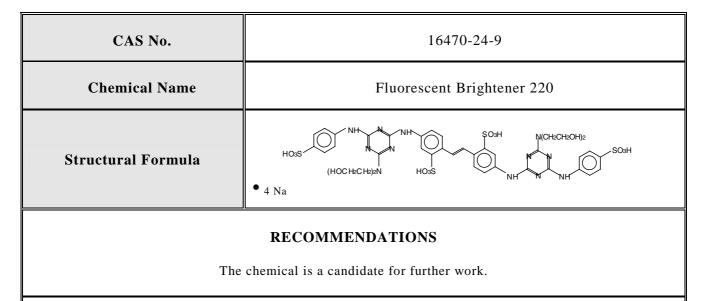
### SIDS INITIAL ASSESSMENT PROFILE



# SUMMARY CONCLUSIONS OF THE SIAR

### Human Health

The acute oral and dermal toxicity is low: oral: LD50 > 15000 mg/kg bw (rat); dermal: LD50 > 2000 mg/kg bw (rat). In the available tests of restricted validity C.I. Fluorescent Brightener 220 is not (after short exposure) or slightly (after prolonged exposure) irritating to the skin and slightly irritating to the eyes. A repeated insult patch test in 103 human volunteers showed no indication of irritation or skin sensitization after application of 0.1% test substance. In a 2-year feeding study in rats there were no adverse effects observed at the highest dose level: NOAEL = 10000 ppm (521 mg/kg bw/day for males; 709 mg/kg bw/day for females). There was no induction of gene mutation in bacteria. There was no induction of cytogenetic effects in an *in vitro* chromosome aberration test in spermatogonia (hamster), in a micronucleus test (mouse) and in a dominant lethal test (mouse, OECD TG 478, GLP). A 2-year feeding study in rats did not result in any carcinogenic effects. A 2-generation study in rats showed no evidence of reproduction toxicity (EPA OPPTS 870.3800, GLP): NOAEL = 300 mg/kg bw/day (parental toxicity); NOAEL = 1000 mg/kg bw/day (reproductive performance and offspring toxicity). Two studies revealed no evidence of teratogenicity in rats and rabbits (EPA OPPTS 870.3700, GLP): rat: NOAEL = 1000 mg/kg bw/day (maternal and fetal toxicity); rabbit: NOAEL = 100 mg/kg bw/day (maternal and fetal toxicity).

### Environment

C.I. Fluorescent Brightener 220 is a salt with a melting point of > 300 °C. The substance is soluble in water with 377 g/l at 20 °C. In view of the melting point, the vapor pressure is predicted to be low. Nevertheless a log Kow is calculated to be -2.83.

The calculation of a Mackay fugacity model is not appropriate for this substance. From the physico-chemical properties it could be concluded that the sole target compartment for C.I. Fluorescent Brightener 220 is water, as the substance is a salt. However, as a high adsorption to soil was experimentally determined, it has to be assumed that the substance will strongly adsorb also to the sediment compartment as well. The substance is not readily biodegradable. Monitoring data showed the substance to be removed by >75 to >95 % through adsorption from sewage. Direct photolysis is a second elimination process for Fluorescent Brightener 220 in the upper layer of surface waters with  $t\frac{1}{2}$  in the range of 3.9 to 5.2 hours. Presently, there is no information about photolysis products. The calculation of the indirect photolysis showed a mean t  $\frac{1}{2}$  of 1.6 hours for cis- and trans-isomers C.I. Fluorescent

Brightener 220 by OH radicals as well as by ozone. Although measured data on bioaccumulation are lacking, it can be concluded from the ionic nature, that the bioaccumulation potential of C.I. Fluorescent Brightener 220 is not significant via the water phase. However, bioaccumulation from the sediment by benthic organisms cannot be excluded.

According to measured data on soil adsorption Fluorescent Brightener 220 can be regarded as a substance with high geoaccumulation properties, as Koc values up to 10,000 were found.

The acute toxicity has been determined for fish, daphnia and algae as follows:

fish (*Brachydanio rerio*) with a 96 h-LC<sub>0</sub> > 1000 mg/l and a 14 d-NOEC of > 859 mg/l daphnia (*Daphnia magna*) with a 48 h-EC<sub>0</sub> of >= 113 mg/l and a 24 h-EC<sub>50</sub> > 1000 mg/l algae (*Scenedesmus subspicatus*) with a 96 h-EC<sub>50</sub> > 1000 mg/l.

Chronic toxicity has been tested for Daphnia magna with a 21 d-NOEC of 10 mg/l on reproduction and for algae (*Scenedesmus subspicatus*) with a 96 h-EC<sub>0</sub> of 500 mg/l. A PNECaqua of 0.2 mg/l is derived from the 21 d-NOEC for Daphnia using an assessment factor of 50. For sediment organism no effect values are available. At a screening approach a PNECsed can be estimated via the equilibrium partitioning method. A PNECsed of 4.3 mg/l was derived. Acute toxicity on *Eisenia fetida* was tested in a limit test according to OECD guideline 207. The 14 d-LC50 was > 10,000 mg/kg. With an assessment factor of 1000, a PNECsoil of 10 mg/kg can be derived.

#### Exposure

The world production of C.I. Fluorescent Brightener 220 amounts to about 35,000 t/a a.i. by 12 producers. The substance is used as a whitening agent in the paper and textile industry. Recommended concentrations for whitening of paper and textiles are in the range of 0.05 to 0.5 % a.i. at maximum. Due to the high molecular weight of the substance and low releases from products human exposure is assumed to be very low.

Releases into the hydrosphere are expected from production, processing of textiles and paper as well as during paper recycling and cleaning of treated textiles in households (washing out). Releases into the atmosphere may not occur as the substance is a salt. Releases of the terrestrial compartment are expected to occur through application of sewage sludge.

## NATURE OF FURTHER WORK RECOMMENDED

No information is available on the toxicity of C.I. Fluorescent Brightener 220 to benthic organisms. Although the substance is not toxic to aquatic organisms the performance of a sediment test is regarded necessary, as it can be assumed that the substance will adsorb to the sediment if released into the hydrosphere. In addition, as the substance is not biodegradable, an accumulation in the sediment may occur. Exposure data from production in the sponsor country show that this life-cycle step will not lead to high water or sediment concentrations. However, there are no information available on the release of fluorescent brightener from processing of paper and textiles as well as from paper recycling and cleaning of treated textiles in households. Therefore, it should be considered to perform a long-term sediment test with the endobenthic organism *Lumbriculus variegatus* or to perform an exposure assessment to clarify the likely impacts on the sediment compartment.