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

New Substances Notification 20281: 2-Oxazolidinone, 3-ethenyl-5-methyl- (Chemical Abstracts Service registry number 3395-98-0)

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 2-oxazolidinone, 3-ethenyl-5-methyl- (Chemical Abstracts Service registry number[1] 3395-98-02).

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 as a component in printing and coating applications. No other uses are anticipated in Canada.

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 the water compartment based on its hydrolysis potential and the rapid predicted biodegradation of its transformation products. The substance is not expected to bioaccumulate based on its low octanol-water partitioning coefficient (log K_{ow} 0-3).

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity to fish, aquatic invertebrates, and algae (median lethal concentration and median effective concentration >100 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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The notified activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity.

Based on the low potential for environmental exposure and ecotoxicity, the substance is unlikely to cause ecological harm in Canada.

Human health risk assessment

Based on the available hazard information, the substance has a moderate acute toxicity by the oral route (median lethal dose (LD_{50}) 300-2000 mg/kg body weight) and a low acute toxicity by the dermal route (LD_{50} >2000 mg/kg body weight). It has a moderate subchronic toxicity following repeated oral doses in mammalian test animals (29-day no-observed-adverse-effects level (NOAEL) 30-300 mg/kg-bw/day). The substance has a low reproductive and developmental toxicity following repeated oral doses in mammalian test animals (NOAEL >100 mg/kg-bw/day, no adverse effects observed at highest dose tested). It is not a dermal sensitizer (sensitization index <3 (local lymph node assay)). It is not mutagenic or clastogenic *in vitro.* Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be in the range of 100-1000 µg/kg bw/day based on the NOAEL of the oral repeated dose 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 a component in printing and coating applications, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 0.1-1 µg/kg bw/day for children and adults. No potential uses that 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, 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.