

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

Significant New Activity No. 18494: Boron phosphate

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. 18494 outlines information requirements for those activities and was published in the *Canada Gazette* Part I, Vol. 150, No. 26 on June 25 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

The chemical, Boron phosphate (Chemical Abstracts Service Registry No. 13308-51-5), can be classified as a boron compound.

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 polymerization catalyst. The potential use of the substance in consumer products, such as modelling clays or household cleaning products and detergents, has also been assessed due to the increased potential for exposure of the general population.

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, and any undissolved substance will partition to soil and sediment. The substance is expected to undergo hydrolysis under environmental conditions and is therefore not expected to be persistent in water. However, the hydrolysis products (boric acid and phosphoric acid) are expected to be persistent in water. The substance is not expected to bioaccumulate because it has a moderate water solubility (10-1000 mg/L) and is expected to hydrolyze in water. Phosphoric acid is not expected to bioaccumulate, while boric acid has been found to bioaccumulate in some aquatic and terrestrial plants.

Ecological Assessment

Based on the available hazard information, the substance has low acute toxicity in fish (median lethal concentration (LC_{50}) >100 mg/L water accommodated fraction). As the substance is expected to rapidly hydrolyze in water, the toxicity of the hydrolysis products was also considered. The long-term water quality guideline for boron (1000-10 000 µg/L) determined by the Canadian Council of Ministers of the Environment (CCME) was selected as the predicted no-effect concentration (PNEC), which was used to estimate the ecological risk due to boron. To estimate ecological risk due to phosphorus, the PNEC was selected as 10-100 µg/L based on the upper limit of total phosphorus that is found in uncontaminated habitats determined by the CCME.

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 cleaning of manufacturing equipment by release of the substance to the aquatic environment via wastewater. The predicted environmental concentration (PEC) for notified activities is estimated to be 10-100 µg/L for boron and phosphorus. Other potential uses of the substance are numerous and include other commercial and industrial applications for which the PEC is not expected to differ significantly from the notified use. Based on a generic exposure scenario for the potential activities, the PEC is estimated to be 1-10 µg/L for boron and phosphorus.

Comparing the PEC for notified and potential activities 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 moderate acute toxicity by oral route (median lethal dose 300-2000 mg/kg body weight) and a low acute toxicity by inhalation route (LC_{50} >5 mg/L/4 hours). It is not a skin sensitizer (stimulation Index of <3 (local lymph node assay)). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

Boron compounds have been associated with reproductive toxicity, blood toxicity and neurotoxicity. The notified substance is a boron-containing compound and is expected to hydrolyze into boric acid. Based on available toxicity information for boric acid, it has low acute toxicity by oral and dermal routes, and a moderate toxicity by inhalation route. It is associated with subchronic and chronic reproductive effects (benchmark dose level (BMDL) 1-10 mg/kg-bw/d), developmental toxicity, malformations, and blood and neurological effects. Boric acid was found not to be mutagenic *in vitro* and *in vivo*, and therefore is unlikely to cause genetic damage. A provisional tolerable daily intake (PTDI) was determined to be 1-10 µg/kg-bw/d based on the BMDL for reproductive effects in mammalian test animals.

When the notified substance is used as a polymerization catalyst, direct exposure of the general population is expected to be negligible. The substance is intended to be used in industrial

applications only with no anticipated commercial or consumer uses. Members of the general population may come into direct contact with products prepared using the substance; however, since the substance acts as a catalyst, it is not expected to be contained within final reaction products or polymers. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels of 0.1 to 1 µg/kg-bw/d for both adults and children.

There are numerous other potential uses for the substance and its hydrolysis products including industrial, commercial and consumer applications. The potential for direct and indirect exposure of the general population resulting from industrial and commercial uses are not expected to be significantly different from the exposure for the notified use, and therefore is considered to be low. Direct exposure to the general population due to the potential use of the substance in consumer products such as modelling clay and household cleaning products and detergents by accidental ingestion and contact with the skin was estimated up to 10 000 µg/kg-bw/d.

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

However, based on a comparison of the PTDI to the estimated direct exposure, the potential uses of the substance in modelling clay and household cleaning products and detergents may result in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks.

Nanomaterial Considerations

While the substance was not notified with a particle size on the nanometer scale, the synthesis of nanosized particles of this substance has been reported. Additional information is being requested for this activity since substances in the 1-100 nanometer size range may exhibit significantly different physical chemical properties, environmental fate, toxicity, and exposure potential. Consequently, more information is necessary to better characterize potential health risks.

Other Considerations

In Canada, boric acid, its salts and its precursors are being evaluated under Part 5 of CEPA. The draft screening assessment conducted under CEPA indicates that boric acid adversely affects fertility, reproduction and development, similar to the assessment conclusions of other jurisdictions.

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 the substance may result in the substance meeting those criteria.

There is a potential risk to the general population related to increased direct exposure to the substance if the substance is used in modelling clay and household cleaning products and detergents, and related to use of the substance as a nanomaterial. Due to these potential risks, a SNAC notice was issued to obtain information to ensure that the substance, in relation to these potential activities, undergoes further assessment SNAC Notice No. 18494 was published in the *Canada Gazette* Part I, Vol. 150, No. 26 on June 25, 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.