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

New Substances Notification No. 18729: Linseed oil, maleated, 2-[(2-methyl-1-oxo-2-propen-1-yl)oxy] ethyl ester, ester with polyalkylene glycol mono- Me ether, compounds with 2-(dimethylamino)ethanol

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 polymer, linseed oil, maleated, 2-[(2-methyl-1-oxo-2-propen-1-yl)oxy] ethyl ester, ester with polyalkylene glycol mono- Me ether, compounds with 2-(dimethylamino)ethanol (Confidential Accession No. 19038-3), can be classified as a polyether-modified linseed oil. The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations* because it contains methacrylate end groups.

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for use as a resin for wood stain. 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, soil and sediment. The substance is not expected to be persistent in water, soil or sediment based on its predicted moderate biodegradability (30-60%). The substance is not expected to bioaccumulate based on its high molecular weight which will limit its ability to cross biological membranes.

Ecological Assessment

Based on the available hazard information, the substance has moderate chronic toxicity (15% effective concentration (EC_{15}) 0.1-10 mg/L) in algae. Using the EC_{15} from the most sensitive organism (algae) and by applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 10-100 µg/L, which was used to estimate the ecological risk.

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 activity is not expected because the end-use application will result in the substance being chemically reacted into the coating matrix once cured, and any residual product will be incinerated. A predicted environmental concentration (PEC) for notified activities was not estimated given the low potential for environmental release of the substance. The PEC is estimated to be 10-100 µg/L for potential cleaning of transportation vessels and manufacturing activities.

Based on the low environmental release expected from notified activities, and comparing the PEC with the PNEC for potential activities, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information, the substance has a low potential for acute toxicity by the oral route of exposure (median lethal dose >2000 mg/kg).

When the notified substance is used as a resin for wood stain in commercial applications, consumers may come into contact with end-use products containing the substance, however direct exposure is not expected because the substance will be already chemically reacted into a stable matrix once cured and will be unavailable for uptake. Direct contact of the general population from consumer applications is expected mainly by dermal contact but direct exposure will also be limited once cured. If contact with unreacted substance occurs, the large molecular weight and anionic surfactant properties of the substance will limit its ability to cross biological membranes; therefore, the potential for systemic exposure is low. Indirect exposure of the general population from environmental media such as drinking water is expected to be low as elevated environmental concentrations from the notified use are not anticipated. No other potential uses of the substance have been identified.

Based on the low potential for direct or indirect exposure and the low acute toxicity, 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 uses, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of CEPA.

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