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^{-4}-10^{-3} mg/kg bw/day for adults and 10^{-3}-10^{-2} mg/kg bw/day for infants.

The target margin of exposure (MOE_T) was calculated to be 1000 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 value to the available exposure doses and is compared to the MOE_T. As the MOE_D is higher than the MOE_T for all estimated human exposures, 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.

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.