

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

New Substances Notification No. 19348: Urea, *N,N'*-(methylenedi-4,1-phenylene)bis[*N'*-cyclohexyl-]
(Chemical Abstracts Service No. 58890-25-8)

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, *N,N'*-(methylenedi-4,1-phenylene)bis[*N'*-cyclohexyl-] (Chemical Abstracts Service Registry Number¹ 58890-25-8).

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as a thickener in lubricant products for automotive parts. Potential uses may include use in other industrial/commercial greases, inks, sealants, coatings and curing agents, and in lubricants for 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 soil and sediment. The substance is expected to be persistent in these compartments based on its very low biodegradability ($\leq 10\%$ over 28 days). The substance is not expected to bioaccumulate based on its predicted low bioaccumulation and bioconcentration factors (< 250 L/kg).

Ecological assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have low acute toxicity in fish, aquatic invertebrates and algae (no adverse effects observed in saturated solutions). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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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 not expected in any significant amount given that environmental releases are not anticipated from either the transport or the storage of the substance. Potential activities such as manufacturing or other industrial, commercial or consumer applications are not expected to significantly increase environmental exposure. A predicted environmental concentration was not calculated due to the low potential for ecotoxicity.

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

Human health assessment

Based on the available hazard information for the substance and surrogate data on structurally related chemicals, the substance has a low acute toxicity by the oral route (median lethal dose (LD₅₀) >2000 mg/kg body weight). It is expected to have low acute toxicity by the dermal route (LD₅₀ >2000 mg/kg body weight) and low subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level >300 mg/kg bw/day). It is not expected to be a skin sensitizer (local lymph node assay, guinea pig maximization and Buehler tests). It is not mutagenic *in vitro*; therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a thickener in lubricant products for automotive parts, direct exposure of the general population is not expected due to the industrial and commercial nature of the use. Indirect exposure of the general population from environmental media is not expected given the specialized industrial and commercial use of the substance, which results in little or no release to the environment. Potential uses of the substance include lubricant products for consumer applications, where direct exposure of the general population is expected to be mainly by contact with the skin at low levels. Systemic exposure will be limited by infrequent use, the low concentration of the notified substance in end-use products and its high molecular weight which will limit its ability to cross biological membranes.

Based on the low toxicity and 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.

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 *Hazardous Products Regulations* for products intended for the workplace.