RISK 1

Initial Risk Assessment of Benzoyl Peroxide in OECD High Production Volume Chemical Program

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Abstract

In Korea, 1,357 tonnes of benzoyl peroxide was produced as a white granule with purities ranging 22 to 95% in 2001. 75% of benzoyl peroxide is mainly used in the manufacture of expandable styrene polymer and other resins as initiators of polymerization and also been used in the treatment of acne vulgaris and the medical product contains mainly 5 to 10% of it. A very small portion of benzoyl peroxide is used as flour bleaching agent. Potential human exposure from workplaces is expected to be negligible because this chemical is produced in closed system in only one company in Korea and when a production facility monitors its workplace for the worker exposure annually, the concentration of airborne aerosols at the personal sampling has been less than 1mg/m^3.

Benzoyl peroxide hydrolyses to benzoic acid rapidly in water and is readily biodegradable. This substance has a low potential for bioaccumulation by BCFWIN model. Ecotoxicity data has been generated in a limited number of aquatic species of algae (72hr-E_bC_{50}; 0.07 mg/l, 72hr-E_gC_{50}: 0.44 mg/l), daphnid (48hr-EC_{50}; 0.07 mg/l) and fish

(96hr-LC_{50}; 0.24 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.

Acute toxicity of benzoyl peroxide is very low since the LD_{50} of oral exposure in mice is >2,000 mg/kg bw and that of in rats is 5,000 mg/kg bw. Positive results from varied sensitisation tests in guinea pigs and mice, and from a maximization test in human volunteers, indicate benzoyl peroxide is a skin sensitizer. In the combined repeated dose and reproduction/development toxicity study, 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 tests and epididymis in male rats. There was no evidence of teratogenic effect of benzoyl peroxide, but body weight of pups at 1,000 mg/kg bw/day was significantly decreased. NOAEL for combined repeated dose and reproduction/development toxicity was 500 mg/kg bw/day. There is no evidence to suggest that benzoyl peroxide is a carcinogen. However, there is some evidence from non-guidelines studies that the substance is a skin tumour promoter.

On the basis of these data, finally benzoyl peroxide was suggested as a candidate for further work as post-SIDS work in OECD since the chemical possesses properties hazards to human health (sensitisation, effect on testes weight, fetal body weight and skin tumour promotion activity) and high acute toxicity to aquatic organisms and some information indicates wide-dispersive use of the substance. It considered necessary at risk assessment and environmental exposure assessment.