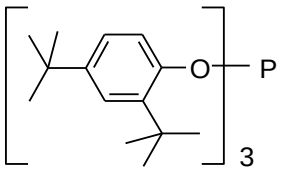
SIDS INITIAL ASSESSMENT PROFILE

CAS No.	31570-04-4
Chemical Name	Tris(2,4-di-tert-butylphenyl)phosphite
Structural Formula	

SUMMARY CONCLUSIONS OF THE SIAR

Physical-chemical properties

Tris(2,4-di-tert-butylphenyl)phosphite is a solid with a typical purity of >99% w/w. It has a melting point of 180 - 186 °C and decomposes above 350 °C. It has a measured vapour pressure of 1.3 x 10^{-10} hPa at 20 °C. The calculated octanol-water partition coefficient (log K_{ow}) is > 6.0, and the water solubility is <0.005 mg/L at 20 °C.

Human Health

Uptake of tris(2,4-di-tert-butyl-phenyl)phosphite from the gastro-intestinal tract is extremely limited. The main metabolite in rats found in the faeces was tris(2,4-di-tert-butyl-phenyl)phosphate, which might have resulted from direct oxidation in the gastrointestinal tract.

The acute oral and acute dermal LD_{50}-values of tris(2,4-di-tert-butyl-phenyl)phosphite are >6,000 mg/kg bw in the rat, mouse and hamster and >2,000 mg/kg bw in the rat, respectively. Clinical signs observed were limited to sedation, dyspnoea, hunched posture, piloerection and ruffled fur, which are common signs observed in such studies.

The substance is not irritating to the skin and the eyes. In a guinea pig test of limited quality (very low concentrations tested) no sensitization was observed. There are no indications for a sensitising potential of tris(2,4-di-tert-butyl-phenyl)phosphate in humans despite its widespread use.

Repeated oral exposure to tris(2,4-di-tert-butyl-phenyl)phosphite did not induce adverse effects. In a 13-week study in rats, no adverse effects were seen at 1000 mg/kg/day, the highest dose tested.

Negative results were obtained in a limited assay for induction of gene mutation in bacteria. Negative results were also obtained in *in vivo* bone marrow assays for clastogenicity (both micronucleus test and metaphase analysis in hamsters). In addition negative results were obtained in a dominant lethal assay in the mouse. The results indicated that tris(2,4-di-tert-butyl-phenyl)phosphite does not have any significant mutagenic potential.

In a carcinogeneicity study in rats treated with doses up to 147 mg/kg be (diet study), tumour incidences were low and could not be related to treatment. No evidence for carcinogenicity is available and the NOAEL is > 147 mg/kg bw/day.

In a two-generation study in rats tris(2,4-di-tert-butyl-phenyl)phosphite did not have any adverse effects on reproductive

parameters at 292.6 mg/kg bw/day. At 1,030 mg/kg bw/day a reduced fertility index was detected in the F0 generation. Decreased foetal weight was observed in the F2-generation at the highest dose of 1030 mg/kg bw/day. The NOAEL for reproductive performance is 292.6 mg/kg bw/day. The NOAEL for developmental toxicity is 4,000 ppm (412 mg/kg bw/day). The NOAEL for maternal and developmental toxicity in rabbits is ≥ 1200 mg/kg bw/day (the highest dose tested in a teratogenicity study performed according to OECD 414). There was no evidence of teratogenicity.

Tris(2,4-di-tert-butylphenyl)phosphate does not possess properties indicating a hazard for human health based on its low hazard profile. Adequate screening-level data are available to characterize the human health hazard for the purposes of the OECD HPV Programme.

Environment

Tris(2,4-di-tert-butylphenyl)phosphite has a calculated half-life for photo-oxidation of 5.4 hours (indirect reaction with OH-radicals). Fugacity modelling (Mackay Level III) predicts that tris(2,4-di-tert-butylphenyl)phosphite will partition to soil and sediment (32% and 67% respectively). Based on the log Kow, tris(2,4-di-tert-butylphenyl)phosphite has a high potential for adsorption to soil (predicted Log Koc 4.6). Limited migration from soil to plants and water was shown. Tris(2,4-di-tert-butylphenyl)phosphite is not readily biodegradable under experimental test conditions (OECD 301B; 6% degradation over 28 days). In a hydrolysis study conducted according to OECD TG 111, tris(2,4-di-tert-butylphenyl)phosphite was shown to be hydrolytically stable under environmentally relevant conditions at pH 4, 7 and 9. A study conducted to assess the biomagnification potential of the substance in fish indicated that it is unlikely to bioaccumulate. Uptake of the substance into test organisms was very low, resulting in a mean lipid normalised whole fish biomagnification factor of 0.0032±0.0020. Mass balance measurements indicated that the majority of the test substance was present in excreted faeces.

Short-term aquatic toxicity tests at 3 trophic levels are available which show no effects at the water solubility limit in any of the tests. A 96h limit test with the fish *Brachydanio rerio* showed no effects at the nominal concentration of 100 mg/l. In a 24h *Daphnia magna* test, immobilisation was observed at nominal concentrations above 320 mg/l but these effects were due to physical interference with the test substance. No effects were observed at nominal concentrations up to 180 mg/l and it is concluded that the substance is not acutely toxic to Daphnia magna at the limit of water solubility. A 72h study with the algae *Scenedesmus subspicatus* showed no effects at the highest nominal test concentration of 75.2 mg/l. (It should be noted that all these tests were conducted at nominal concentrations greatly in excess of the water solubility limit). In a growth inhibition test no effects on activated sludge were found at the water solubility level (3h EC50 > 100 mg/l nominal concentration). There are no sediment or terrestrial effect data.

The substance does not possess properties indicating a hazard for the environment based on its low hazard profile. Adequate screening-level data are available to characterize the environmental hazards for the purposes of the OECD HPV Programme.

Exposure

For the year 2002 the global market for tris(2,4-di-tert-butylphenyl)phosphite was about 55,000 tonnes. The substance is used as as an antioxidant and/or stabiliser in matrices of polymers (packaging materials).

During production and processing there may be exposure of workers. The inhalatory route will be the most important route of exposure (particle size 10-100 μm diameter (respirable)).

During end-use consumers may be exposed to the substance due to low migration from the matrix (regulatory migration limit for this chemical is 60 mg/kg food).

There is potential environmental exposure during production and processing of tris(2,4-di-tert-butylphenyl)phosphite and by leaching from waste at landfills.