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

New Substances Notification No. 19354: Ferrate(12-), tris[diphosphato(4-)kO,kO"][μ-[2-(hydroxy-kO:kO)-1,2,3-propanetricarboxylato(4-)kO1, kO2, kO3]][μ-[2-(hydroxy-kO:kO)-1,2,3-propanetricarboxylato(4-)-kO1, kO2, kO3:kO2]][μ-[2-(hydroxy-k0:k0)-1,2,3-propanetricarboxylato(4-)kO1, kO3:kO2]]tetra-, sodium (1:12) (Chemical Abstracts Service No. 1802339-56-5)

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 ferrate(12-), tris[diphosphato(4-)kO,kO"][μ-[2-(hydroxy-kO:kO)-1,2,3-propanetricarboxylato(4-)kO1, kO2, kO3]][μ-[2-(hyrdroxy-kO:kO)-1,2,3-propanetricarboxylato(4-)-kO1, kO2, kO3:kO2]][μ-[2-(hydroxy-k0:k0)-1,2,3-propanetricarboxylato(4-)kO1, kO3:kO2]]tetra-, sodium (1:12) (Chemical Abstracts Service Registry Number[1] 1802339-56-5).

Notified and potential activities

The substance is proposed to be manufactured in and imported into Canada in quantities greater than 10 000 kg/yr for the notified use as a pharmaceutical ingredient for export only. Potential uses may include patient use if these pharmaceuticals become available in Canada.

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 soil and sediment. The substance is not expected to be persistent in these compartments based on its very high biodegradability (>85% over 28 days). The substance is not expected to bioaccumulate based on its high molecular weight which will limit its ability to cross biological membranes, and due to natural metabolic processes.

Ecological assessment

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Based on the available hazard information, the substance has low acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration and median effective concentration >100 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 manufacturing by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.1-1 µg/L, and from packaging by release of the substance to water resulting in a PEC in the range of 1-10 µg/L. For potential activities such as use in pharmaceuticals in Canada, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC in the range of 0.01-0.1 µg/L.

Based on the low potential for environmental exposure, the substance is unlikely to cause ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance has a low subchronic toxicity following repeat oral doses in mammalian test animals (90-day, 16 week, 32 week and 42 week no-observed-adverse-effect levels (NOAELs) >100 mg/kg bw/day). It is not a skin sensitizer (0% response (Buehler scale)). It is not mutagenic *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The point of departure (POD) was considered to be >100 mg/kg bw/day based on tissue effects observed in sub-chronic studies.

When the notified substance is used as a pharmaceutical ingredient, direct exposure of the general population is assessed by the Therapeutics Products Directorate of Health Canada. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 10^{-6}-10^{-5} mg/kg bw/day for children and adults. Potential uses of the substance include pharmaceuticals used in Canada, where indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 10^{-8}-10^{-7} mg/kg bw/day for children and adults.

Based on a comparison of the POD to the estimated indirect human 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.

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, 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.