

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

Ministerial Condition No: 17202: 2-Propanone, reaction products with phenol,
Chemical Abstracts Service Registry No. 72162-28-8

Regulatory Decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), and pursuant to section 83 of that 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.

In order to ensure that the substance does not cause harm to the Canadian environment or human health, its manufacture and/or import is authorized subject to conditions on its handling and disposal as described in [Ministerial Condition No. 17202](#) published in the *Canada Gazette* Part I, Vol. 147, No. 29, July 20, 2013.

Substance Identity

The substance is a chemical that can be classified as an unknown or variable composition, complex reaction product or biological material (UVCB). The principal components of the substance are phenolic derivatives, including Bisphenol A (BPA).

Notified Activities

The substance is proposed to be imported into Canada in quantities greater than 10,000 kg/yr for use in the production of resins used for wood sheet goods.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water and sediments. The substance is not expected to be persistent in water; however, it is expected to be persistent in sediment based on many studies showing that BPA does not degrade or degrades only slowly under conditions of low or no oxygen. The substance is not expected to be bioaccumulative based on the moderate octanol-water partition coefficient ($\log K_{ow} = 3.32$) for BPA and measured bioconcentration factor values ranging from 3.5 to 68 L/kg in fish for BPA.

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has moderate ($LC_{50}/EC_{50} = 1\text{-}10\text{ mg/L}$) acute toxicity in fish, daphnia and algae and high ($EC_{50} < 0.1\text{ mg/L}$) chronic toxicity in fish. The predicted no effect concentration was calculated to be $< 1\text{ }\mu\text{g/L}$ using the EC_{50} from the most sensitive organism (fish), which was used to estimate the environmental 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 may potentially occur from release of the substance to water following cleaning of transportation vessels. The predicted environmental concentration for this activity is estimated to be $> 1\text{ }\mu\text{g/L}$.

The substance is a mixture containing BPA, and as such, is subject to Environment Canada's "Notice Requiring the Preparation and Implementation of Pollution Prevention Plans with Respect to BPA in Industrial Effluents" (*Canada Gazette*, Part I, Vol. 146, No. 15 - April 14, 2012). This is required of any industrial facility that manufactures or uses BPA (neat substance or part of a mixture) in a quantity greater than 100 kg per year that results in aqueous discharges that contain BPA at the final discharge point of the facility. Environment Canada has published a draft performance agreement between the Government of Canada and a number of "Participating Companies". As such, other potential releases of the substance from uses other than those described in the notification are already addressed with existing risk management strategies.

Based on the potential for aquatic exposures to exceed the predicted no-effect concentration, the substance is anticipated to cause ecological harm in Canada. The risks have been identified with releases from the cleaning of transportation vessels.

Human Health Assessment

Based on the available toxicity information, it is concluded that the substance has low acute oral toxicity ($LD_{50} > 2000\text{ mg/kg bw}$) and is not mutagenic *in vitro*. Based on the available hazard information on structurally related chemicals, it is concluded that the notified substance is likely to have low-to-moderate repeated-dose oral toxicity (NOAEL 30 mg/kg bw/day to $> 300\text{ mg/kg bw/day}$) and low repeated-dose inhalation toxicity (NOAEL $> 3\text{ mg/L/6hr}$). Based on the available hazard information on structurally related chemicals, the notified substance may be of concern for potential adverse effects on the endocrine, immune and developing nervous systems; however, it is not expected to be genotoxic or carcinogenic.

Hazards related to substances used in the workplace should be classified accordingly under the Workplace Hazardous Materials Information System (WHMIS).

When used as notified, direct and indirect exposure of the general public to the substance is expected to be low. No other potential uses are reasonably envisaged for the notified substance. If the substance is released following cleaning of transportation vessels, potential exposure of the general population from drinking water is estimated to be significantly less than

a dose level which is deemed to cause no adverse effects to humans based on animal toxicity study.

Based on the low potential for direct and indirect exposure expected for the general population, 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.

Other Considerations

The substance contains BPA. BPA was assessed in 2008 by both Environment Canada and Health Canada and was found to meet the definition of “toxic” under paragraphs 64(a) and 64(c) of CEPA 1999. The substance was then added to Schedule 1 of CEPA on October 13, 2010. Risk management action milestones published online:

http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-2/bisphenol-a/bpa-risk_hazard-eng.php.

Assessment Conclusion

The substance is suspected to be harmful to the environment according to the criteria under paragraph 64(a) of CEPA 1999.

Due to the identified environmental risks related to the aquatic toxicity if the substance is used in the production of resins used for wood sheet goods, a Ministerial Condition was issued to restrict the manner in which the notifier may manufacture and/or import the substance with conditions on its handling and/or disposal in order to mitigate these potential risks. Ministerial Condition No. 17202 was published in the *Canada Gazette* Part I, Vol. 147, No. 29, July 20, 2013.

A conclusion under CEPA 1999, on this substance, is not relevant to, nor does it preclude, an assessment against the hazard criteria for WHMIS that are specified in the *Controlled Products Regulations* for products intended for workplace use.