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

New Substances Notification 20370: D-Fructose, 6-*O*-α-D-glucopyranosyl- (Chemical Abstracts Service registry number 13718-94-0)

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 D-fructose, 6-*O*-α-D-glucopyranosyl- (Chemical Abstracts Service registry number[1] 13718-94-0).

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 replacement of highly digestible carbohydrates in food and natural health product preparations. Potential uses may include use in oral care products, animal feeds, textile dyes, construction materials and biological (waste water) treatment systems, and as a stabilizer in pharmaceuticals.

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. The substance is not expected to be persistent in this compartment based on very high biodegradation (>85% over 28 days). The substance is not expected to bioaccumulate based on very high water solubility, very low octanol-water partition coefficient (log K_{ow} ≤0) and low predicted bioaccumulation factor (<250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low acute toxicity to fish (median lethal concentration >100 mg/L) and to aquatic invertebrates and algae (median effective concentration >100 mg/L). The substance is expected to have low chronic toxicity to fish (no-observed-

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effect-concentration and lowest-observed-effect-concentration >10 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 activity is expected to be mainly from formulation of foods and natural health products containing the substance by release of the substance to water at low rates. For potential activities such as manufacturing of construction materials, pharmaceutical formulation, textile dyeing and waste water treatment, environmental exposure is expected to be mainly from release of the substance to water at low rates. For potential use in animal feeds, the pre-market assessment of environmental exposure is assessed by the Canadian Food Inspection Agency. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity.

Based on the low potential for ecotoxicity and environmental exposure, 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). The substance has low subchronic toxicity following repeated oral doses in mammalian test animals (90-day no-observed-adverse-effect level (NOAEL) >100 mg/kg-bw/day; 26-week NOAEL >100 mg/kg-bw/day; 2-year NOAEL >100 mg/kg-bw/day). The substance has a low developmental toxicity following repeated oral doses in mammalian test animals (NOAEL >300 mg/kg-bw/day). It is not a dermal sensitizer (>10% estimated concentration required to produce a stimulation index of 3 (local lymph node assay)). It is not expected to be mutagenic *in vitro* or clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage. Carcinogenicity studies with mammalian test animals indicate that the substance is not expected to be a carcinogenic hazard.

When the notified substance is used in natural health products and foods, direct exposure of the general population is assessed by the Natural and Non-Prescription Health Products Directorate and Food Directorate of Health Canada, respectively. Potential uses of the substance include as animal feed, in oral care products or stabilizer in pharmaceuticals, where direct exposure is assessed by the appropriate Canadian Agency or the appropriate Health Canada directorate. Potential uses of the substance also include use in textile dyes, construction materials and waste water treatment systems, where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern. 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.

Based on the low toxicity and 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.

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.