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

Significant New Activity No. 17122: 2-Propenoic acid, 2-methyl-, alkyl ester, polymer with ethenylbenzene, methyl 2-methyl-2-propenoate and 2-oxiranylmethyl 2-methyl-2-propenoate, *tert*-Bu peroxide-initiated

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 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.

However, a significant new activity (SNAc) Notice was recommended based on uncertainties regarding potential human health impacts of the substance in relation to certain new activities. SNAc No. 17122 outlines information requirements for those activities and was published in the *Canada Gazette* Part I, Vol. 147, No. 24 - June 15, 2013. Notification is required prior to commencement of those activities identified as a potential risk to ensure the substance undergoes further assessment and risk management consideration.

Substance Identity

The substance is a polymer that can be classified as an acrylic copolymer. The substance does not meet the Reduced Regulatory Requirement criteria.

Notified Activities

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

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to suspended particulate matter in water and settle to sediments or partition to soil because of its low water extractability and moderate log K_{ow} (> 3-6). The substance is expected to be persistent in the environment based on

structural considerations and low water extractability, limiting availability for biodegradation and hydrolysis. The substance is not expected to be bioaccumulative based on its moderate log K_{ow} and limited availability via the aquatic environment.

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 chemicals, the substance has a low to moderate potential for acute toxicity by the oral route of exposure (LD_{50} > 1000 mg/kg bw), and a moderate potential for acute toxicity by the inhalation route of exposure (LC_{50} > 200 mg/m^3). It is non-irritating to skin and may have the potential to be a skin sensitizer, although the results were equivocal. It is weakly mutagenic and clastogenic *in vitro*; however it may not be clastogenic *in vivo.* Therefore the substance has the potential to cause genetic damage. A representative surrogate substance provided a conservative estimate of the toxicity of the substance from repeated exposure associated with the low molecular weight components of the notified substance. This surrogate substance exhibits moderate repeated-dose toxicity by the inhalation route of exposure (NOAEL > 100 mg/m^3).

When used in industrial coating applications, direct exposure of the general population is not expected. The general public may come into dermal contact with the coatings; however, upon application and curing, the substance will be fully reacted and not expected to be released. Indirect exposure of the general public from environmental media is expected to be low when the substance is used as notified. However, if the substance is used in coatings and adhesives which are intended for application by consumers, an increased direct exposure potential via dermal contact to the skin may exist.

Based on the low potential for direct and indirect exposure of the general population, the substance is not likely to pose a significant health risk to the general population when used as notified and is therefore unlikely to be harmful to human health.

However, based on potential risk to the general population, related to the potential for genotoxicity and carcinogenicity, use of the substance in coatings and adhesives that are consumer products may significantly alter the exposure of the general population resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks.

Assessment Conclusion

When used as notified, the substance is not suspected to be harmful to human health or the environment according to the criteria under section 64 of CEPA 1999. However, it is suspected that a significant new activity in relation to the substance may result in the substance meeting those criteria.

Due to the potential risk to the general population related to the potential for genotoxicity and carcinogenicity if the substance is used in coatings and adhesives that are consumer products, a SNAc Notice was issued to obtain information to ensure that the substance, in relation to these potential activities, undergoes further assessment. SNAc No. 17122 was published in the *Canada Gazette* Part I, Vol. 147, No. 24 on June 15, 2013.