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

New Substances Notification No. 18283: Peroxide, bis (4-methylbenzoyl)

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 chemical, peroxide, bis (4-methylbenzoyl) (Chemical Abstracts Service Registry No. 895-85-2), can be classified as an organic aryl peroxide.

Notified and potential activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for use as a curing agent and cross-linker for the manufacturing of silicon rubbers. Potential uses may include as an additive in food packaging, cosmetics, adhesives, construction materials and paints, as well as other industrial uses.

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 not expected to be persistent in soil or the aquatic environment based on its very high biodegradability (>85%) and very short hydrolysis half-life (<10 days) in the presence of moisture. The substance is not expected to bioaccumulate based on its modelled bioconcentration and bioaccumulation factors (<5000 L/kg).

Ecological assessment

Given the low water solubility of the substance and its rapid hydrolysis, aquatic toxicity testing was carried out on its hydrolysis products rather than the notified substance. Based on the available hazard information on the hydrolysis products of the notified substance, the substance is expected to have moderate acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration (LC_{50}) and median effective concentration (EC_{50}) 1-100 mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrate) and by applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 100-1000 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 activity is expected to be mainly from cleaning of transport vehicles by release of the substance to the aquatic environment via wastewater. The predicted environmental concentration (PEC) for notified activities is estimated to be 1-10 µg/L. The PEC from potential activities is expected to be similar to that of the notified activity.

Comparing the PEC for notified and potential activities with the PNEC, the ratio is less than 1. This along with other lines of evidence including environmental fate, hazard, and exposure indicates that the substance is unlikely to cause ecological harm in Canada.

Human health assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has a low acute toxicity by the oral and dermal routes (median lethal dose >2000 mg/kg body weight) and is expected to have low acute toxicity by the inhalation route (LC_{50} >20 mg/L). It has a low subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level >300 mg/kg-bw/d). It is not a skin sensitizer (% 0 response (Buehler scale)). It is not mutagenic *in vitro* or clastogenic *in vivo*, and is likely to be of low concern for carcogenicity based on surrogate substances. Therefore, the substance is unlikely to cause genetic damage. The substance is structurally similar to benzoyl peroxide but shows lower overall hazard potential.

When the notified substance is used as a curing agent and cross-linker in manufacture of silicon rubber products, direct exposure of the general population is not expected due to the industrial nature of the use . Consumers may come into contact with products containing the substance; however the substance will be chemically reacted into a stable matrix once cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is expected to be very low due to the low solubility and rapid hydrolysis of the substance. Potential uses of the substance include use as an additive in food packaging, cosmetics, adhesives, construction materials and paints, as well as other industrial uses. If used in consumer products such as cosmetics, there is potential for high direct exposure of the general population, but low indirect exposure as the substance is unlikely to partition to water or air.

Based on the low acute and subchronic toxicity and low potential for genotoxicity and carcinogenicity, 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 for notified or potential uses.

Assessment conclusion

When the substance is used as notified or for other identified potential uses, it 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 the *Hazardous Products Regulations* for products intended for workplace use.