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

New Substances Notification 21385: Phosphonic acid, *P*,*P*',*P*'',*P*'''-[1,2-ethanediylbis[nitrilobis(methylene)]]tetrakis-, calcium sodium salt (2:5:6) (Chemical Abstracts Service Registry Number 138314-12-2)

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 notified chemical is phosphonic acid, *P*,*P*',*P*'',*P*'''-[1,2-ethanediylbis[nitrilobis(methylene)]] tetrakis-, calcium sodium salt (2:5:6) (Chemical Abstracts Service Registry Number[1] 138314-12-2).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in industrial applications. Potential uses may include use as a dishwasher detergent additive.

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, sediment and soil. The substance is expected to be persistent in these compartments based on very low ready biodegradation (≤ 10% in 28 days). The substance is not expected to bioaccumulate based on very low octanol-water partition coefficient (log K_{ow} ≤ 0) and corresponding low estimates of bioaccumulation (< 250 L/kg).

Environmental risk assessment

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Based on the available hazard information, the substance has low acute toxicity to fish and aquatic invertebrates (median lethal concentration (LC_{50}) and median effective concentration (EC_{50}) > 100 mg/L) and is expected to have low chronic toxicity to fish and algae (no-observed-effect-concentration (NOEC) > 10 mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 40 to account for acute to chronic extrapolation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1-10 mg/L, which was used to estimate the risk to the environment.

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 low. A predicted environmental concentration (PEC) was not calculated due to the low potential for environmental exposure. For potential activities such as manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 0.1-1 mg/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 harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance is expected to have a low acute toxicity by the oral and dermal routes (median lethal dose (LD_{50}) > 2000 mg/kg body weight) and a low acute toxicity by the inhalation route (LC_{50} > 1 mg/L/4 hr; no mortalities observed at the highest dose tested). The substance is expected to have a low to moderate subchronic toxicity following repeated oral doses in mammalian test animals (90-day study no-observed-adverse-effect level < 100 mg/kg-bw/day; 2-year studies lowest-observed-adverse-effect level 10-100 mg/kg-bw/day). It is not expected to be mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in industrial applications, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media is not expected given the specialized industrial use of the substance, which results in little or no release to the environment. Potential uses of the substance include dishwashing detergents, where direct exposure of the general population is expected to be mainly by contact with the skin at low to moderate levels; however, systemic exposure will be limited (i.e., low) by the large molecular weight and low octanol-water partition coefficient of the substance which will limit absorption through the skin. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels that do not pose a concern.

Based on 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.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

Assessment conclusion

When the substance is used as notified or for other identified potential activities, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

A conclusion under CEPA for this substance is not relevant to, nor does it preclude, an assessment against the hazard criteria for the Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or the *Hazardous Products Regulations* for products intended for the workplace.