

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

New Substances Notification No. 18926: Benzamide, 3,3'-[(2-chloro-1,4-phenylene)bis[imino(1-acetyl-2-oxo-2,1-ethanediyl)azo]]bis[4-methyl-

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 benzamide, 3,3'-[(2-chloro-1,4-phenylene)bis[imino(1-acetyl-2-oxo-2,1-ethanediyl)azo]]bis[4-methyl- (Chemical Abstracts Service No. 253430-12-5).

Notified and Potential Activities

The substance is proposed to be imported Canada in quantities greater than 10 000 kg/yr for use as a pigment for plastics and printing toners. Potential uses may include printing inks, spray paints, lacquers and varnishes.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to soil and sediment. The substance is expected to be persistent in soil and sediment based on its low biodegradation potential ($\leq 10\%$ over 28 days). The substance is not expected to bioaccumulate based on its estimated low bioconcentration and bioaccumulation factors (< 250 L/kg) and its low water solubility (0.01-10 mg/L) which will limit bioavailability.

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has low acute toxicity in fish, aquatic invertebrates and algae (no adverse effects observed in saturated solution) and low chronic toxicity in algae (no-observed-effect concentration > 10 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 low. The notified substance will be imported and used in low concentrations (<5%), and will be consumed during use. For potential uses such as a pigment for other applications including paints, lacquers and varnishes, environmental exposure is expected to be similar to that of the notified use. A predicted environmental concentration was not calculated due to the low potential for environmental exposure.

Based on the low levels of ecotoxicity, bioavailability and environmental exposure, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information, the substance has low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg body weight) and a low subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/d). It is not a skin sensitizer (0-8% response (guinea pig maximization test)). It is not mutagenic or clastogenic *in vitro*. The reliability of the mutagenicity test for assessing azo substances is questionable; however, structurally similar azo pigments were also found to be non-genotoxic. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be 1000-10 000 µg/kg-bw/d based on the NOAEL of the oral subchronic toxicity study in mammalian test animals.

When the notified substance is used industrially as a pigment for plastics, consumers may come into direct dermal contact with end-use articles containing the substance; however, direct exposure is expected to be limited as the substance will be present at low concentrations (<1%) and will be encapsulated within a polymer matrix. Direct oral exposure is also possible from food-contact materials and the dietary exposure level was estimated to be 0.1-1 µg/kg-bw/d. Indirect exposure of the general population from environmental media such as drinking water is expected to be low.

If the substance is used in consumer spray paints, lacquers and varnishes, direct exposure of the general population is expected to be mainly by inhalation at levels of 0.01-0.1 µg/kg-bw/d. If the substance is used in printing inks, the indirect exposure from drinking water following recycling of paper was estimated to be 0.1-1 µg/kg-bw/d.

Based on a comparison of the PTDI to the estimated exposures, 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 used as notified or for other identified potential uses, the substance 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 *Hazardous Products Regulations* for products intended for the workplace.