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

Ministerial Condition No. 18427: 1-Propanaminium, 3-amino-*N*-(carboxymethyl)-*N*,*N*-dimethyl, *N*-(C_{8-18} and C_{18}-unsaturated acyl) derivatives, inner salts

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/or import is authorized subject to conditions on its use as described in Ministerial Condition No. 18427 published in the *Canada Gazette* Part I, Vol. 150, No. 18, April 30, 2016.

Substance Identity

1-Propanaminium, 3-amino-*N*-(carboxymethyl)-*N*,*N*-dimethyl, *N*-(C_{8-18} and C_{18}-unsaturated acyl) derivatives, inner salts (Chemical Abstracts Service Registry No. 147170-44-3) is a chemical of unknown or variable composition, complex reaction product, or biological materials (UVCB) that can be classified as an amidopropyl betaine with a variable structure.

Notified and Potential Activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 1,000 kg/yr for use as a surfactant. No other activities are anticipated in Canada.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water. The substance is not expected to be persistent in water. The substance is not expected to bioaccumulate, based on its water solubility and propensity to biodegrade.

Ecological Assessment

Based on the available hazard information for a structurally related chemical, the substance has moderate (median lethal concentration (LC_{50}) 1-10 mg/L) acute toxicity in aquatic biota. The predicted no effect concentration was calculated to be 10-100 µg/L using the 96-h LC_{50} from the most sensitive organism (fish), which was used to estimate the ecological risk.

The notified and other potential (transportation and releases due to potential use in other surfactant applications) activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. The predicted environmental concentration for notified activities is estimated to be within the range of 0.0001-0.1 mg/L.

Based on the predicted range of environmental concentrations in conjunction with the moderate acute toxicity, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on the substance, the substance has a low potential for acute toxicity by the dermal route of exposure (median lethal dose >2000 mg/kg body weight). It is not a dermal sensitizer, although impurities of the substance are considered dermal sensitizers. Based on a study for a structurally related substance, the notified substance is not expected to be mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When used as notified, direct exposure of the general population is expected to be mainly by contact with the skin. Indirect exposure of the general population from environmental media (i.e., drinking water) is expected to be low.

Based on the dermal exposure in conjunction with the dermal sensitization potential associated with impurities of the substance, the substance is anticipated to be harmful to human health. The risk is related to direct dermal contact with impurities of the substance in water when used as a surfactant.

Assessment Conclusion

The substance is suspected to be harmful to human health according to the criteria under paragraph 64(*c*).

Due to the identified risk to the general population related to dermal sensitization, Ministerial Condition No. 18427 was published in the *Canada Gazette* Part I, Vol. 150, No. 18 on April 30, 2016, to restrict the manner in which the notifier may manufacture and/or import the substance, in order to mitigate the risks.