

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

New Substances Notification No. 19233: Fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyl ether and triethyl ether and triethylenetetramine (Chemical Abstracts Service No. 186321-96-0)

### 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 determined that the substance is 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 in Canada to human life or health.

In order to ensure that the substance does not cause harm to the Canadian environment or human health, its manufacture and import are authorized subject to conditions as described in [Ministerial Condition No. 19233](#) published in the *Canada Gazette* Part I, Vol. 151, No. 42, October 21, 2017.

### Substance identity

The notified chemical is fatty acids, tall-oil, reaction products with bisphenol A, epichlorohydrin, glycidyl tolyl ether and triethyl ether and triethylenetetramine (Chemical Abstracts Service Registry Number<sup>1</sup> 186321-96-0), and is a substance referred to as unknown or variable composition, complex reaction products or biological materials (UVCB).

### Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 in kg/yr for the notified use in industrial and commercial two-part coatings. Potential uses may include coatings for consumer use, and in industrial, commercial or consumer adhesives, sealants, fillers, grout and caulk products.

### 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 expected to be persistent in these compartments based on its very low biodegradability ( $\leq 10\%$  at 28 days). The substance is not expected to bioaccumulate based on its low to moderate octanol-water partition coefficient ( $\log K_{ow} < 5$ ).

### Ecological assessment

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<sup>1</sup> The Chemical Abstracts Services 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 on the substance and surrogate data on structurally related chemicals, the substance is expected to have moderate acute toxicity in fish (median lethal concentration in the range of 1-100 mg/L), high acute toxicity in aquatic invertebrates and algae (median effective concentration ( $EC_{50}$ ) <1 mg/L), and high chronic toxicity in algae (no-observed-effect-concentration <0.1 mg/L). Using the  $EC_{50}$  from the most sensitive organism (algae) and by applying an assessment factor of 50 to account for species sensitivity variation and acute to chronic extrapolation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1-10 µg/L, which was used to estimate the ecological risk.

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 formulation and cleaning of transportation vessels by release of the substance to water at rates in the range of 0.1-10 kg/day-site. For potential activities such as manufacturing, environmental exposure is expected to be mainly by release of the substance to water at rates in the range of 10-100 kg/day-site. The predicted environmental concentration (PEC) is estimated to be in the range of 1-10 µg/L for formulation and in the range of 10-100 µg/L for cleaning of transport vessels and potential manufacturing activities.

Comparing the PEC with the PNEC, the substance is anticipated to cause ecological harm in Canada. The risks have been identified with the moderate to high acute toxicity in aquatic organisms combined with release of the substance to water when used for the notified or other potential activities.

### **Human health assessment**

Based on the available hazard information, the substance has a low acute toxicity by the oral and dermal routes (median lethal dose >2000 mg/kg body weight) and low subchronic toxicity following repeat oral doses in mammalian test animals (42-49 day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/day). The substance has low reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL >1000 mg/kg-bw/day). It is expected to be a moderate to strong skin sensitizer (29-64% response (guinea pig maximization test) and 0.1-1% estimated concentration required to produce a stimulation index of 3 (local lymph node assay)). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in two-part coatings, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 0.1-1 µg/kg-day. If potential uses of the substance were to include paints for consumer use, direct exposure of the general population is expected to be mainly by contact with the skin at conservatively estimated levels in the range of 1000-10 000 µg/kg-event. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 1-10 µg/kg-day.

Based on the low potential for exposure from the notified use, and considering other available lines of evidence, 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.

However, the substance is a moderate to strong skin sensitizer and potential use of the substance in consumer paints could significantly alter the exposure and/or conditions of use resulting in the substance becoming harmful to human health.

### **Assessment conclusion**

The substance is suspected to have a harmful effect on the environment according to the criteria under paragraph 64 (a) of the Act and to potentially constitute a danger to human health according to the criteria under paragraph 64 (c).

Due to the identified risk to the environment related to the aquatic toxicity and to human health related to dermal sensitization if used in consumer paints, a ministerial condition was issued to restrict the manner in which the notifier may manufacture or import the substance with conditions on its use or disposal in order to mitigate these potential risks. Ministerial Condition No. 19233 was published in the *Canada Gazette* Part I, Vol. 151, No. 42 on October 21, 2017.

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.