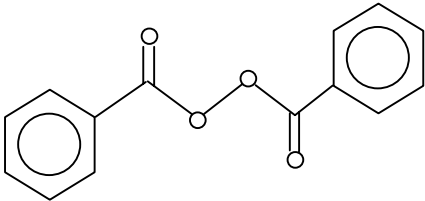


SIDS INITIAL ASSESSMENT PROFILE

CAS No.	94-36-0
Chemical Name	Benzoyl peroxide
Structural Formula	$\text{C}_{14}\text{H}_{10}\text{O}_4$ 

SUMMARY CONCLUSIONS OF THE SIAR**Human Health**

The dry chemical becomes explosive above 105°C and when subjected to impact or friction.

The acute oral toxicity of benzoyl peroxide is very low: LD50 >2,000 mg/kg bw in mice, and 5,000 mg/kg bw in rats. No deaths occurred in male rats following inhalation of 24.3 mg/L. Visible effects included eye squint, dyspnea, salivation, lacrimation, erythema and changes of respiratory rates and motor activity.

Benzoyl peroxide was slightly irritating to skins in 24 hr-patch tests. Benzoyl peroxide was not irritating to the eyes of rabbits if washed out within 5 minutes after instillation, however, if the chemical was not washed out until 24 hours later, it proved to be irritating.

Positive results from sensitisation tests in guinea pigs and mice, and from a maximization test in human volunteers, indicate that benzoyl peroxide is a skin sensitizer.

In the combined repeated dose and reproduction/developmental toxicity study (OECD TG 422), benzoyl peroxide did not produce hematological or biochemical adverse effects. Repeated administration by oral gavage up to 1,000 mg/kg bw/day for 29 days resulted in decreased weights of testes and epididymis in male rats. The NOAEL for repeated dose toxicity was 500 mg/kg bw/day.

This substance did not cause gene mutation in bacteria (OECD TG 471 & 472) and *in vitro* chromosomal aberration in CHL (Chinese Hamster Lung) cells. An *in vivo* mammalian erythrocytes micronucleus test (OECD TG 474) produced negative result. The available evidence supports the conclusion that benzoyl peroxide is not a mutagen.

There is no evidence to suggest that benzoyl peroxide is a carcinogen. However, there is some evidence from non-guidelines studies that benzoyl peroxide is a skin tumour promoter.

In the combined repeated dose and reproduction/developmental toxicity study [OECD TG 422], no treatment-related changes in precoital time, rate of copulation, fertility and gestation were noted in any treated group. Adverse effects were shown at the highest dose of 1,000 mg/kg bw/day in parental male rats with the reduction of reproductive organ weight and slight testes degeneration. In parental female rats, no adverse effects were observed during the test period. The NOAEL for reproduction toxicity in male rats was 500 mg/kg bw/day. In the offspring, the only effect seen was that body weight gain of pups at dose of 1,000 mg/kg bw/day was significantly decreased. The NOAEL for developmental toxicity was 500 mg/kg bw/day.

Environment

Benzoyl peroxide is commercially produced as a white granule with purities ranging from 22 to 95%. It has a melting point of 104 -106 °C, vapor pressure of 0.00929 Pa, solubility of 9.1 mg/L in water at 25 °C, and log P_{ow} of 3.43 at 25 °C. For indirect photolysis in the atmosphere, the half-life is estimated to be 3 days with the AOPWIN model. The substance is readily biodegradable (OECD TG 301C: 83% by BOD after 21 days) and hydrolyses rapidly in water [OECD TG 111] with a half-life of 11.87 hrs at pH 4.0 and 5.20 hr at pH 7.0 at 25 °C. The main hydrolysis product of benzoyl peroxide is benzoic acid (a SIDS assessment of benzoic acid is available: CAS No. 65-85-0). The estimated BCF of 92 with the BCFWIN model suggests that the chemical has a low potential for bioaccumulation.

The following studies for aquatic organisms are available:

Green algae (*Selenastrum capricornutum*): 72 hr-E_bC₅₀ is 0.07 mg/L (biomass) and 0.44 mg/L (growth rate).
Invertebrates (*Daphnia magna*): 48 hr-EC₅₀ is 0.07 mg/L.
Fish (*Oryzias latipes*): 96 hr-LC₅₀ is 0.24 mg/L.
Microorganism (*activated sludge*): 30 min.-EC₅₀ is 35 mg/L.

The toxicity observed is assumed to be due to benzoyl peroxide rather than benzoic acid, which shows much lower toxicity to aquatic organisms. One can assume that effects occur before hydrolysis takes place.

A generic fugacity model (Mackay level III) was used for environmental fate estimation. If the most realistic emission pattern to water is assumed then the substance will remain in the aquatic compartment.

Exposure

In Korea, the total production volume of benzoyl peroxide was 1,357 tonnes in 2001, and the chemical is produced in only one company. The amounts of import and export were estimated as 268 and 293 tonnes/year, respectively. 75% benzoyl peroxide is mainly used in the manufacture of expandable styrene polymer and other resins as initiators of polymerization. Benzoyl peroxide has also been used in the treatment of acne vulgaris and the medical product contains mainly 5-10 % benzoyl peroxide. A very small portion of benzoyl peroxide is used as flour bleaching agent.

The Danish, Norwegian and Swedish product register indicates that this substance is used in adhesives, cosmetics, dental products, process regulators, fillers, construction materials and paints. These products may contain 2-80 % of the substance depending upon the product.

The major routes of occupational exposure are inhalation and dermal. Limited data on exposure are available. At a production facility monitoring its workplace for the worker exposure annually, the concentration of airborne aerosols at personal sampling has been less than 1 mg/m³.

RECOMMENDATION

The chemical is a candidate for further work.

RATIONALE FOR THE RECOMMENDATION AND NATURE OF FURTHER WORK RECOMMENDED

Human Health: The chemical possesses properties indicating hazards to human health (sensitisation, effect on testes weight, fetal body weight and skin tumour promotion activity) and is a candidate for further work, i.e. exposure assessment, and if considered necessary, risk assessment.

Environment: It is expected that the possibility of any environmental releases of benzoyl peroxide is low in the sponsor country. However, this substance is a candidate for further work, even if it hydrolyses rapidly and has a low bioaccumulation potential. The substance shows high acute toxicity to aquatic organisms and some information indicates wide-dispersive use of this substance. This could lead to local concern for the aquatic environment and therefore environmental exposure assessment is recommended.