

[FOREWORD](#)

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# **C.I. Pigment Brown 24**

CAS N°: 68186-90-3

## SIDS Initial Assessment Report

For

### SIAM 15

Boston, Massachusetts, 22-25 October 2002

1. **Chemical Name:** C.I. Pigment Brown 24
2. **CAS Number:** 68186-90-3
3. **Sponsor Country:** Japan  
Mr. Motohiko Kato, Ministry of Foreign Affairs, Japan
4. **Shared Partnership with:** BASF AG
5. **Roles/Responsibilities of the Partners:**
  - € Name of industry sponsor /consortium Dr. Hubert, Lendle BASF AG  
E-mail : hubert.lendle@basf-ag.de
  - € Process used
6. **Sponsorship History**
  - € How was the chemical or category brought into the OECD HPV Chemicals Programme ? This substance is sponsored by Japan under the ICCA Initiative and is submitted for first discussion at SIAM 15.
7. **Review Process Prior to the SIAM:** The industry collected new data and prepared the updated IUCLID, and draft versions of the SIAR and SIAP. Japanese government peer-reviewed the documents, audited selected studies.  
No testing (X)  
Testing ( )
8. **Quality check process:**
9. **Date of Submission:**
10. **Date of last Update:**
11. **Comments:**

**SIDS INITIAL ASSESSMENT PROFILE**

<b>CAS No.</b>	68186-90-3
<b>Chemical Name</b>	C.I. Pigment Brown 24
<b>Structural Formula</b>	Complex inorganic coloured pigment based on titanium oxide; in the rutile lattice, titanium ions are partially replaced by chromium (III) and antimony (V) ions.  (Ti, Cr, Sb) O <sub>2</sub>
<b>SUMMARY CONCLUSIONS OF THE SIAR</b>	
<b>Category/Analogue Rationale</b>	
<p>In some circumstances, available data for C.I. Pigment Yellow 53 (CAS No. 8007-18-9, a nickel antimony doped rutile) may be presented to assist the weight of evidence approach for C.I. Pigment Brown 24, since it is closely related structurally and similar regarding its non-bioavailability. Its toxicological profile was also essentially similar to C.I. Pigment Yellow 53, therefore, analogy considerations can be made where the non-bioavailability is the determining parameter of non-toxicity. This was the case for reproductive and developmental toxicity.</p>	
<b>Human Health</b>	
<p>The acute toxicity of C.I. Pigment Brown 24 after oral exposure is negligible: oral LD50 in rats &gt; 10000 mg/kg body weight.</p> <p>C.I. Pigment Brown 24 is minimally irritating to the rabbit skin and may cause slight particle mediated irritating effects after instillation into the rabbit eye. Coloration of the skin occurred within the first 3 days after application. No data are available on sensitisation; the substance contains chromium, but no evidence for its bioavailability was seen in a repeat oral study in the rat (see below).</p> <p>No signs of clinical toxicity or histopathological changes were seen in a 90-day dietary study in the rat. A NOAEL of 500 mg/kg was identified from this study. In this study there was no evidence for chromium accumulation in the liver or kidney of rats, and traces of antimony (below 30 µg/kg tissue) were found only in the high dose group. These traces of antimony may be available from the acid-soluble impurities of the pigment. The small amount of antimony is considered to have no toxicological significance.</p> <p>C.I. Pigment Brown 24 induced no gene mutation in bacteria nor in mammalian cells and no clastogenic or aneugenic effects in mammalian cells with or without addition of a metabolic activation system. Therefore, the <i>in vitro</i> data indicates that C.I. Pigment Brown 24 would not exhibit a genotoxic potential <i>in vivo</i>.</p> <p>There are no specific studies on carcinogenicity available.</p> <p>No effects on gonads were observed in the 90 day feeding study on rats at doses of up to 500 mg/kg b.w./day (see above). A developmental toxicity study is not considered necessary because the substance showed no bioavailability with toxicological relevance after oral exposure (see above). In analogy to C.I. Pigment Yellow 53 where no reproductive or developmental effects were seen in a screening test conducted in rats tested up to 1000 mg/kg bw according to OECD Guideline 422, no effects are expected with C.I. Pigment Brown 24.</p>	
<b>Environment</b>	
<p>C.I. Pigment brown 24 is a solid, complex inorganic coloured pigment, based on titanium dioxide with chromium (III) and antimony (V) ions partially replacing titanium ions in the rutile lattice. It is practically inert and has a melting point above 1000°C. The vapour pressure is estimated to be negligible. C.I. Pigment brown 24 has an extremely low solubility in water; the concentration of chromium and antimony in filtrates (10 g/l) has been</p>	

measured by atomic absorption to be <0.01 mg/l.

The following aquatic effect concentrations (nominal) are available:

*Leuciscus idus*: LC<sub>50</sub> (96 h) > 10,000 mg/l; *Daphnia magna*: EC<sub>50</sub> (48 h) > 100 mg/l; *Desmodesmus subspicatus*: EC<sub>50</sub> (72 h) > 100 mg/l; *Pseudomonas putida*: EC<sub>50</sub> (30 min) > 10,000 mg/l.

The substance is not acutely toxic to aquatic organisms (fish, invertebrates and algae) in tests with either aqueous eluates or suspensions prepared with nominal concentrations far exceeding its water solubility.

No data are available on terrestrial organisms.

The substance is inorganic and thus not biologically degradable. According to the low water solubility and the structural properties of the pigment, bioaccumulation is not expected.

#### **Exposure**

Pigment brown is used for coloring plastics, ceramics, building materials and coatings. The estimated world production amounts to 10,000 – 15,000 tonnes.

No data are available concerning exposure. Pigments released from production sites and not having been eliminated mechanically, will probably absorb to sewage sludge. In the end products, the pigments are fixed in the matrix and a release into the environment during use phase is not expected.

#### **RECOMMENDATION**

The chemical is currently of low priority for further work.

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

The chemical is currently of low priority for further work based on a low hazard potential.

## SIDS Initial Assessment Report

### 1 IDENTITY

#### 1.1 Identification of the Substance

CAS Number:	68186-90-3
Chemical Name:	C.I. Pigment Brown 24
Empirical Formula:	(Ti, Cr, Sb) O <sub>2</sub>
Structure	Complex inorganic coloured pigment based on titanium dioxide; in the rutile lattice titanium ions are partially replaced by 2 to 6 % chromium (III) and 8.5 to 14 % antimony (V) ions According to the intended use, medium particle size varies between 0.5 and 1.5 $\mu\text{m}$ .
Synonyms:	Chrome Antimony Titanate Chrome antimony titaniumoxide rutil Chrome rutile yellow C. I. 77310 Titanium, Antimony, Chromium III oxide rutile

#### 1.2 Purity/Impurities/Additives

Substance type: inorganic

Physical status: solid

Purity: > 99% w/w (acid-soluble impurities amount to 10 –20 mg/kg antimony and 10-20 mg/kg chromium(III). These impurities are not fixed in the lattice and are extractable with HCl. After 2 extractions with HCl, the acid soluble impurities are reduced to amounts below the detection limit (<1 mg/kg for Sb and <1 mg/kg for Cr)

#### 1.3 Physico-Chemical properties

C.I. Pigment Brown 24 has an extremely low solubility in water; the concentration of chromium and antimony in filtrates of a 10 g/l solution after 2h-stirring has been measured by atomic absorption to be <0.01mg/l (BASF AG, 2002). The melting point of C.I. Pigment Brown 24 is greater than 1000°C and the density reached 4-5 g/cm<sup>3</sup> (DIN-ISO 787/10) (BASF AG, 2000a). A negligible vapour pressure can be assumed for this mixed metal oxide. Chromium and antimony partially substituted titanium in the titanium dioxide lattice and are not available as metal ions or metal oxides (MAK-Begründung Nickeltitangelb, 1983).

### 2 GENERAL INFORMATION ON EXPOSURE

The estimated world production amounts to 10,000 – 15,000 tons, thereof in Europe 5,000 – 10,000 t/a (including Germany with 5,000 – 10,000 t/a), in the NAFTA 1,000 – 5,000 and in Asia 1,000 to 5,000 t/a (including Japan with 1,000 to 5,000) (BASF AG, 2002).

Pigment brown is used for coloring plastics, ceramics, building materials and coatings.

In the Swiss Product Register, about 80 industrial products are listed (main category: “paint and dyes”, a few in the category: “plastic moulding”), and 3 consumer products (category: “dyes for

artists”). The SPIN database lists for the year 2001 for Norway 111 products (754 tons), for Denmark 128 products (372 tons), for Finland 5 products (0 tons). For Sweden 191 products are given for the year 2000 (354 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.

## **2.1 Environmental Exposure and Fate**

### Environmental Exposure

Doped rutile pigments are manufactured by reacting finely divided metal oxides, hydroxides or carbonates in the solid state at a temperature of 1000 to 1,200 °C. The production is based on reactive anatase, or titanium dioxide hydrolysate containing sulfuric acid, and on the oxidation of trivalent antimony with oxygen in the form of nitric acid or air. For the production of C.I. Pigment Brown 24 trivalent chromium raw materials are used.

Raw-material dust, and gases (e.g. SO<sub>3</sub> and NO<sub>x</sub>), emitted during the calcination step are removed from the flue gas by dust separators and alkaline flue scrubbers. The raw-material dust can be recycled. Soluble metal salts can be removed by neutral precipitation in the waste-water treatment plant, and suspended pigment particles can be mechanically separated from the water from washing and purification steps. Altogether, only a small amount of waste is produced with each tonne of product (Endriß H., 1998).

In the end products, the pigments are fixed in the matrix and a release into the environment during the use phase is not expected (coatings) or impossible (colored plastics and ceramics). Pigments released from production sites and not having been eliminated mechanically will probably absorb to sewage sludge.

### Environmental Fate

Distribution modelling is not applicable since several physical parameters are not available.

C.I. Pigment Brown 24 is an inorganic substance, biodegradation therefore is not assumed.

No data on bioaccumulation are available. However, regarding the extremely low water solubility, experiences from rodent investigations and the structure-related inert properties of the rutil, bioavailability and therefore bioconcentration is not expected.

(See also data on bioavailability in mammals after oral exposure [section 3.2.5 and 3.2.9])

## **2.2 Human Exposure**

No data are available concerning exposure with the practically inert pigment.

## **3 HUMAN HEALTH HAZARDS**

### **3.1 Hazard Assessment Experience with Human Exposure**

#### **3.1.1 Experience with human exposure**

No data available.

## 3.2 Effects on Human Health

In analogy to C.I. Pigment Yellow 53 (a nickel antimony titanium dioxide rutile with similar low bioavailability as C.I. Pigment Brown 24), which resulted in no reproductive or developmental effects in a screening test according to OECD guideline 422, no effects are expected with C.I. Pigment Brown 24, a chrome antimony titanium dioxide rutile.

### 3.2.1 Toxicokinetics, Metabolism and Distribution

Concentration of chromium and antimony were analysed in liver and kidney of rats after oral exposure to C.I. Pigment Brown 24 in a 90-days feeding study at doses of 0, 10, 100, 1000, 10,000 mg/kg diet, respectively (corresponding to 0, 0.5, 5, 50, 500 mg/kg b.w./day) (Bomhard E. et al., 1982) (see section 3.2.5): The chemical analysis included the determination of chromium and antimony in liver and kidney of 5 rats per gender per dose group after 1, 2 and 3 months of exposure. The detection limit for antimony was 5 µg/kg tissue and for chromium 2 µg/kg.

In male and female rats the antimony concentrations in liver and kidney were below the detection limit at doses up to 1,000 ppm (50 mg /kg b.w./day). In the high dose groups the antimony levels slightly increased with exposure duration and reached max. 27 µg/kg in the liver of males (range 15-40 µg/kg) and 17 µg/kg in females (kidney 14 µg/kg in males and 15 µg/kg in females). These traces most likely originate from the content of acid-soluble components (10 –20 mg antimony /kg pigment, that is 5 – 10 µg/kg b.w. or 125 - 250 µg/kg organ weight at the highest dose) and therefore do not indicate bioavailability of the pigment itself. Anyhow, the traces are considered to have no toxicological significance. No measurable effect on chromium content of liver and kidney at any dose level and exposure duration was detected in male and female rats.

#### Conclusion

In a 90 day feeding study on rats (up to 500 mg C.I. Pigment Brown 24 /kg b.w./day) no bioavailability was demonstrated. However, traces of antimony may be available from the acid-soluble impurities of the pigment.

### 3.2.2 Acute Toxicity

The acute oral toxicity of C.I. Pigment Brown 24 was investigated in male and female Sprague Dawley rats with an LD<sub>50</sub> greater than 10,000 mg/kg body weight (BASF AG, 1978). The test followed in principle the procedure described in OECD guideline 401 and is valid with restrictions to judge the acute oral toxicity (validity 2). Ten rats per gender received a single oral administration of the test substance. No deaths occurred after administration and during the 14 days post observation period. No substance related effects were found on body weight development and no adverse effects were reported after necropsy.

#### Conclusion

There was no acute toxicity at oral doses of 10000 mg/kg body weight .

### 3.2.3 Irritation

#### Skin Irritation

Following the experimental design according to Federal Register 38, No. 187, § 1500.41, S. 27019, 27. Sept. 1973, the application of 50% C.I. Pigment Brown 24 in water to the intact skin of 6 rabbits resulted in slight irritation after 24 h (slight edema in 3/6 animals) and similar effects were seen on abraded skin (slight edema in 4/6 animals); no edema was observed after 72 h and 8 d, respectively.

The evaluation of erythema could not be performed due to treatment related colouring of the skin (overall primary skin irritation value 0.58) (BASF AG, 1978). This staining of the skin by the test substance appears to be superficial, however, as another study has shown that it could be removed by washing with soap (Bayer AG, 1997). The results of the study are acceptable based on the experimental protocol applied (validity 2).

#### Conclusion

C.I. Pigment Brown 24 is considered minimally irritating to the rabbit skin due to both the slight degree and the reversibility of the effects after 8 days as well as the six times longer exposure period to the test material under occlusive conditions in the protocol of Draize.

#### Eye Irritation

Following the experimental design according to Federal Register 38, No. 187, § 1500.42, S. 27019, 27. Sept. 1973, no effects on cornea and iris were observed 24, 48 and 72 h after instillation of the test substance (BASF AG, 1978). Concerning effects on conjunctivae slight irritation (slight reddening and secretion) was observed after 24 h, these effects were reversible (after 72 h no secretion and only slight reddening in 3 out of 6 rabbits; overall primary irritation value 2,22). The result indicates a mechanically mediated slight irritation of the mucous membrane due to the instillation of test substance particles into the eyes. No substance related staining of the eye was observed. The results of the study are acceptable based on the experimental protocol applied (validity 2).

#### Conclusion:

C.I. Pigment Brown 24 may be slightly irritating to the eye.

### **3.2.4 Sensitisation**

No data available. The substance contains chromium, but this was proven to be not bioavailable.

### **3.2.5 Repeated Dose Toxicity**

In a feeding study (Bomhard E. et al., 1982) which followed essentially OECD guideline 408 rats received 0, 10, 100, 1000, 10000 mg C.I. Pigment Brown 24 per kg diet (corresponding to 0, 0.5, 5, 50, 500 mg/kg b.w./day) for 90 days. 15 animals per dose per gender were used for toxicological investigations (30 animals per gender in the control group) and additionally 10 animals per dose and gender for analytical investigations (control 20 animals per gender). Rats were observed daily; food consumption and body weight gain were determined once per week. Haematology, urinalysis and clinical and biochemical investigations were conducted after one month and at the end of the study (no post exposure observation period). Organ weights were determined at necropsy (thyroid gland, thymus, heart, lung, liver, spleen, kidneys, adrenal glands, and gonads). Complete histopathological investigations (above mentioned organs studied plus aorta, eyes, intestine, femur, brain, urinary bladder, pituitary, cervical lymph nodes, stomach, oesophagus, epididymides, pancreas, prostate, seminal vesicle, bone marrow of sternum, trachea, uterus, and skeletal muscles) were performed on 5 rats per gender of control and the high dose group.

No deaths, no overt signs of reactions to the treatment, no effects on body weight gain (similar food consumption in all groups) or organ weights, no treatment related findings from haematological or biochemical investigations and urinalysis were detected. No macroscopic pathological changes attributable to treatment and no treatment related effects in histopathology were observed. Since no substance related effects were observed up to the highest dose tested the NOEL and NO(A)EL of

this study is defined to be 500 mg/kg body weight. The study followed good scientific principles as to experimental design and reporting and is therefore considered valid (validity 2).

### Conclusion

In a 90 day feeding study on rats doses up to 500 mg/kg bw/day resulted in no adverse effects in clinical observations, haematology, urine analysis, clinical chemistry and macro- and microscopical pathology.

NOAEL = 500 mg/kg b.w./day (highest dose tested)

### **3.2.6 Mutagenicity**

C.I. Pigment Brown 24 has no mutagenic activity in *in vitro* studies according to current guideline standards. A suspension of the insoluble test substance induced no gene mutation in bacterial reverse mutation assay (comparable to OECD guideline 471 & 472; max. concentration 5 mg/plate; no cytotoxicity) on *Salmonella typhimurium* (Corning Hazelton, 1995) strain TA98, TA100, TA1535, TA1537, TA1538, and on *E. coli* WP2uvrA (Corning Hazelton, 1996) and in the mouse lymphoma assay (comparable to the OECD guideline 476, max. concentration 100 µg/ml, no cytotoxicity) (Corning Hazelton, 1996), each with and without metabolic activation. Furthermore, no aneugenic or clastogenic activity was observed in the micronucleus test on V79 Chinese hamster lung cells with and without metabolic activation (according to the proposed new OECD guideline for the *in vitro* micronucleus test; max. concentration 25 µg/ml; no cytotoxicity) (BASF AG, 2001).

### Conclusion

All *in vitro* studies performed followed current guidelines and are thus acceptable and valid as regards both experimental design and reliability of the results derived thereof. C.I. Pigment Brown 24 induced, with or without addition of a metabolic activation system, no gene mutation in bacteria or mammalian cells and no clastogenic or aneugenic effects in mammalian cells. There are no *in vitro* data to indicate that C.I. Pigment Brown 24 would exhibit a genotoxic potential *in vivo*. No data are available on the genotoxicity of C.I. Pigment Brown 24 *in vivo*.

### **3.2.7 Carcinogenicity**

No data available.

### **3.2.8 Toxicity for Reproduction**

No effects on organ weights and macro- and micro-histopathology of gonads (testes, epididymides, prostate, seminal vesicle, ovary and uterus) were observed in the 90 day feeding study on rats at doses up to 500 mg/kg bw/day (see section 3.2.5).

### **3.2.9 Developmental Toxicity**

A developmental toxicity study is not considered necessary because the substance showed no bioavailability with toxicological relevance after oral exposure (see section 3.2.5). In analogy to C.I. Pigment Yellow 53 (a nickel antimony titanium dioxide rutile with similar data on bioavailability to C.I. Pigment Brown 24 (Endriß H., 1998) which resulted in no reproductive or developmental effects in a screening test according to OECD guideline 422, no effects are expected with C.I. Pigment Brown 24, a chrome antimony titanium dioxide rutile.

### 3.3 Initial Assessment for Human Health

There is no acute toxicity of C.I. Pigment Brown 24 after oral exposure, based on the following data: No death of male and female rats up to 10,000 mg/kg body weight with no toxic signs.

C.I. Pigment Brown 24 is not irritating to the rabbit skin and slightly irritating to the rabbit eye. No data are available on sensitisation; the data on bioavailability of the chromium (sensitising component of the pigment) indicated no sensitising potential.

In a 90 day feeding study on rats doses up to 500 mg/kg bw/day resulted in no adverse effects in clinical observations, haematology, urine analysis, clinical chemistry and macro- and microscopical pathology [NOAEL = 500 mg/kg bw/day (highest dose tested)]. In this study, no increase in chromium concentration was detected in liver and kidney of rats and only traces of antimony (below 30 µg/kg tissue) were found, but only in the high dose group. These traces indicate very low bioavailability of the antimony contained in the pigment. Hence, antimony is considered to have no toxicological significance.

C.I. Pigment Brown 24 induced, with or without addition of a metabolic activation system, no gene mutation either in bacteria or in mammalian cells and no clastogenic or aneugenic effects in mammalian cells.

There are no specific studies on carcinogenicity or toxicity to reproduction available.

No effects on gonads were observed in the 90 day feeding study on rats at doses up to 500 mg/kg bw/day (see above). A developmental toxicity study is not considered necessary because the substance showed no bioavailability with toxicological relevance after oral exposure (see above). In analogy to C.I. Pigment Yellow 53 (a nickel antimony titanium dioxide rutile with similar data on bioavailability to C.I. Pigment Brown 24), which resulted in no reproductive or developmental effects in a screening test according to OECD guideline 422, no effects are expected with C.I. Pigment Brown 24, a chromium antimony titanium dioxide rutile.

## 4 HAZARDS TO THE ENVIRONMENT

The following acute toxicity tests with aquatic organisms are available:

*Leuciscus idus*: LC<sub>50</sub> (96 h) > 10000 mg/l; NOEC (96 h) = 10000 mg/l (BASF AG, 2000b)

*Daphnia magna*: EC<sub>50</sub> (48 h) > 100 mg/l; EC<sub>0</sub> (48 h) × 100 mg/l (BASF AG, 2000c)

*Scenedesmus subspicatus*: ErC<sub>50</sub> (72 h) > 100 mg/l; ErC<sub>10</sub> (72 h) > 100 mg/l;

NOEC (72 h) × 100 mg/l (BASF AG, Project No. 99/0484/60/1, 2000c)

*Pseudomonas putida*: EC<sub>50</sub> (30 min) > 10000 mg/l; EC<sub>10</sub> (30 min) > 10000 mg/l (BASF AG, 1997)

All values were related to nominal concentrations of suspensions (tests on fish and bacteria) or aqueous extracts (test on daphnids and algae), no analytical monitoring was performed. In previous analytical studies on aqueous extracts of a suspension of this insoluble pigment it has been shown, that the expected concentration of the substance in the extract is below the detection limit of the analytical method (concentration of total amount of chromium, antimony and titanium in a filtrate from a 100 mg/l stock solution has been <0.0005 mg/l). Tests on toxicity to fish indicate that the test substance is held in suspension during the whole exposure period (coloured and cloudy test solution).

However, based on short-term tests from each of the four trophic levels, C.I. Pigment Brown 24 can be regarded as acutely not harmful to aquatic organisms.

No data are available on terrestrial organisms.

The cited studies are carried out according to nationally and/or internationally accepted guidelines and are considered as valid.

#### **4.1 Initial Assessment for the Environment**

C.I. Pigment brown 24 is a solid, complex inorganic coloured pigment, based on titanium dioxide with chromium (III) and antimony (V) ions partially replacing titanium ions in the rutile lattice. It is practically inert and has a melting point above 1000 °C. The vapour pressure is estimated to be negligible. C.I. Pigment brown 24 has an extremely low solubility in water; the concentration of chromium and antimony in filtrates (10 g/l) has been measured by atomic absorption to be <0.01 mg/l.

The following aquatic effect concentrations (nominal) are available: *Leuciscus idus*: LC50 (96 h) > 10000 mg/l; *Daphnia magna*: EC50 (48 h) > 100 mg/l; *Desmodesmus subspicatus*: EC50 (72 h) > 100 mg/l; *Pseudomonas putida*: EC50 (30 min) > 10000 mg/l.

The substance is not acutely toxic to aquatic organisms (fish, invertebrates and algae) in tests with either aqueous eluates or suspensions prepared with nominal concentrations far exceeding its water solubility.

No data are available on terrestrial organisms.

The substance is inorganic and thus not biologically degradable. According to the low water solubility and the structural properties of the pigment, bioaccumulation is not expected.

## **5 RECOMMENDATIONS**

This chemical is currently of low priority for further work based on a low hazard potential.

## 6 REFERENCES

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**ANNEX****Date of the literature search (August 27, 2001)****Toxicology**

JETOC  
RTECS  
AGRICOLA  
CABA  
CANCERLIT  
TOXCENTER  
TOXLINE  
JICST-EPLUS  
LIFESCI  
TOXLIT  
EMBASE  
ESBIOBASE  
EMBAL  
HEALSAFE  
CSNB  
MEDLINE  
IRIS  
ATSDR TOX. PROFILES  
ATSDR TOX: FAQs  
CHEMFINDER  
CIVS  
GESTIS  
GINC  
NICNAS  
NTP

**Ecology**

AQUASCI  
BIOSIS  
EMBASE  
ESBIOBASE.  
LIFESCI  
OCEAN  
POLLUAB  
SCISEARCH  
TOXCENTER  
TOXLINE  
ULIDAT  
DATALOG  
CHEMFATE  
BIODEG  
AQUIRE  
HSDB

# I U C L I D

  

# D a t a S e t

**Existing Chemical** ID: 68186-90-3  
**CAS No.** 68186-90-3  
**EINECS Name** C.I. Pigment Brown 24  
**EC No.** 269-052-1  
**Molecular Formula** <no data>

**Producer Related Part**  
**Company:** BASF AG  
**Creation date:** 07-MAY-1996

**Substance Related Part**  
**Company:** BASF AG  
**Creation date:** 07-MAY-1996

**Memo:** master

**Printing date:** 01-DEC-2004  
**Revision date:**  
**Date of last Update:** 26-NOV-2004

**Number of Pages:** 44

**Chapter (profile):** Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 10  
**Reliability (profile):** Reliability: without reliability, 1, 2, 3, 4  
**Flags (profile):** Flags: without flag, SIDS

**1.0.1 Applicant and Company Information**

**Type:** lead organisation  
**Name:** BASF AG  
**Contact Person:** Product Safety **Date:**  
Dr. Hubert Lendle  
GUP/Z - Z570  
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**Telefax:** +49 621 60 6644712  
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**Homepage:** www.basf-ag.com

**Flag:** Critical study for SIDS endpoint  
01-APR-2004

**Type:** cooperating company  
**Name:** Bayer AG  
**Country:** Germany

**Flag:** Critical study for SIDS endpoint  
13-DEC-2001

**Type:** cooperating company  
**Name:** Broll Buntpigmente GmbH  
**Country:** Germany

**Flag:** Critical study for SIDS endpoint  
13-NOV-2001

**Type:** other: cooperating organisation  
**Name:** Color Pigments Manufacturers Ass. (CMPA), Inc.  
**Country:** United States

**Flag:** Critical study for SIDS endpoint  
13-NOV-2001

**Type:** cooperating company  
**Name:** Dr. Hans Heubach GmbH & Co. KG  
**Country:** Germany

**Flag:** Critical study for SIDS endpoint  
13-NOV-2001

**Type:** cooperating company  
**Name:** Ishihara Sangyo Kaisha, Ltd.  
**Country:** Japan

**Flag:** Critical study for SIDS endpoint  
13-NOV-2001

**Type:** cooperating company  
**Name:** Kawamura Chemical Co.  
**Country:** Japan

**Flag:** Critical study for SIDS endpoint  
13-NOV-2001

1.0.2 Location of Production Site, Importer or Formulator

1.0.3 Identity of Recipients

1.0.4 Details on Category/Template

1.1.0 Substance Identification

1.1.1 General Substance Information

**Substance type:** inorganic  
**Physical status:** solid  
**Purity:** > 99 - % w/w  
**Colour:** yellow  
**Odour:** odourless

**Flag:** non confidential, Critical study for SIDS endpoint  
14-FEB-2003

(1)

1.1.2 Spectra

1.2 Synonyms and Tradenames

C.I. 77310

**Flag:** non confidential, Critical study for SIDS endpoint  
07-MAY-1996

C.I. Pigment Brown 24 (9CI)

**Flag:** non confidential, Critical study for SIDS endpoint  
07-MAY-1996

Chromantimontitanlederfarbenrutil

**Flag:** non confidential, Critical study for SIDS endpoint  
07-MAY-1996

Chrome antimony titanate buff

**Flag:** non confidential, Critical study for SIDS endpoint  
07-MAY-1996

Chrome antimony titanium buff rutile

**Flag:** non confidential, Critical study for SIDS endpoint  
07-MAY-1996

Chrome titanium yellow

**Flag:** non confidential, Critical study for SIDS endpoint  
07-MAY-1996

Pigment Brown 24

**Flag:** non confidential, Critical study for SIDS endpoint  
07-MAY-1996

### 1.3 Impurities

### 1.4 Additives

### 1.5 Total Quantity

**Remark:** Production quantity (Year of reference: 2001):

Europe : 5000 - 10000 t/a  
includes Germany: 5000 - 10000 t/a

USA : 1000 - 5000 t/a

Asia : 1000 - 5000 t/a  
includes Japan : 1000 - 5000 t/a

World : approx. 15000 t/a

**Flag:** non confidential, Critical study for SIDS endpoint  
04-DEC-2001

### 1.6.1 Labelling

**Labelling:** no labelling required (no dangerous properties)

**Flag:** non confidential, Critical study for SIDS endpoint  
14-NOV-2002 (1)

### 1.6.2 Classification

**Classified:** no classification required (no dangerous properties)

**Flag:** non confidential, Critical study for SIDS endpoint  
14-NOV-2002 (1)

### 1.6.3 Packaging

### 1.7 Use Pattern

**Type:** type  
**Category:** Use resulting in inclusion into or onto matrix

**Flag:** non confidential, Critical study for SIDS endpoint  
07-MAY-1996

**Type:** industrial  
**Category:** Paints, lacquers and varnishes industry

**Flag:** non confidential, Critical study for SIDS endpoint  
07-MAY-1996

**Type:** industrial  
**Category:** Polymers industry

**Flag:** non confidential, Critical study for SIDS endpoint  
07-MAY-1996

**Type:** use  
**Category:** Colouring agents

**Flag:** non confidential, Critical study for SIDS endpoint  
07-MAY-1996

### 1.7.1 Detailed Use Pattern

### 1.7.2 Methods of Manufacture

**Type:** Production

**Remark:** Doted rutile pigments are manufactured by reacting finely divided metal oxides, hydroxides or carbonates in the solid state at a temperature of 1000 to 1,200 °C. The production is based on reactive anatase, or titanium dioxide hydrolysate containing sulfuric acid, and on the oxidation of trivalent antimony with oxygen in the form of nitric acid or air. For the production of C.I. Pigment Brown 24 the chromium raw materials are used. The reactions proceed more readily if the components are reactive, finely divided and intimately mixed. Adding mineralizers promotes solid-state reaction during calcination, which is performed either continuously in a rotary, annular or tunnel furnace, or batchwise in a directly fired car-bottom or rotary-hearth furnace. After calcination, the resulting clinker is wet-ground and any soluble salts are washed out. The product is dried either in a spray-drying tower, when low-dusting, free-flowing grades are required, or by standard means, which, however, necessitates subsequent grinding to a pigment powder.

Raw-material dust, and gases (e.g. SO<sub>3</sub> and NO<sub>x</sub>), emitted during the calcination step are removed from the flue gas by dust separators and alkaline flue scrubbers. The raw-material dust can be recycled. Soluble metal salts can be removed by neutral precipitation in the waste-water treatment plant, and suspended pigment particles can be mechanically separated from the water from washing and purification steps. Altogether, only a small amount of waste is produced with each tonne of product.

**Flag:** non confidential, Critical study for SIDS endpoint  
15-NOV-2002 (2)

**Type:** Production

**Remark:** The finished C.I. Pigment Brown 24 contains about 2 to 6 % chromium(III) and 8.5 to 14 % antimony(V) (all data calculated as metal).

**Flag:** non confidential, Critical study for SIDS endpoint  
15-NOV-2002 (3)

**1.8 Regulatory Measures**

**1.8.1 Occupational Exposure Limit Values**

**Type of limit:** MAK (DE)  
**Limit value:** other: no MAK- or BAT-value established

**Flag:** non confidential, Critical study for SIDS endpoint  
14-FEB-2003 (4)

**1.8.2 Acceptable Residues Levels**

**1.8.3 Water Pollution**

**Classified by:** KBwS (DE)  
**Labelled by:** KBwS (DE)  
**Class of danger:** 0 (generally not water polluting)

**Remark:** ID-Number: 1956  
**Flag:** non confidential, Critical study for SIDS endpoint  
14-NOV-2002 (5)

**Classified by:** other: VwVwS (Germany) of 17.05.1999, Annex 3  
**Labelled by:** other: VwVwS (Germany) of 17.05.1999, Annex 3  
**Class of danger:** 0 (generally not water polluting)

**Flag:** non confidential, Critical study for SIDS endpoint  
14-NOV-2002 (1)

**1.8.4 Major Accident Hazards**

**1.8.5 Air Pollution**

**1.8.6 Listings e.g. Chemical Inventories**

**Type:** TSCA  
**Flag:** non confidential, Critical study for SIDS endpoint  
13-NOV-2001 (6)

**Type:** DSL  
**Flag:** non confidential, Critical study for SIDS endpoint  
13-NOV-2001 (6)

**Type:** AICS  
**Flag:** non confidential, Critical study for SIDS endpoint  
13-NOV-2001 (6)

**Type:** PICCS  
**Flag:** non confidential, Critical study for SIDS endpoint  
13-NOV-2001 (6)

**Type:** EINECS  
**Additional Info:** EINECS No. 269-052-1

**Flag:** non confidential, Critical study for SIDS endpoint  
21-FEB-2002 (6)

**Type:** ECL  
**Additional Info:** ECL Serial No. KE-07865

**Flag:** non confidential, Critical study for SIDS endpoint  
21-FEB-2002 (6)

#### 1.9.1 Degradation/Transformation Products

**EINECS-Name:** No hazardous decomposition products if stored and handled as prescribed/indicated.

**Flag:** non confidential, Critical study for SIDS endpoint  
14-NOV-2002 (1)

#### 1.9.2 Components

#### 1.10 Source of Exposure

#### 1.11 Additional Remarks

#### 1.12 Last Literature Search

**Type of Search:** Internal and External  
**Chapters covered:** 3, 4  
**Date of Search:** 19-NOV-2003

25-NOV-2003

#### 1.13 Reviews

-

### 2.1 Melting Point

**Value:** > 1000 degree C

**Reliability:** (4) not assignable  
Manufacturer / producer data without proof  
**Flag:** Critical study for SIDS endpoint  
04-DEC-2000 (7)

### 2.2 Boiling Point

#### 2.3 Density

**Type:** density  
**Value:** = 4 - 5 g/cm<sup>3</sup> at 20 degree C

**Method:** other: (DIN-ISO 787/10)  
**GLP:** no

**Reliability:** (4) not assignable  
Manufacturer / producer data without proof  
**Flag:** Critical study for SIDS endpoint  
14-FEB-2003 (7)

#### 2.3.1 Granulometry

#### 2.4 Vapour Pressure

**Remark:** A negligible vapour pressure can be assumed for this mixed metal oxide.  
**Flag:** Critical study for SIDS endpoint  
14-FEB-2003 (8)

#### 2.5 Partition Coefficient

##### 2.6.1 Solubility in different media

**Solubility in:** Water

**Remark:** C.I. Pigment Brown 24 has an extremely low solubility in water; the concentration of chromium and antimony in filtrates of a 10 g/l solution after 2h-stirring has been measured by atomic absorption to be <0.01mg/l  
**Flag:** Critical study for SIDS endpoint  
14-FEB-2003 (9)

**pH value:** = 7 - 8  
**Conc.:** 50 g/l at 20 degree C  
**Descr.:** not soluble

**Method:** other: (DIN-ISO 787/9)

**GLP:** no

**Result:** The pH-value has been determined from a pigment suspension having a concentration of 50 g/l.

**Reliability:** (4) not assignable  
Manufacturer / producer data without proof

**Flag:** Critical study for SIDS endpoint

14-FEB-2003

(7)

#### 2.6.2 Surface Tension

#### 2.7 Flash Point

**Remark:** not applicable

**Reliability:** (4) not assignable

**Flag:** Critical study for SIDS endpoint

04-DEC-2000

(7)

#### 2.8 Auto Flammability

#### 2.9 Flammability

#### 2.10 Explosive Properties

#### 2.11 Oxidizing Properties

#### 2.12 Dissociation Constant

#### 2.13 Viscosity

#### 2.14 Additional Remarks

### 3.1.1 Photodegradation

**Test substance:** other TS: Chromantimontitanlederfarbenrutil

**Remark:** No data are available  
**Flag:** Critical study for SIDS endpoint  
12-MAR-2003

### 3.1.2 Stability in Water

### 3.1.3 Stability in Soil

### 3.2.1 Monitoring Data (Environment)

### 3.2.2 Field Studies

### 3.3.1 Transport between Environmental Compartments

**Method:** other

**Remark:** No data are available.  
**Flag:** Critical study for SIDS endpoint  
12-MAR-2003

### 3.3.2 Distribution

**Media:** air - biota - sediment(s) - soil - water  
**Method:** Calculation according Mackay, Level I

**Remark:** Distribution modelling is not applicable since several physical parameters (molecular weight, water solubility, vapour pressure and partition coefficient) are not available.

**Flag:** Critical study for SIDS endpoint  
11-DEC-2001 (10)

### 3.4 Mode of Degradation in Actual Use

### 3.5 Biodegradation

**Method:** other

**Remark:** C.I. Pigment Brown 24 is an inorganic substance, biodegradation is therefore not assumed.

**Flag:** Critical study for SIDS endpoint  
12-MAR-2003 (8)

### 3.6 BOD5, COD or BOD5/COD Ratio

**3.7 Bioaccumulation**

**Year:** 2002  
**Test substance:** as prescribed by 1.1 - 1.4

**Remark:** No data on bioaccumulation are available. However, regarding the extremely low water solubility, experiences from rodent investigations and the structure-related inert properties of the rutil, bioavailability and therefore bioconcentration is not expected.

**Flag:** Critical study for SIDS endpoint  
12-MAR-2003

(8)

**3.8 Additional Remarks**

AQUATIC ORGANISMS

4.1 Acute/Prolonged Toxicity to Fish

**Type:** static  
**Species:** Leuciscus idus (Fish, fresh water)  
**Exposure period:** 96 hour(s)  
**Unit:** mg/l **Analytical monitoring:** no  
**LC0:** >= 1000

**Method:** other: Bestimmung der akuten Wirkung von Stoffen auf Fische. Arbeitskreis "Fischtest" im Hauptausschuss "Detergentien" (15.10.73)  
**Year:** 1977  
**GLP:** no

02-OCT-2001

(11)

**Type:** static  
**Species:** Leuciscus idus (Fish, fresh water)  
**Exposure period:** 96 hour(s)  
**Unit:** mg/l **Analytical monitoring:** no  
**NOEC:** = 10000  
**LC50:** > 10000

**Method:** other: DIN 38412 Part 15  
**Year:** 1982  
**GLP:** no  
**Test substance:** as prescribed by 1.1 - 1.4

**Remark:** Cloudy and coloured test solution; undissolved test substance visible on the bottom of aquaria; results on the basis of nominal concentrations,

**Result:** RESULTS: EXPOSED  
- No mortality after 96 h  
- No symptoms observed at 1, 4, 24, 48, 72, 96h  
RESULTS: CONTROL  
- No animals showed adverse effects  
- Positive control conducted with Chloroacetamide, LC50 (48h) =32 mg/l (normal sensitivity)

**Test condition:** DILUTION WATER  
according to DIN 38412, part 11 (Oct. 1982)  
TEST SYSTEM  
- concentrations: 0, 5000, 10000 mg/l  
- Number of animals per test concentration: 10  
- Loading: 4.7 g fish/l test water  
- Test temperature: 21 degree C  
- pH 7.5-8.3 during exposure in all 3 groups  
- Oxygen content during exposure: 6.9-8.5 mg/l in all 3 groups  
- Test parameter: mortality and symptoms  
- Effects checked after directing the fish towards the front pane of aquaria (cloudy content, see remark); at the end of test period (96h) fish transferred into clean water for determination of symptoms.

**Reliability:** (2) valid with restrictions  
Comparable to OECD guideline 203  
**Flag:** Critical study for SIDS endpoint

12-MAR-2003

(12)

#### 4.2 Acute Toxicity to Aquatic Invertebrates

**Type:** static  
**Species:** Daphnia magna (Crustacea)  
**Exposure period:** 48 hour(s)  
**Unit:** mg/l **Analytical monitoring:** no  
**EC0:** >= 100  
**EC50:** > 100  
**EC100:** > 100

**Method:** OECD Guide-line 202  
**Year:** 1984  
**GLP:** yes  
**Test substance:** as prescribed by 1.1 - 1.4

**Method:** Test also according to EEC directive 92/32/EEC Annex V, C.2 (1992), EPA OPPTS850.1010 (1996), ISO 6341 (1989)

**Result:** RESULTS: EXPOSED  
- Nominal concentrations: 0, 12.5, 25, 50, 100 mg/l  
- Effect data (Immobilisation): No immobilisation at any dose group or control; other effects: no

RESULTS CONTROL: valid negative (immobility 0%) and positive control

**Test condition:** STOCK AND TEST SOLUTION AND THEIR PREPARATION  
Unsoluble TS (water solubility < 1 mg/l) stirred in the M4 medium (see dilution water) for ca. 20 h at ca. 20 °C; undissolved TS removed by filtration with a membrane filter (pore width 0.2 µm); nominal concentration of the filtrate 100 mg/l; further dilution of this filtrate with M4 medium; prepared nominal concentrations: control, 12.5, 25, 50, 100 mg/l.

DILUTION WATER  
M4 medium

TEST SYSTEM  
- Test volume: 10 ml  
- Number of replicates (individuals/vessel): 4 (5)  
- Test temperature: 20.4-20.5 °C  
- Dissolved oxygen: 8.2-8.5 mg/l  
- pH: 8.1-8.4

MONITORING OF TEST SUBSTANCE CONCENTRATION: Test performed with an aqueous extract (filtrate) of the TS. Test performed without concentration control analysis because the recovery rate in the filtrate was below the detection limit.

STATISTICS:  
Results allowed no statistical evaluation of the data.

**Reliability:** (1) valid without restriction  
guideline study

**Flag:** Critical study for SIDS endpoint  
12-MAR-2003 (13)

#### 4.3 Toxicity to Aquatic Plants e.g. Algae

**Species:** other algae: Scenedesmus subspicatus Chodat SAG 86.81  
**Endpoint:** growth rate

**Exposure period:** 72 hour(s)  
**Unit:** mg/l  
**NOEC:** >= 100  
**LOEC:** > 100  
**EC10:** > 100  
**EC50:** > 100  
**EC90 :** > 100

**Analytical monitoring:** no

**Method:** OECD Guide-line 201 "Algae, Growth Inhibition Test"  
**Year:** 1984  
**GLP:** yes  
**Test substance:** as prescribed by 1.1 - 1.4

**Method:** Test also according to EEC directive 92/69/EEC, Annex V, Part C.3. (1992) and EPA OPPTS 850.5400 (1996)

**Remark:** MONITORING OF TEST SUBSTANCE CONCENTRATION:  
 Test performed with an aqueous extract (filtrate) of the TS.  
 Test performed without concentration control analysis because the recovery rate in a filtrate is below the detection limit (see also data in section 4.2).

**Result:** CONTROL  
 In negative control cell multiplication factor after 72h: 149-fold; positive control with potassium dichromate EC50 (72h)= 0.41 mg/l;

INHIBITION OF ALGAL BIOMASS AFTER 72h

	Concentration in mg TS/l							
	0	1.56	3.13	6.25	12.5	25	50	100
Inhibition								
in % of control	0	-1.6	-4.5	-1.4	0.5	-1.0	1.0	-15.4

EbC10 (72h) > 100 mg/l  
 EbC50 (72h) > 100 mg/l  
 EbC90 (72h) > 100 mg/l

INHIBITION OF GROWTH RATES AFTER 72h

	Concentration in mg TS/l							
	0	1.56	3.13	6.25	12.5	25	50	100
Inhibition								
in % of control	0	-0.7	-2.0	0.1	-0.3	-2.3	-1.0	-4.0

ErC10 (72h) > 100 mg/l  
 ErC50 (72h) > 100 mg/l  
 ErC90 (72h) > 100 mg/l

**Test condition:** STOCK SOLUTION AND DILUTION  
 The test was performed with an aqueous extract (filtrate) of the test substance (water solubility < 1mg/l); TS stirred in demineralized water for ca. 20h at 20°C, undissolved TS removed by membrane filtration (pore size 0.2 µm), nominal concentration of the filtrate 125 mg/l, further dilution to nominal concentrations: 100, 50, 25, 12.5, 6.25, 3.13, 1.56 mg/l.

TEST MEDIUM  
 prepared according to guideline (see above)

PERFORMANCE OF THE TEST  
 test temperature 23°C, max. difference 2°C;  
 test vessels 250 ml Erlenmeyer flasks plugged with silicon sponge caps; test volume 100 ml;

pH values in uninoculated tests 7.8-7.9 at start of experiments and 7.9 after 72 h, in inoculated tests pH 7.6-7.8 after 72 h;  
test parameter:  
1) in vivo chlorophyll-a-fluorescence at 435 nM wavelength after 0, 24, 48, 72 h;  
2) control culture: additionally cell counting after 72 h in a counting chamber

STATISTICS

EC values calculated by linear regression analysis from dose-response relationship; NOEC and LOEC: Duncan multiple range test at 95% significance level

**Reliability:**

(1) valid without restriction guideline study

**Flag:**

Critical study for SIDS endpoint

12-MAR-2003

(14)

**4.4 Toxicity to Microorganisms e.g. Bacteria**

**Type:** aquatic  
**Species:** Pseudomonas fluorescens (Bacteria)  
**Unit:** mg/l **Analytical monitoring:** no  
**EC0:** > 10000

**Method:** other  
**Year:** 1977  
**GLP:** no

**Method:** Growth inhibition test according to Bringmann, G. & Kuehn, R.: Z.f. Wasser- und Abwasser-Forschung 10(3/4), 87-98 (1977)

11-DEC-2001

(15)

**Type:** aquatic  
**Species:** Pseudomonas putida (Bacteria)  
**Exposure period:** 30 minute(s)  
**Unit:** mg/l **Analytical monitoring:** no  
**EC10:** > 10000  
**EC50:** > 10000  
**EC90 :** > 10000

**Method:** other: DIN 38412 Part 27 (draft)  
**GLP:** no

**Test substance:** other TS: Sicotangelb K 1910 (C.I. Pigment Brown 24; CAS 68286-90-3); purity ca. 100%

**Method:** Bacterial oxygen consumption test according to Robra, K.H., gwf. Wasser-Abwasser 117, 80-86 (1976)

**Result:** The results show the nominal concentrations of the TS that inhibited oxygen consumption of the microorganisms.

**Test condition:**

- Test solution stirred for 17 h at 293 °K and than used as dispersion (insoluble in water) in the oxygen consumption test
- test volume 100 ml (5 ml glucose [198 g/l] and 95 ml test substance including bacterial suspension)
- assay batch aerated for 30 min
- decline in concentration of dissolved oxygen measured in a flow cell
- pH of the test mix: 7.2 (low dose) - 8.0 (high dose)

- temperature: 25°C  
- tested concentrations: control, 1250, 2500, 5000, 10000  
mg/l (nominal)

**Reliability:** (2) valid with restrictions  
Acceptable, well documented study report which meets basic  
scientific principles.

**Flag:** Critical study for SIDS endpoint

12-DEC-2001 (16) (17)

#### **4.5 Chronic Toxicity to Aquatic Organisms**

##### **4.5.1 Chronic Toxicity to Fish**

##### **4.5.2 Chronic Toxicity to Aquatic Invertebrates**

TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Sediment Dwelling Organisms

4.6.2 Toxicity to Terrestrial Plants

4.6.3 Toxicity to Soil Dwelling Organisms

4.6.4 Toxicity to other Non-Mamm. Terrestrial Species

4.7 Biological Effects Monitoring

4.8 Biotransformation and Kinetics

4.9 Additional Remarks

**Memo:** 1

**Remark:** Sicotan Gelb K 2011 verhaelt sich in einem Organismus und in der Umwelt praktisch inert bzw. ist nicht bioverfuegbar. Dies wird bestaetigt durch die toxikologischen Daten und Daten zur oekotoxischen Wirkung.

**5.0 Toxicokinetics, Metabolism and Distribution**

**Type:** Toxicokinetics  
**Species:** rat  
**No. of animals, males:** 5  
**No. of animals, females:** 5  
**Doses, males:** 10, 100, 1000, 10000 mg/kg diet (0.5, 5, 50, 500 mg/kg bw/day)  
**Doses, females:** 10, 100, 1000, 10000 mg/kg diet (0.5, 5, 50, 500 mg/kg bw/day)  
**Route of administration:** oral feed  
**Exposure time:** 90 day(s)

**Method:** other:comparable to OECD guideline 408  
**GLP:** no data

**Remark:** The detected traces of antimony (see results) most likely originate from the acid-soluble impurities of the pigment (10-20 mg antimony/kg pigment, that is 5-10 microgram/kg bw or 125-250 microgram/kg organ weights at the highest dose) and therefore do not indicate bioavailability of the pigment itself.

**Result:** TOXICICITY  
No deaths, no overt signs of reactions to the treatment, no effects on body weight gain (similar food consumption in all groups) or organ weight, no treatment related findings from haematological or biochemical investigations and urinalysis.  
No macroscopic pathological changes attributable to treatment. No treatment related effects observed in histopathology.

CHEMICAL ANALYSIS  
Antimony  
In males and females the Sb concentrations in liver and kidney were below the detection limit at doses up to 1000 ppm. In the high dose groups the Sb levels slightly increased with exposure duration and reached max. 27 ppb in the liver (3 mo) of males (range 15-40 ppb) and 17 ppb in females (kidney 14 ppb in males and 15 ppb in females).  
Chromium  
No measurable effect on chromium content of liver and kidney at any dose level and exposure duration.

AUTHORS CONCLUSION  
The bioavailable traces of metals are considered to have no toxicological significance.

**Test condition:** EXPERIMENTAL DESIGN  
15 animals per dose per gender for toxicological investigations and 30 animals per gender in the control group;  
additionally 10 animals per dose and gender for analytical investigations and 20 animals per gender in the control group.  
Tests started at the age of 4- 5 weeks; TS given in powdered food (Altromin); feed and tape water ad libitum.

General observations:  
Rats observed daily; food consumption and body weight gain determined once per week.

Haematological, clinical and biochemical investigations:  
RBC, reticulocytes, platelets, haemoglobin, haematocrit,  
total and differential WBC, MCV, ALP, GOT, GPT, creatinine,  
urea, glucose, cholesterol, total plasma proteins and urine  
proteins, urinalysis conducted after one month and at the  
end of the study on 5 males and 5 females of each group; in  
addition thromboplastin time and glutamate dehydrogenase  
activity measured after three months.

Gross and histopathological investigations:  
organ weight determined for thyroid gland, thymus, heart,  
lung, liver, spleen, kidneys, adrenal glands, and gonads and  
histopathology performed together with aorta, eyes,  
intestine, femur, brain, urinary bladder, pituitary,  
cervical lymph nodes, stomach, oesophagus, epididymides,  
pancreas, prostate, seminal vesicle, bone marrow of sternum,  
trachea, uterus, skeletal muscles from 5 animals per gender  
of control and top dose group.

Statistics:  
Data on weight determinations, hematology and clinical  
chemistry compared by Wilcoxon U-test, level of significance  
 $p < 0.05$ .

Chemical Analysis:  
After 1, 2 and 3 months liver and kidneys from 5 animals per  
gender and dose group analysed for their chromium and  
antimony contents by AAS.

**Test substance:**

The detection limit for antimony was 5 ppb, chromium 2 ppb.  
other TS: technical grade chrome rutile yellow (C.I. pigment  
brown 24); characterized on a molar base as  $(\text{Ti}_{0.94}\text{Sb}_{0.03}\text{Cr}_{0.03})\text{O}_2$   
and as 85%  $\text{TiO}_2$ , 10%  $\text{Sb}_2\text{O}_5$ , 5%  $\text{Cr}_2\text{O}_3$  on weight%  
base

**Reliability:**

(2) valid with restrictions

**Flag:**

Critical study for SIDS endpoint

25-NOV-2004

(19)

**5.1 Acute Toxicity**

**5.1.1 Acute Oral Toxicity**

**Type:** LD50  
**Species:** rat  
**Strain:** no data  
**Sex:** no data  
**Vehicle:** no data  
**Doses:** no data  
**Value:** > 10000 mg/kg bw

**Method:** other: no data  
**GLP:** no  
**Test substance:** as prescribed by 1.1 - 1.4

**Reliability:** (4) not assignable  
secondary literature

25-NOV-2004

(20)

**Type:** LD50

**Species:** rat  
**Strain:** Sprague-Dawley  
**Sex:** male/female  
**No. of Animals:** 10  
**Vehicle:** other: see freetext  
**Value:** > 10000 mg/kg bw

**Method:** other: comparable to OECD guideline 401  
**GLP:** no

**Result:** MORTALITY:  
- No mortality  
CLINICAL SIGNS:  
- No symptoms of poisoning; body weight gain comparable to historical controls  
NECROPSY FINDINGS:  
- No macroscopical effects, no data on organs examined

**Test condition:** TEST CONDITION  
- Day-night rhythm: 12:12h  
- Temperature: 22 +/-1 °C  
- Rel. humidity: 55 +/-10%  
- food and water ad libitum, withdrawal 16 h before application  
ADMINISTRATION:  
- Suspension prepared in 0.5% carboxymethyl cellulose prior to application, stirred during application period  
- Doses: one dose, 10000 mg/kg bw, gavage  
- Volume administered: 31.6 ml/kg bw  
- Post exposure observation period: 14 d  
EXAMINATIONS:  
- body weight measured prior to application and 7 and 14 d after dosing  
- clinical symptoms determined 15, 30 min and 1, 2, 4, 5 and 24 h after application, then daily  
- rats sacrificed on day 14, autopsy performed

**Test substance:** C.I. pigment brown 24, characterized as TiO<sub>2</sub> 79,9 %, Sb<sub>2</sub>O<sub>5</sub> 13,4 %, Cr<sub>2</sub>O<sub>3</sub> 5,2 %, SiO<sub>2</sub> 1,5 %  
(crosscontamination with material from ball mill)  
As 40 ppm, Pb 140 ppm, Cu 7 ppm, Zn 40 ppm, Ni 2 ppm

**Reliability:** (2) valid with restrictions  
**Flag:** Critical study for SIDS endpoint

26-NOV-2004 (21)

### 5.1.2 Acute Inhalation Toxicity

**Type:** other: Inhalation Risk Test  
**Species:** rat  
**Strain:** no data  
**Sex:** no data  
**No. of Animals:** 12  
**Vehicle:** other: air  
**Exposure time:** 7 hour(s)

**Method:** other: according to Smyth, H.F. et al., Am. Ind. Hyg. Ass. J. 23, 95-107 (1962)  
**Year:** 1962  
**GLP:** no

**Result:** No mortality during the exposure period, no symptoms of poisoning; autopsy revealed no macroscopical effects.

**Test substance:** C.I. pigment brown 24, characterized as TiO<sub>2</sub> 79,9 %, Sb<sub>2</sub>O<sub>5</sub> 13,4 %, Cr<sub>2</sub>O<sub>3</sub> 5,2 %, SiO<sub>2</sub> 1,5 %  
(crosscontamination with material from ball mill)  
As 40 ppm, Pb 140 ppm, Cu 7 ppm, Zn 40 ppm, Ni 2 ppm

**Test condition:** For enrichment of the atmosphere 200 l air per h conducted through a layer of the product (height 5 cm); test at room temperature. Rats sacrificed.

**Reliability:** (3) invalid  
unsuitable test system

26-NOV-2004

(21)

**5.1.3 Acute Dermal Toxicity****5.1.4 Acute Toxicity, other Routes****5.2 Corrosiveness and Irritation****5.2.1 Skin Irritation**

**Species:** rabbit  
**Concentration:** 50 %  
**Exposure:** Occlusive  
**No. of Animals:** 6  
**Vehicle:** water  
**Result:** slightly irritating

**Method:** other: according to Federal Register 38, No. 187, § 1500.41, S. 27019, 27. Sept. 1973

**Year:** 1973  
**GLP:** no

**Result:** Intact skin:  
Evaluation of erythema after 24 and 72 hrs not possible due to treatment related staining of the skin (no histological examination of the epidermis in full thickness has been conducted, thus conclusion of dermal penetration of the test substance cannot be drawn from this study. In another study, however, it was reported that the staining of the skin could be removed by washing with soap, thereby corroborating that the staining was only superficial; ref. Bayer AG, basic data set, unpublished 20th Feb. 1997); no erythema after 8 d. Slight edema in 3/6 animals after 24 h, no edema after 72 h or 8 d.

Abraded skin:  
Evaluation of erythema impossible after 24 and 72 h due to colouring of skin, no erythema after 8 d but scaling in 3/6 rabbits.  
Edema in 4/6 rabbits after 24 h, no edema after 72 h or 8 d.

Overall primary skin irritation value: 0.58  
slightly irritating

**Test condition:** Application of 50% TS in water, Effects recorded after 24 and 72 h and 8 d.

**Test substance:** C.I. pigment brown 24, characterized as TiO<sub>2</sub> 79,9 %, Sb<sub>2</sub>O<sub>5</sub> 13,4 %, Cr<sub>2</sub>O<sub>3</sub> 5,2 %, SiO<sub>2</sub> 1,5 %  
(crosscontamination with material from ball mill)

**Reliability:** As 40 ppm, Pb 140 ppm, Cu 7 ppm, Zn 40 ppm, Ni 2 ppm  
(2) valid with restrictions  
**Flag:** Critical study for SIDS endpoint  
26-NOV-2004 (21)

**Species:** rabbit  
**Result:** not irritating

**Method:** other  
**GLP:** no  
**Test substance:** other TS: not specified

**Remark:** 2 animals, 500 mg/animal, exposure period 24h, postexposure period 7d

**Reliability:** (4) not assignable  
Secondary literature  
14-MAR-2003 (22)

### 5.2.2 Eye Irritation

**Species:** rabbit  
**Concentration:** undiluted  
**No. of Animals:** 6  
**Result:** slightly irritating

**Method:** other: according to Federal Register 38, No. 187, § 1500.42, S. 27019, 27. Sept. 1973

**Year:** 1973  
**GLP:** no

**Result:** No effects on cornea and iris.  
After 24 hrs clear reddening of conjunctivae in 1/6 rabbits, slight reddening in 5/6; slight secretion in 4/6 rabbits.  
After 48 hrs slight reddening of conjunctivae in 5/6 of animals; one rabbit without symptoms; slight secretion in 1/6 rabbits.  
After 72 hrs three of six animals without symptoms; slight reddening of conjunctivae in 3/6 rabbits, no secretion.  
No substance related staining has been observed.

The result indicates a mechanically mediated slight, reversible irritation of the mucous membrane due to the instillation of test substance particles into the eyes.  
**Test condition:** Readings after 24, 48, 72 h.  
**Test substance:** C.I. pigment brown 24, characterized as TiO<sub>2</sub> 79,9 %, Sb<sub>2</sub>O<sub>5</sub> 13,4 %, Cr<sub>2</sub>O<sub>3</sub> 5,2 %, SiO<sub>2</sub> 1,5 %  
(crosscontamination with material from ball mill)

**Reliability:** As 40 ppm, Pb 140 ppm, Cu 7 ppm, Zn 40 ppm, Ni 2 ppm  
(1) valid without restriction  
comparable to guideline study  
**Flag:** Critical study for SIDS endpoint  
26-NOV-2004 (21)

**Species:** rabbit  
**Result:** not irritating

**Method:** other  
**GLP:** no  
**Test substance:** other TS: not specified

**Remark:** 2 animals, 50 mg/animal, postexposure period 7d  
**Reliability:** (4) not assignable  
Secondary literature

25-OCT-2001

(22)

### 5.3 Sensitization

### 5.4 Repeated Dose Toxicity

**Species:** rat **Sex:** male/female  
**Strain:** other: Wistar TNO W74  
**Route of administration:** oral feed  
**Exposure period:** 90 days  
**Frequency of treatment:** daily ad libitum  
**Post exposure period:** no  
**Doses:** 10, 100, 1000, 10000 mg/kg diet (0.5, 5, 50, 500 mg/kg bw/day)  
**Control Group:** yes, concurrent vehicle  
**NOAEL:** = 500 mg/kg bw

**Method:** other:comparable to OECD guideline 408

**GLP:** no data

**Test substance:** other TS: technical grade chrome rutile yellow (C.I. pigment brown 24); characterized on a molar base as (Ti<sub>0.94</sub> Sb<sub>0.03</sub> Cr<sub>0.03</sub>)O<sub>2</sub> and as 85% TiO<sub>2</sub>, 10% Sb<sub>2</sub>O<sub>5</sub>, 5% Cr<sub>2</sub>O<sub>3</sub> on weight% base

**Remark:** The detected traces of antimony (see results) most likely originate from the acid-soluble impurities of the pigment (10-20 mg antimony/kg pigment, that is 5-10 microgram/kg bw or 125-250 microgram/kg organ weight at the highest dose) and therefore do not indicate bioavailability of the pigment itself.

**Result:** TOXICICITY  
No deaths, no overt signs of reactions to the treatment, no effects on body weight gain (similar food consumption in all groups) or organ weight, no treatment related findings from haematological or biochemical investigations and urinalysis.  
No macroscopic pathological changes attributable to treatment. No treatment related effects observed in histopathology.

#### CHEMICAL ANALYSIS

##### Antimony

In males and females the Sb concentrations in liver and kidney were below the detection limit at doses up to 1000 ppm. In the high dose groups the Sb levels slightly increased with exposure duration and reached max. 27 ppb in the liver (3 months) of males (range 15-40 ppb) and 17 ppb in females (kidney 14 ppb in males and 15 ppb in females).

##### Chromium

No measurable effect on chromium content of liver and kidney at any dose level and exposure duration.

#### AUTHORS CONCLUSION

The bioavailable traces of metals are considered to have no toxicological significance.

**Test condition:** EXPERIMENTAL DESIGN

15 animals per dose per gender for toxicological investigations and 30 animals per gender in the control group; additionally 10 animals per dose and gender for analytical investigations and 20 animals per gender in the control group. Tests started at the age of 4- 5 weeks; TS given in powdered food (Altromin); feed and tap water ad libitum.

General observations:  
Rats observed daily; food consumption and body weight gain determined once per week.

Haematological, clinical and biochemical investigations: RBC, reticulocytes, platelets, haemoglobin, haematocrit, total and differential WBC, MCV, ALP, GOT, GPT, creatinine, urea, glucose, cholesterol, total plasma proteins and urine proteins, urinalysis conducted after one month and at the end of the study on 5 males and 5 females of each group; in addition thromboplastin time and glutamate dehydrogenase activity measured after three months.

Gross and histopathological investigations: organ weight determined from thyroid gland, thymus, heart, lung, liver, spleen, kidneys, adrenal glands, and gonads and histopathology performed together with aorta, eyes, intestine, femur, brain, urinary bladder, pituitary, cervical lymph nodes, stomach, oesophagus, epididymides, pancreas, prostate, seminal vesicle, bone marrow of sternum, trachea, uterus, skeletal muscles from 5 animals per gender of control and top dose group.

Statistics:  
Data on weight determinations, hematology and clinical chemistry compared by Wilcoxon U-test, level of significance  $p \leq 0.05$ .

Chemical Analysis:  
After 1, 2 and 3 months liver and kidneys from 5 animals per gender and dose group analysed for their chromium and antimony contents by AAS.  
The detection limit for antimony was 5 ppb, chromium 2 ppb.

**Reliability:**

**Flag:**

14-MAR-2003

(2) valid with restrictions  
Critical study for SIDS endpoint

(19)

### **5.5 Genetic Toxicity 'in Vitro'**

**Type:** Ames test  
**System of testing:** Salmonella typhimurium TA 1535, TA 100, TA 1537, TA 98  
**Concentration:**  $\geq 5000$  ug/plate  
**Metabolic activation:** with and without  
**Result:** negative

**Method:** other: according to Ames  
**GLP:** yes  
**Test substance:** other TS: C.I. Pigment Brown 24 96.5 %

**Reliability:** (4) not assignable  
secondary literature

14-MAR-2003

(23)

**Type:** Mouse lymphoma assay  
**System of testing:** L5178Y mouse lymphoma cells, heterozygous at the TK locus  
**Concentration:** 3.13, 6.25, 12.5, 25, 50, 100 µg/ml  
**Cytotoxic Concentration:** no cytotoxicity at any concentration tested (see also solubility in freetext)  
**Metabolic activation:** with and without  
**Result:** negative

**Method:** other: Clive et al., Mutat. Res. 189, 143-156 (1987)  
**Year:** 1987  
**GLP:** yes  
**Test substance:** other TS: Chrome Antimony Titanate, no further details

**Method:** Test comparable to OECD guideline 476  
**Result:** With metabolic activation (MA):  
Trial 1 not acceptable because of cell culture problems, but no mutagenicity was observed; in trial 2 no significant increase in mutant frequency (minimum criterion: 2-fold vehicle control) and no dose-related response, no cytotoxicity (relative growths 78.2% to 116.9%).  
Without MA:  
Trial 1 is not acceptable because of cell culture problems but no mutagenicity of the TS was detected; in trial 2 no cytotoxicity of TS (71.2-92.8% relative growths), but no treatment induced mutant frequency that exceeded minimum criterion and no dose related trend was observed.

Valid positive controls with and without MA; mutant frequency in controls within acceptable range as well as acceptable cloning efficiencies (without MA 87.7% and with MA 100.3%)

AUTHORS EVALUATION

TS was negative with and without activation under the conditions of testing; there was no cytotoxicity; the TS was insoluble and was tested at concentrations where it was possible to remove the TS at the end of exposure period.

**Test condition:** METABOLIC ACTIVATION (MA) SYSTEM

S-9 mix with liver homogenate from male Sprague-Dawley rats treated with 500 mg/kg Aroclor1254 5 d prior to sacrifice

CONTROLS

Untreated (negative) control (only in cytotoxicity test) and vehicle control (DMSO); positive control methyl methanesulfate (without MA) and methylcholanthrene (with MA)

MEDIA

- culture medium: RPMI 1640 supplemented with PluronicF68, L-glutamine, sodium pyrovate, antibiotics and 10% horse serum
- treatment medium: Fischers medium with same supplements but 5% horse serum
- cloning medium: like culture medium but 20% horse serum and without PluronicF68 and addition of BBL purified agar (0.24%)
- selection medium: cloning medium containing 3 µg/ml of TFT (5-trifluorothymidine)

PERFORMANCE OF TEST

TS formed a suspension in DMSO at concentrations from 0.195 to 100 mg/l; higher concentrations are not included because of the insolubility of the TS (visible precipitates could not be removed by washing and dosing period could therefore not be controlled); in preliminary rangefinding tests no cytotoxicity at 1000 µg/ml; 2 independent trials; 3 vehicle controls and 2 positive controls in each trial; exposure period 4 h; expression period 2 d; selection period 10-14 d.

Since the TS was negative, colony sizing was not performed (total mutant colonies documented).

**Reliability:**

**Flag:**

14-MAR-2003

(2) valid with restrictions  
Critical study for SIDS endpoint

(24)

**Type:**

Ames test

**System of testing:**

Salmonella typhimurium TA98, 100, 1535, 1537, 1538

**Concentration:**

100, 250, 500, 1000, 2500, 5000 µg/plate

**Cytotoxic Concentration:**

no cytotoxicity at any concentration/exp. design  
(compare with solubility/precipitates, see freetext)

**Metabolic activation:**

with and without

**Result:**

negative

**Method:**

other: Maron and Ames, Mutat. Res. 113, 173-215 (1983)

**Year:**

1983

**GLP:**

yes

**Test substance:**

other TS: Chrome Antimony Titanate, LOT no.: CP653-1 (Color Pigments Manufactures Assoc.), no further data

**Method:**

Comparable with OECD guideline 471

**Result:**

In preliminary dose range-finding studies (TA100, 6.8-5000 µg/plate, 10 doses) no cytotoxicity with and without S9-mix; precipitates at 1000 µg/plate (background lawn could not be evaluated).

GENOTOXIC EFFECTS:

- With and without metabolic activation: no positive results at any dose level in all tested strains.

-CYTOTOXIC CONCENTRATION:

- No cytotoxicity of the TS at any dose level; precipitates at 1000 µg/plate.

CONTROLS:

spontaneous revertants in negative controls within the normal range; valid positive controls.

Evaluation:

Under the condition of this study the TS did not cause an increase in the number of revertants of any tester strain either with or without metabolic activation.

**Test condition:**

SYSTEM OF TESTING

- Type: plate incorporation method

- Metabolic activation system: S9-mix, liver microsomes prepared from male Sprague-Dawley rats i.p. injected with 500 mg/kg Aroclor1254.

- number of plates per concentration/control: 3

- Solvent: DMSO, insoluble TS formed suspension which remained in all dilutions

- Controls: negative (vehicle control and sterility control) and positive control:

-S9 mix: 2-nitrofluorene (TA98, TA1538), sodium azide (TA1535, TA100), ICR-191 (TA1537)

+S9 mix: 2-Aminoanthracene (five strains)  
- Cytotoxicity: evaluated via bacterial background lawn and reduction in revertant colonies

CRITERIA FOR EVALUATING RESULTS:

TA98 and TA100 considered positive if the TS produced at least a 2-fold increase in revertants per plate over vehicle control and a dose response to increasing concentrations; same criteria for the other strains but 3-fold increase.

**Reliability:**

(2) valid with restrictions

No 2nd independent trial

**Flag:**

Critical study for SIDS endpoint

14-MAR-2003

(25)

**Type:**

Micronucleus test in vitro

**System of testing:**

V79 Chinese Hamster Lung Cells

**Concentration:**

0.78-25 µg/ml (see freetext for further details)

**Cytotoxic Concentration:**

no cytotoxic response under any exp. condition

**Metabolic activation:**

with and without

**Result:**

negative

**Method:**

other: see freetext

**GLP:**

yes

**Test substance:**

other TS: Pigment Brown 24 obtained from BASF AG, purity 99.4%

**Method:**

Test according to a proposal for a new OECD guideline for the in vitro micronucleus test (1998).

Literature:

Kallweit et al., 1999, Mut Res 439, 183-199

Seelbach et al., 1993, Mut Res 303, 163-169

Seelbach et al., 1993, Toxicol in vitro, 7, 185-193

**Result:**

TS precipitation in the vehicle observed at all test doses, in culture "obviously soluble up to 6.25 µg/ml". Osmolality and pH values not influenced by the treatment.

GENOTOXIC EFFECTS:

With and without metabolic activation in both trials no increase in the number of micronuclei at any dose level.

CYTOTOXIC CONCENTRATION:

No suppression of the mitotic activity at any dose level (determination of mitotic index); determination of the proliferation index (allows measurement of colony size) revealed no cytotoxic response under any exp. condition as well as the cell counts showed no growth inhibition; cell attachment was not influenced at any dose.

CONTROLS:

Spontaneous micronuclei in negative controls within the normal range; valid positive controls.

EVALUATION:

Under the condition of this study the TS did not cause an increase in the number of micronuclei of the tester strain either with or without metabolic activation. TS considered not to induce clastogenic or aneugenic effects.

**Test condition:**

METABOLIC ACTIVATION (MA) SYSTEM

S-9 mix with liver homogenate from male Sprague-Dawley rats treated with 500 mg/kg Aroclor1254 5 d prior to sacrifice

CONTROLS

concurrent vehicle controls (DMSO); concurrent positive controls ethyl methanesulfonate (without MA) and cyclophosphamide (with MA)

MEDIA

- culture medium: MEM medium with 10% fetal calf serum & 2% antibiotics
- treatment medium: same medium without fetal calf serum

PERFORMANCE OF TEST

DMSO used as vehicle. Max. doses in the different exp. designs 12.5-25 µg/ml; higher doses could not be evaluated due to TS precipitation which interfered with evaluation of cells (determined in pretests).

In all exp. groups duplicate cultures used; 1000 cells per culture analysed;

1st Trial (mixed population method):

- a) 24 h exposure, 24 h harvest time, without S9-mix
  - b) 4 h exposure, 24 h harvest time, with S9-mix
- concentrations in a) and b): 0, 1.25, 2.5, 5, 10, 15 µg/ml

2nd Trial using the mitotic shake off method (24 h mitotic shake off):

- a) 24 h exposure, 27 h preparation time, without S9-mix; concentrations 0, 0.78, 1.56, 3.12, 6.25, 12.5 µg/ml
- b) 4 h exposure, 27 h preparation time, with S9-mix; concentrations 0, 1.56, 3.12, 6.25, 12.5, 25 µg/ml

STATISTICS

No statistical analysis due to the clear negative findings.

EVALUATION CRITERIA

No significant increase in the number of micronuclei at any dose level above concurrent negative control and within historical control data; number of micronuclei in concurrent negative control within the normal range; significant increase in number of micronuclei in positive controls. Stability of the TS verified by reanalysis; homogeneity given.

**Test substance:**

**Reliability:**

**Flag:**

14-MAR-2003

(1) valid without restriction  
Critical study for SIDS endpoint

(26)

**Type:**

**System of testing:**

**Concentration:**

**Cytotoxic Concentration:**

**Metabolic activation:**

**Result:**

Bacterial reverse mutation assay  
E. coli WP2uvrA  
100, 250, 500, 1000, 2500, 5000 µg/plate  
no cytotoxicity at any concentration/exp. design (compare with solubility/precipitates, see freetext)  
with and without  
negative

**Method:**

**GLP:**

**Test substance:**

other: comparable to OECD guideline 472  
yes  
other TS: Chrome Antimony Titanate, LOT no.: CP653-1 (Color Pigments Manufactures Assoc.), no further data

**Result:**

In preliminary dose range-finding study (6.7-5000 µg/plate, 10 doses) no cytotoxicity with and without S9-mix; precipitates at 1000 µg/plate (background lawn could not be evaluated).

GENOTOXIC EFFECTS:  
- With and without metabolic activation: no positive results at any dose level.  
-CYTOTOXIC CONCENTRATION:  
- No cytotoxicity of the TS at any dose level; precipitates at 1000 µg/plate.  
CONTROLS:  
spontaneous revertants in negative controls within the normal range; valid positive controls.

Evaluation:  
Under the condition of this study the TS did not cause an increase in the number of revertants of the tester strain either with or without metabolic activation.

**Test condition:**

SYSTEM OF TESTING  
- Type: plate incorporation method  
- Metabolic activation system: S9-mix, liver microsomes prepared from male Sprague-Dawley rats i.p. injected with 500 mg/kg Aroclor1254.  
- number of plates per concentration/control: 3  
- Solvent: DMSO, insoluble TS formed suspension which remained in all dilutions  
- Controls: negative (vehicle control and sterility control) and positive control with (2-aminoanthracene) and without S9-mix (4-nitroquinoline-N-oxide).  
- Cytotoxicity: evaluated via bacterial background lawn and reduction in revertant colonies

CRITERIA FOR EVALUATING RESULTS:  
Considered positive if the TS produced at least a 2-fold increase in revertants per plate over vehicle control and a dose response to increasing concentrations.

**Reliability:**

(2) valid with restrictions

**Flag:**

No 2nd independent trial  
Critical study for SIDS endpoint

15-OCT-2001

(25)

**5.6 Genetic Toxicity 'in Vivo'**

**5.7 Carcinogenicity**

**5.8.1 Toxicity to Fertility**

**Type:** other: repeated dose toxicity  
**Species:** rat  
**Sex:** male/female  
**Strain:** other: Wistar TNO W74  
**Route of administration:** oral feed  
**Exposure Period:** 90 days  
**Frequency of treatment:** daily ad libitum  
**Doses:** 10, 100, 1000, 10000 mg/kg diet (0.5, 5, 50, 500 mg/kg bw/day)

**Method:** other:comparable to OECD guideline 408  
**GLP:** no data

**Test substance:** other TS: technical grade chrome rutile yellow (C.I. pigment brown 24); characterized on a molar base as (Ti<sub>0.94</sub> Sb<sub>0.03</sub> Cr<sub>0.03</sub>)O<sub>2</sub> and as 85% TiO<sub>2</sub>, 10% Sb<sub>2</sub>O<sub>5</sub>, 5% Cr<sub>2</sub>O<sub>3</sub> on weight%

base

**Result:** no effects on organ weights and macro-and micro-histopathology of gonads (testes, epididymides, prostate, seminal vesicle, ovary and uterus) were observed in the 90 day feeding study on rats at doses up to 500 mg/kg bw/ day

**Reliability:** (2) valid with restrictions

**Flag:** Critical study for SIDS endpoint

14-MAR-2003 (19)

#### 5.8.2 Developmental Toxicity/Teratogenicity

#### 5.8.3 Toxicity to Reproduction, Other Studies

#### 5.9 Specific Investigations

#### 5.10 Exposure Experience

**Remark:** no data available

24-AUG-2001

#### 5.11 Additional Remarks

**Type:** other: update info

**Remark:** no relevant new data located, 16. March 1998

16-MAR-1998

**6.1 Analytical Methods**

**6.2 Detection and Identification**

7.1 Function

7.2 Effects on Organisms to be Controlled

7.3 Organisms to be Protected

7.4 User

7.5 Resistance

**8.1 Methods Handling and Storing**

**Safe Handling:** Breathing must be protected when large quantities are decanted without local exhaust ventilation.

**Fire/Exp. Prot.:** Avoid dust formation.

**Storage Req.:** Keep container tightly closed.

**Transport Code:** Not classified as hazardous under transport regulations.

**Remark:** Personal protective equipment

Respiratory protection:  
Suitable respiratory protection for higher concentrations or long-term effect: Particle filter EN 143 Type P1, low efficiency, (solid particles of inert substances).

Hand protection:  
Chemical resistant protective gloves (EN 374) e.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), polyvinylchloride (0.7 mm) and other.  
Manufacturer's directions for use must be observed because of great diversity of types.

Eye protection:  
Safety glasses with side-shields (frame goggles) (EN 166)

General safety and hygiene measures:  
Handle in accordance with good industrial hygiene and safety practice. Due to the coloring properties of the product closed work clothes should be used, to avoid stains during manipulation. Hands and/or face should be washed before breaks and at the end of the shift.

**Flag:** non confidential, Critical study for SIDS endpoint  
15-NOV-2002 (1)

**8.2 Fire Guidance**

**Hazards:** Evolution of fumes/fog. Harmful vapours can be released in case of fire.

**Prot. Equipment:** Wear a self-contained breathing-apparatus.

**Ext. Medium:** water spray, dry extinguishing media, foam, carbon dioxide

**Add. Information:** The degree of risk is governed by the burning substance and the fire conditions. Contaminated extinguishing water must be disposed of in accordance with official regulations.

**Flag:** non confidential, Critical study for SIDS endpoint  
15-NOV-2002 (1)

**8.3 Emergency Measures**

**Type:** other: general advice

**Remark:** Remove contaminated clothing.

**Flag:** non confidential, Critical study for SIDS endpoint  
15-NOV-2002 (1)

**Type:** injury to persons (skin)

**Remark:** Wash thoroughly with soap and water.

**Flag:** non confidential, Critical study for SIDS endpoint  
15-NOV-2002 (1)

**Type:** injury to persons (eye)

**Remark:** Wash affected eyes for at least 15 minutes under running water with eyelids held open.

**Flag:** non confidential, Critical study for SIDS endpoint  
15-NOV-2002 (1)

**Type:** injury to persons (oral)

**Remark:** Rinse mouth and then drink plenty of water.

**Flag:** non confidential, Critical study for SIDS endpoint  
15-NOV-2002 (1)

**Type:** injury to persons (inhalation)

**Remark:** If difficulties occur after dust has been inhaled, remove to fresh air and seek medical attention.

**Flag:** non confidential, Critical study for SIDS endpoint  
15-NOV-2002 (1)

**Type:** other: Note to physician

**Remark:** If difficulties occur after dust has been inhaled, remove to fresh air and seek medical attention.

**Flag:** non confidential, Critical study for SIDS endpoint  
15-NOV-2002 (1)

**Type:** accidental spillage

**Remark:** Personal precautions:  
Avoid dust formation. Use personal protective clothing.

Environmental precautions:  
Contain contaminated water/firefighting water. Do not discharge into drains/surface water/groundwater.

Methods for cleaning up or taking up:  
For small amounts: Pick up with suitable appliance and dispose of.  
For large amounts: Contain with dust binding material and dispose of.  
Avoid raising dust.

**Flag:** non confidential, Critical study for SIDS endpoint  
15-NOV-2002 (1)

**8.4 Possib. of Rendering Subst. Harmless****8.5 Waste Management**

**Memo:** other: must be dumped or incinerated in accordance with local regulations.

**Flag:** non confidential, Critical study for SIDS endpoint  
15-NOV-2002 (1)

**8.6 Side-effects Detection**

**8.7 Substance Registered as Dangerous for Ground Water**

**8.8 Reactivity Towards Container Material**

- (1) BASF AG, Safety data sheet SICOTAN GELB L 1910, 04.07.2002 (30047688)
- (2) H.Endriß, Inorganic coloured pigments today, Curt R. Vincentz Verlag, Hannover, 1998
- (3) personal communication, Dr. Hartmut Endriss, BASF AG, 11/2002
- (4) MAK- und BAT-Werte-Liste 2002 (Mitteilung 38 vom 01.07.2002), WILEY-VCH Verlag GmbH, Weinheim, Germany
- (5) Catalogue of Substances Hazardous to Water - Umweltbundesamt Berlin, status 11.11.2002
- (6) National Chemical Inventories 2001 Issue 1
- (7) BASF AG, Safety data sheet Sicotan Gelb L 2011, 02.10.2000
- (8) BASF AG, expert judgement, 2002
- (9) BASF AG, personal communication, 12.08.2002
- (10) BASF AG, Umweltanalytik, Mitteilung vom 24.03.95
- (11) Bayer AG, Safety data sheet, cited in BAYER base data set
- (12) BASF AG, Department of Toxicology, unpublished data, Project No. 10F0066/885110, 25.10.1988
- (13) BASF AG, department of ecology, unpublished data (Project No. 99/0484/50/1), 17.01.2000
- (14) BASF AG, department of ecology, unpublished data (Report No. 99/0484/60/1), 04.05.2000
- (15) Safety Data Sheet Bayer AG (zitiert nach EUCLID Data Sheet vom 18.08.1994, Bayer AG)
- (16) BASF AG, Dep. Ecology, unpublished data, Datenerhebung für oekotoxikologische Untersuchungen vom 18.1.1988
- (17) BASF AG, Dep. Ecology, unpublished data, Project No. 01/88/0121, 02.01.1997
- (18) BASF AG, Mitteilung vom 20.03.95
- (19) Bomhard E. et al. (1982), Toxicol. Lett. 14, 189-194
- (20) Bayer AG, unpublished data, 23.11.1972, cited in Bayer base data set, last update 19.08.1994
- (21) BASF AG, Department of Toxicology, unpublished data, substance 77/146, 28.03.1978
- (22) Bayer AG, unpublished data, 29.03.1979, cited in Bayer base data set, last update 18.08.1994
- (23) Bayer AG, unpublished data, Report No. 19909, Jan. 1991, cited in Bayer base data set, last update 18.08.1994

- (24) Corning Hazelton, CHV STUDY No. 16595-0-431, Apr. 1996, sponsored by Color Pigments Manufacturers Association
- (25) Corning Hazelton, CHV Study No. 16595-0-409, June 1995, sponsored by Color Pigments Manufacturers Association
- (26) BASF Aktiengesellschaft, Product Safety, unpublished data, Report No.: 33M0278/994093 (2001)

10.1 End Point Summary

10.2 Hazard Summary

10.3 Risk Assessment