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

New Substances Notification 16711: Metal hydroxy phosphate (Confidential Accession No. 18430-7)

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 based on the available information, that when used as notified, 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.

The significant new activity (SNAc) provisions of CEPA were applied to the substance because of potential environmental and human health impacts that could arise as a result of potential new activities. Order 2012-87-05-01 Amending the Domestic Substances List outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 146, No. 17 on August 15, 2012. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergoes further assessment and risk management consideration.

Substance identity

The notified chemical is metal hydroxy phosphate (Confidential Accession No. 18430-7).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 1000 kg/yr for the notified use in plastic packaging. Potential uses may include coatings, paints, inks, applications with polymeric matrices, chemical processes and technical applications or plastic applications other than the notified use.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to water, soil and sediment. The substance is not expected to be persistent as it will dissociate into its elemental ions in aqueous environments. However, the released metal ions will be persistent in soil and sediment because they cannot degrade any further. The substance and its dissociation products are not expected to bioaccumulate based on the moderate bioaccumulation factors (<1000 L/kg) and ionic nature of the disassociation products, and evidence from animal food chain studies indicating that biomagnification of the metal ion does not occur.

Environmental risk assessment

Based on the available hazard information, the substance is expected to have moderate to high acute toxicity in fish and aquatic invertebrates (median lethal concentration and median effective concentration (EC_{50}) <100 mg/L) and high acute toxicity in algae (EC_{50} <1 mg/L).

The substance is expected to dissociate in water. The toxicity of the free metal ion was considered to represent the worst-case hazard potential as it is known to be toxic to aquatic organisms. The Canadian Council of Ministers of the Environment set the Canadian Water Quality Guidelines for this metal in the range of 0.001-0.01 µg/L. A Priority Substances List assessment under CEPA determined a critical toxicity value in the range of 0.1-1 µg/L, which was selected as the predicted no-effect concentration (PNEC) and 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 activities is expected to be mainly from formulation and plastic production by release of the substance to water resulting in predicted environmental concentration (PEC) in the range of 0.1-1 µg/L. However, if the substance is used in coatings, paints and inks, an increased exposure potential may exist from manufacturing and formulation by release of the substance to water that could result in a PEC in the range of 1-10 µg/L. If the substance is manufactured in Canada, an increased exposure potential may exist by release of the substance to water that could result in a PEC in the range of 10-100 µg/L.

Comparing the PEC for the notified use 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.

However, the use of the substance in coatings, paints and inks or the manufacture of the substance in Canada may significantly alter environmental release and exposure resulting in the substance becoming harmful to the environment. In addition, should the substance be manufactured as a nanomaterial, it may have different properties and behaviours. See “Nanomaterial considerations” section below for further information. Consequently, more information is necessary to better characterize potential environmental risks associated with these potential activities.

Human health risk assessment

Based on the available hazard information, the substance has a low to moderate acute toxicity by the oral route (median lethal dose (LD_{50}) >300 mg/kg body weight) and low acute toxicity by the dermal route (LD_{50} >2000 mg/kg body weight). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The metal ions and phosphate disassociation products are not expected to result in systemic toxicity. Poorly soluble particles, such as the notified substance, are associated with respiratory toxicity.

When the notified substance is used in plastic packaging, consumers may come into contact with end-use products containing the substance; however, the substance will be encapsulated within a stable matrix once the product is cured. Some leaching of the substance from end-use products may occur under acidic conditions leading to direct exposure of the general population by ingestion at low levels. Indirect exposure of the general population from environmental media is expected to be at low levels given the specialized industrial use of the substance, which results in little to no release to the environment. Potential uses include other types of plastic, where direct and indirect exposure of the

general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the low toxicity when not at the nanoscale and the low potential for exposure, 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.

However, the potential manufacturing of the substance at the nanoscale could significantly alter the exposure and/or conditions of use resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

Nanomaterial considerations

While the substance was not notified with a particle size on the nanometer scale, there is evidence that it may be available in the form of nanoneedles, nanotubes, nanocrystals and nanoflowers. Substances in the 1-100 nanometer size range may exhibit significantly different physical and chemical properties, environmental fate, toxicity, and exposure potential. More information is necessary to better characterize potential environmental and health risks.

Assessment conclusion

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

Due to the potential risk to the environment related to aquatic toxicity if the substance were to be used in coatings, paints and inks or manufactured in Canada, and due to the identified potential for engineering or use of the substance at the nanometer scale and the uncertainty predicting environmental fate, hazard and exposure in those scenarios, the SNAc provisions under CEPA were applied to the substance in order to obtain information to ensure that the substance undergoes further assessment before these potential activities are undertaken. Order 2012-87-05-01 was published in the *Canada Gazette* Part II, Vol. 146, No. 17 on August 15, 2012.

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