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

New Substances Notifications 19770, 20287 and 21069: 2-Pyrrolidinone, 1-butyl- (Chemical Abstracts Service Registry Number 3470-98-2)

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 determined that the substance is anticipated to enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

In order to ensure that the substance does not cause harm to the Canadian environment or human health, its manufacture and import are authorized subject to conditions as described in:
- Ministerial Condition No. 19770 published in the *Canada Gazette* Part I, Vol. 153, No. 9 on March 2, 2019
- Ministerial Condition No. 20287 published in the *Canada Gazette* Part I, Vol. 154, No. 27 on July 4, 2020
- Ministerial Condition No. 21069 published in the Canada Gazette Part I, Vol. 156, No. 22 on May 28, 2022

Substance identity

The notified chemical is 2-pyrrolidinone, 1-butyl- (Chemical Abstracts Service Registry Number[1] 3470-98-2).

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 consumer coatings and a variety of commercial and industrial applications. Potential uses may include cosmetics and additional consumer applications.

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

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compartments based on its short half-life in air (1-6 hours) and its high to very high inherent biodegradation (>85% over 56 days and 60-80% over 112 days). The substance is not expected to bioaccumulate based on its low octanol-water partition coefficient (log K_{ow} 0-3).

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity in fish and aquatic invertebrates (median lethal concentration (LC_{50}) >100 mg/L and median effective concentration >100 mg/L, respectively) and low chronic toxicity in fish, aquatic invertebrates and algae (no-observed-effect-concentration >10 mg/L for both fish and aquatic invertebrates; 10% effective growth rate concentration >10 mg/L for algae). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 and formulation vessels by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 100-1000 µg/L. For potential activities such as manufacturing and formulation in other industrial, commercial and consumer applications, environmental exposure is expected to be similar to that of the notified uses.

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

Human health risk assessment

Based on the available hazard information, the substance has moderate acute toxicity by the oral route (median lethal dose (LD_{50}) 300-2000 mg/kg body weight), low acute toxicity by the dermal and inhalation routes (dermal LD_{50} >2000 mg/kg body weight; inhalation LC_{50} >5 mg/L/4hr) and low subchronic toxicity following repeat oral dose in test animals (90-day no-observed-adverse-effect level (NOAEL) >100 mg/kg-bw/day). The substance has moderate developmental toxicity following repeated dose exposure by oral, dermal and inhalation routes of exposure in mammalian test animals (no-observed-adverse-effect level (NOAEL) in the range of 50-500 mg/kg-bw/day). It is not a skin sensitizer (>10% estimated concentration required to produce a stimulation index of 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 1-10 mg/kg-bw/day by the oral, dermal and inhalation routes. The PTDI is the estimated level of long-term exposure without risk of adverse health effects.

When the notified substance is used as a solvent in industrial and commercial applications, direct exposure of the general population is not expected due to the industrial and commercial nature of the use. When the notified substance is used in consumer coatings, direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range

of 1-10 mg/kg body weight or by inhalation at levels in the range of 0.1-10 mg/kg body weight. Potential uses of the substance include consumer paint strippers, where direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range of 1-10 mg/kg body weight or by inhalation at levels in the range of 0.1-1 mg/kg body weight. Potential uses of the substance include consumer cleaning products, where direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range of 0.01-10 mg/kg body weight or by inhalation at levels in the range of 10^{-7}-1 mg/kg body weight. Potential uses of the substance include cosmetics, where direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range of 1-1000 mg/kg-bw/day for children and adults and in the range of 0.1-1000 mg/kg-bw/day for babies. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 0.001-0.01 mg/kg-bw/day.

Based on the potential consumer exposure combined with the moderate developmental toxicity, the substance is anticipated to be harmful to human health. These risks are associated with use of the substance in cosmetics and certain consumer applications.

Other considerations

This substance is controlled in another jurisdiction. A United States Environmental Protection Agency Consent Order (P-14-0627) has been applied to the substance. The terms of the Consent Order include restricting the concentration of the substance in certain consumer products.

Assessment conclusion

The substance is not suspected to have a harmful effect on the environment according to the criteria under paragraph 64(*a*) or (*b*) of the Act, but is suspected to constitute a danger to human health according to the criteria under paragraph 64 (*c*).

Due to the identified risk to human health related to developmental toxicity, ministerial conditions were issued to restrict the manner in which the notifier may manufacture, import and use the substance with conditions on its use in order to mitigate these potential risks.

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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.