

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

New Substances Notification 20628: 2,5-Furandione, reaction products with polybutadiene
(Chemical Abstracts Service Registry Number 68441-88-3)

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 2,5-furandione, reaction products with polybutadiene (Chemical Abstracts Service Registry Number¹ 68441-88-3). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because 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 10 000 kg/yr for the notified use in rubbers, adhesives and sealants in vehicles. Potential uses may include rubber compounding and paints.

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 the low hydrolysis and predicted biodegradation. The substance is not expected to bioaccumulate based on the low water extractability (< 2%) and very high predicted adsorption-desorption coefficient ($\log K_{oc} > 4.5$), which will limit its bioavailability.

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Environmental risk assessment

Based on its low water extractability (<2%), the substance is expected have low bioavailability and low potential for hazard to the environment. Therefore, a predicted no-effect concentration was not calculated.

Environmental exposure from the notified or potential activities is not expected due to the low water extractability. Therefore, a predicted environmental concentration was not calculated.

Based on its low hazard potential and low environmental exposure, 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 oral route (median lethal dose >2000 mg/kg body weight). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The substance contains structural features associated with pulmonary sensitization and systemic toxicity via inhalation.

When the notified substance is used in rubbers, adhesives and sealants, 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 or air is not expected given the low potential for environmental release.

Potential uses of the substance include industrial, commercial and consumer applications, where direct and indirect exposure of the general population are expected to be at levels that do not pose a concern, similar to that of the notified use. The functional group of concern is a reactive moiety that is expected to be consumed during the manufacturing of all end-use products.

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.

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