

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

Ministerial Condition No: 17432: Alcohols, C<sub>12-18</sub>, ethoxylated, reaction products with 1,6-diisocyanatohexane and polyethylene-polypropylene glycol

### **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 that 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 is authorized subject to conditions on its use, handling, and disposal as described in [Ministerial Condition No. 17432](#) published in the *Canada Gazette* Part I, Vol. 149, No. 42- October 17, 2015.

### **Substance Identity**

The notified substance is a polymer that can be classified as an ethoxylated allophanate with terminal aliphatic isocyanate moieties. The substance does not meet the [Reduced Regulatory Requirements criteria](#).

### **Notified Activities**

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/year for use as a cross-linker (links polymer chains together) in two-component polyurethane formulations for industrial and commercial painting and coating applications.

### **Environmental Fate and Behaviour**

Based on its physical and chemical properties, if released to the environment, the substance is expected to react with moisture and/or water and the reaction products will tend to partition to soils and sediments. The stable reaction products are expected to be persistent in these compartments based on their limited potential for abiotic and biotic degradation. The substance and its reaction products are not expected to be bioaccumulative based on its modelled bioaccumulation factor (BAF) and bioconcentration factor (BCF).

## Ecological Assessment

Ecotoxicity data are not required for this notification because water extractability is less than 2%. The ecotoxicity of polymers with water extractability less than 2% is generally considered to be low. Based on this, the substance is not anticipated to constitute an ecological risk.

## Human Health Assessment

Based on the available hazard information on the substance and surrogate data on structurally related polymers, the substance has the potential for low acute toxicity by the oral route of exposure ( $LD_{50} > 2000$  mg/kg bw) and by the dermal route of exposure ( $LD_{50} > 2000$  mg/kg). On the basis of data from structurally related substances, the notified substance may not cause irritation to skin or eyes, however it may cause respiratory irritation and sensitization following acute or repeated-dose dermal or inhalational exposure. On the basis of an *in vivo* test, the substance shows the potential for high skin sensitization ( $EC_{30} = 0.1-1.0\%$ ). On the basis of data from structurally related polymers, the substance is not expected to be mutagenic or cause chromosomal aberrations *in vitro* or *in vivo*. Therefore the substance is considered unlikely to cause genetic damage.

When used industrially or commercially, as a cross-linker in two-component polyurethane formulations for painting and coating applications, direct exposure of the general population to the unreacted substance is not expected. Environmental release is not anticipated to occur, and the substance reacts rapidly with water to form insoluble, inert masses. Therefore, indirect exposure of the general population from media such as drinking water is expected to be low from the notified uses.

Given the intended use in paints and coatings for concretes such as garage floors, balconies, decorative floors and furniture based on concrete, the potential exists for the use of the substance in similar or other types of products intended for consumers. If used in an unreacted form in consumer products, the direct exposure potential would be significantly different from the one described above, and direct dermal or inhalational exposure could occur. The primary concern would be exposure to the uncured substance when a consumer is using or applying a product.

Based on the potential for direct dermal and inhalation exposure in conjunction with a high potential for skin or respiratory sensitization, a risk to human health was identified. The risk is related to direct contact with the notified substance when used in consumer products.

## Assessment Conclusion

The substance is suspected to have the potential to be harmful to human health according to the criteria under paragraph 64(c) of CEPA.

Due to the identified risk to the general population related to dermal and inhalational sensitisation if the substance is used in an unreacted form in consumer products, a [Ministerial Condition No. 17432](#) was published in the Canada Gazette Part 1, Vol. 149, No. 42-October 17,

2015 to restrict the manner in which the notifier may use, handle, and dispose of the substance in order to mitigate these potential risks.

A conclusion under CEPA on this substance does not concern, 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 workplace use.