

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

New Substances Notification 20181: Urea, polymer with formaldehyde and 1,3,5-triazine-2,4,6-triamine, methylated (Chemical Abstracts Service registry number 68442-58-0)

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 polymer is urea, polymer with formaldehyde and 1,3,5-triazine-2,4,6-triamine, methylated (Chemical Abstracts Service registry number¹ 68442-58-0). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because its number average molecular weight is less than 1000 daltons.

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 industrial adhesive. Potential uses may include industrial coatings, textile applications, and papermaking.

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 expected to be persistent in water, soil and sediments based on expected hydrolytic stability and low predicted ready biodegradation potential (10-30% over 28 days). The substance is not expected to bioaccumulate based on its low predicted bioaccumulation factor (<250 L/kg) and low experimental octanol-water partition coefficient (log K_{ow} 0-3).

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity to fish and daphnia (median lethal concentration and median effective concentration >100 mg/L) and moderate chronic toxicity to algae (10% effective concentration (EC_{10}) <10 mg/L). Using the EC_{10} from algae and by applying an assessment factor of 10 to account for species sensitivity variation and mode of action, the

¹ The Chemical Abstracts Service registry number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

predicted no-effect concentration (PNEC) was calculated to be in the range of 100-1000 µg/L, which was used to estimate the ecological risk.

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 activities is expected to be mainly from equipment and transport vessel cleaning by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L. 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 ecological harm 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).

When the notified substance is used as an industrial adhesive, 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 expected to be at low levels given the limited environmental releases. No potential uses which could significantly increase human health risks compared to the notified uses were identified.

Based on the low potential for exposure, 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 for other identified potential activities, it is not expected to be harmful to human health or 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.