

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

New Substances Notification 21307: Fatty acids, C<sub>16-22</sub> and C<sub>18</sub>-unsatd., triesters with polypropylene glycol ether with glycerol (3:1) (Chemical Abstracts Service Registry Number 2566495-55-2)

### **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 fatty acids, C<sub>16-22</sub> and C<sub>18</sub>-unsatd., triesters with polypropylene glycol ether with glycerol (3:1) (Chemical Abstracts Service Registry Number<sup>1</sup> 2566495-55-2), and is considered a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

### **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 as a fat substitute in various food products. Potential uses include use as an industrial transformer fluid and as a component of grease formulations.

### **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 ready biodegradation (> 60% over 28 days). The substance is not expected to bioaccumulate based on low octanol-water partition coefficient (log K<sub>ow</sub> 0-3) and low predicted bioconcentration factors (< 250 kg/L).

### **Environmental risk assessment**

---

<sup>1</sup> The Chemical Abstracts Service Registry Number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

Based on the available hazard information, the substance is expected to have low acute toxicity to fish, aquatic invertebrates and algae (no adverse effects observed in saturated solutions). A predicted no-effect concentration was not calculated given the low potential for hazard to the environment.

The notified and other potential activities in Canada were assessed to estimate the environmental exposure of the substance throughout its life cycle. Environmental exposure from the notified activity is expected to be mainly from food processing and use resulting in release of the substance to water. For potential activities, such as use as a lubricant and transformer fluid, environmental exposure is expected to be similar or lower than that of the notified uses. A predicted environmental concentration was not calculated due to the low potential for ecotoxicity.

Based on the low potential for ecotoxicity, the substance is unlikely to cause harm to the environment in Canada.

### **Human health risk assessment**

Based on the available hazard information, the substance has a low acute toxicity by the dermal route (median lethal dose > 2000 mg/kg body weight) and low subchronic toxicity following repeated oral (dietary) doses in mammalian test animals (90-day and 1-year no observed-adverse-effect level > 100 mg/kg-bw/day). It is not expected to be a dermal sensitizer (guinea pig maximization test). It is not mutagenic or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a fat substitute in various foods and snack foods, direct exposure of the general population is expected to be mainly by ingestion at levels in the range of 0.88 to 75% of the food product. The Food Directorate of Health Canada is responsible for the human health risk assessment associated with the use of food ingredients, and therefore, the risk from this application is not addressed in this assessment. The potential use as a lubricant in grease formulations or as a transformer fluid is expected to result in negligible, direct dermal exposure to the general public. Indirect exposure of the general population from notified and potential uses of the substance 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 the low potential for indirect exposure to the general population from notified and potential uses, the substance is 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 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 the *Hazardous Products Regulations* for products intended for the workplace.