

201-16302B

**I. General Information**

CAS Number: C.I. Pigment Red 48 (Calcium), CAS NO.: 7023612  
Name: 2-Naphthalenecarboxylic acid, 3-hydroxy-4-(5-chloro-4-methyl-2-sulfophenyl)azo]-, calcium salt

CAS Number: C.I. Pigment Red 48 (Barium), CAS NO.: 7585413  
Name: 2-Naphthalenecarboxylic acid, 3-hydroxy-4-(5-chloro-4-methyl-2-sulfophenyl)azo]-, barium salt

CAS Number: C.I. Pigment Red 52 (Calcium), CAS NO.: 17852992  
Name: 2-Naphthalenecarboxylic acid, 3-hydroxy-4-(4-chloro-5-methyl-2-sulfophenyl)azo]-, Calcium salt

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**II. Physical-Chemical Data**

**A1. Melting Point**

**Test Substance**

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4-(5-chloro-4-methyl-2-sulfophenyl)azo]-, Manganese salt

Remarks:

**Method**

Method: Measured  
Remarks: Mean of the Joback, and the Gold and Ogle methods

**Results**

Melting point value: 360 °C  
Remarks:

**References**

National Printing Ink Research Institute, Raw Materials Handbook, 2000

**Other**

Data is consistent with melting points for the class of pigments and other available measurements

## A2. Melting Point

### Test Substance

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4- [(4- methyl-2-sulfophenyl)azo]-, calcium salt

Remarks:

### Method

Method: Measured

Remarks:

### Results

Melting point value: 357.5 °C

Remarks:

### References

Unpublished company data  
reliable with restrictions

### Other

Data is consistent with melting points for the class of pigments and other available measurements.

**B. Boiling Point****Test Substance**

Test substance: SOLID  
Remarks:

**Method**

Method:  
Remarks:

**Results**

Boiling point value:  
Remarks:

**References****Other****C1. Vapor Pressure****Test Substance**

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4- (5-chloro-4- methyl-2-sulfophenyl)azo]-, Calcium salt  
Remarks:

**Method**

Method: Estimation  
Remarks: Modified Grain method

**Results**

Vapor pressure value: 2.9 E-019 mm Hg  
Temperature:

Remarks:

**References**

MPBPWIN v 1.40 in EPIWIN v 3.10, Syracuse Research Corporation,  
Syracuse, New York

**Other**

## C2. Vapor Pressure

### Test Substance

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4-[(4- methyl-2-sulfophenyl)azo]-, calcium salt

Remarks:

### Method

Method: OECD TG104,

Remarks:

### Results

Vapor pressure value: <130 PA

Temperature: 25 °C

Remarks:

### References

Ministry of Health and Welfare (MHW),  
Ministry of International Trade and Industry (MITI)  
Environment Agency (EA), Japan (1993)

### Other

**D. Partition Coefficient****Test Substance**

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4- [(4- methyl-2-sulfohenyl)azo]-, calcium salt

Remarks:

**Method**

Method: Measured Value, OECD 117

Remarks: GLP

**Results**

Log P<sub>ow</sub>: -2.5 at pH 3, 2.4 at pH 4, 1.1 at pH 7

Remarks:

**References**

Ministry of Health and Welfare (MHW),  
Ministry of International Trade and Industry (MITI)  
Environment Agency (EA), Japan (1993)

**Other**

## E. Water Solubility

### Test Substance

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4- [(4- methyl-2-sulfohenyl)azo]-, calcium salt

Remarks:

### Method

Method: Measured Value OECD 105

Remarks: GLP

### Results

Value: 8.9 mg/L

Temperature: 25 °C

Description: Very Low Solubility

Remarks:

### References

Ministry of Health and Welfare (MHW),  
Ministry of International Trade and Industry (MITI)  
Environment Agency (EA), Japan (1993)

### Other

### III. Environmental Fate Endpoints

#### A. Photodegradation

##### Test Substance

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4- [(4- methyl-2-sulfophenyl)azo]-, calcium salt

Remarks:

##### Method

Method: Estimate  
Test type: Water\sunlight  
Remarks:

##### Results

Temperature:  
Degradation Rate

2.25 x 10<sup>-11</sup> mol/l/s

: Half-life  
Ozone reaction:  
Remarks:

.049 years  
No ozone reaction estimation

##### Conclusions

##### References

Lyman, W. J., W. F. Reehl and D. H. Rosenblatt (1981) "Handbook of Chemical Property Estimation Method", McGraw Hill Book Co.

##### Other

## A2. Photodegradation

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4- (5-chloro-4- methyl-2-sulfophenyl)azo]-, Calcium salt

Remarks:

### Method

Method: Estimation

Test type: Water

Remarks:

### Results

Temperature:

Hydroxyl radicals reaction

OH Rate constant:

Half-life 1.56 E6OH/cm3

Ozone reaction: .957 Days

Remarks:

### Conclusions

### References

AopWin v1.90 in EPIWIN v3.10, Syracuse Research Corporation, Syracuse, New York

### Other

## **B. Stability in Water**

### **Test Substance**

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4- [(4- methyl-2-sulfohenyl)azo]-, calcium salt

Remarks:

### **Method**

Method: OECD Test 111

Test type: abiotic hydrolysis

GLP: Yes

Remarks:

### **Results**

Half-life: not hydrolyzed at pH 4, 7 and 9

Percent hydrolyzed in

5 days (120 hs)

at 50 °C :

Remarks:

### **Conclusions**

### **Data Quality**

Remarks: Reliable without Restriction

### **References**

Ministry of Health and Welfare (MHW),  
Ministry of International Trade and Industry (MITI)  
Environment Agency (EA), Japan (1993)

### **Other**

### C. Biodegradation

#### Test Substance

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4- [(4- methyl-2-sulfophenyl)azo]-, calcium salt

Remarks:

#### Method

Method: OECD 301C

Test type: Biological Oxygen Demand (BOD)

GLP: Yes

Year: 1993

Remarks: Degree of degradation after 28 days (Japanese standard activated sludge)

#### Results

Results: 12.9 and 9 percent from BOD

Remarks:

#### Conclusions

#### Data Quality

Remarks: This was a well-documented study that followed established guidelines and was conducted under GLP assurances.

#### References

Ministry of Health and Welfare (MHW),  
Ministry of International Trade and Industry (MITI)  
Environment Agency (EA), Japan (1992)

#### Other

**D. Transport between Environmental Compartments (Fugacity)**

**Test Substance**

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4- (5-chloro-4- methyl-2-sulfophenyl)azo]-, Calcium salt  
Remarks:

**Method**

Test type:  
Model used: Estimation  
Level III Fugacity Model; EPIWIN:EQC from Syracuse Research Corporation  
Remarks:

**Results**

Model data and results:

|          | Distribution (%) |
|----------|------------------|
| Air      | .0424            |
| Water    | 1.17             |
| Soil     | 51.9             |
| Sediment | 46.9             |

Remarks: Since no experimental values were available the physical chemical values utilized in this model were default parameters from within EPIWIN.

**Conclusions**

**References**

Meylan, W. (1993). User's Guide for the Estimation Programs Interface (EPI), Version 3.10, Syracuse Research Corporation, Syracuse, New York 13210. The Level III model incorporated into EPIWIN is a Syracuse Research Corporation adaptation of the methodology described by Mackay *et al.* 1996; *Environ. Toxicol. Chem.* **15(9)**, 1618-1626 and 1627-1637.

**Other**

#### IV. Ecotoxicity

##### A. Acute Toxicity to Fish

###### Test Substance

Test substance:

Remarks:

2-Naphthalenecarboxylic acid, 3-hydroxy-4- [(4- methyl-2-sulfophenyl)azo]-, calcium salt  
Purity was 87.1%

###### Method

Method:

Test type:

GLP:

Year:

Species/strain:

Analytical monitoring:

Exposure period:

Remarks:

OECD 203

Flow through

No

1992

Oryzias latipes (Orange Killifish)

No; Exposure solutions, temperature, pH, dissolved oxygen

96-Hour

A group of 10 fishes were exposed to 5 nominal concentrations(17.1-180), DMSO Control(.5mg/l)and laboratory water control

###### Results

Nominal concentration:

Measured concentration:

Endpoint value:

Biological observations:

96-hour LC<sub>50</sub> 33 mg/L, 72-hour LC<sub>50</sub> 44mg/L, 48 hour LC<sub>50</sub> 80-120 mg/L

Statistical methods:

Remarks:

###### Conclusions

Reliable with restrictions, This appears to be a well documented study.

###### Data Quality

Reliability:

Remarks:

###### References

Ministry of Health and Welfare (MHW),  
Ministry of International Trade and Industry (MITI)  
Environment Agency (EA), Japan (1992)

###### Other

## A2. Acute Toxicity to Fish

### Test Substance

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4- [(4- methyl-2-sulfophenyl)azo]-, calcium salt

### Remarks:

Purity was 87.1% (area)

### Method

Method: Japanese Industrial Standard (JIS K 0102-1986-71)  
Test type: Flow through  
GLP: Yes  
Year: 1992  
Species/strain: *Oryzias latipes* (Orange Killifish)  
Analytical monitoring: No; Exposure solutions, temperature, pH, dissolved oxygen  
Exposure period: 96-Hour  
Remarks: A group of 10 fishes were exposed to 5 nominal concentrations(17.1-180), DMSO Control (.5mg/l)and laboratory water control

### Results

Nominal concentration:  
Measured concentration:  
Endpoint value: 48 hour  $LC_{50}$  =50 mg/L  
Biological observations:

Statistical methods:  
Remarks:

### Conclusions

Reliable without restrictions

### Data Quality

Reliability:  
Remarks:

### References

Ministry of Health and Welfare (MHW),  
Ministry of International Trade and Industry (MITI)  
Environment Agency (EA), Japan (1992)

### Other

**B. Acute Toxicity to  
Aquatic Invertebrates**

**Test Substance**

Test substance:

2-Naphthalenecarboxylic acid, 3-hydroxy-4- [(4- methyl-2-sulfophenyl)azo]-,  
calcium salt

Remarks

Purity was 87.%

**Method**

Method:

Test type:

OECD 202.

GLP:

Flow through, open system

Year:

Yes

Species/strain:

1984

Analytical monitoring:

Daphnid (*Daphnia magna*)

Exposure period:

No

Remarks:

21-days

**Results**

Nominal concentration:

Measured concentration:

90-940 mg/L

Endpoint value:

48 -hour LC<sub>50</sub> 43 mg/l, 96 hour 18 mg/L, 7 days 13 mg/L, 14 days 10 mg/L ,21  
days 9.7 mg/L,

Reproduction

Biological observations:

EC<sub>50</sub> (21 days) 9.1 mg/L, LC<sub>50</sub> (14 days) 4.4 mg/L  
NOEC 3.0 mg/L, LOEC 9.4

Statistical methods:

Remarks:

95% confidence level within a range

40 daphnids(4 replicates; 10 organisms per replicate) were exposed to 5 nominal  
concentrations (90-940 mg/L) control of DMSO: HCO-40 =9:1 (100mg/L) and  
laboratory water control

**Conclusions**

**Data Quality**

Reliability:

Remarks:

Reliable without restrictions

This was a well-documented OECD guideline study conducted under GLP  
assurances.

Ministry of Health and Welfare (MHW),  
Ministry of International Trade and Industry (MITI)  
Environment Agency (EA), Japan (1992)

**References**

**Other**

### C. Toxicity to Aquatic Plants

#### Test Substance

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4- [(4- methyl-2-sulfophenyl)azo]-, calcium salt

Remarks: Purity 87%

#### Method

Method: OECD 201  
Test type: Biomass  
GLP: no  
Year: 1992  
Species/strain: Selenastrum capricornutum ATCC 22662  
Endpoint basis:  
Exposure period: 72 hours  
Analytical procedures:  
Remarks:

#### Results

Nominal concentration: 13 concentrations 1.0 to 1000 mg/L  
Measured concentration:  
Endpoint value: EC<sub>50</sub> (72 hour) 190mg/L  
NOEC: 5.8 mg/L (p<.05)  
Biological observations:  
Was control response satisfactory: Yes  
Statistical Methods:  
Remarks:

#### Conclusions

#### Data Quality

Reliability: Reliable with restriction. This is a well documented study.  
Remarks:

#### References

Ministry of Health and Welfare (MHW),  
Ministry of International Trade and Industry (MITI)  
Environment Agency (EA), Japan (1992)

#### Other

## V. Toxicological Data

### A. Acute Toxicity

#### Test Substance

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4-(5-chloro-4-methyl-2-sulfophenyl)azo]-, Barium salt  
Remarks: Purity was unknown

#### Method

Method: Acute lethality; Other  
Test type: LD<sub>50</sub> estimate  
GLP: No (Pre-GLP)  
Year: 1968  
Species/strain: Rat/unknown  
Route of exposure: Oral gavage  
Dose levels: Unknown  
Remarks:

#### Results

Value: LD<sub>50</sub> = >5,000 mg/kg.  
Deaths at each dose:  
Remarks:

#### Conclusions

Material would be considered as not toxic.

#### Data Quality

Reliability: Reliable with restrictions  
Remarks: The study was conducted quite some time ago and hence many study details are missing from the report and not available. However, basic data are given and results are consistent with other data for pigments of this class.

#### References

Mone J.G. 1968, Federation Series on Coating Technology, Unit 9 Organic Pigments, Federation of Societies for Paint Technology, Philadelphia, PA 19107.

#### Other

**Acute toxicity**

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4-(5-chloro-4-methyl-2-sulfophenyl)azo]-, Calcium salt and 2-Naphthalenecarboxylic acid, 3-hydroxy-4-(4-chloro-5-methyl-2-sulfophenyl)azo]-, Calcium salt

Remarks: Purity was unknown

**Method**

Method:  
Test type: Acute lethality; Other  
GLP: LD<sub>50</sub> estimate  
Year: No (Pre-GLP)  
Species/strain: 1968  
Route of exposure: Rat/unknown  
Dose levels: Oral gavage  
Remarks: Unknown

**Results**

Value:  
Deaths at each dose: LD<sub>50</sub> = >5,000 mg/kg.  
Remarks:

**Conclusions**

Material would be considered as not toxic.

**Data Quality**

Reliability:  
Remarks: Reliable with restrictions  
The study was conducted quite some time ago and hence many study details are missing and not available. However, basic data are given and results are consistent with other data for these pigments and pigments of this class.

**References**

Mone J.G. 1968, Federation Series on Coating Technology, Unit 9, Organic Pigments, Federation of Societies for Paint Technology, Philadelphia, PA 19107.

**Other**

## Repeated Dose Toxicity

### Test Substance

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4-[(4- methyl-2-sulfophenyl)azo]-,  
Remarks: calcium salt  
Commercial purity 98%

### Method

Method:  
Test type: OECD 422  
GLP: Combined Repeat Dose and Reproductive/ Development  
Year: Yes  
Species/strain: 1992  
Route of exposure: Rat Male and Female  
Duration of test: Gavage  
Exposure levels: 42 days  
Sex: 0, 100, 300 or 1,000 mg/kg  
Exposure period: Male and female  
Post-exposure observation: 42 days including 14 days before mating  
Remarks:

### Results

NOAEL (NOEL):

<100mg/kg/day, doses= 300 and 100 mg/kg/day

All animals survived to the end of the studies. No clinical findings indicative of chemical toxicity were observed; red-stained feces of exposed animals were due to contact with D & C Red No.7 and were not indicative of toxicity. The mean body weight gains and food consumption of the dosed group, in both sexes, were comparable to those in the control groups throughout the study. No biologically significant changes in hematological parameters were noted in any dosed male groups. Male rats that received 300 mg/kg or greater showed significantly decreased levels for serum calcium and phosphorus. Significant decreases in serum potassium and total cholesterol levels, and significant increases in chloride and GOT levels were also shown in the males that received 1000 mg/kg. No other significant differences in clinical parameters were observed in the dosed male groups. Male rats that received 1000 mg/kg showed a significant increase in relative kidney weights, and females that received 100 or 1000 mg/kg showed decreases in thymus weights in comparison with the controls. No other significant differences in organ weights were observed in both the males and females. At the terminal necropsy, gross pathological changes included a small thymus in 2 and 5 female rats that received 100 and 1000 mg/kg, respectively; no marked changes were noted in the dosed males. In the histopathological examinations, predominant alterations occurred in the kidney suggesting effects of D & C Red No. 7 in dosed rats. The lesions included regenerated renal tubular epithelium in male rats receiving 300 mg/kg or greater, and those with necrotic or foamy tubular epithelial cells in the dosed females. These lesions were of greater severity and/or occurred with an increased incidence in the higher dose groups. There were no histopathological changes in the sexual organs of the females that showed no evidence of the copulation, pregnancy or parturition, under the test conditions. study.

**Conclusions**

Test substance is not significantly toxic

**Data Quality**

Reliability:

Reliable without restriction

Remarks:

**References:**

Ministry of Health and Welfare (MHW),  
Ministry of International Trade and Industry (MITI)  
Environment Agency (EA), Japan (1993)

**Other**

**C. Genetic Toxicity - Mutation**

**Test Substance**

Test substances: 2-Naphthalenecarboxylic acid, 3-hydroxy-4-(5-chloro-4- methyl-2-sulfophenyl)azo]-, Barium salt and 2-Naphthalenecarboxylic acid, 3-hydroxy-4-(5-chloro-4- methyl-2-sulfophenyl)azo]-, Calcium salt

Remarks:

**Method**

Method: In Vitro Mutagenicity  
Test type: Ames  
GLP: Unknown  
Year: Unknown  
Species/strain: Salmonella typhimurium  
Metabolic activation: Yes, barium salt (and manganese salt)  
Concentration tested:  
Remarks:

**Results**

Result: Negative  
Cytotoxic concentration:  
Precipitation concentration:  
Genotoxic effects  
    With activation: Negative  
    Without activation: Negative  
Statistical methods:  
Remarks:

**Conclusions**

**Data Quality**

Reliability:  
Remarks: Reliable with restrictions

**References**

Löser E, (1988) ETAD Report. Toxicological Testing of Major Colourants T201E, See also, Milvy P. & Kay K (1978), J Toxicol. Envir. Hlth. Vol. 4, p.31, and NPIRI Raw Materials Handbook, 2000

**C. Genetic Toxicity - Mutation**

**Test substance:**

2-Naphthalenecarboxylic acid, 3-hydroxy-4-[(4- methyl-2-sulfophenyl)azo]-, calcium salt

Remarks:

98% pure

**Method**

Method: Japanese guideline for screening mutagenicity testing of chemicals  
Test type: Ames  
GLP: Yes  
Year: Japan (1993b)  
Species/strain: Salmonella typhimurium  
Metabolic activation: With and without  
Concentration tested: 5000 ug/plate with and without activation  
Remarks:

#### Results

Result: Negative in all bacterial strains with and without activation  
Cytotoxic concentration:  
Precipitation concentration:  
Genotoxic effects  
    With activation: Negative  
    Without activation: Negative  
Statistical methods:  
Remarks:

#### Conclusions

#### Data Quality

Reliability: Reliable without restriction   Remarks:

#### References

Ministry of Health and Welfare (MHW),  
Ministry of International Trade and Industry (MITI)  
Environment Agency (EA), Japan (1993)

#### Other

**D. Genetic Toxicity – Chromosomal Aberrations**

**Test Substance**

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4-[(4- methyl-2-sulfophenyl)azo]-, calcium salt  
Remarks: Commercial purity 98%

**Method**

Method: Japanese Guideline for Screening Mutagenicity Testing of Chemicals  
Test type: Cytogenetics Assay  
GLP: Yes  
Year: 1993  
Species/strain: Chinese Hamster CHL Cells  
Exposure period:  
Remarks: Activation system: S-9 fraction from the liver of Phenobarbital and 5,6-Benzoflavone induced male SD derived rats with NADPH-generating system  
No. replicates: 1

**Results**

Result:  
Genotoxic effects: Negative  
Concentration tested: Negative  
Statistical methods: 0, 124, 500, 1000, or 2500 ug/plate  
Remarks:

**Conclusions**

**Data Quality**

Reliability: Reliable without restriction  
Remarks:

**References**

**Other**

Ministry of Health and Welfare (MHW),  
Ministry of International Trade and Industry (MITI)  
Environment Agency (EA), Japan (1993)

**E. Developmental Toxicity**

**Test Substance**

Description included in OECD 422 study described above

Test substance:

Remarks:

**Method**

Method:

GLP:

Year:

Species/strain:

Sex:

Route of exposure:

Exposure levels:

Actual doses received:

Exposure period:

Duration of test:

Remarks:

**Results**

Maternal toxicity

NOEL:

NOEL for

teratogenicity:

NOEL for fetotoxicity:

Parental toxic

responses:

Fetal toxic responses

dose:

Statistical Methods:

Remarks:

**Conclusions**

**Data Quality**

Reliability:

Remarks:

**References**

**Other**

## F. Toxicity to Reproduction

### Test Substance

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4-[(4-methyl-2-sulphophenyl)azo]-, calcium salt  
Remarks: Commercial purity 98%

### Method

Method: OECD 422  
GLP: Yes  
Year: 1993a  
Species/strain: Rat  
Sex: male and female  
Route of exposure: gavage  
Exposure levels: 0, 100, 300 or 1000 mg/kg  
Exposure period: males 42 days including 14 before mating/females 14 days before mating to day 3 lactation  
Duration of test:  
Remarks:

### Results

Maternal toxicity NOEL: Parental, 1000mg/kg/day  
Parental toxic responses:  
Fetal toxic responses dose:  
Statistical Methods:  
Remarks: Pertinent pregnancy and offspring parameters, e.g. mating performance, duration of gestation, pup viability, body weight and sex distribution, and gross anomalies, were determined. No treatment-related adverse effects were detected. Under the conditions of this study, NOEL for reproductive/developmental toxicity of the rats was 1,000mg/kg/day. Method: Combined Repeated Dose and Reproductive/Developmental toxicity Screening Test

### Conclusions

### Data Quality

Reliability: Reliable without restriction  
Remarks:

### References

Ministry of Health and Welfare (MHW),  
Ministry of International Trade and Industry (MITI)  
Environment Agency (EA), Japan (1993) MHW

### Other

**Acute toxicity**

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4-(5-chloro-4- methyl-2-sulfophenyl)azo]-, Barium salt and 2-Naphthalenecarboxylic acid, 3-hydroxy-4-(5-chloro-4- methyl-2-sulfophenyl)azo]-, Calcium salt

Remarks:

**Method**

Method: Irritation to the rabbit eye

Test type: eye irritation

GLP: unknown

Year: 1972

Species/strain: rabbitt

Route of exposure:

Dose levels:

Remarks:

**Results**

Value: negative

Deaths at each dose:

Remarks:

**Conclusions****Data Quality**

Reliability: unassignable

Remarks:

**References**

Company data

**Other**

**Acute toxicity**

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4-(5-chloro-4- methyl-2-sulfophenyl)azo]-, Barium salt **and** 2-Naphthalenecarboxylic acid, 3-hydroxy-4-(5-chloro-4- methyl-2-sulfophenyl)azo]-, Calcium salt

Remarks:

**Method**

Method: Skin irritation to the rabbit  
Test type: Skin irritation  
GLP: unknown  
Year: 1972  
Species/strain: rabbit  
Route of exposure:  
Dose levels:  
Remarks:

**Results**

Value: negative  
Deaths at each dose:  
Remarks:

**Conclusions****Data Quality**

Reliability: unassignable  
Remarks:

**References**

Company data, A subchronic, 18 month dermal toxicity study for C.I. Pigment Red 57 has also been reported. An aqueous suspension of pigment was applied to 50 male and 50 female mice twice weekly for 18 months. Survival was unaffected and there were no clear effects on the gross or microscopic appearance of a range of tissues. See BIBRA Report (1993)

**Other**

## Chronic Dose Toxicity

### Test Substance

Test substance: 2-Naphthalenecarboxylic acid, 3-hydroxy-4-[(4- methyl-2-sulfophenyl)azo]-, calcium salt  
Remarks:

## Method

Method: Chronic Toxicity  
Test type: Repeated oral dose  
GLP: unknown  
Year: Reported in (1993)  
Species/strain: Rat  
Route of exposure: Oral gavage  
Duration of test: two years  
Exposure levels: .05, .3, and 2%  
Sex: 70 Males and 70 Females (The offspring of rats which had been tested at the same levels for 60 days prior to mating and throughout pregnancy and lactation)  
Exposure period:  
Post-exposure observation period:  
Remarks:

## Results

NOAEL (NOEL): NOAEL 150 mg/kg/bw/day

## Conclusions

At the end of the study, the weights and gross appearance of the major organs were unaffected, except in the high dose male rats which showed organ weight variations relative to their reduced body weight. Microscopic examination of the major tissues (limited to the control and high dose animals) revealed an increased incidence of kidney changes in both males and females. When pathologists from the U.S. Food and Drug administration subsequently examined tissue sections from the kidneys of all treated rats, they concluded that the test substance exacerbated a spontaneous kidney disease in aged rats (chronic progressive nephrosis) in the mid- and high-dose males and in high dose females. An acceleration of testicular changes ( degeneration of testicular tubules), common in aging rats, was also reported in high dose males, but the increased incidence was of no statistical significance.

## Data Quality

Reliability: unassignable  
Remarks:

## References

Reported in detail in the BIBRA (1993) Profile for Lithol rubine. See also, Opinion of the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (a scientific advisory body to the European Commission) Concerning Pigment Red 57, adopted May 25, 2004.

**Chronic toxicity Notes:** Chronic studies using mice and dogs are also reported, the lowest NOEAL is at 150 mg/kg/bw/day, study reported above

**Other**

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