

# CPMA

MR # 297590

COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.

Company Sanitized

July 17, 2006

RECEIVED  
CPMA  
06 AUG -11 AM 7:18

REDACTED

VIA COURIER

Environmental Protection Agency  
Office of Pollution Prevention  
and Toxics  
EPA East Building  
Document Control Office (Room 6428)  
1201 Constitution Avenue, NW  
Washington, DC 20460-0001  
Telephone: (202) 564-8930



Attn: TSCA Section 4, Ms. Catherine Roman

Re: Color Pigments Manufacturers Association, Inc. Test Plan for Benzenesulfonic Acid, [[4-[[4[(Phenylamino)phenyl][4-(Phenylimino)-2,5-cyclohexadien-1-ylidene]methyl]phenyl]amino]- CAS No. 1324-76-1, Pursuant to 40 CFR '790.45, and the Toxic Substances Control Act, Final Rule Entitled "Testing of Certain High Production Volume Chemicals", March 16, 2006, 71 Fed. Reg. 13708, 40 CFR '799.5085

Dear Ms. Roman:

Pursuant to 40 CFR '790.5085, we have enclosed two copies of our proposed Test Plan for analyzing Benzenesulfonic Acid, [[4-[[4[(Phenylamino)phenyl][4-(Phenylimino)-2,5-cyclohexadien-1-ylidene]methyl]phenyl]amino]- CAS No. 1324-76-1 hereafter Colour

U. S Environmental Protection Agency  
TSCA Section 4  
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Index ("C.I") Pigment Blue 61, (the "Test Plan") pursuant to 40 CFR '790.45, and the Toxic Substances Control Act, Final Rule Entitled "Testing of Certain High Production Volume Chemicals", March 16, 2006, 71 Fed. Reg. 13708, 40 CFR '799.5085 (the "Test Rule"). This Test Plan follows up on our letter of July 5, 2006 indicating that a consortium of the two manufacturers of this pigment has been formed to address the HPV Test Rule requirements cited above.

We have enclosed two separate copies of the Test Plan: The first is a complete confidential version which attaches copies of the confidential study reports and includes confidential references to those studies in the Test Plan robust summaries. The second version of the Test Plan, intended for inclusion in the public docket is redacted to remove confidential studies as attachments and [REDACTED]. The second version is labeled "REDACTED".

We request, on behalf of the individual members of the consortium, that EPA maintain the confidential study reports and confidential references to those studies in the complete confidential version of the Test Plan as confidential business information pursuant to the Toxic Substances Control Act. As discussed in more detail in the substantiation provided below, this information is valuable to the individual companies which are members of the consortium, and this information has not been

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disclosed outside of the consortium or shared between members of the consortium.

The CPMA is an industry trade association representing color pigment companies in Canada, Mexico, and the United States. CPMA represents small, medium, and large color pigments manufacturers throughout Canada, Mexico and the United States, accounting for 95% of the production of color pigments in North America. Color pigments manufacturers located in other countries with sales in Canada, Mexico and the United States, and suppliers of intermediates to the color pigments industry are also members of the association.

**Substantiation of Confidentiality Pursuant to 40 CFR '790.7**

[TEXT REMOVED]

**Available Data Relevant to the Requirements of the Test Rule**

As discussed above, we have enclosed complete copies of study reports and robust summaries for these study reports. We ask that EPA review these studies in light of the requirements of the Test Rule and accept these complete studies in satisfaction of the requirements of a number of the data points required by the Test Rule.

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The following is a list of the required data points relevant to the requirements of the Test Rule for which we have enclosed existing data:

**A. Relevant Physical Chemical Properties**

1. Melting point (Thermal Decomposition, melting point is not relevant for C.I. Pigment Blue 61.)
2. solubility in water, solubility in octanol and Log/Kow.

**B. Environmental Fate**

**C1. Aquatic Toxicity**

**D. Acute Mammalian Toxicity**

**E1. Mammalian Toxicity Genotoxicity**

**E2. Mammalian Chromosome Aberration**

**F1. Mammalian Toxicity/Repeated Dose**

Combined Repeated Dose Toxicity Study

As discussed in the enclosed Test Plan, where available, we have enclosed confidential studies for the analog substance C.I. Pigment Blue 56. A full justification for using data from the structurally similar compound is included in the Test Plan.

Also, please note that, due to the extremely low predicted solubility of C.I. Pigment Blue 61, we have used an alternative method of analyzing for solubility and octanol water partition coefficient. Since the water solubility of this compound is measured in micrograms per liter, we are proposing to independently

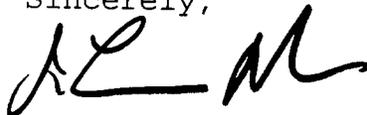
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analyze the water and octanol solubility of the compound and to report the values obtained. Recent advances in the field of solubility research have allowed us to analyze the solubility of pigments at levels previously not achievable. Until recently, such analysis would not produce meaningful information.

Please review the enclosed studies, summaries, analog data, and proposed studies at your earliest convenience. Obviously, the scope of further studies that CPMA will undertake will depend on EPA's analysis of this information.

If there are any questions which you would like to discuss in this regard, please call me at the number provided above. Should there be any significant issues which require further discussion with respect to either, technical matters or the claims of confidentiality, please call and we will arrange a meeting with the appropriate representatives.

Sincerely,



J. Lawrence Robinson  
President

# CPMA

MR# 297590

## COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.

August 2, 2006

**VIA FEDERAL EXPRESS**

Environmental Protection Agency  
Office of Pollution Prevention  
and Toxics  
EPA East Building  
Document Control Office (Room 6428)  
1201 Constitution Avenue, NW  
Washington, DC 20460-0001  
Telephone: (202) 564-8930

RECEIVED  
06 AUG -1 AM 7:18

Attn: TSCA Section 4, Ms. Catherine Roman

Dear Ms. Roman:

**Re: Color Pigments Manufacturers Association, Inc. Test Plan for Benzenesulfonic Acid, [[4-[[4[(Phenylamino)phenyl][4-(Phenylimino)-2,5-cyclohexadien-1-ylidene]methyl]phenyl]amino]- CAS No. 1324-76-1, Pursuant to 40 CFR §790.45, and the Toxic Substances Control Act, Final Rule Entitled "Testing of Certain High Production Volume Chemicals", March 16, 2006, 71 Fed. Reg. 13708, 40 CFR §799.5085**

Attached is a redacted July 17, 2006 letter to you that was omitted from the materials provided to EPA Concerning the above-referenced Test Plan.

CONTAIN NO CBI

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Please let me know if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Lawrence Robinson". The signature is stylized and cursive.

J. Lawrence Robinson  
President

July 17, 2006

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06 JUL 19 AM 6:03

**REDACTED**

**TEST PLAN AND ROBUST SUMMARIES  
PURSUANT TO 40 CFR 799.5085  
CERTAIN HIGH PRODUCTION VOLUME CHEMICALS  
C.I. PIGMENT BLUE 61  
CAS No. 1324-76-1  
July 17, 2006**

Color Pigments Manufacturers Association, Inc.  
300 North Washington Street  
P.O. Box 20839  
Alexandria, Virginia 22320-1839

Telephone: 703-684-4044  
Facsimile: 703-684-1795  
E-mail: JLR@CPMA.com  
Attn: J. Lawrence Robinson, President

**Company Sanitized**

297213

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## 1. Identification of Test Rule

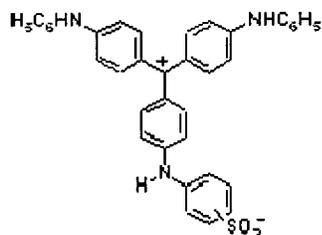
The following test plan is provided on behalf of the Color Pigments Manufacturers Association, Inc. ("CPMA"), pursuant to the Toxic Substances Control Act ("TSCA"), Final Rule Entitled "Testing of Certain High Production Volume Chemicals", March 16, 2006, 71 Fed. Reg. 13708, 40 CFR 1799.5085, (the "Final Rule"). This test plan follows up on the CPMA letter dated June 5 2006 regarding establishment of a consortia sponsored by CPMA for C.I. Pigment Blue 61.

## 2. Identification of Test Substance

Chemical Abstracts Service Number: 1324-76-1

Generic Description: C.I. Pigment Blue 61

Benzenesulfonic acid, [[4-[[4-(phenylamino)phenyl][4-(phenylimino)-2,5-cyclohexadien-1-ylidene]methyl]phenyl]amino ]-



## 3. Rationalization for Use of Surrogate Data

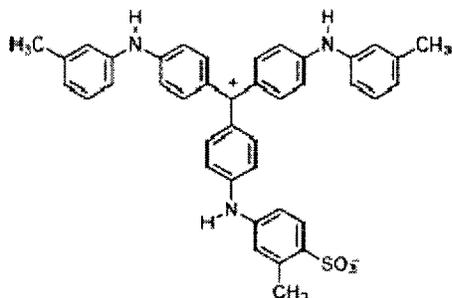
As a means to reduce the number of tests that need to be conducted, the EPA allows for the use of data from structurally similar compounds to characterize specific SIDS endpoints. The Final Rule states "if persons required to test under the Final Rule become aware of additional relevant scientifically adequate existing data (including structure-activity relationships (SAR) information or a scientifically defensible category approach) and submit this information to EPA at any time before testing is initiated, the Agency would consider such data to determine if they satisfy the testing requirement and would take appropriate necessary action to ensure that the testing in this is no longer required." 71 Fed. Reg. 13713, see also (US EPA 1999a on HPV policy). Accordingly, the CPMA believes that data from the available studies for C.I. Pigment Blue 56 (CAS No. 6417-46-5) meets the needed criteria for use as a surrogate in the completion of some SIDS endpoints.

As shown below, both color pigments, C.I. Pigment Blue 61 and C.I. Pigment Blue 56, are derived from the similar processes. C.I. Pigment Blue 61 and C.I. Pigment Blue 56 are similar compounds sharing the same basic chemical structures. C.I. Pigment Blue 56 differs from C.I. Pigment Blue 61 only in the addition of methyl groups to the pigments basic triarylcarbonium structure. These minor differences do not significantly alter the basic physicochemical properties or the basic biological effects. Both compounds have similar physical, acute toxicity and mutagenicity characteristics. Accordingly, available data for C.I. Pigment Blue 56 is used when necessary to fulfill required endpoints. These studies using C.I. Pigment Blue 56 are summarized below and enclosed for review with this test plan. No new tests will be performed on C.I. Pigment Blue 56 at this time.

Generic Description: C.I. Pigment Blue 56

Chemical Abstracts Service Number: 6417-46-5

Benzenesulfonic acid, 2 Methyl[[4-[[4-[(3-methylphenyl)amino]]phenyl][4-[(3-methylphenyl)imino]-2,5-cyclohexadien-1-ylidene]methyl]phenyl]amino ]-



**4. The Name and Addresses of the Test Sponsors**

Color Pigments Manufacturers Association, Inc.  
300 North Washington Street  
P.O. Box 20839  
Alexandria, Virginia 22320-1839

Telephone: 703-684-4044  
Facsimile: 703-684-1795  
E-mail: JLR@CPMA.com  
Attn: J. Lawrence Robinson, President

**5A. The Names and Addresses of the Testing Facilities**

This information is not yet available, laboratories under consideration include:

RCC Europe  
NOTOX Europe  
Dupont Haskell

**5B. Brief Summaries of the Training and Experience of Each Professional**

This information is not yet available. All of the above laboratories under consideration are recognized high quality institutions, the credentials of staff conducting and supervising studies should not be a concern.

**6. Identity and Data on the Chemical Substance(s) Being Tested**

A combined representative sample of C.I. Pigment Blue 61 derived from samples generated by both member manufacturers will be analyzed and used for all required tests.

**7. Test Rule Requirements**

List of studies required by the Test Rule  
See 71 Fed. Reg. 13733-13734.

Studies designated letters by A, B, C1, D, E1, E2 and F1 in the Test Rule.

**A. Relevant Physical Chemical Properties**

Including:

1. Melting point \*
2. Boiling point (ASTM E 1719) (N/A)
3. Vapor pressure (ASTM E1782) (N/A)
4. n-Octanol/Water partition coefficient log Kow  
(Based on estimated Log Kow ASTM E 1148 Shake flask, 40 CFR 799.6784 Shake Flask or Column elution, Generator Column)\*
5. Water solubility (Either 40 CFR 799.6784 Shake flask or column elution if required at all.)\*

**B. Environmental Fate:**

Biodegradation (Semicontinuous Activated Sludge or Zahn Wellens) \*

**C1. Aquatic Toxicity:**

Either Test Group 1, acute toxicity to fish and daphnia, toxicity to plants or Test Group 2, Chronic toxicity to daphnia toxicity to plants as determined an assessment of n-Octanol/Water partition coefficient log Kow. >4.2 = Group 2, <4.2 = Group 1 \*

**D. Acute Mammalian Toxicity:**

Acute Oral Toxicity (rat) \*

**E1. Mammalian Toxicity Genotoxicity:**

Bacterial Reverse Mutation Test \*

**E2. Mammalian Chromosome Aberration:**

In Vitro Mammalian Chromosome Aberration Test \*

**F1. Mammalian Toxicity/Repeated Dose:**

Combined Repeated Dose Toxicity Study \*  
with the Reproduction/Developmental  
Toxicity Screening or equivalent

\* Indicates existing data summarized and submitted  
with this test plan

## 8. Robust Summaries of Existing Studies

### A. Genetic Toxicity

#### A1. Genetic Toxicity - Mutation

Test substance: C.I. Pigment Blue 61  
 Remarks:

##### Method

Method: OECD 471  
 Test type: Ames  
 GLP: Yes  
 Year: 1985  
 Species/strain: Salmonella typhimurium and Echerichia Coli  
 TA 1535, TA100, TA 1537, TA 98 and E Coli WP2  
 uvrA  
 Metabolic activation: With and without S9  
 Concentration tested: 4 - 5750 ug/plate with and without  
 activation

Remarks:

#### Results

Result: Negative in all bacterial strains with  
 and without activation

Cytotoxic concentration:

Precipitation concentration: Precipitation found from about 100  
 ug/Plate

##### Genotoxic effects

With activation: Negative

Without activation: Negative

Statistical methods:

Remarks:

#### Conclusions

#### Data Quality

Reliability: Reliable without restriction

Remarks:

#### References

#### Other

**A2. Genetic Toxicity - Mutation**

Test substance: C.I. Pigment Blue 56 AP3600

Remarks:

**Method**

Method: Ames Test Protocol enclosed  
Test type: Ames  
GLP: Yes  
Year: 1985  
Species/strain: Salmonella typhimurium  
TA 1535, TA100, TA 1537, TA 98

Metabolic activation: With and without S9

Concentration tested: 50-5000 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**

**A3. Genetic Toxicity - Mutation**

Test substance: C.I. Pigment Blue 61

Remarks:

**Method**

Method: Ames Test Protocol enclosed  
Test type: Ames  
GLP: No  
Year: 1981  
Species/strain: Salmonella typhimurium and Echerichia Coli  
TA 1535, TA100, TA 1537, TA 98 and E Coli WP2 uvrA

Metabolic activation: With and without S9

Concentration tested: 4-10000 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

**B. Genetic Toxicity B Chromosomal Aberrations****Test Substance**

Test substance: C.I. Pigment Blue 56

Remarks:

**Method**

Method: OECD 474  
Test type: Cytogenetics Assay  
GLP: Yes  
Year: 1994  
Species/strain: NMRI Mouse  
Exposure period: 12 to 48 hours  
Remarks:

**Results**

Result: Negative  
Genotoxic effects: Negative  
Concentration tested: 2000 mg/kg  
Statistical methods: Not mutagenic  
Remarks:

**Conclusions** Reliable without restriction

**Data Quality**

Reliability:  
Remarks:

**References****Other**

**C. Acute Toxicity****C1. LD-50****Acute toxicity**

Test substance: C.I. Pigment Blue 61

Remarks:

**Method**

Method: Acute lethality; Other  
 Test type: LD<sub>50</sub> estimate  
 GLP: No (Pre-GLP)  
 Year: 1977  
 Species/strain: SPF Wistar Rat  
 Route of exposure: Oral gavage  
 Unknown  
 Dose levels:  
 Remarks:

**Results**

LD<sub>50</sub> = >15,000 mg/kg,  
 Value: None  
 Deaths at each dose:  
 Remarks:

Material would be considered as not toxic.

**Conclusions**

Reliable with restrictions  
**Data Quality** Data is consistent with other LD-50 values for triarylcation pigments.  
 Reliability:  
 Remarks:

**References****Other**

**C. Acute Toxicity**

C1. LD-50

**Acute toxicity**

Test substance: C.I. Pigment Blue 56

Remarks:

**Method**

Method: Acute lethality; Other  
 Test type: LD<sub>50</sub> estimate  
 GLP: No (Pre-GLP)  
 Year: 1977  
 Species/strain: SPF Wistar Rat  
 Route of exposure: Oral gavage  
 Dose levels: Unknown  
 Remarks:

**Results**

Value: LD<sub>50</sub> = >15,000 mg/kg,  
 Deaths at each dose: None  
 Remarks:

Material would be considered as not toxic.

**Conclusions****Data Quality**

Reliability: Reliable with restrictions  
 Remarks: Data is consistent with other LD-50 values for triarylcation pigments.

**References****Other**

**C. Acute Toxicity**

C1. LD-50

**Acute toxicity**

Test substance: C.I. Pigment Blue 61

Remarks:

**Method**

Method: Acute lethality; Other  
 Test type: LD<sub>50</sub> estimate  
 GLP: No  
 Year: 1981  
 Species/strain: Sprague Dawley Rat  
 Route of exposure: Oral gavage  
 Dose levels: 5 g/kg body weight  
 Remarks: 5 male and 5 female rats weighing 200-300 grams

**Results**

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

Material would be considered as not toxic.

**Conclusions****Data Quality**

Reliability: Reliable, well documented with Quality Assurance  
 Remarks: Data is well documented and consistent with other  
 LD-50 values for all similar organic pigments.

**References****Other**

**C. Acute Toxicity****C2. LC-50****Acute toxicity**

Test substance: C.I. Pigment Blue 61

Remarks:

**Method**

Method: Acute lethality; Other  
 Test type: LC<sub>50</sub> estimate  
 GLP: Yes  
 Year: 1981  
 Species/strain: Sprague Dawley Rat  
 Route of exposure: Inhalation  
 Dose levels: .048 mg/L, one hour  
 5 male and 5 female rats weighing 200-300 grams  
 Remarks:

**Results**

LC<sub>50</sub> = >48 mg/M<sup>3</sup>  
 Value:  
 Deaths at each dose:  
 Remarks:

No acute hazard by inhalation at anticipated concentrations.

**Conclusions**

Necropsy findings did not show any compound - related gross pathology. No compound residues were visible in the lung tissues

**Data Quality**

Reliability:  
 Remarks: Reliable without restriction  
 Data is well documented

**References****Other**

**C. Acute Toxicity**

C2. LC-50

**Acute toxicity**

Test substance: C.I. Pigment Blue 61

Remarks:

**Method**

Method: Acute lethality; Other  
 Test type: LC<sub>50</sub> estimate  
 GLP: Yes  
 Year: 1976  
 Species/strain: Sprague Dawley Rat  
 Route of exposure: Inhalation  
 Dose levels: 2.0 mg/L, one hour  
 Remarks: 10 male and 10 female rats weighing 200-300 grams

**Results**

Value: LC<sub>50</sub> = >2.48 mg/L  
 Deaths at each dose: none  
 Remarks:

**Conclusions**

No acute hazard by inhalation at anticipated concentrations.

**Data Quality**

Reliability: Some tinting was noted in the lungs. (result expected from high dose study) All other major organs appeared healthy upon inspection.  
 Remarks: Reliable well documented study

**References****Other**

**C. Acute Toxicity****C3. Dermal Toxicity****Acute toxicity**

Test substance: C.I. Pigment Blue 61

Remarks:

**Method**

Method: Acute Dermal Toxicity  
 Test type:  
 GLP: No  
 Year: 1981  
 Species/strain: 10 New Zealand Albino Rabbits  
 Route of exposure: Dermal  
 Dose levels: 6g/Kg body weight  
 Remarks:

**Results**

Value:  $LD_{50} = >2g/kg$   
 Deaths at each  
 dose:  
 Remarks:

**Conclusions**

No adverse effects were reported during the 14 day observation period. Necropsy results indicated some discoloration on internal organs indicating that some skin absorption does occur

**Data Quality**

Reliability: Reliable, well documented with quality assurance  
 Remarks:

**References****Other**

**C. Acute Toxicity****C4. Primary Skin Irritation****Acute toxicity**

Test substance: C.I. Pigment Blue 61

Remarks:

**Method**

Method: Primary Skin Irritation Index  
Test type:  
GLP: No  
Year: 1981  
Species/strain: 6 New Zealand Albino Rabbits  
Route of exposure: Dermal  
Dose levels: 1.3 grams of 40 % past at each patch site  
Remarks:

**Results**

Value: 1.3/8.0 material would be considered slightly  
Deaths at each dose: irritating  
Remarks:

**Conclusions**

Reactions were generally slight erythematia and very slight edema at all patch sites. No corrosive damage was noted at any test site

**Data Quality**

Reliability: Reliable, well documented with quality assurance  
Remarks:

**References****Other**

**C. Acute Toxicity****C5. Primary Eye Irritation****Acute toxicity**

Test substance: C.I. Pigment Blue 61

Remarks:

**Method**

Method: Primary eye Irritation Index

Test type:

GLP: No

Year: 1981

Species/strain: 6 New Zealand Albino Rabbits

Route of exposure: Dermal

Dose levels: .10 grams

Remarks:

**Results**

Value: 0-4 not irritating

Deaths at each

dose:

Remarks:

**Conclusions**

Irritation effects were limited to redness and swelling of the conjunctiva. No involvement of the cornea or iris was seen.

**Data Quality**

Reliability: Reliable, well documented with quality assurance

Remarks:

**References****Other**

**C. Acute Toxicity****C6. Local Lymph Node Assay****Acute toxicity**

Test substance: C.I. Pigment Blue 61

Remarks:

**Method**

Method: Sensitization test  
 Test type: Contact Allergenic Potential  
 GLP: Yes  
 Year: 2003  
 Species/strain: 16 Female Mice CBA/CaOlaHsd 3 test groups of 4  
 Route of exposure: animals each 1 Control.  
 Dose levels: Dermal and Injection  
 Remarks: 5%, 10% and 25 % (w/w) in acetone :olive Oil (v/v)  
 Topical application to the dorsal surface of each  
 left ear lobe.  
 5 days after topical application all mice were  
 administered 250  $\mu$ l of h-methyl thymidine. Draining  
 lymph nodes were excised and pooled for each  
 experimental group. After further processing HTdR  
 levels were measured as the number of radioactive  
 Value: disintegrations per minute.  
 Deaths at each dose:  
 Remarks:

1.2 to 1.8 on sensitization index.

**Conclusions****Data Quality**

Reliability: non sensitizer  
 Remarks:

Reliable, without restriction

**References****Other**

**D. Repeated Dose Toxicity****Test Substance**

Test substance: C.I. Blue Pigment Blue 61  
 Remarks:

**Method**

Method: Repeat Dose  
 Test type:  
 GLP: No, pre- GLP  
 Year:  
 Species/strain: Mixed Race Albino Rat  
 Route of exposure: Oral  
 Duration of test: 18 Days  
 Exposure levels: 500 mg/kg applied 14 times

Sex:  
 Exposure period: 18 days  
 Post-exposure observation period: 4 days  
 Remarks:

No pathological changes were observed. After the observation period, all animals were killed and dissected. The sections displayed no abnormal changes either macroscopically or during the histological examination of the organs including, heart, lungs, liver, kidneys and spleen that could be attributed to the pigment

**Results**

NOEC: 500 mg/Kg

**Conclusions**

Test substance is not significantly toxic, results are consistent with other repeated dose studies involving pigments with extremely low solubility in octanol and water

**Data Quality**

Reliability: Reliable documented study, results are consistent with all other tests of similar organic pigments.

Remarks:

**References:****Other**

**E. Acute Toxicity to Fish**

**Test Substance** C.I. Pigment Blue 56

Test substance:

Remarks:

**Method**

Method: OECD 203

Test type: Static system

GLP: Yes

Year: 1992

Species/strain: Brachydanio rerio

Analytical

monitoring: 96-Hour

Exposure period: A group of 10 fish were exposed to 500mg/L nominal

Remarks: concentrations

**Results**

Nominal  
concentration: 96-hour LC<sub>50</sub> >500mg/L

Measured  
concentration:  
Endpoint value:

Biological  
observations:

Statistical  
methods:

Remarks:

Reliable without restriction

**Conclusions****Data Quality**

Reliability:

Remarks:

**References****Other**

**F. Biodegradation****F1. Biodegradation****Test Substance**

Test substance: C.I. Pigment Blue 56

Remarks:

**Method**

Method: OECD 301B

Test type: Modified Sturm Test

GLP: Yes

Year: (1992)

Remarks: Not readily biodegradable

**Results**

Results: <20% of maximum based on CO<sub>2</sub> generated from

Remarks: degradation of C.I. Pigment Blue 56

**Conclusions****Data Quality**

Remarks: This is a well-documented study.

**References****Other**

**F2. Biodegradation****Test Substance**

Test substance: C.I. Pigment Blue 56

Remarks:

**Method**

Method: OECD 209

Test type: Activated Sludge, Respiration Inhibition Test

GLP: Yes

Year: 1992

Remarks:

**Results**

Results: EC-50 >1000mg/L

Remarks: EC-20 >1000mg/L

EC-80 >1000mg/L

**Conclusions**

Pigment Blue 56 is harmless to activated sludge

**Data Quality**

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

**References****Other**

**G. Physical-Chemical Data****G1. Melting Point****Test Substance**

Test substance: C.I. Pigment Blue 61

Remarks:

**Method**

Method: Measured Thermal decomposition

Remarks: Melting point is not relevant to C.I. Pigment Blue 61

**Results**

Thermal Decomp.  
value: 240 °C

Remarks:

**References**

Melting point is not relevant to the analysis of C.I. Pigment Blue 61. As temperature rises, C.I. Pigment Blue 61 thermally decomposes before it melts. The thermal decomposition temperature has been analyzed in a recent high quality study. A copy of the referenced study is enclosed.

**Other**

**G2. Boiling Point****Test Substance**

Test substance: SOLID N/A, See discussion regarding melting point  
Remarks: above.

**Method**

Method:  
Remarks:

**Results**

Boiling point  
value:  
Remarks:

**References****Other**

**G3. Vapor Pressure**

**Test Substance**

Test substance: C.I. Pigment Blue 61

Remarks: Not applicable , Solid material

**Method**

Method:

Remarks:

**Results**

Vapor pressure  
value:

Temperature:

Remarks:

**References**

**Other**

**G4. Partition Coefficient****Test Substance**

Test substance: C.I. Pigment Blue 61

Remarks:

**Method**

Method: Calculated, based on actual solubility analysis

Remarks:

**Results**Log  $K_{ow}$ : 3.96

Remarks:

**References****Other**

Due to its extremely low estimated solubility, measured in micrograms per liter, it is unlikely that a meaningful test can be performed using the methods described in the Final Rule. We have measured actual solubility in water and solubility in octanol and used these values to calculate an octanol water partition coefficient. A recently developed high resolution solubility procedure has been used to quantify the solubility of C.I. Pigment Blue 61 in water and octanol. The results indicate that water solubility is 2.5 g/l, the solubility of C.I. Pigment Blue 61 in octanol is 23 mg/L. These values provide an actual calculated log  $kow$  3.96. A complete report describing the procedures used in determining solubility is enclosed for your review.

**G5. Water Solubility****Test Substance**

Test substance: C.I. Pigment Blue 61

Remarks:

**Method**

Measured

Method:

Remarks:

2.5 g/L

**Results**

Value: Ambient

Temperature:

Description: Extremely Low Solubility

Remarks:

**References****Other**

9. Studies to be undertaken by CPMA:

- A. Since repeated dose toxicity data is available, only Developmental Toxicity Screening, or equivalent, may remain to be completed and is proposed at this time.

10. Study Protocols

Not Available at this time

11. Schedule for Testing

The schedule for the remaining study will be determined after EPA review of the enclosed existing studies.

ENCLOSED CONFIDENTIAL STUDIES HAVE BEEN REMOVED

Company Equitized