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

New Substances Notification 21339: 2-Furancarboxaldehyde, 5-(chloromethyl)-
(Chemical Abstracts Service Registry Number 1623-88-7)

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-furancarboxaldehyde, 5-(chloromethyl)- (Chemical Abstracts Service Registry Number[1] 1623-88-7).

Notified and potential uses

The substance is proposed to be manufactured in Canada in quantities greater than 10 000 kg/yr for the notified use as a chemical intermediate. 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 and air. The substance is not expected to be persistent in these compartments based on its rapid rate of hydrolysis and ready biodegradation (> 60% over 28 days) of both the notified substance and its products of hydrolysis. The substance and its products of hydrolysis are not expected to bioaccumulate based on low octanol-water partition coefficients (log K_{ow} 0-3) and corresponding low estimates of bioaccumulation.

Environmental risk assessment

Based on the available hazard information, the substance and its products of hydrolysis have moderate acute toxicity to fish, aquatic invertebrates, and algae (median lethal concentration

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and median effective concentration 1-100 mg/L) and are expected to have moderate chronic toxicity to fish and aquatic invertebrates (no-observed-effect concentration (NOEC) 0.1-10 mg/L). Using the NOEC from the most sensitive organism (fish) and by applying an assessment factor of 5 to account for mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100 µg/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 by release of the substance to water, resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L, and from cleaning of transportation vessels by release of the substance to water, resulting in a PEC in the range of 1-100 µg/L ,with the exact value being below the PNEC value. No potential activities that could significantly increase environmental risks compared to those notified were identified.

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 moderate acute toxicity by the oral route (median lethal dose (LD_{50}) 300-2000 mg/kg body weight) and high acute toxicity by the dermal route (LD_{50} 200-1000 mg/kg-bw). It has high subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level < 30 mg/kg-bw/day). It is expected to be a dermal sensitizer. It is mutagenic and clastogenic *in vitro*. Therefore, the substance has the potential to cause genetic damage. However, exposure to the notified substance is unlikely because it hydrolyses rapidly to form other substances that do not share these properties.

Given the tendency for the notified substance to hydrolyse rapidly, exposure and hazard for the products of hydrolysis were considered. Based on the available toxicity information for the hydrolysis products, these substances have low toxicity by the oral and dermal route. These substances are not dermal sensitizers and are negative for genotoxicity to humans. The population is routinely exposed to the two main hydrolysis products, 5-hydroxymethyl furfural and levulinic acid, in food.

When the notified substance is used as a chemical intermediate, 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 estimated to be at levels in the range of 1×10^{-7}-1×10^{-2} mg/kg bw/day for both infants and adults. Exposure to the notified substance is unlikely, however, because the notified substance hydrolyses rapidly to form other substances. No potential uses that could significantly increase human health risks compared to the notified use were identified.

The target margin of exposure (MOE_T) was calculated to be 100 based on the available information. The MOE_T is the level of exposure at or above which there is no expected risk to 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 indirect 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, 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.