

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

New Substances Notification No. 18533: D-Glucose, reaction products with nitric acid and sodium nitrate (1:1), sodium salts

### **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 chemical, d-Glucose, reaction products with nitric acid and sodium nitrate (1:1), sodium salts (Chemical Abstracts Service Registry No. 1362053-75-5), is a substance of unknown or variable composition, complex reaction products, or biological material (UVCB) that can be classified as neutral organics.

### **Notified and Potential Activities**

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for use as a corrosion inhibitor in industrial applications, and in consumer detergents. Potential uses may include other industrial applications, personal care products and as an additive in foods.

### **Environmental Fate and Behaviour**

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water. The substance is not expected to be persistent in water based on its high potential for biodegradation (60-85%). The substance is not expected to bioaccumulate based on its very low octanol-water partition coefficient ( $\log K_{ow} \leq 0$ ).

### **Ecological Assessment**

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 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 activity is expected to be mainly from the cleaning of transportation and formulation vessels, formulation, and use as an industrial corrosion inhibitor via the release of the substance to water at low levels. A predicted environmental concentration for notified activities was not estimated given the expected low level of release and low ecotoxicity of the substance.

Based on the low ecotoxicity and anticipated low to moderate exposure, low persistence and low bioaccumulation, the substance is unlikely to cause ecological harm in Canada.

### **Human Health Assessment**

Based on the available hazard information, the substance has a low acute toxicity by oral route (median lethal dose >2000 mg/kg body weight). It is mutagenic *in vitro*. Therefore, the substance has the potential to cause genetic damage. The substance contains nitrites (1-5% by weight) which have been associated with carcinogenicity, and which are expected to be responsible for the experimentally observed genotoxicity. The Joint Food and Agriculture Organization of the United Nations/World Health Organization Expert Committee on Food Additives and the European Commission's Scientific Committee on Foods have established an Acceptable Daily Intake (ADI) for nitrite of 0.07 mg/kg-bw/d.

When the notified substance is used in industrial applications, direct exposure of the general population is not expected. When the notified substance is used as a chelating agent in consumer detergents, exposure of the general population to the substance is expected to be mainly by contact with the skin. Given the very low octanol-water partition coefficient ( $\log K_{ow} \leq 0$ ) and ionic nature of the substance, it is not expected to be able to cross dermal barriers efficiently. Cumulative exposure from notified use in consumer cleaning products is not expected to exceed 0.05 mg/kg-bw/d. The potential for indirect exposure of the general population from environmental media such as drinking water is expected to be low.

Potential uses for the substance include other industrial applications, personal care products and, as an additive in foodstuffs. Given the very low octanol-water partition coefficient ( $\log K_{ow} \leq 0$ ) and ionic nature of the substance, it is not expected to be able to cross dermal barriers efficiently and dermal contact from its use in personal care products will result in a combined level of biological exposure of 0.001-0.01 mg/kg-bw/d. Potential exposure associated with the use of the substance as a food additive is under the jurisdiction of the *Food and Drug Regulations* and associated Marketing Authorizations and was not assessed. The potential for indirect exposure of the general population due to potential uses of the substance is low.

Based on a comparison of the ADI for nitrite to the estimated exposure levels for notified and potential uses, 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 uses, it is not suspected to be harmful to human health or the environment according to the criteria under section 64 of CEPA.

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 the *Hazardous Products Regulations* for products intended for workplace use.