

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

New Substances Notification 20960: Urea, reaction products with ethylene glycol and formaldehyde (Chemical Abstracts Service Registry Number 1628834-01-4)

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 urea, reaction products with ethylene glycol and formaldehyde (Chemical Abstracts Service Registry Number¹ 1628834-01-4), 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 as a sour gas scavenger in industrial 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 air and water. The substance is not expected to be persistent in these compartments because it will be subject to rapid photooxidation, hydrolysis and biodegradation. The substance is not expected to bioaccumulate based on low predicted bioconcentration and bioaccumulation factors (< 250 L/kg).

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Environmental risk assessment

Based on the available hazard information, the substance has low to moderate acute toxicity to fish (median lethal concentration [LC₅₀] > 1 mg/L), moderate acute toxicity to aquatic invertebrates (median effective concentration and LC₅₀ 1-100 mg/L) and moderate chronic toxicity to algae (10% effective concentration [EC₁₀] 0.1-10 mg/L). The substance is expected to have low to moderate chronic toxicity to aquatic invertebrates (no-observed-effect-concentration 1-10 mg/L and EC₁₀ > 10 mg/L). Using the EC₁₀ from the most sensitive organism (algae) and by applying an assessment factor of 5 to account for acute to mode of action, the predicted no effect concentration (PNEC) was calculated to be in the range of 100-1000 µg/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 activity is expected to be mainly from cleaning of transportation vessels from release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 10-100 µg/L. For potential activities such as manufacturing and formulation, environmental exposure is expected to be mainly from release of the substance to water resulting in PECs in the range of 1-10 µg/L and 0.1-1 µg/L, respectively.

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 low acute toxicity by the oral and dermal routes (median lethal dose > 2000 mg/kg body weight) and is expected to have a low subchronic dermal toxicity following repeated dermal doses in mammalian test animals (28-day no-observed-adverse-effect level 60-600 mg/kg-bw/day with no toxicity observed at the highest dose tested). The notified substance releases formaldehyde on reaction; however, this is a minor by-product (< 0.1%). Given the known toxicity of formaldehyde, the substance may have the potential to cause genetic damage. It is also a dermal irritant and a dermal sensitizer; effects thought to be related to the release of formaldehyde. Formaldehyde is on the List of Toxic Substances in Schedule 1 of CEPA and is managed under several Canadian federal Acts and Regulations.

When the notified substance is used as a gas scavenger to remove hydrogen sulfide from petroleum-based hydrocarbons, 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 is not expected given the specialized industrial use of the substance, which results in little or no release to the environment. No potential uses were identified that could significantly increase human health risks compared to the notified uses.

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 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.