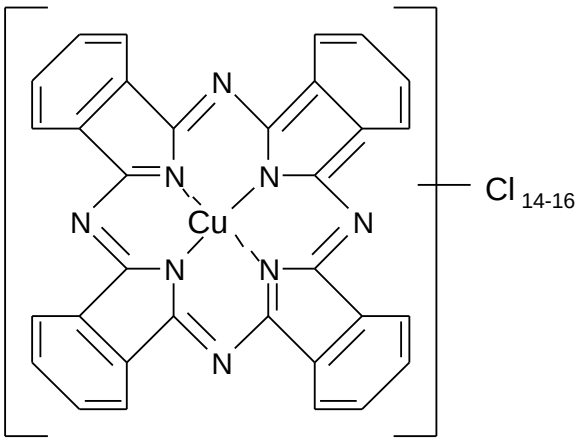
SIDS INITIAL ASSESSMENT PROFILE

CAS No.	1328-53-6
Chemical Name	C.I. Pigment Green 7 Copper, [tetradecachloro-29H,31H-phthalocyaninato(2-)-N{29},N{30},N,{31},N{32}]-
Structural Formula	

SUMMARY CONCLUSIONS OF THE SIAR

Analogue Rationale

C.I. Pigment Blue 15 (CAS-No. 147-14-8) will be used as an analogue for C.I. Pigment Green 7 (CAS-No. 1328-53-6). Both pigments belong to the same class of organic pigments bearing the same core structure (Cu-Phthalocyanine). While C.I. Pigment Blue 15 represents the unmodified version of the molecule, C.I. Pigment Green 7 is chlorinated 14 to 16 fold per phthalocyanine. They both are of high molecular weight and show extremely low water solubility. Furthermore, data from subchronic toxicity studies and genetic toxicity *in vitro* support the analogy.

Data on C.I. Pigment Blue 15 will be used to address the reproduction and developmental toxicity endpoints, as well as biodegradability.

Human Health

C.I. Pigment Green 7 is of low acute oral toxicity (LD_{50}, oral, rat: > 2000 mg/kg bw). The available data concerning the inhalation route are not sufficient to provide a well founded assessment of the inhalation toxicity of the substance. No data are available on the dermal route.

C.I. Pigment Green 7 is not irritating to the rabbit skin and eye. One isolated case of positive patch reaction to C.I. Pigment Green 7 (10 % in pet.) was reported for humans. However, there are no reliable references on a sensitizing potential of C.I. Pigment Green 7.

In a 28-day gavage study on rats with C.I. Pigment Green 7, doses up to 1000 mg/kg bw/day resulted in no adverse effects in clinical observations, hematology, urine analysis, clinical chemistry as well as macro- and microscopical

pathology. The NOEL determined was 1000 mg/kg bw/day for both sexes. In a 28-day feeding study on rats with the analogue C.I. Pigment Blue 15 slight but significant changes in some blood parameters were detected in the 200 and 1000 mg/kg bw/day male groups and increases of absolute organ weights in the 1000 mg/kg bw/day group. Due to the minor severity of the effects a NOAEL of 1000 mg/kg bw/day is derived.

90-day feeding studies on rats and mice with C.I. Pigment Green 7 showed no adverse effects with NOAELs of 4600 mg/kg bw/day for male rats and 5000 mg/kg bw/day for female rats and 16,000 mg/kg bw/day for female mice and 20,000 mg/kg bw/day for male mice. The NOAELs from the rat and mouse studies are the highest tested doses.

In vitro genotoxicity tests indicated that the substance has no genotoxic activity. C.I. Pigment Green 7 was not mutagenic in bacteria (Ames test) with and without metabolic activation systems. Furthermore, it did not induce chromosomal aberrations or aneugenic activity in mammalian cell cultures. Data for *in vivo* genotoxicity tests are not available. These data were partly supported by Ames test results with the analogue C.I. Pigment Blue 15.

Data from subchronic studies showed no changes in the reproductive systems of both sexes in terms of organ weights, gross pathology and histopathology. Additionally, data derived from a reproduction toxicity screening test in rats with the analogous substance C.I. Pigment Blue 15 showed no effects on mating performance, fertility and during autopsy of the pups. Therefore, and taking the low bioavailability of the compound into account, an induction of effects on fertility and development by C.I. Pigment Green 7 is not indicated.

Environment

In the Sponsor country C.I. Pigment Green 7 contains < 2.5 ppm of HCB. This quantity may not be representative for other production sites.

C.I. Pigment Green 7 is a dark green crystalline powder. It has a very low calculated water solubility ($7 * 10^{-18}$ - $2 * 10^{-16}$ mg/l at 20 °C), and a low measured n-octanol solubility (0.07 mg/l at 20 °C). C.I. Pigment Green 7 has a calculated log K_{OW} of 17.4 and a vapour pressure of < 0.001 Pa at 25 °C. The relative density is 1.8 – 2.47 and the melting point is 480 °C. For the boiling point, no data or reliable calculations are available, it is assumed to be >1000 °C.

The degradation in the atmosphere through reaction with hydroxyl radicals was calculated for a chlorinated phthalocyanine without metal complexation using SRC-AOP v3.10. The half-time was calculated to 1.9 hours (12 hour day, $1.5 * 10^6$ OH/cm^3) and 5.9 hours (24 hour day, $0.5*10^6$ OH/cm^3).

C.I. Pigment Green 7 is expected to sorb readily to soils and sediments. Thus, the mobility in soil is likely to be limited.

Modelling of the distribution behaviour in the environment is not possible since several physical parameters are not available and standard calculations are not useable for metal-complexed dye-stuffs. However, as C.I. Pigment Green 7 is almost insoluble in water and volatility is estimated to be negligible due to its physical state, it may be expected that soil and sediment will be the main target compartments.

Biodegradation test results are not available. According to the structure and the low solubility in water, C.I. Pigment Green 7 is not expected to be biodegradable. C.I. Pigment Blue 15 was not biodegradable in a test conducted according to OECD TG 301C (0 % degradation after 14 days). Hydrolysis at environmental pH conditions is not expected due to the structure of the molecule.

The BCF has been measured to be < 2.1 to 74 at an exposure concentration of 0.01 mg/l, although this was above water solubility. Thus, a relevant bioaccumulation is not expected.

Several studies for freshwater organisms and one study for terrestrial organisms are available. The lowest effect concentrations are summarized below:

Fish:
Salmo gairdneri (*O. mykiss*) LC_{50} (96h) = 355.6 mg/l (nominal)

Invertebrates:
Daphnia magna EC_{50} (48h) = 153.6 mg/l (nominal)
Daphnia magna NOEC (21d) > 1 mg/l (nominal)
These investigations were performed well above the estimated water solubility limit. Effects occurred only far above the water solubility limit, it is possible that these effects could have also been caused by physical effects of the substance.

Algae:
For growth rate and biomass the EC_{50} for *Desmodesmus subspicatus* after 72 h lies above the water solubility. Due to the test design the raw eluate has to be diluted (8:1:1) due to the addition of algal suspension and enriched medium. At the highest technically feasible concentration of the eluate (due to the test design, 80 % of the water solubility) 9.1 % effect on growth rate and 28.4 % effect on biomass appeared. The NOEC lies at 1/10 of the water solubility for both endpoints.

Based on these data, C.I. Pigment Green 7 is considered as not harmful to aquatic organisms.

One study for soil dwelling organisms is available. The NOEC (14d) for *Eisenia fetida* was > 1000 mg/l.

Exposure

The uses of C.I. Pigment Green 7 include colorants in inks, paints and plastics. It is also used in textile printing, spin dying, ball-point pen inks, colouring of detergents, soaps, coating of glass fibers, greases, stains and xerographic imaging. Further uses for wallpaper, rubber, paper surfacing, book cloth, Linoleum are described. C.I. Pigment Green 7 is approved for food contact applications and is approved by EPA for seed dressings. C.I. Pigment Green 7 has a FDA approval for use as a contact lens colorant. In 2002 the estimated world production amounts to about 17 000 tonnes.

Releases into the environment may occur during production and processing of C.I. Pigment Green 7, as well as from the use of the substance or products containing it. Pigments released from production sites and not having been eliminated mechanically, will probably absorb to sewage sludge. C.I. Pigment Green 7 is not monitored in the effluent of the waste water treatment plant of one company in the Sponsor country. Via production and further processing, less than 25 kg of C.I. Pigment Green 7 were emitted into the air in 2000 at the plant of one company in the Sponsor country according to the German Emission Register.

Emission data from other production and processing sites are not available.

In the Swiss Product Register (status May 2002), about 331 products are listed under different names, about 74 of them are consumer products. In the Danish product register 633 products with a total quantity of 773 t/a are mentioned (year not given). In the Swedish product register 304 products with a total quantity of 133 t/a are listed, 33 of these are available to consumers. The SPIN database lists for the year 2001 for Norway 186 products (261 tons), for Denmark 733 products (909 tons), for Finland 4 products (0.1 tons). For Sweden 302 products are given for the year 2000 (111 tons). The preparations listed for Norway and Sweden include products for consumer use, in Denmark and Finland, none of the products is for consumer use (SPIN database, 2004).

According to an exposure assessment for copper from the manufacture, processing and use of three copper phthalocyanine pigments which has been established 1988 by the US EPA, releases to the air occur primarily during conditioning of the pigments. Estimations of the exposure of populations 100 meters from the source to free copper via inhalation gave an airborne concentration of < 0.001 mg/m^3 for manufacture and 0.002 mg/m^3 for conditioning. The inhalation exposure was estimated to 1.7 mg/year and 3.97 mg/year, respectively.

Concerning consumer exposure the above cited report gives the following estimations:
Human exposure via drinking water to Cu released from manufacturing was estimated using site-specific surface water flow rates for a known manufacturing site. Exposure of an individual drawing water 10 km downstream was estimated to be 7.3 µg/year. Releases from conditioning at the same site resulted in a drinking water exposure of < 1 µg/year.

Human exposure via drinking water to free copper released from paint manufacturing operations were estimated and gave a mean drinking water exposure of < 0.001 mg/year (50 %ile) and 0.004 mg/year (10 %ile), respectively, assuming no removal at the waste water treatment.

An exposure assessment for significant releases and consumer uses of the pigments was conducted regarding exposure to the copper as an impurity in the pigments. The estimation was performed for Pigment blue 15 using the worst-case consumer scenario "use of a pigment containing interior housepaint". The annual exposure to the pigment was estimated to be approximately 412 mg/year.

As the substance has no relevant bioaccumulation potential, human exposure through the environment is not expected. No monitoring data are available.

C.I. Pigment Green 7 produced in the Sponsor country contains small amounts (< 2.5 ppm) of HCB (hexachlorobenzene, CAS: 118-74-1) as impurity. Environment Canada is continuing work on HCB in pigments to determine the use and distribution as well as what, if any, levels of HCB releases may occur from these uses. The collection of information related to the incidental presence of HCB in pigments will be used to make a decision on the appropriate actions to be taken in the future. HCB is internationally recognized as to be hazardous to both human health and the environment.

RECOMMENDATION AND RATIONALE FOR THE RECOMMENDATION AND NATURE OF FURTHER WORK RECOMMENDED

The chemical is currently of low priority for further work due to its low hazard profile.