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

Ministerial Condition No. 17269: Formaldehyde, reaction products with bisphenol A and diethylenetriamine, Chemical Abstracts Service Registry No. 72361-54-7

Regulatory Decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), 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 have or may have an immediate or long term harmful effect on the environment or its biological diversity and 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 or import is authorized subject to conditions on its use, handling, and disposal as described in Ministerial Condition No. 17269 published in the *Canada Gazette* Part I, Vol. 147, No. 47, November 23, 2013.

Substance Identity

The substance is an Unknown or Variable composition Complex reaction products and Biological material (UVCB) that can be classified as phenolic aliphatic amine.

Notified Activities

The substance is proposed to be manufactured in or imported into Canada in quantities greater than 10 000 kg/yr for industrial use as a curing agent.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to soil and to suspended solids and sediments in water. The substance is expected to be persistent in these compartments based on its very low potential for biodegradation and hydrolysis. The substance is not expected to be bioaccumulative based on its low octanol-water partition coefficient (log K_{ow} = 0-3) and low bioconcentration/bioaccumulation factor (<250 L/kg).

Ecological Assessment

Based on the available hazard information, the substance has moderate acute toxicity (EC_{50} = 1-100 mg/L) to daphnids. The predicted no effect concentration was calculated to be 10-100 µg/L using the 48 hr EC_{50} from the available toxicity data, which was used to estimate the environmental risk.

The notified and other potential uses 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 release of the substance to water following cleaning of transportation vessels. The predicted environmental concentration for notified activities is estimated to be 10-100 µg/L. Based on the potential for this aquatic exposure to exceed the predicted no effect concentration, the substance may cause ecological harm in Canada, if the release of the substance to water following cleaning of transportation vessels is not handled in a controlled manner.

Environmental exposure resulting from potential activities for the substance (i.e. different possible uses of the substance beyond those notified) is not anticipated to be significant.

Human Health Assessment

Based on the available hazard information on the substance, it has a low potential for acute toxicity by the dermal route of exposure (LD_{50} > 2000 mg/kg bw). It is mutagenic *in vitro* in a bacterial reverse mutation assay. Therefore the substance has the potential to cause genetic damage.

Hazards related to substances used in the workplace should be classified accordingly under the Workplace Hazardous Materials Information System (WHMIS).

When used industrially as a curing agent, direct exposure of the general population to the substance in its unreacted form is not expected. There is a potential for indirect exposure of the general population via drinking water if rinse water from the cleaning of transportation vessels is released to the environment (conservatively estimated to be < 2 µg/kg bw/day). The potential for exposure is not expected to change significantly when the substance is used in similar industrial applications. However, if the substance is used as curing agent in products made available to consumers, an increased potential for direct exposure of the skin may exist.

Based on the low potential for both direct and indirect exposure, the substance is unlikely to be harmful to human health as a result of the notified industrial use. However, based on the mutagenicity of the substance and the increased potential for direct skin exposure, the use of the substance as a curing agent in products made available to consumers may result in the substance becoming harmful to human health.

Assessment Conclusion

The substance is suspected to be harmful to the environment according to the criteria under paragraph 64(*a*) of CEPA 1999 and to have the potential to be harmful to human health according to paragraph 64(*c*).

Due to the identified environmental risks related to aquatic toxicity and the potential for human health risks related to its use in consumer products, a Ministerial Condition was published in the *Canada Gazette* Part I, Vol. 147, No. 47 on November 23, 2013 to restrict the manner in which

the notifier may manufacture or import the substance, with conditions on its use, handling, and disposal in order to mitigate these risks.

A conclusion under CEPA 1999 on this substance is not relevant to, nor does it preclude, an assessment against the hazard criteria for WHMIS that are specified in the *Controlled Products Regulations* for products intended for workplace use.