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

Significant New Activity No. 18642: Fatty acids, C_{12-20}, 1,2,2,6,6-pentamethyl-4-piperidinyl esters

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.

However, a significant new activity (SNAc) notice was adopted based on uncertainties regarding potential human health impacts of the substance in relation to certain new activities. SNAc No. 18642 outlines information requirements for those activities and was published in the *Canada Gazette* Part I, Vol. 150, No. 34, August 20, 2016. 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

Fatty acids, C_{12-20}, 1,2,2,6,6-pentamethyl-4-piperidinyl esters (Chemical Abstracts Service Registry No. 1357160-95-2) is a chemical of unknown or variable composition, complex reaction products, or biological material (UVCB) that can be classified as a hindered amine.

Notified and Potential Activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for use as a light stabilizer in plastic articles. The potential use of the substance in paints, cosmetics or personal care products has also been assessed and the available information was determined to be inadequate to assess activities under the conditions of potential use.

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 sediment. The substance is not expected to be persistent in soil and sediment based on its moderate biodegradability (30-60%) and an estimated half-life of <182 days in soil and <365 days in sediment. The substance is not expected to bioaccumulate based on its low bioconcentration and bioaccumulation factors (<250 L/kg) and its insolubility resulting in low uptake and high rates of metabolic clearance.

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has moderate to high acute toxicity in fish, aquatic invertebrates, and algae (median lethal concentration (LC_{50}) and median effective concentration (EC_{50}) <100 mg/L). It is expected to have high chronic toxicity in algae (no-observed-effect concentration (NOEC) <0.1 mg/L) and moderate to high chronic toxicity in aquatic invertebrates (NOEC <10 mg/L). Given that the LC_{50}, EC_{50} and NOEC results reported exceed the water solubility limit of the substance, there is uncertainty as to whether the observed toxicity is due to physical fouling rather than the inherent toxicity of the notified substance. Using the NOEC from the most sensitive organism (algae) and applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 1-10 µg/L, which was used to estimate the ecological risk. The substance has low chronic toxicity in soil invertebrates (NOEC >10 mg/kg soil dw). A PNEC for soil was not estimated given the low potential for ecological risk to soil organisms.

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 expected to be mainly from plastic production involving the blending of the substance into plastic material and processing of final materials resulting in particle settling and release to waste water following wash down. The predicted environmental concentration (PEC) for notified activities is estimated to be 0.01-0.1 µg/L. The substance could potentially be used in the formulation of coatings or for manufacturing activities. If used in coating formulations, the PEC of the substance is expected to be the same as the PEC for the notified use. However, if the substance is used for manufacturing activities, an increased exposure potential may exist from release of the substance to water resulting in a PEC of 1-10 µg/L.

Comparing the PEC with the PNEC, the ratio is less than 1. This along with other lines of evidence including environmental fate, hazard, and exposure, indicates that 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 oral and dermal toxicity (median lethal dose >2000 mg/kg body weight) and a low potential for subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level >300 mg/kg-bw/d). It is a moderate skin sensitizer (effective concentration 1-10% (local lymph node assay)). It is not mutagenic *in vitro* and not clastogenic *in vitro* or *in vivo*. The substance has a moderate potential to cause polyploidy *in vitro*. While polyploidy identified *in vitro* suggests that the substance may have the potential to cause genetic damage, it did not induce damage indicative of aneugenic activity in an *in vivo* micronucleus test, although exposure of the target organ in this study could not be confirmed. Therefore, more information is needed to determine whether the substance causes genetic damage.

When the notified substance is used as a light stabilizer in plastic articles, direct exposure of the general population is not expected. The general population may come into direct contact with

end-use products containing the substance; however, the substance will be present at a low concentration (<1%) and is expected to be immobile in the polymer matrix limiting migration and release. Indirect exposure of the general population from environmental media such as drinking water or air is expected to be low. However, if the substance is used as a component in paints, cosmetics or personal care products, an increased direct exposure potential by contact with the skin may exist. Blood concentrations of the notified substance resulting from dermal exposure to paints, cosmetics and personal care products containing the substance were estimated to be 1-10 µg/mL for paint and 10-100 µg/mL for personal care products.

Based on the low potential for direct or indirect exposure of the general population for the notified use, the substance is not likely to pose a significant health risk to the general population when used as notified. However, based on the increased potential for direct dermal exposure for potential uses in paints, cosmetics and personal care products and the uncertainty regarding its potential to cause genetic damage, more information is necessary to better characterize potential health risks.

Assessment Conclusion

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

Due to the potential risk to the general population related to genetic toxicity if the substance is used in paint, cosmetics or personal care products, a SNAc notice was issued to obtain information to ensure that the substance, in relation to these potential activities, undergoes further assessment before such activities can be undertaken. SNAc Notice No. 18462 was published in the *Canada Gazette* Part I, Vol. 150, No. 34 on August 20, 2016.

A conclusion on this substance under CEPA 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 *Hazardous Products Regulations* for products intended for the workplace.