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

New Substances Notification 20517: Dextrin, hydrogen 2-(dodecen-1-yl) butanedioate, sodium salt (Chemical Abstracts Service registry number 1218992-20-1)

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 polymer is dextrin, hydrogen 2-(dodecen-1-yl) butanedioate, sodium salt (Chemical Abstracts Service registry number[1] 1218992-20-1). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains a high percentage of low molecular weight components and its number average molecular weight is less than 1000 daltons.

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 50 000 kg/yr for the notified use in personal care products. No other uses are anticipated 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 the water. As a surfactant, some of the substance will also be present at the surface of the water or suspended organic matter. The substance is not expected to be persistent in these compartments based on ready biodegradation (60-85% over 28 days). The substance is not expected to bioaccumulate based on the low octanol-water partitioning coefficient (log K_{ow} <0).

Environmental risk assessment

Based on the available hazard information, the substance is expected to have moderate acute toxicity to fish (median lethal concentration (LC_{50}) 1-100 mg/L) and low toxicity to aquatic invertebrates and algae (LC_{50} and median effective concentration >100 mg/L). Using the no-observed-effect concentration from the most sensitive organism (algae) and by applying an assessment factor of 100 to account for species

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sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 0.01-0.1 mg/L, which was used to estimate the ecological risk.

The notified 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 processing and consumer use from release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.001-0.1 mg/L and 0.0001-0.01 mg/L, respectively. No potential activities that could significantly increase environmental risks compared to those notified were identified.

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 risk assessment

Based on the available hazard information, the substance is expected to have a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight) and low subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level 1000 mg/kg-bw/day). It is not mutagenic *in vitro* and is not clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a component of cosmetics and personal care products, direct exposure of the general population is expected to be mainly by contact with the skin. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels given the low potential for environmental release. No potential uses that could significantly increase human health risks compared to the notified uses were identified.

Based on the low toxicity, 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, 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.